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Briefings on How To Use the Federal Register
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WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

ATLANTA, GA

WHEN: September 20; at 9:00 a.m.
WHERE: Room 808, 75 Spring Street, SW.
Richard B. Russell Federal Building
Atlanta, GA
RESERVATIONS: Call the Federal Information Center
404–331–6895

WASHINGTON, DC

WHEN: September 25; at 9:00 a.m.
WHERE: Office of the Federal Register
First Floor Conference Room
1100 L Street NW., Washington, DC
RESERVATIONS: 202–523–5240

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Separate Parts In This Issue

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Presidential Determination No. 89–25 of August 28, 1989

Extension of the Exercise of Certain Authorities Under the Trading With the Enemy Act

Memorandum for the Secretary of State, the Secretary of the Treasury

Under Section 101(b) of Public Law 95–223 (91 Stat. 1625; 50 U.S.C. App. 5(b) note), and a determination made by former President Reagan on September 8, 1988 (53 FR 35289), the exercise of certain authorities under the Trading With the Enemy Act is scheduled to terminate on September 14, 1989.

I hereby determine that the extension for one year of the exercise of those authorities with respect to the applicable countries is in the national interest of the United States.

Therefore, pursuant to the authority vested in me by Section 101(b) of Public Law 95–223, I extend for one year, until September 14, 1990, the exercise of those authorities with respect to countries affected by:

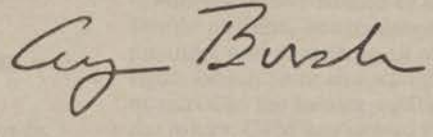
(1) the Foreign Assets Control Regulations, 31 CFR Part 500;

(2) the Transaction Control Regulations, 31 CFR Part 505;

(3) the Cuban Assets Control Regulations, 31 CFR Part 515; and

(4) the Foreign Funds Control Regulations, 31 CFR Part 520.

The Secretary of the Treasury is directed to publish this Determination in the **Federal Register.**



THE WHITE HOUSE,
Washington, August 28, 1989.

[FR Doc. 89–21200
Filed 9–5–89; 2:27 pm]
Billing code 3195–01–M

Rules and Regulations

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 302

Procedures for Selecting Candidates for Appointment in the Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is adopting as final its interim regulations governing procedures used to select candidates for appointments in the excepted service to clarify the rights of applicants entitled to 10-point veterans preference when numerical scores are not assigned. The regulations require that applicants entitled to 10 point preference on a basis other than compensable disability will be referred after compensably disabled 10-point preference eligibles but before applicants entitled to 5-point veterans preference.

EFFECTIVE DATE: October 10, 1989.

FOR FURTHER INFORMATION CONTACT: Tracy Spencer, (202) 632–6817.

SUPPLEMENTARY INFORMATION: On May 9, 1989 (54 FR 19869), OPM issued interim regulations revising final regulations issued September 13, 1988 (53 FR 35291), which permitted agencies to refer candidates for excepted appointments in order of veterans preference without other ranking. Under the unranked referral procedures, applicants eligible for 10-point veterans preference based on a compensable service-connected disability of 10 percent or more were to be referred first (unless the position is a scientific or professional one at grade GS–9 or above), followed by other veteran preference eligibles and, last, by applicants not eligible for veterans preference.

The interim regulations revised this order by providing for applicants entitled to 10-point veterans preference under 5 U.S.C. 2108(3)(D) through (G) to be referred in a separate category following compensably disabled veterans entitled to 10-point preference under 5 U.S.C. 2108(3)(C), but ahead of eligibles entitled to 5-point preference under 5 U.S.C. 2108(3) (A) and (B). Selections must be made from the highest available preference category as long as at least three candidates remain in that category. This revision ensures that eligibles in each preference category receive the full preference provided by law.

We received no comments on the interim regulations.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation affects only the procedures used to appoint certain Federal employees.

List of Subjects in 5 CFR Part 302

Administrative practice and procedures, Government employees.

Office of Personnel Management.

Constance Berry Newman,

Director.

PART 302—[AMENDED]

Accordingly, OPM is adopting its interim rule amending 5 CFR part 302 published in the **Federal Register** (54 FR 19869, May 9, 1989) as a final rule without change.

(Authority: 5 U.S.C. 1302, 3301, 3302, 8151; E.O. 10577 (3 CFR 1954–1958, Comp., p. 218); § 302.105 also issued under 5 U.S.C. 1104; Pub. L. 95–454, sec. 3(5); § 302.501 also issued under 5 U.S.C. 7701 et seq.)

[FR Doc. 89–21036 Filed 9–6–89; 8:45 am]
BILLING CODE 6325–01–M

5 CFR Part 315

Noncompetitive Appointments of Former Incumbents of Positions Brought into the Competitive Service; Technical Amendment

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is amending its regulations permitting noncompetitive appointment based on former incumbency of a position brought into the competitive service to cover former employees entitled to restoration following a compensable injury. Currently, the regulations refer only to former employees entitled to restoration following active military service.

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: Tracy E. Spencer, (202) 632–6817.

SUPPLEMENTARY INFORMATION: By law (5 U.S.C. 8151(b)(1)), an employee who is found by the Department of Labor to be fully recovered from a compensable on-the-job injury or disability within 1 year after the date compensation begins, or from the time compensable disability recurs if the recurrence begins after the injured employee resumes regular full-time employment with the United States, is entitled to be restored to his or her former position, or an equivalent position, and to receive all attendant rights which he or she would have acquired in the former position but for the injury. OPM has issued regulations implementing this statutory entitlement for employees in both the competitive and the excepted service. It has come to our attention, however, that the langauge of the part 315 regulations would not clearly cover an eligible employee whose position was brought into the competitive service while the employee was off the rolls as a result of a compensable injury.

When positions are brought from the excepted into the competitive service, employees occupying those positions under nontemporary appointment may be retained and converted to career or career-conditional appointments. Since an employee restored under 5 U.S.C. 8151 is entitled to acquire the tenure he or she would have gained by remaining on the job, such an employee whose

position has been brought into the competitive service is entitled to be restored in a competitive appointment. However, the applicable regulations in 5 CFR part 353 provide for restoration in a position of like status to that previously held. While this language, together with the language of the law, could be read as permitting restoration in a competitive appointment when the status of the position itself has changed, the existing part 315 regulation does not provide explicit authority for the noncompetitive appointment of an employee whose previous service was under excepted appointments. To provide such explicit authority, OPM is amending the regulation which permits noncompetitive appointment based on former incumbency of a position brought into the competitive service to afford the same benefit to persons entitled to restoration following compensable injury as is already afforded to those entitled to restoration following military duty.

OPM is also amending § 315.607, which authorizes noncompetitive appointment of present and former Peace Corps personnel, to remove a duplicate paragraph.

Waiver of Notice of Proposed Rulemaking and 30-day Delay of Effective Date

Under 5 U.S.C. 553(b)(3)(B) and (d)(3), I find that good cause exists for waiving the general notice of proposed rulemaking and for making the amendment effective in less than 30 days. The regulations reflect a statutory entitlement that is already in effect.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation affects only the procedures used to appoint certain Federal employees.

List of Subjects in 5 CFR Part 315

Administrative practice and procedures, Government employees.

Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM is amending 5 CFR Part 315 as follows:

PART 315—[AMENDED]

1. The authority citation for Part 315 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3301, and 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; §§ 315.601 and 315.609 also issued under 22 U.S.C. 3651 and 3652; §§ 315.602 and 315.604 also issued under 5 U.S.C. 1104, Pub. L. 95–454, sec. 3(5); § 315.603 also issued under 5 U.S.C. 8151, Pub. L. 93–416; § 315.605 also issued under E.O. 12034, 43 FR 1917, Jan. 13, 1978; § 315.606 also issued under E.O. 11219, 3 CFR 1964–1965 Comp., p. 303; § 315.607 also issued under 22 U.S.C. 2506, 93 Stat. 371, E.O. 12137, 22 U.S.C. 2506, 94 Stat. 2158; § 315.608 also issued under E.O. 12362, 47 FR 21231; § 315.610 also issued under 5 U.S.C. 3304(d), Pub. L. 99–586; § 315.710 also issued under E.O. 12596, 52 FR 17537; Subpart I also issued under 5 U.S.C. 3321, E.O. 12107.

2. Section 315.603 is amended by adding a new paragraph (a)(3) to read as follows:

§ 315.603 Appointment based on former incumbency of a position brought into the competitive service.

(a) * * *

(3) *Employee recovered from compensable injury.* An agency may appoint a former incumbent of a permanent excepted position who was serving under an appointment not limited to 1 year or less, when the position has been brought into the competitive service *and* when:

(i) The employee is entitled to restoration based on recovery from compensable injury in accordance with 5 U.S.C. 8151 and part 353;

(ii) The employee's position was brought into the competitive service either before the employee's separation for compensable injury or during his or her period of statutory restoration rights following such injury, and the employee's separation for compensable injury occurred before the end of the time limits set forth in § 315.701(c);

(iii) the agency initiates the appointment within 6 months after cessation of compensation; and

(iv) The employee performed 6 months of statisfactory service immediately before the date his or her position was brought into the competitive service in the civilian executive branch of the Government, unless OPM has excepted his or her particular type of case from this requirement by a provision of the Federal Personnel Manual.

§ 315.603 [Amended]

3. Section 315.603 is amended by revising paragraph (d)(2) to read as follows:

(d) * * *

(2) A person appointed under paragraph (a)(2) or (a)(3) of this section acquires a competitive status automatically on completion of probation.

§ 315.607 [Amended]

4. Section 315.607 is amended by removing paragraph (b)(3).

[FR Doc. 89–21037 filed 9–6–89; 8:45 am]

BILLING CODE 6325–01–M

5 CFR Parts 872 and 873

RIN 3206–AD75

Additional Optional Life Insurance and Family Optional Life Insurance under FEGLI

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is adopting as final its interim regulations issued on April 5, 1989, concerning the Federal Employees' Group Life Insurance (FEGLI) Program. The interim regulations: (1) Eliminated a requirement to be under age 36 to cancel a declination of additional optional life insurance; (2) clarified to whom benefits shall be paid on family optional insurance when an employee predeceases a covered family member and the family member dies within 31 days after the death of the insured; and (3) eliminated a requirement to be in a pay and duty status for the cancellation of a declination of family optional insurance to become effective.

EFFECTIVE DATE: October 10, 1989.

FOR FURTHER INFORMATION CONTACT: Bill Smith, (202) 632–4634.

SUPPLEMENTARY INFORMATION: On April 5, 1989, OPM published interim regulations in the **Federal Register** (54 FR 13665) implementing the three changes noted above. OPM received two comments from interested parties, one from an employee organization and one from an individual. The employee organization supported the changes. The individual respondent recommended that employees who missed out on the opportunity to obtain additional coverage due to the age restriction be afforded a one time opportunity to enroll for a 60 day period after the final regulations are published. The 60 day period would allow employees who have acquired a spouse or children since the last FEGLI open season an opportunity to enroll. This recommendation can not be adopted. Unless there are legislatively-imposed effective dates, regulatory provisions are effective prospectively. In making this change, OPM recognized the need to put it into effect at the earliest possible date, and accomplished that end by publishing these changes as interim

rules effective immediately upon publication (i.e., April 5, 1989).

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect Federal employees and their family members.

List of Subjects in 5 CFR Parts 872 and 873

Administrative practice and procedure, Government employees, Life insurance.

Office of Personnel Management.

Constance B. Newman,

Director.

PARTS 872 and 873—[AMENDED]

1. The authority citation for Parts 872 and 873 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. The interim regulations amending 5 CFR 872.205, 873.102 and 873.205, that were published at 54 FR 13665 on April 5, 1989, are adopted as final rules without change.

[FR Doc. 89–21038 Filed 9–6–89; 8:45 am]

BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1980

Guaranteed Farmer Program Loan

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule, correction.

SUMMARY: The Farmers Home Administration (FmHA) corrects a final rule published January 13, 1989 (54 FR 1534) involving subpart B of part 1980 of its regulations. The title of Attachment 2 of Exhibit A to subpart B of part 1980 was included in the final rule but not the designation as Attachment 2. Attachment 3 of Exhibit A to subpart B of part 1980 was inadvertently omitted in the final rule. The intended effect of this action is to correct this error.

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: Ann B. Dill, Guaranteed Loan Making Branch, Farmers Home Administration, USDA, Room 5440, Washington, DC 20250. Telephone: (202) 382–1186.

SUPPLEMENTARY INFORMATION: On January 13, 1989, FmHA published a final rule to implement changes to its guaranteed farmer program loan regulations necessary to implement the Agricultural Credit Act of 1987. Subpart B of part 1980 was republished in its entirety. Exhibit A to 7 CFR part 1980, subpart B contains the Approved Lender Program for guaranteed operating, farm ownership and soil and water loans. When the final rule was published, an error was made in the heading of Attachment 2. The title of the Attachment was included but not the designation as Attachment 2. An error was also made omitting the existing Attachment 3 of Exhibit A to subpart B of part 1980. This attachment is the Approved Lender Program Application for Guarantee, and is necessary to an orderly operation of that program.

The following correction is made to 54 FR on pages 1589 and 1592, respectively, dated January 13, 1989:

PART 1980—GENERAL

1. The authority citation for part 1980 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart B—Farmer Program Loans

Exhibit A—[Amended]

2. Exhibit A, the title of Attachment 2—Farmers Home Administration Approved Lender Program (ALP) is changed as follows:

Attachment 2—Farmers Home Administration Approved Lender Program (ALP)

Lender's Agreement for Operating Line of Credit Guarantee (Contract of Guarantee Cases)

3. Exhibit A, Attachment 3—Farmers Home Administration Approved Lender Program (ALP) is added to read as follows:

Attachment 3

TO: County Supervisor, FmHA

SUBJECT: Request for Loan Note Guarantee under Approved Lender Agreement Applicable to Loan Note Guarantee Cases (Attachment 1). Principal Amount of Loan $_____

AND/OR

Request for Line of Credit Guarantee under Approved Lender Agreement Applicable to Contract of Guarantee Cases (Attachment 2). Line of Credit Ceiling $_____.

Principal Amount of Initial Advance $_____.

Lender Agreement Dated _____.

Lender IRS I.D. No. _____.

Request is made for issuance of a guarantee(s) in the following case.

Applicant's Name _____

Address _____

Social Security or IRS Tax No._____

County_____ State_____

Percent Guarantee Requested_____%

Interest rate to borrower_____% If variable, state method determined and frequency of adjustment

Specific amounts and purposes of loan/line of credit are as follows:

Proposed repayment terms: _____

Proposed closing date if request is approved:

Special or unique conditions or problems:

Applicant's Financial Condition:

New Worth $_____ _____

	Assets value	Debt	Amount due in 12 months
Current [1]			
Intermediate [2]			
Long Term [3]			
Totals			

[1] Current: Cash savings, marketable bonds, receivables, 60 day sales of goods available within 60 days.

[2] Intermediate: Machinery, livestock, retirement accounts, cash value life insurance, securities household goods, receivable 60 days to 1 year.

[3] Long term: Real estate, contracts and notes receivable amount beyond current year.

Ratio Calculation from Financial Information and Operating Plans:

Total Assets of $_____ divided by Total Liabilities _____ = Net Capital Ratio

Annual Cash Operating Expenses $_____ divided by Gross Income $_____ = Operating Ratio _____

Net Income $_____ divided by Total Assets $_____ = Profit to Assets

Debt Repayment $_____ divided by Gross Income $_____ = Debt Repayment

Security Proposed:

Item	Value	Prior liens (if any)	Equity value
Totals			

Briefly list any special conditions and narrate security accounting, reporting limitations and supervision etc., contained in proposed loan/line of credit agreement. See 7 CFR part 1980, subpart B, § 1980.113(d)(7)

The applicant's total farming operation is as follows: (Include total acres owned and/or leased broken down to use and indicate irrigated, double crop, etc., if any. Includes totals of all livestock owned and/or tended and describe operation purchasing, marketing, breeding details. Use attachments if necessary.)

The undersigned certifies that:

1. The information contained in this request is correct and that a complete application containing all required items described in § 1980.113(d) of part 1980, subpart B are on file and may be examined by FmHA at any time during regular business hours prior to or after FmHA responds to this request for a loan note guarantee or contract of guarantee.

2. Before a Loan Note Guarantee or Contract of Guarantee is issued by FmHA, the lender will certify to conditions in § 1980.60 of 7 CFR part 1980, Subpart A.

3. The lender will provide a Guarantee Loan Closing Report on Form FmHA 1980–19 and a check for the amount of the guarantee fee at the time the Loan Note Guarantee or Contract of Guarantee is issued.

4. This proposed loan/line of credit is considered sound, will be fully secured and is within the borrower's repayment ability.

5. All applicable requirements have been or will be met.

6. The loan or advance under the line of credit cannot be made without an FmHA guarantee.

(Name of Lender)

By _____

Title _____

(Lender's IRS I.D. Tax No.)

Date _____

Dated: August 14, 1989.

Roland R. Vautour,

Under Secretary for Small Community and Rural Development.

[FR Doc. 89–21007 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–07–M

Packers and Stockyards Administration

9 CFR Part 201

Technical Amendment

AGENCY: Packers and Stockyards Administration, USDA.

ACTION: Final rule—technical amendment.

SUMMARY: The Packers and Stockyards Administration is making two corrections to the control numbers assigned by the Director of the Office of Management and Budget upon approval of the reporting and recordkeeping requirements, and deleting a reference to a regulation no longer in effect.

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: Calvin W. Watkins, Deputy Administrator, Packers and Stockyards Administration, U.S. Department of Agriculture, Room 3039 South Building, Washington, DC 20250–2800, (202) 447–7063.

SUPPLEMENTARY INFORMATION: This merely corrects some errors and does not impose any requirements on the affected public, therefore:

(a) It is not a "major rule" as in E.O. 12291 section 1(b);

(b) It will not have a significant economic impact on a substantial number of small entities as in 5 U.S.C. 605;

(c) Notice and public procedure on it are unnecessary as in 5 U.S.C. 553(b)(B) so notice of proposed rulemaking is not required by 5 U.S.C. 553(b); and

(d) Good cause is hereby found for making it effective in less than 30 days as in 5 U.S.C. 553(d)(3).

List of Subjects in 9 CFR Part 201

Reporting and recordkeeping requirements, Packers, Stockyards, Dealers and market agencies.

Accordingly, part 201, Chapter II of title 9 of the Code of Federal Regulations is amended as set forth below:

PART 201—REGULATIONS UNDER THE PACKERS AND STOCKYARDS ACT

1. The authority citation for part 201 continues to read as follows:

Authority: 7 U.S.C. 222, 228(a), 7 CFR 2.17(e), 2.56.

2. Section 201.10 is amended by changing the Office of Management and Budget control number to "0590–0001".

§ 201.10 Requirements and procedures.

* * * * *

(Approved by the Office of Management and Budget under control number 0590–0001)

3. Section 201.99 is amended by changing the Office of Management and Budget control number to "0590–0001".

§ 201.99 Purchase of livestock by packers on a carcass grade, carcass weight, or carcass grade and weight basis.

* * * * *

(Approved by the Office of Management and Budget under control number 0590–0001)

4. Section 201.200(c) is amended by removing ", or by § 201.68 relating to financing packers by dealers or vice versa." As revised, paragraph (c) reads as follows:

§ 201.200 Sale of livestock to a packer on credit.

* * * * *

(c) The provisions of this section shall not be construed to permit any transaction prohibited by § 201.61(a) relating to financing by market agencies selling on a commission basis.

Done at Washington, DC, this 1st day of September, 1989.

B.H. (Bill) Jones,

Administrator, Packers and Stockyards Administration.

[FR Doc. 89–21008 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–KD–M

FARM CREDIT ADMINISTRATION

12 CFR Part 611

RIN 3052–AA00

Organization; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correction.

SUMMARY: On December 15, 1988, the Farm Credit Administration (FCA) published a final rule which amended the regulation relating to organizational authorities of Farm Credit institutions (53 FR 50381). On January 23, 1989, a correction to that final rule was published in the **Federal Register** (54 FR 2994). The FCA is revising the correction document to remove a word that was incorrectly added.

EFFECTIVE DATE: February 22, 1989.

FOR FURTHER INFORMATION CONTACT: Gary L. Norton, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: In the January 23, 1989 correction to the final rule, an error was inadvertently made in 12 CFR 611.310.

PART 611—ORGANIZATION

1. On page 2994, third column, the word "director," was incorrectly added in § 611.310(c). Paragraph (c) is corrected to read as follows:

Subpart C—Election of Directors

§ 611.310 Eligibility for membership on bank and association boards and subsequent employment.

* * * * *

(c) No bank director shall, within 1 year after the date when he or she ceases to be a member of the board, serve as a salaried officer or employee of such bank, or any association with which the bank has a discount or agent relationship.

* * * * *

Dated: August 31, 1989.

David A. Hill,

Secretary, Farm Credit Administration Board.

[FR Doc. 89–20915 Filed 9–6–89; 8:45 am]

BILLING CODE 6705–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

RIN 3245–AB86

Business Loan Policy

AGENCY: Small Business Administration, (SBA).

ACTION: Final rule.

SUMMARY: This rule implements section 102 of Public Law 100–590 (102 Stat. 2989), enacted November 3, 1988 (1988 legislation), which authorizes SBA certified and preferred participating lenders to retain one-half of the guaranty fee payable to the SBA on loans of $50,000 or less.

EFFECTIVE DATE: September 7, 1989.

ADDRESSES: For further information, contact Charles R. Hertzberg, Deputy Associate Administrator for Financial Assistance, Small Business Administration, 1441 L Street NW., Washington, DC 20416. Telephone (202) 653–6574.

SUPPLEMENTARY INFORMATION: On March 6, 1989, SBA published in the **Federal Register** (54 FR 9233), a notice of proposed rulemaking to implement section 102 of the 1988 legislation. The Agency received eight written comments all of which supported the rule as proposed.

The SBA charges a guaranty fee for a participating lender to obtain the SBA guaranty. On loans with maturities in excess of twelve months, the guaranty fee is two percent of the amount that SBA guarantees. Such fee is paid by the lender to SBA, but the lender may pass that charge on to the small business concern borrower. This is true whether the loan being guaranteed by SBA is a regular loan, a loan made under the Certified Lenders Program (CLP) (under which a lender is promised a three-day turnaround review by SBA), or a loan made under the Preferred Lenders Program (PLP) (under which the loan may be approved by a lender without prior processing review by SBA). Under this final rule, any certified or preferred lender which makes a loan of $50,000 or less, with a maturity in excess of twelve months, could retain one-half of the guaranty fee payable to the SBA.

One commenter suggested that the lender be given an option not to charge the borrower the one-half of the guaranty fee which the lender is permitted to keep under the 1988 legislation. The commenter stated that this could be a useful marketing tool for the lender in competitive markets and would be of assistance to the borrower. SBA has no objection to this proposal, and neither the statute nor the regulation prohibits this procedure. The purpose of the 1988 legislation is to encourage a lender to make small SBA guaranteed loans, and this may be effected by allowing the lender not to pay to SBA the full amount of the guaranty fee. Section 7(a)(18) of the Small Business Act (15 U.S.C. 636(a)(18)) places the obligation on the lender to pay the guaranty fee to SBA. That section then authorizes the lender, if it chooses, to be reimbursed by the borrower. If the lender elects not to charge the borrower for all or any part of the guaranty fee, that is permissible. The borrower which is not charged for the guaranty fee is released from an expense which inures to its benefit. The 1988 legislation apparently presumes that a lender ordinarily chooses to charge the borrower for the full amount of the guaranty fee payable to SBA, but that need not be the situation in every case. The thrust of the 1988 legislation is to authorize SBA to collect from the lender only one-half of the guaranty fee attributable to a loan of $50,000 or less. If a lender chooses to absorb the other half of the guaranty fee, to the borrower's benefit, SBA has no objection since the Agency is still receiving the mandated one-half of the guaranty fee.

A commenter recommended that the size of loan eligible for this program be increased from $50,000 to $100,000. Such an increase would require additional legislation. Accordingly, SBA is precluded from adopting this suggestion.

Another suggestion was to allow financial institutions to use their own standard closing documents. SBA has not adopted this recommendation. SBA's forms have been interpreted in many court decisions over the years, which permits a degree of certainty as to their meaning. This enables SBA to provide financial assistance to small business concerns on a nationwide basis without fear of adverse legal implications.

The Agency has reconsidered its earlier decision on application forms for these small loans. Accordingly, at an early date, SBA will issue new and simplified application forms for loans of $50,000 or less. Until such new forms are approved, printed, and circulated, SBA personnel are authorized to continue to use existing forms.

For purposes of the Regulatory Flexibility Act (5 U.S.C. 605(b)), SBA certifies that this final rule will not have a significant impact on a substantial number of small entities because recent history indicates to SBA that a large number of loans $50,000 or less will not be made.

SBA certifies that this final rule does not constitute a major rule for the purposes of Executive Order 12291, since the change is not likely to result in an annual effect on the economy of $100 million or more because it is not anticipated that such a large number of $50,000 loans will be made. In 1986, the average SBA loan was $150,000, for 1987 it was $160,000, and for 1988 it was $161,000.

The final rule would not impose additional reporting or recordkeeping requirements which would be subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

The final rule will not have federalism implications warranting the preparation of a Federal Assessment in accordance with Executive Order 12612.

The revision and amendment sequences were misstated for the final regulation published on May 30, 1989 (54 FR 22877), amending part 120 of SBA regulations (13 CFR part 120). The correct sequence is revision 7, amendment 5.

List of Subjects in 13 CFR Part 120

Loan programs/business.

Pursuant to the authority contained in section 5(b)(6) of the Small Business Act (15 U.S.C. 634(b)(6)) and section 136 of Public Law 100–590 (102 Stat. 2989), SBA hereby amends part 120, chapter I, title 13, Code of Federal Regulations, as follows:

Part 120—Business Loan Policy

1. The authority citation for part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6) and 636 (a) and (h).

2. Section 120.104–1 is amended by adding a new Paragraph (f) to read as follows:

§ 120.104–1 Guaranty fees.

* * * * *

(f) *Retention of Guaranty Fee for Small Loans.* When a Certified Lender or Preferred Lender makes a loan of $50,000 or less, with a maturity in excess of twelve months, it shall pay SBA an amount equal to one percent of the amount of the deferred participation share of such loan.

Dated: August 16, 1989.

Susan Engeleiter,

Administrator.

[FR Doc. 89–20929 Filed 9–6–89; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 175

[T.D. 89–85]

Tariff Classification of Scroll Cut Tin Free Steel Sheet

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final interpretative rule.

SUMMARY: This document gives notice of a change in the tariff classification of scroll-cut tin free steel sheet, cut to length, and scroll-cut tin free steel sheet which has been laquered, painted or varnished (but not decorated, designed or otherwise finished). Customs previously published notice of the proposed change in classification and invited comments.

This merchandise has heretofore been classified under the provision for other articles of iron or steel, not coated or plated with precious metal, in item 657.25, Tariff Schedules of the United States (TSUS). The column 1 rate of duty under item 657.25, TSUS, is 5.7 percent ad valorem. Merchandise so classified is not subject to import restrictions imposed by Voluntary Restraint Agreements or VRAs.

The merchanise in question will now be classified under the provision for plates, sheets, and strip, of iron or steel, whether or not cut, pressed, or stamped to nonrectangular shape, if electrolytically coated or plated with base metal other than tin, lead, or zinc, in item 609.17, TSUS. The column 1 rate of duty under item 609.17, TSUS, is 5.7 percent ad valorem. Merchandise so classified is subject to VRAs.

EFFECTIVE DATE: This decision will be effective as to merchandise entered, or withdrawn from warehouse for consumption, on or after October 20, 1989.

FOR FURTHER INFORMATION CONTACT: James A. Seal, Commercial Rulings Division, Office of Regulations and Rulings (202) 566–8181.

SUPPLEMENTARY INFORMATION:

Background

In response to a petition received on behalf of Bethlehem Steel Corporation under the authority of section 516, Tariff Act of 1930, as amended (19 U.S.C. 1516), Customs agreed to review the classification of scroll-cut, tin free steel sheet, and tin free steel sheet which has been scroll-cut and also lacquered, painted or varnished (but not decorated, designed or finished). Customs published notice in the **Federal Register** on April 18, 1989 (54 FR 15440), that the classification in question was under review and invited public comments on the proposed change. Five (5) comments were received in response to the notice.

The merchandise affected by this decision is tin free steel sheet, which is black plate (*i.e.*, cold-rolled steel sheets, not coated, in thicknesses ranging from 0.0055 inches to 0.0149), electrolytically coated with metallic chromium oxide, and cut to a nonrectangular shape by scroll cutting. Scroll cutting involves the shearing of each end of a sheet to form a pattern of interlocking notches which fit into one another. The sheet may then be lacquered, painted, or varnished. These sheets are suitable for use in making cans and can ends for beverages and other food products.

Effective January 1, 1989, the Harmonized Tariff Schedule of the United States Annotated (HTSUSA), replaced the Tariff Schedules of the United States (TSUS) as the tariff code of this country. However, because the VRAs will continue in effect through September of 1989, and a product's coverage under a particular Arrangement will depend on how it is classified under the TSUS, it is necessary, for purposes of the VRAs, to resolve this issue under the TSUS.

In a letter dated March 13, 1978 (056338), Customs ruled that scroll-cut electrolytic tin plate or sheet was classifiable under the provision for articles of iron or steel, not coated or plated with precious metal, of tin plate, under item 657.15, TSUS, if of tin plate. If of iron or steel without actual tin plating, classification was held to be under the provision for other articles of iron or steel, in item 657.20, TSUS. The scroll-cut sheets in this case were found to be articles or products, rather than sheets. By letter dated September 11, 1978 (057211), Customs ruled that scroll-cut tinplate sheets were classifiable in item 657.15, TSUS. The ruling noted that the scroll pattern was designed to serve a specific purpose which takes the tinplate beyond the description of a basic material. Finally, a letter dated April 23, 1986 (077760), cited rulings 056338 and 057211, and confirmed that scroll-cut tin free steel sheets sprayed with an epoxy phenolic lacquer, then heated and dried, were classifiable in item 657.25, TSUS.

Summary of Comments

Of the five (5) comments received, three (3) favored the proposed change and two (2) opposed the change. Those favoring the change made the following arguments:

(1) The merchandise is encompassed by item 609.17, TSUS, because it is a steel sheet for purposes of the TSUS, is electrolytically coated other than with tin, lead, or zinc, and is cut to a nonrectangular shape by scroll cutting;

(2) Scroll cutting is not an additional process that advances the merchandise beyond the status of a basic shape or form because the steel sheet is still within the product description contained in item 609.17;

(3) The provision in item 609.17, TSUS, is relatively more specific than the provision in item 657.25, TSUS, for articles of iron or steel; and

(4) Conclusions reached in some of the existing rulings on this merchandise are based on incorrect statements of fact.

Those opposing the proposed change in classification made the following arguments:

(1) The classification of scroll-cut tin free steel sheet is well known in the importing community, as evidenced by the cited Customs rulings;

(2) There has been no change in the way the merchandise is manufactured that might serve as a basis for changing its classification; and

(3) Because scroll-cut tin free steel sheet has previously been excluded from coverage under the VRAs, any proposal to change the tariff status of this merchandise should be addressed at negotiating sessions with an individual country or countries.

Analysis of Comments

Customs agrees with the comments submitted in favor of the proposed change in classification. The merchandise in question satisfies each of the particular requirements necessary for classification in item 609.17, TSUS. With respect to scroll cutting, Customs believes that no step in the creation of merchandise otherwise classifiable as a basic shape or form of iron or steel can, at the same time, be an advancement of that merchandise beyond the status of a basic shape or form. Scroll cutting merely results in steel sheet which is nonrectangular in shape, as provided for in item 609.17. The additional steps of lacquering, painting or varnishing scroll-cut, tin free steel sheet are permissible treatments allowed by Schedule 6, Part 2, Headnote 1, TSUS. Customs believes that the requirements for classification in item 609.17, TSUS, are more difficult to satisfy than are those of item 657.25. Consequently, item 609.17 is the relatively more specific provision. Finally, Customs believes that conclusions contained in some of the cited rulings on this merchandise may have been based not on incorrect statements, but on a misapplication of the stated facts.

With respect to the comments opposing the change in classification, Customs believes the fact that classification of this merchandise in item 657.25, TSUS, may be well documented by the existing rulings, and the fact that there has been no change in the way this merchandise is made, does not override its obligation to classify and assess duty on merchandise in its condition as imported. Moreover, concerning the comment that the proposed change in classification would bring within the coverage of the VRAs merchandise not previously intended by the negotiators to be included, Customs notes that this result was anticipated because the VRAs were negotiated with the understanding that changes in classification might occur. Relevant provisions in Part 177, Customs Regulations (19 CFR Part 177), giving Customs the authority to modify or revoke rulings, were well known to the negotiators of the VRAs.

Decision

After careful analysis of the submitted comments, and further review of the matter, the proposed change in classification of scroll-cut tin free steel sheet and scroll-cut tin free steel sheet which has been lacquered, painted or varnished (but not decorated, designed or finished), is adopted. The merchandise in question will be classified under the provision for plates, sheets, and strip, of iron or steel, whether or not cut, pressed, or stamped to nonrectangular shape, plated or covered with chromium oxide or with chromium and chromium oxide, in item 609.1710, Tariff Schedules of the United States Annotated (TSUSA).

This change in classification is effective as to merchandise entered, or withdrawn from warehouse, for consumption, on or after 30 days from the date of publication of this decision in the Customs Bulletin.

Customs rulings of March 13, 1978 (056338), September 11, 1978 (057221), and April 23, 1986 (077760) are hereby revoked.

Drafting Information

The principal author of this document was James A. Seal, Commercial Rulings Division, U.S. Customs Service. However, personnel from other offices participated in its development.

Michael H. Lane,

Acting Commissioner of Customs.

Approved: August 31, 1989.

Salvatore R. Martoche,

Assistant Secretary of the Treasury.

[FR Doc. 89-20899 Filed 9-6-89; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification; Nitrofurazone Ointment; Technical Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a sponsor change from Wendt Laboratories to Quality Plus Essar Corp. for a new animal drug application (NADA) for nitrofurazone ointment. The agency is issuing this technical amendment to amend § 524.1580b(b) (21 CFR 524.1580b(b)).

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: J. Taylor Madill, Center for Veterinary Medicine (HFV-231), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3336.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 1987 (52 FR 36022), FDA published a document reflecting the change of sponsor of several NADA's from Wendt Laboratories to Quality Plus Essar Corp. That document provided for a sponsor change for NADA 118-506 Nitrofurazone ointment, but it failed to amend the corresponding regulation in § 524.1580b(b) to reflect the sponsor change.

List of Subjects in 21 CFR Part 524

Animal drugs.

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, 21 CFR Part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 524 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§ 524.1580b [Amended]

2. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing the number "015579," from the first sentence.

Dated: August 31, 1989.

Robert C. Livingston,

Deputy Director, Office of New Animal Drug Evaluation Center for Veterinary Medicine.

[FR Doc. 89-20967 Filed 9-6-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Change of Sponsors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for new animal drug applications (NADA's) from Hess & Clark, Inc., to Feed Specialties Co., Inc., and from SDS Biotech Corp. to Fermenta Animal Health Co.

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1414.

SUPPLEMENTARY INFORMATION: Feed Specialties Co., Inc., 1877 NE. 58th Avenue, Des Moines, IA 50313, has informed FDA that it has acquired NADA 48–480 which provides for use of a Type A medicated article containing 50 grams of chlortetracycline per pound in making Type C medicated feeds. The feeds are indicated for use as growth promotants in chickens and turkeys. Hess & Clark, Inc., the former sponsor, has confirmed the change of sponsor. Accordingly, the agency is amending 21 CFR 558.15 to reflect the change of sponsor.

Additionally, an error in § 558.15(g)(1) has been noted. In § 558.15(g)(1), in the table, under "Drug sponsor," the two entries for "SDS Biotech Corp." (i.e. at "Bacitracin methylene disalicylate" and at "Chlortetracycline") are incorrect in that they refer to NADA's that have been transferred from SDS Biotech Corp. to Fermenta Animal Health Co., a subsidiary of SDS Biotech Corp., by a publication in the **Federal Register** of August 8, 1986 (51 FR 28546). Therefore, § 558.15 is further amended to reflect the correct sponsor.

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, 21 CFR 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.

§ 558.15 [Amended]

2. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* is amended in paragraph (g)(1) in the table, under the "Drug Sponsor" heading, by revising the entry for "A. L. Laboratories, Inc., SDS Biotech Corp." to read "A. L. Laboratories, Inc., Fermenta Animal Health Co." and by revising the entry for "American Cyanamid Co., SDS Biotech Corp., Hess & Clark, Pfizer, Inc., and VPO, Inc." to read "American Cyanamid Co., Fermenta Animal Health Co., Feed Specialties Co., Inc., Pfizer, Inc., and VPO, Inc."

Dated: August 31, 1989.

Robert C. Livingston,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 89–20968 Filed 9–6–89; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[T.D. 8259]

RIN 1545–AM99

Real Estate Mortgage Investment Conduits; Reporting Requirements and Other Administrative Matters

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary income tax regulations relating to real estate mortgage investment conduits. The relevant provisions in the Internal Revenue Code were added or amended by the Tax Reform Act of 1986 and by the Technical and Miscellaneous Revenue Act of 1988. These regulations prescribe the manner in which an entity elects status as a real estate mortgage investment conduit (REMIC) for Federal income tax purposes and the procedures to be followed when filing a Federal income tax return as a REMIC. The regulations also require REMICs and certain other issuers to file information returns with the Internal Revenue Service and to provide notice to holders of REMIC interests or other debt instruments to which section 1272(a)(6) applies of income and certain allocable expenses attributable to their interests.

In addition, the temporary regulations set forth in this document generally serve as the text of the proposed regulations cross-referenced in the notice of proposed rulemaking in the Proposed Rules section of this issue of the **Federal Register.**

DATES: These regulations are effective after December 31, 1986, except as follows:

With respect to certain reporting requirements, §§ 1.67–3T(f), and 1.6049–7T(b)(1) and the amendements to § 1.1275–3T(b) are effective September 7, 1989.

Sections 1.6049–7T(e)(2)(x) and 1.6049–7T (f)(2)(i)(G) and (f)(2)(ii)(K) are effective for calendar years beginning after December 31, 1989.

Sections 1.860F–4T(e)(1)(ii) (A) and (B), 1.6049–7T(c) (6) through (14), 1.6049–7T(e) (1), (2) (i) through (ix), (3), (4), and (5), 1.6049–7T(f)(3) (i) and (ii), and 1.6049–7T (f)(5)(i) and (f)(7) are effective for calendar quarters and calendar years beginning after December 31, 1988.

Section 1.6049–7T(f)(2)(ii) (E), (F), and (I) are effective for calendar quarters and calendar years beginning after December 31, 1987.

Sections 1.860F–4T(e)(1)(ii)(D) and 1.6049–7T(f)(3)(iii) are effective for calendar quarters and calendar years beginning after December 31, 1987 and ending before January 1, 1990.

Section 1.860F–4T(e)(1)(ii)(C) is effective for calendar quarters and calendar years beginning after December 31, 1986 and ending before January 1, 1988.

With respect to who may sign a REMIC return, § 1.860F–4T(c)(1) is effective for REMICs with a startup day on or after November 10, 1988.

Finally, the § 1.6049–7T(g) requirement to set forth information on the face of the debt instrument is effective for debt instruments issued after April 8, 1988.

FOR FURTHER INFORMATION CONTACT: Laura Ann M. Lauritzen, 202–566–6624 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collections of information contained in this regulation have been reviewed and, pending receipt and evaluation of pubic comments, approved by the Office of Management and Budget (OMB) under control number 1545–1018.

The estimated total annual reporting and/or recordkeeping burden for the requirements contained in §§ 1.860D–1T(d), 1.860F–4T, 1.1275–3T(b), 1.6049–7T(b), 1.6049–7T(e), 1.6049–7T (f)(1) through (f)(6) of this regulation is reflected on Forms 1066, 1099–INT, 1099–OID, 8281, and 8811. The estimated annual burden per respondent/recordkeeper varies from *0.1* hours to *20.0* hours, depending on individual

circumstances, with an estimated average of *1.5* hours.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents/recordkeepers may require more or less time, depending on their particular circumstances.

For further information concerning this collection of information, and where to submit comments on this collection of information, the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register.**

Issuance of Proposed Regulation

The rules contained in this document are also being issued as proposed regulations by the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register.** Pursuant to section 7805(f) of the Internal Revenue Code, a copy of the rules will be submitted to the Administrator of the Small Business Administration for comment on their impact on small business.

Background

This document sets forth temporary income tax regulations (26 CFR part 1) under sections 860D, 860F, and 6049 (d)(7) of the Internal Revenue Code of 1986 (Code), relating to real estate mortgage investment conduits or REMICs. Section 671 of the Tax Reform Act of 1986 (the 1986 Act) added to the Code new sections 860A through 860G to provide rules relating to real estate mortgage investment conduits. Section 674 of the 1986 Act amended section 6049 to impose certain information reporting requirements with respect to REMIC interests and certain other debt instruments. Section 1006(t) of the Technical and Miscellaneous Revenue Act of 1988 (TAMRA) amended certain provisions in sections 860A through 860G and section 6049.

In general, a REMIC is a fixed pool of mortgages in which multiple classes of interests are held by investors and which elects to be taxed as a REMIC. The regulations under section 860D prescribe the manner in which an entity elects status as a REMIC. The regulations under section 860F govern the filing of the REMIC's income tax return and, together with the regulations under section 6049, require notice of income and other information to be provided to REMIC investors and the Internal Revenue Service.

Explanation of Provisions

Treatment of a REMIC as a Partnership

Except in determining who may sign a REMIC return, section 860F(e) provides that, for purposes of subtitle F of the Code (Procedure and Administration), a REMIC is treated as a partnership and any holder of a residual interest is treated as a partner. Thus, the rules relating to the tax treatment of partnership items (subchapter C of chapter 63 of the Code) generally apply to a REMIC. For example, under § 1.860F–4T(d), a REMIC may designate a tax matters person in the same manner in which a partnership may designate a tax matters partner under § 301.6231(a)(7)–1T. If there is only one holder of the REMIC residual interest, however, § 1.860F–4T(a) provides an exception to the application of those rules.

REMIC Income Tax Return and Election

Section 1.860F–4T(b) generally requires a REMIC to file an income tax return annually with the Internal Revenue Service. The Service has developed Form 1066, U.S. Real Estate Mortgage Investment Conduit Income Tax Return, for this purpose. As required by section 860F(e), the return must include the amount of the daily accruals determined under section 860E(c). The due date and any extensions for filing the REMIC's annual return are determined as if the REMIC were a partnership that uses the calendar year. Section 1.860F–4T(c)(1) provides that the REMIC return must be signed by a person who is authorized to sign the return of the entity absent the REMIC election.

As provided in § 1.860D–1T(d)(1), a qualified entity, as defined in § 1.860D–1T(c)(4), elects to be treated as a REMIC by timely filing, for its first taxable year, a Form 1066, U.S. Real Estate Mortgage Investment Conduit Income Tax Return, signed by a person authorized to sign that return under § 1.860F–4T(c). The Commissioner may, however, upon a showing of good cause, grant a reasonable extension of time under § 1.9100 for electing REMIC status. Once made, the election is irrevocable for that taxable year and all succeeding taxable years.

Section 1.860D–1T(d)(2) requires that the REMIC provide certain information with its income tax return for the first taxable year of the REMIC's existence. That information includes the REMIC's employer identification number (a REMIC may apply for an EIN on Form SS–4, Application for Employer Identification Number), information concerning the terms of each class of regular interest and the designated residual interest, and any other information that is required by the form. Each REMIC's EIN must differ from that of any other REMIC or other entity.

The REMIC must also provide on its first return a description of the prepayment and reinvestment assumptions that are made pursuant to section 1272(a)(6). Finally, pursuant to § 1.860D–1T(d)(3), sufficient records must be kept concerning investments to show the REMIC's compliance with the provisions of sections 860A through 860G during each taxable year.

Notice to Residual Interest Holders

At the close of each calendar quarter, a REMIC is required under § 1.860F–4T(e)(1) to provide to each person who held a residual interest in the REMIC during the quarter notice on Schedule Q (Form 1066) of certain information. That information includes (a) the residual holder's share of REMIC taxable income or net loss for the calendar quarter, (b) the amount of the excess inclusion with respect to the holder's residual interest, (c) in the case of certain holders, the allocable investment expenses for the quarter, and (d) for calendar years after 1987, the percentage of the REMIC's assets that are qualifying real property loans under section 593, assets described in section 7701(a)(19), and real estate assets defined in section 856(c)(6)(B). A residual interest holder may rely upon the information provided on Schedule Q concerning the percentage of assets tests in determining the tax treatment of its residual interest under sections 593, 7701(a)(19)(C), and 856. This right of reliance will be explicitly stated in future regulations under those code sections.

For calendar quarters after 1988, in determining the information to be reported to REMIC interest holders concerning the percentage of assets tests, § 1.860F–4T(e)(1)(ii) (concerning residual interests) and § 1.6049–7T(f)(3)(i) (concerning regular interests) direct a REMIC to compute the applicable percentages by reference to the average adjusted basis of the REMIC's assets during the calendar quarter. This differs from the rule now contained in temporary regulation § 1.860F–4T(e)(1)(i)(D) and § 1.6049–7T(f)(3)(i), which direct a REMIC to compute the applicable percentages by reference to the average fair market value of the REMIC's assets during the calendar quarter. The Service intends that, for calendar quarters in 1989, a

REMIC may use either method and that no REMIC will be penalized for having used one method rather than the other.

Section § 1.860F–4T(e)(2) requires that Schedule Q be mailed (or otherwise delivered) to each holder of a residual interest during a calendar quarter not later than the last day of the month following the close of the calendar quarter. Further, § 1.860F–4T(e)(4) provides that a copy of Schedule Q for each person who was a residual interest holder at any time during a REMIC's taxable year and for each quarter in which that person was a residual interest holder must be attached to the REMIC's income tax return for that taxable year. Quarterly notice to the Internal Revenue Service is not required.

Reporting to the Internal Revenue Service

Section 1.6049–7T(b)(1) requires every REMIC and issuer of a collateralized debt obligation (as defined in § 1.6049–7T(d)(2)) to file Form 8811, Information Return for Real Estate Mortgage Investment Conduits (REMICs) and Issuers of Collateralized Debt Obligations, with the Internal Revenue Service by the later of July 31, 1989, or 30 days after the startup day (as defined in section 860G(a)(9)) of the REMIC or the issue date (as defined in section 1275(a)(2)) of a collateralized debt obligation. Further, a new Form 8811 must be filed within 30 days of any change in the information previously provided on Form 8811.

The information required on Form 8811 includes the name, title, address, and telephone number of a person to be contacted by the Internal Revenue Service for information concerning the form. The form also requires designation of a person to be contacted by certain brokers, middlemen, corporations, non-calendar year taxpayers, and other persons specified in § 1.6049–7T(e)(4) for financial information necessary to complete Form 1099.

Reporting to certain brokers, middlemen, corporations, non-calendar year taxpayers, and other persons specified in § 1.6049–7T(e)(4)

The Internal Revenue Service will print in Publication 938 the information on Form 8811 concerning the representative to be contacted by persons specified in § 1.6049–7T(e)(4). For calendar quarters after 1988 a person specified in § 1.6049–7T(e)(4) may request in writing or by telephone the tax information specified in § 1.6049–7T(e)(2) from a REMIC or an issuer of a collateralized debt obligation. Pursuant to § 1.6049–7T(e)(3), the REMIC or issuer must then supply the tax information by telephone, by written statement, by causing it to be published in a publication generally read by persons permitted to make the request, or by any other method agreed to by the parties, by the later of 30 days after the close of the calendar quarter for which the information was requested, or two weeks after the receipt of the request.

The information the REMIC or the issuer of a collateralized debt obligation is required to provide includes: (a) Name, address, and Employer Identification Number of the REMIC or issuer of the collateralized debt obligation; (b) the Committee on Uniform Security Identification Procedure (CUSIP) number, account number, serial number, or other identifying number or information for each class of interest; (c) interest and original issue discount includible in the holder's gross income for each accrual period during the specified calendar quarter; (d) the length of the accrual period; (e) the adjusted issue price at the beginning of each accrual period in the specified calendar quarter; and (f) information necessary to compute the accrual of market discount.

A REMIC must also provide certain information with respect to the percentage of the REMIC's assets that are qualifying real property loans under section 593, assets described in section 7701(a)(19), and real estate assets under section 856(c)(6)(B). A regular interest holder may rely on the information provided by the REMIC concerning the percentage of assets tests in determining the tax treatment of its regular interest under sections 593, 7701(a)(19)(C), and 856. This right of reliance will be explicitly stated in future regulations under those code sections.

Reporting to regular interest holders

Section 6049 of the Code requires that certain returns of information be made regarding payments of interest. Under section 6049(d)(7) and § 1.6049–7T(a), the term "interest" includes amounts includible in the gross income of any holder of a REMIC regular interest or a collateralized debt obligation.

As required by § 1.6049–7T(b)(2), an information return must be made with respect to any payment of interest (as defined in § 1.6049–7T(a)) aggregating $10 or more. For calendar quarters and calendar years after 1988, this return must be made by a REMIC or an issuer of a collateralized debt obligation and by any broker or middleman who holds as a nominee any REMIC regular interest or any collateralized debt obligation for the actual owner. Information returns are not required, however, with respect to amounts includible as interest by certain holders specified in § 1.6049–7T(c).

Section 1.6049–7T(b)(2)(iii)(A) requires that for amounts includible as interest, other than original issue discount, the information return be made on Form 1099 for each calendar year showing the aggregate amount includible, the name, address, and taxpayer identification number of the record holder, and such other information as is required by the form. Section 1.6049–7T(b)(2)(iii)(B) requires similar information with respect to amounts of original issue discount includible by any record holder of a REMIC regular interest or a collateralized debt obligation.

The information returns required under § 1.6049–7T(b)(2) are to be filed annually in the manner prescribed in paragraph (b)(2)(iv) of that section. Generally, § 1.6049–7T(f) requires that the information provided to the Service and, if applicable, an additional statement containing information regarding market discount and original issue discount be furnished to each person in whose income amounts are includible as interest in the time and manner specified in paragraphs (f) (5) and (6) of that section respectively. Under § 1.6049–7T(f)(3), certain information regarding REMIC assets must also be provided to investors.

Nominee requirement to furnish information to corporations, non-calendar year taxpayers, and other persons specified in § 1.6049–7T(c) (9) through (14)

Section 1.6049–7T(f)(7)(i) requires brokers and middlemen holding as nominees REMIC regular interests or collateralized debt obligations to provide in writing or by telephone the information specified in § 1.6049–7T(e)(2). The information must be provided to corporations, non-calendar year taxpayers, and other persons specified in § 1.6049–7T(c) (9) through (14) in the time prescribed in § 1.6049–7T(f)(7)(ii).

Information required on debt instrument

Under § 1.6049–7T(g), the issuer of any REMIC regular interest or any collateralized debt obligation is required to set forth certain information on the face of the regular interest or collateralized debt obligation. This requirement is effective, however, only with respect to any regular interest or collateralized debt obligation that is issued after April 8, 1988.

Reporting original issue discount on debt instruments not subject to section 1272(a)(6)

Section 1.1275–3T(b) is revised to require issuers to provide additional information with the Form 8281. The issuer must provide a schedule showing the amount of original issue discount per unit of original principal amount that accrues for each accrual period and specify the unit of original principal amount if other than $1,000, specify the yield to maturity, and state whether the debt instrument is a variable rate debt instrument.

Notice to pass-through interest holders who hold regular interests in single-class REMICs

Section 1.67–3T(f) currently provides that a single-class REMIC (generally, one that would be classified as a trust had it not elected REMIC status) must furnish quarterly statements to certain of its regular interest holders showing each such interest holder's allocable share of the REMIC's investment expense. Quarterly reporting is no longer required. Section 1.67–3T(f) now provides that a REMIC is reqwuired to report annually to its regular interest holders.

Special Analyses

It has been determined that these regulations are not major regulations as defined in Executive Order 12291. Therefore, a regulatory impact analysis is not required.

A general notice of proposed rulemaking is not required by 5 U.S.C. 553 for temporary regulations. Therefore, these regulations do not constitute regulations that are subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

The principal author of these temporary regulations is Laura Ann M. Lauritzen, Office of the Assistant Chief Counsel (Financial Institutions and Products), Internal Revenue Service. However, personnel from other offices of the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR 1.61–1 Through 1.281–4

Deductions, Exemptions, Income tax, Taxable income.

26 CFR 1.851–1 Through 1.860F–4

Income taxes, Investment companies, Real estate investment trusts, Real estate mortgage investment conduits.

26 CFR 1.1271–1 Through 1.1297–3

Income taxes, Capital gains and losses, Original issue discount, Applicable Federal rate, Market discount, Short-term obligations, Stripped bonds and stripped coupons, Tax-exempt obligations.

26 CFR 1.6001–1 Through 1.6109–2

Income taxes, Administration and procedure, Filing requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, Title 26, Parts 1 and 602 of the Code of Federal Regulations are amended as follows:

PART 1—[AMENDED]

Paragraph 1. The authority for Part 1 is amended by adding the following citations:

Authority: 26 U.S.C. 7805; * * * § 1.860F–4T also issued under 26 U.S.C. 860G(e); * * * § 1.1275–3T also issued under 26 U.S.C. 1275(c); * * * § 1.6049–7T also issued under 26 U.S.C. 860G(e), 26 U.S.C. 1275(c), and 26 U.S.C. 6049(d)(7)(D). * * *

Par. 2. Paragraphs (f)(1) and (f)(2)(ii) of § 1.67–3T are revised to read as follows:

§ 1.67–3T Allocation of expenses by real estate mortgage investment conduits (temporary).

* * * * *

(f) *Notice to pass-through interest holders*—(1) *Information required.* A REMIC must provide to each pass-through interest holder to which an allocation of allocable investment expense is required to be made under paragraph (a)(1) of this section notice of—

(i) The aggregate amount of expenses paid or accrued during the calendar quarter (calendar year in the case of a regular interest holder) for which a REMIC is allowed a deduction under section 212, and

(ii) The proportionate share of these expenses allocated to that pass-through interest holder, as determined under paragraph (c) of this section.

(2) *Statement to be furnished.*

* * * * *

(ii) *To regular interest holder.* For each calendar year, a single-class REMIC (as described in paragraph (a)(2)(ii)(B) of this section) must provide to each pass-through interest holder who held a regular interest during the calendar year the notice required under paragraph (f)(1) of this section. Quarterly reporting is not required. The information required to be included in the notice may be separately stated on the statement described in § 1.6049–7T(f) instead of on a separate statement provided in a separate mailing. See § 1.6049–7T(f) (4) and (6)(i)(A).

* * * * *

Par. 3. Sections 1.860D–1T and 1.860F–4T are revised to read as follows:

§ 1.860D–1T Definition of a REMIC (temporary).

(a) *In general.* [Reserved]

(b) *Specific requirements.* [Reserved]

(c) *Segregated pool of assets*—(1) *Formation of REMIC.* A REMIC may be formed as a segregated pool of assets rather than as a separate entity. To constitute a REMIC, the assets identified as part of the segregated pool must be treated for all Federal income tax purposes as assets of the REMIC and interests in the REMIC must be based solely on assets of the REMIC.

(2) *Identification of assets.* [Reserved]

(3) *Transfer of property for interests.* [Reserved]

(4) *Qualified entity defined.* For purposes of this section, the term "qualified entity" includes an entity or a segregated pool of assets within an entity.

(d) *Election to be treated as a real estate mortgage investment conduit*—(1) *In general.* A qualified entity, as defined in paragraph (c)(4) of this section, elects to be treated as a REMIC by timely filing, for the first taxable year of its existence, a Form 1066, U.S. Real Estate Mortgage Investment Conduit Income Tax Return, signed by a person authorized to sign that return under § 1.860F–4T(c). See § 1.9100 for rules regarding extensions of time for making elections. Once made, this election is irrevocable for that taxable year and all succeeding taxable years.

(2) *Information required to be reported in the REMIC's first taxable year.* For the first taxable year of the REMIC's existence, the qualified entity, as defined in paragraph (c)(4) of this section, must provide either on its return or in a separate statement attached to its return—

(i) The REMIC's employer identification number, which must not be the same as the identification number of any other entity,

(ii) Information concerning the terms and conditions of the regular interests and the residual interest of the REMIC, or a copy of the offering circular or prospectus containing such information,

(iii) A description of the prepayment and reinvestment assumptions that are made pursuant to section 1272(a)(6) and the regulations thereunder, including a

statement supporting the selection of the prepayment assumption,

(iv) The form of the electing qualified entity under State law or, if an election is being made with respect to a segregated pool of assets within an entity, the form of the entity that holds the segregated pool of assets, and

(v) Such other information as is required by the form.

(3) *Requirement to keep sufficient records.* A qualified entity, as defined in paragraph (c)(4) of this section, that elects to be a REMIC must keep sufficient records concerning its investments to show that it has complied with the provisions of sections 860A through 860G and the regulations thereunder during each taxable year.

§ 1.860F-4T REMIC reporting requirements and other administrative rules (temporary).

(a) *In general.* Except as provided in paragraph (c) of this section, for purposes of subtitle F of the Internal Revenue Code, a REMIC is treated as a partnership and any holder of a residual interest in the REMIC is treated as a partner. A REMIC is not subject, however, to the rules of subchapter C of chapter 63 of the Code, relating to the treatment of partnership items, for a taxable year if there is at no time during the taxable year more than one holder of a residual interest in the REMIC.

(b) *REMIC tax return*—(1) *In general.* To satisfy the requirement under section 6031 to make a return of income for each taxable year, a REMIC must file the return required by paragraph (b)(2) of this section. The due date and any extensions for filing the REMIC's annual return are determined as if the REMIC were a partnership.

(2) *Income tax return.* The REMIC must make a return, as required by section 601(a), for each taxable year on Form 1066, U.S. Real Estate Mortgage Investment Conduit Income Tax Return. The return must include—

(i) The amount of principal outstanding on each class of regular interests as of the close of the taxable year,

(ii) The amount of the daily accruals determined under section 860E(c), and

(iii) the information specified in § 1.860D-1T(d)(2) (i), (iv), and (v).

(c) *Signing of REMIC return*—(1) *In general.* Although a REMIC is generally treated as a partnership for purposes of subtitle F, for purposes of determining who is authorized to sign a REMIC's income tax return for any taxable year, the REMIC is not treated as a partnership and the holders of residual interests in the REMIC are not treated as partners. Rather, the REMIC return must be signed by a person who could sign the return of the entity absent the REMIC election. Thus, the return of a REMIC that is a corporation or trust under applicable State law must be signed by a corporate officer or a trustee, respectively. The return of a REMIC that consists of a segregated pool of assets must be signed by a person who could sign the return of the entity that owns the assets of the REMIC under applicable State law.

(2) *REMIC whose startup day is before November 10, 1988*—(i) *In general.* The income tax return of a REMIC whose startup day is before November 10, 1988, may be signed by any person who held a residual interest during the taxable year to which the return relates, or, as provided in section 6903, by a fiduciary, as defined in section 7701(a)(6), who is acting for the REMIC and who has furnished adequate notice in the manner prescribed in § 301.6903-1(b).

(ii) *Startup day.* For purposes of paragraph (c)(2) of this section, startup day means any day selected by a REMIC that is on or before the first day on which interests in such REMIC are issued.

(iii) *Exception.* A REMIC whose startup day is before November 10, 1988, may elect to have paragraph (c)(1) of this section apply, instead of paragraph (c)(2) of this section, in determining who is authorized to sign the REMIC return. See section 1006(t)(18)(A) of the Technical and Miscellaneous Revenue Act of 1988 (102 Stat. 3426) and regulations thereunder for the time and manner for making this election.

(d) *Designation of tax matters person.* A REMIC may designate a tax matters person in the same manner in which a partnership may designate a tax matters partner under § 301.6231(a)(7)-1T. For purposes of applying that section, all holders of residual interests in the REMIC are treated as general partners.

(e) *Notice to holders of residual interests*—(1) *Information required.* As of the close of each calendar quarter, a REMIC must provide to each person who held a residual interest in the REMIC during that quarter notice on Schedule Q (Form 1066) of information specified in paragraphs (e)(1) (i) and (ii) of this section.

(i) *In general.* Each REMIC must provide to each of its residual interest holders the following information:

(A) That person's share of the taxable income or net loss of the REMIC for the calendar quarter;

(B) The amount of the excess inclusion (as defined in section 860E and the regulations thereunder), if any, with respect to that person's residual interest for the calendar quarter;

(C) If the holder of a residual interest is also a pass-through interest holder (as defined in § 1.67-3T(a)(2)), the allocable investment expenses (as defined in § 1.67-3T(a)(3)) for the calendar quarter, and

(D) Such other information as is required by Schedule Q (Form 1066).

(ii) *Information with respect to REMIC assets*—(A) *95 percent asset test.* For calendar quarters after 1988, each REMIC must provide to each of its residual interest holders the following information:

(*1*) The percentage of REMIC assets that are qualifying real property loans under section 593,

(*2*) The percentage of REMIC assets that are assets described in section 7701(a)(19), and

(*3*) The percentage of REMIC assets that are real estate assets defined in section 856(c)(6)(B), computed by reference to the average adjusted basis (as defined in section 1011) of the REMIC assets during the calendar quarter (as described in paragraph (e)(1)(iii) of this section). If the percentage of REMIC assets represented by a category is at least 95 percent, then the REMIC need only specify that the percentage for that category was at least 95 percent.

(B) *Additional information required if the 95 percent test not met.* If, for any calendar quarter after 1988, less than 95 percent of the assets of the REMIC are real estate assets defined in section 856(c)(6)(B), then, for that calendar quarter, the REMIC must also provide to any real estate investment trust (REIT) that holds a residual interest the following information:

(*1*) The percentage of REMIC assets described in section 856(c)(5)(A), computed by reference to the average adjusted basis of the REMIC assets during the calendar quarter (as described in paragraph (e)(1)(iii) of this section),

(*2*) The percentage of REMIC gross income (other than gross income from prohibited transactions defined in section 860F(a)(2)) described in section 856(c)(3) (A) through (E), computed as of the close of the calendar quarter, and

(*3*) The percentage of REMIC gross income (other than gross income from prohibited transactions defined in section 860F(a)(2)) described in section 856(c)(3)(F), computed as of the close of the calendar quarter. For purposes of this paragraph (e)(1)(ii)(B)(*3*), the term "foreclosure property" contained in section 856(c)(3)(F) has the meaning specified in section 860G(a)(8).

In determining whether a REIT satisfies the limitations of section 856(c)(2), all REMIC gross income is deemed to be derived from a source specified in section 856(c)(2).

(C) *For calendar quarters in 1987.* For calendar quarters in 1987, the percentages of assets required in paragraphs (e)(1)(ii) (A) and (B) of this section may be computed by reference to the fair market value of the assets of the REMIC as of the close of the calendar quarter (as described in paragraph (e)(1)(iii) of this section), instead of by reference to the average adjusted basis during the calendar quarter.

(D) *For calendar quarters in 1988 and 1989.* For calendar quarters in 1988 and 1989, the percentages of assets required in paragraphs (e)(1)(ii) (A) and (B) of this section may be computed by reference to the average fair market value of the assets of the REMIC during the calendar quarter (as described in paragraph (e)(1)(iii) of this section), instead of by reference to the average adjusted basis of the assets of the REMIC during the calendar quarter.

(iii) *Special provisions.* For purposes of paragraph (e)(1)(ii) of this section, the percentage of REMIC assets represented by a specified category computed by reference to average adjusted basis (or fair market value) of the assets during a calendar quarter is determined by dividing the average adjusted basis (or for calendar quarters before 1990, fair market value) of the assets in the specified category by the average adjusted basis (or, for calendar quarters before 1990, fair market value) of all the assets of the REMIC as of the close of each month, week, or day during that calendar quarter. The monthly, weekly, or daily computation period must be applied uniformly during the calendar quarter to all categories of assets and may not be changed in succeeding calendar quarters without the consent of the Commissioner.

(2) *Quarterly notice required*—(i) *In general.* Schedule Q must be mailed (or otherwise delivered) to each holder of a residual interest during a calendar quarter no later than the last day of the month following the close of the calendar quarter.

(ii) *Special rule for 1987.* Notice to any holder of a REMIC residual interest of the information required in paragraph (e)(1) of this section for any of the four calendar quarters of 1987 must be mailed (or otherwise delivered) to each holder no later than March 28, 1988.

(3) *Nominee reporting*—(i) *In general.* If a REMIC is required under paragraph (e) (1) and (2) of this section to provide notice to an interest holder who is a nominee of another person with respect to an interest in the REMIC, the nominee must furnish such notice to the person for whom it is a nominee.

(ii) *Time for furnishing statement.* The nominee must furnish the notice required under paragraph (e)(3)(i) of this section to the person for whom it is a nominee no later than 30 days after receiving this information.

(4) *Reports to the Internal Revenue Service.* A copy of Schedule Q for each person who was a residual interest holder at any time during a REMIC's taxable year and for each quarter in which that person was a residual interest holder must be attached to the REMIC's income tax return for that taxable year. Quarterly notice to the Internal Revenue Service is not required.

Par. 4. Paragraph (b) of § 1.1275–3T is amended as follows:

1. In paragraph (b)(1), after the last sentence, by adding the sentence, "Any person making an offering of interests in a REMIC or other debt instrument subject to section 1272(a)(6), however, is not treated as an issuer of publicly offered debt instruments having original issue discount and, consequently, is not required to make an information return on Form 8281."

2. In paragraph (b)(2)(i) by removing the language "address, and" and adding in its place the language "address, telephone number, and".

3. By redesignating paragraphs (b)(2)(iv), (v), (vi), (vii), (viii), and (ix) as paragraphs (b)(2) (v), (vi), (vii), (ix), (x), and (xi) respectively.

4. Redesignated paragraphs (b)(2)(ix)(D), (E) and (F) and further redesignated as paragraphs (b)(2)(ix) (E), (F) and (G) respectively.

5. By adding a new paragraph (b)(2)(iv) immediately after paragraph (b)(2)(iii), a new paragraph (b)(2)(viii) immediately after paragraph (b)(2)(vii), and a new paragraph (b)(2)(ix)(D) immediately after paragraph (b)(2)(ix)(C), to read as follows:

§ 1.1275–3T Original issue discount information reporting requirements.

* * * * *

(b) *Information required to be reported to Secretary—*

* * * * *

(2) *Information required to be reported.*

* * * * *

(iv) A schedule showing the amount of original issue discount per unit of original principal amount that accrues for each accrual period and specify the unit of original principal amount if other than $1,000;

* * * * *

(viii) The yield to maturity;

(ix) * * *

(D) Whether the debt instrument is a variable rate debt instrument described in § 1.1275–5(a);

* * * * *

Par. 5. Section 1.6049–7T is revised to read as set forth below.

§ 1.6049–7T Returns of information with respect to REMIC regular interests and collateralized debt obligations (temporary).

(a) *Definition of interest*—(1) *In general.* For purposes of section 6049(a), for taxable years beginning after December 31, 1986, the term "interest" includes:

(i) Interest actually paid with respect to a collateralized debt obligation (as defined in paragraph (d)(2) of this section),

(ii) Interest accrued with respect to a REMIC regular interest (as defined in section 860G(a)(1)), or

(iii) Original issue discount accrued with respect to a REMIC regular interest or a collateralized debt obligation.

(2) *Interest deemed paid.* For purposes of this section and in determining who must make an information return under section 6049(a), interest as defined in paragraph (a)(1) (ii) and (iii) of this section is deemed paid when includible in gross income under section 860B(b) or section 1272.

(b) *Information required to be reported to the Commissioner*—(1) *Requirement of filing Form 8811 by REMICs and other issuers*—(i) *In general.* Except in the case of a REMIC all of whose regular interests are owned by another REMIC, every REMIC and every issuer of a collateralized debt obligation (as defined in paragraph (d)(2) of this section) must make an information return on Form 8811, Information Return for Real Estate Mortgage Investment Conduits (REMICs) and Issuers of Collateralized Debt Obligations. Form 8811 must be filed in the time and manner prescribed in paragraph (b)(1)(iii) of this section. The submission of Form 8811 to the Internal Revenue Service does not satisfy the election requirement specified in § 1.860D–1T(d) and does not require election of REMIC status.

(ii) *Information required to be reported.* The following information must be reported to the Commissioner on Form 8811—

(A) The name, address, and employer identification number of the REMIC or the issuer of a collateralized debt obligation (as defined in paragraph (d)(2) of this section);

(B) The name, title, address, and telephone number of the official or

representative of the REMIC or the issuer of a collateralized debt obligation who will provide to any person specified in paragraph (e)(4) of this section the interest and original issue discount information specified in paragraph (e)(2) of this section;

(C) The startup day (as defined in section 860G(a)(9)) of the REMIC or the issue date (as defined in section 1275(a)(2)) of the collateralized debt obligation;

(D) The Committee on Uniform Security Identification Procedure (CUSIP) number, account number, serial number, or other identifying number or information, of each class of REMIC regular interest or collateralized debt obligation;

(E) The name, title, address, and telephone number of the official or representative of the REMIC or the issuer of a collateralized debt obligation whom the Internal Revenue Service may contact, and

(F) Such other information as is required by Form 8811.

(iii) *Time and manner of filing of information return*—(A) *Manner of filing.* Form 8811 must be filed with the Internal Revenue Service at the address specified on the form. The information specified in paragraph (b)(1)(ii) of this section must be provided on Form 8811 regardless of whether other information returns are filed by use of electronic media.

(B) *Time for filing.* Form 8811 must be filed by each REMIC or issuer of a collateralized debt obligation by the later of July 31, 1989, or 30 days after the startup day (as defined in section 860G(a)(9)) in the case of a REMIC or the issue date (as defined in section 1275(a)(2)) in the case of a collateralized debt obligation. Further, each REMIC or issuer of a collateralized debt obligation must file a new Form 8811 within 30 days after the change of any information previously provided on Form 8811.

(2) *Requirement of reporting by REMICs, issuers, and nominees*—(i) *In general.* Every person described in paragraph (b)(2)(ii) of this section who pays to another person $10 or more of interest (as defined in paragraph (a) of this section) during any calendar year must file an information return on Form 1099, unless the interest is paid to a person specified in paragraph (c) of this section.

(ii) *Person required to make reports.* The persons required to make an information return under section 6049(a) and this section are—

(A) REMICs or issuers of collateralized debt obligations (as defined in paragraph (d)(2) of this section), and

(B) Any broker or middleman who holds as a nominee any REMIC regular interest or any collateralized debt obligation.

(iii) *Information to be reported*—(A) *REMIC regular interests and collateralized debt obligations not issued with original issue discount.* An information return on Form 1099 must be made for each holder of a REMIC regular interest or collateralized debt obligation not issued with original issue discount, but only if the holder has been paid interest (as defined in paragraph (a) of this section) of $10 or more for the calendar year. The information return must show—

(*1*) The name, address, and taxpayer identification number of the record holder,

(*2*) The CUSIP number, account number, serial number, or other identifying number or information, of each REMIC regular interest or collateralized debt obligation, with respect to which a return is being made,

(*3*) The aggregate amount of interest paid or deemed paid to the record holder for the period during the calendar year for which the return is made,

(*4*) The name, address, and taxpayer identification number of the person required to file this return, and

(*5*) Such other information as is required by the form.

(B) *REMIC regular interests and collateralized debt obligations issued with original issue discount.* An information return on Form 1099 must be made for each holder of a REMIC regular interest or a collateralized debt obligation issued with original issue discount, but only if the holder has been paid interest (as defined in paragraph (a) of this section and as determined under section 1272(a)(6) and the regulations thereunder) of $10 or more for the calendar year. The information return must show—

(*1*) The name, address, and taxpayer identification number of the record holder,

(*2*) The CUSIP number, account number, serial number, or other identifying number or information, of each REMIC regular interest or collateralized debt obligation, with respect to which a return is being made,

(*3*) The aggregate amount of original issue discount deemed paid to the record holder for the period during the calendar year for which the return is made,

(*4*) The aggregate amount of interest, other than original issue discount, paid or deemed paid to the record holder for the period during the calendar year for which the return is made,

(*5*) The name, address, and taxpayer identification number of the person required to file this return, and

(*6*) Such other information as is required by the form.

(C) *Cross-reference.* See § 1.67–3T(f)(3)(ii) for additional information required to be included on an information return on Form 1099 with respect to certain holders of regular interests in REMICs described in § 1.67–3T(a)(2)(ii).

(iv) *Time and place for filing a return with respect to amounts includible as interest.* The returns required under paragraph (b)(2) of this section for any calendar year must be filed after September 30 of that year, but not before the payor's final payment to the payee for the year, and on or before February 28 of the following year. These returns must be filed with the appropriate Internal Revenue Service Center, the address of which is listed in the instructions for Form 1099. For extensions of time for filing returns under this section, see § 1.6081–1. For magnetic media filing requirements, see § 301.6011–2.

(c) *Information returns not required.* An information return is not required under section 6049(a) and this section with respect to payments of interest, if the holder of a REMIC regular interest or a collateralized debt obligation is—

(1) An organization exempt from taxation under section 501(a) or an individual retirement plan;

(2) The United States or a State, the District of Columbia, a possession of the United States, or a political subdivision or a wholly-owned agency or instrumentality of any one or more of the foregoing;

(3) A foreign government, a political subdivision thereof, or an international organization;

(4) A foreign central bank of issue (as defined in § 1.895–1(b)(1) to be a bank which is by law or government sanction the principal authority, other than the government itself, issuing instruments intended to circulate as currency);

(5) Any trust which is described in section 4947(a)(1) (relating to certain charitable trusts);

(6) For calendar quarters and calendar years after 1988, a broker (as defined in section 6045(c) and § 1.6045–1(a)(1)) who holds any REMIC regular interest or collateralized debt obligation;

(7) For calendar quarters and calendar years after 1988, a middleman (as defined in § 1.6049–4(f)(4)) who holds as a nominee any REMIC regular interest or collateralized debt obligation;

(8) For calendar quarters and calendar years after 1988, a corporation (as

defined in section 7701(a)(3)), whether domestic or foreign;

(9) For calendar quarters and calendar years after 1988, a dealer in securities or commodities required to register as such under the laws of the United States or a State;

(10) For calendar quarters and calendar years after 1988, a real estate investment trust (as defined in section 856);

(11) For calendar quarters and calendar years after 1988, an entity registered at all times during the taxable year under the Investment Company Act of 1940;

(12) For calendar quarters and calendar years after 1988, a common trust fund (as defined in section 584(a));

(13) For calendar quarters and calendar years after 1988, a financial institution such as a mutual savings bank, savings and loan association, building and loan association, cooperative bank, homestead association, credit union, industrial loan association or bank, or other similar organization; and

(14) For calendar quarters and calendar years after 1988, any trust which is exempt from tax under section 664(c) (*i.e.*, a charitable remainder annuity trust or a charitable remainder unitrust).

(d) *Special provisions and definitions*—(1) *Incorporation of referenced rules.* The special rules of § 1.6049–4(d) are incorporated in this section, as applicable. Sections 1.6049–4(d)(2) and 1.6049–5(c) do not, however, apply to any REMIC regular interest or any other debt instrument to which section 1272(a)(6) applies.

(2) *Collateralized debt obligation.* For purposes of this section, the term "collateralized debt obligation" means any debt instrument (except a tax-exempt obligation) described in section 1272(a)(6)(C)(ii) that is issued after December 31, 1986.

(e) *Requirement of furnishing information to certain nominees, corporations, and other specified persons*—(1) *In general.* For calendar quarters and calendar years after 1988, each REMIC or issuer of a collateralized debt obligation (as defined in paragraph (d)(2) of this section) must provide the information specified in paragraph (e)(2) of this section in the time and manner prescribed in paragraph (e)(3) of this section to any persons specified in paragraph (e)(4) of this section who request the information.

(2) *Information required to be reported.* For each class of REMIC regular interest or collateralized debt obligation and for each calendar quarter specified by the person requesting the information, the REMIC or issuer of a collateralized debt obligation must provide the following information—

(i) The name, address and Employer Identification Number of the REMIC or issuer of a collateralized debt obligation;

(ii) The CUSIP number, account number, serial number, or other identifying number or information, of each specified class of REMIC regular interest or collateralized debt obligation;

(iii) Interest paid on a collateralized debt obligation for each calendar quarter, and the aggregate amount for the calendar year if the request is made for the last quarter of the calendar year;

(iv) Interest accrued on a class of REMIC regular interest for each accrual period during such calendar quarter, and the aggregate amount for the calendar year if the request is made for the last quarter of the calendar year;

(v) Original issue discount accrued for each accrual period during such calendar quarter, and the aggregate amount for the calendar year if the request is made for the last quarter of the calendar year;

(vi) The daily portion of original issue discount per unit of original principal amount as determined under section 1272(a)(6) and the regulations thereunder for each accrual period and specify the unit or original principal amount if other than $1,000;

(vii) The length of the accrual period;

(viii) The adjusted issue price (as defined in section 1275(a)(4)(B)(ii)) of the REMIC regular interest or the collateralized debt obligation at the beginning of each accrual period for the requested quarters,

(ix) The information required by paragraph (f)(3) of this section, and

(x) For calendar years after 1989, the information required by paragraphs (f)(2)(i)(G) or (f)(2)(ii)(K) of this section.

(3) *Time and manner for providing information*—(i) *Manner of providing information.* The information specified in paragraph (e)(2) of this section may be provided as follows—

(A) By telephone;

(B) By written statement sent by first class mail to the address provided by the requesting party;

(C) By causing it to be printed in a publication generally read by and available to persons specified in paragraph (e)(4) and by notifying the requesting persons in writing or by telephone of the publication in which it will appear, the date of its appearance, and, if possible, the page upon which it appears; or

(D) By any other method agreed to by the parties. If the information is published, then the publication should also specify the date and, if possible, the page on which corrections, if any, will be printed.

(ii) *Time for furnishing the information.* Each REMIC or issuer of a collateralized debt obligation must furnish the information specified in paragraph (e)(2) of this section by the later of—

(A) 30 days after the close of the calendar quarter for which the information was requested, or

(B) Two weeks after the receipt of the request.

(4) *Persons entitled to request information.* The following persons may request the information specified in paragraph (e)(2) of this section from a REMIC or issuer of a collateralized debt obligation in the manner prescribed in paragraph (e)(5) of this section:

(i) Any broker who holds on its own behalf or as a nominee any REMIC regular interest or collateralized debt obligation,

(ii) Any middleman who is required to make an information return under section 6049(a) and paragraph (b)(2) of this section and who holds as a nominee any REMIC regular interest or collateralized debt obligation,

(iii) Any corporation or non-calendar year taxpayer who holds a REMIC regular interest or collateralized debt obligation directly, rather than through a nominee,

(iv) Any other person specified in paragraphs (c) (9) through (14) of this section who holds a REMIC regular interest or collateralized debt obligation directly, rather than through a nominee, or

(v) A representative or agent for a person specified in paragraphs (e)(4) (i), (ii), (iii), or (iv) of this section.

(5) *Manner of requesting information from the REMIC.* A requesting person specified in paragraph (e)(4) of this section should obtain Internal Revenue Service Publication 938, Real Estate Mortgage Investment Conduit (REMIC) and Collateralized Debt Obligation Reporting Information. This publication contains a directory of REMICs and issuers of collateralized debt obligations. The requesting person can locate the REMIC or issuer from whom information is needed and request the information from the official or representative of the REMIC or issuer at the address or telephone number specified in Publication 938. The information may be requested in writing or by telephone. The request should specify the calendar quarters (*e.g.*, all calendar quarters in 1989) and the classes of REMIC regular interests or collateralized debt obligations for which information is needed.

(f) *Requirement of furnishing statement to recipient*—(1) *In general.* Every person filing a Form 1099 under section 6049(a) and this section must furnish to the holder (the person whose identifying number is required to be shown on the form) a written statement showing the information required by paragraph (f)(2) of this section. The written statement provided by a REMIC must also contain the information specified in paragraph (f)(3) of this section.

(2) *Form of statement*—(i) *REMIC regular interests and collateralized debt obligations not issued with original issue discount.* For REMIC regular interests or collateralized debt obligations issued without original issue discount, the written statement must specify for the calendar year the following information:

(A) The aggregate amounts shown on Form 1099 to be included in income by that person;

(B) The name, address, and taxpayer identification number of the person required to file this form;

(C) The name, address, and taxpayer identification number of the person who must include the amount of interest in gross income;

(D) A legend, including a statement that the amount is being reported to the Internal Revenue Service, that conforms to the legend on Form 1099, Copy B, For Recipient;

(E) The CUSIP number, account number, serial number, or other identifying number or information, of each REMIC regular interest or collateralized debt obligation, with respect to which a return is being made;

(F) All other items shown on Form 1099 for the calendar year; and

(G) For calendar years after 1989, information necessary to compute accrual of market discount including:

(*1*) For each accrual period in the calendar year, a fraction, the numerator of which equals the interest allocable to that accrual period, and the denominator of which equals the remaining interest as of the beginning of the accrual period, and

(*2*) [Reserved].

The interest allocable to each accrual period and the remaining interest are calculated by taking into account events which have occurred before the close of the accrual period and the prepayment assumption, if any, determined as of the startup day (as defined in section 860G(a)(9)) of the REMIC or the issue date (as defined in section 1275(a)(2)) of the collateralized debt obligation that would be made in computing original issue discount if the debt instrument had been issued with original issue discount.

(ii) *REMIC regular interests and collateralized debt obligations issued with original issue discount.* For REMIC regular interests or collateralized debt obligations issued with original issue discount, the written statement must specify for the calendar year the following information:

(A) The aggregate amount of original issue discount includible in gross income of the holder for the calendar year with respect to the REMIC regular interest or the collateralized debt obligation;

(B) The aggregate amount of interest, other than original issue discount, includible in the gross income of the holder for the calendar year with respect to the REMIC regular interest or the collateralized debt obligation;

(C) The name, address, and taxpayer identification number of the person required to file this form;

(D) The name, address, and taxpayer identification number of the person who must include the amount of interest specified in paragraph (f)(2)(ii) (A) and (B) of this section in gross income;

(E) For calendar years after 1987, the daily portion of original issue discount per unit of original principal amount as determined under section 1272(a)(6) and the regulations thereunder for each accrual period and specify the unit of original principal amount if other than $1,000;

(F) For calendar years after 1987, the length of the accrual period;

(G) All other items shown on Form 1099 for the calendar year;

(H) A legend, including a statement that the information required under paragraph (f)(2)(ii) (A), (B), (C), (D) and (G) of this section is being reported to the Internal Revenue Service, that conforms to the legend on Form 1099, Copy B, For Recipient;

(I) For calendar years after 1987, the adjusted issued price (as defined in section 1275(a)(4)(B)(ii)) of the REMIC regular interest or the collateralized debt obligation at the beginning of each accrual period with respect to which interest income is required to be reported on Form 1099;

(J) The CUSIP number, account number, serial number, or other identifying number or information, of each class of REMIC regular interest or collateralized debt obligation, with respect to which a return is being made; and

(K) For calendar years after 1989, information necessary to compute accrual of market discount including:

(*1*) For each accrual period in the calendar year, a fraction, the numerator of which equals the original issue discount allocable to that accrual period, and the denominator of which equals the remaining original issue discount as of the beginning of that accrual period, and

(*2*) [Reserved].

The original issue discount allocable to each accrual period and the remaining original issue discount are calculated by taking into account events which have occurred before the close of the accrual period and the prepayment assumption determined as of the startup day (as defined in section 860G(a)(9) of the REMIC or the issue date (as defined in section 1275(a)(2)) of the collateralized debt obligation.

(3) *Information with respect to REMIC assets*—(i) *95 percent asset test.* For calendar years after 1988, the written statement provided by a REMIC must also contain the following information for each calendar quarter:

(A) The percentage of REMIC assets that are qualifying real property loans under section 593,

(B) The percentage of REMIC assets that are assets described in section 7701(a)(19), and

(C) The percentage of REMIC assets that are real estate assets defined in section 856(c)(6)(B), computed by reference to the average adjusted basis (as defined in section 1011) of the REMIC assets during the calendar quarter (as described in section 1.860F–4T(e)(1)(iii)). If for any calendar quarter the percentage of REMIC assets represented by a category is at least 95 percent, then the statement need only specify that the percentage for that category, for that calendar quarter, was at least 95 percent.

(ii) *Additional information required if the 95 percent test not met.* If, for any calendar quarter after 1988, less than 95 percent of the assets of the REMIC are real estate assets defined in section 856(c)(6)(B), then for that calendar quarter, the REMIC's written statement must also provide to any real estate investment trust (REIT) that holds a regular interest the following information:

(A) The percentage of REMIC assets described in section 856(c)(5)(A), computed by reference to the average adjusted basis of the REMIC assets during the calendar quarter (as described in § 1.860F–4T(e)(1)(iii)),

(B) The percentage of REMIC gross income (other than gross income from prohibited transactions defined in section 860F(a)(2)) described in section 865(c)(3) (A) through (E), computed as of the close of the calendar quarter, and

(C) The percentage of REMIC gross income (other than gross income from prohibited transactions defined in

section 860F(a)(2)) described in section 865(c)(3)(F), computed as of the close of the calendar quarter. For purposes of this paragraph (f)(3)(ii)(C), the term "foreclosure property" contained in section 865(c)(3)(F) shall have the meaning specified in section 860G(a)(8). In determining whether a REIT satisfies the limitations of section 856(c)(2), all gross income is deemed to be derived from a source specified in section 856(c)(2).

(iii) For calendar years 1988 and 1989, the percentage of assets required in paragraph (f)(3) (i) and (ii) of this section may be computed by reference to the average fair market value of the assets of the REMIC during the calendar quarter (as described in § 1.860F–4T(e)(1)(iii)), instead of by reference to the average adjusted basis of the assets of the REMIC during the calendar quarter.

(4) *Cross-reference.* See § 1.67–3T(f)(2)(ii) for additional information that may be separately stated on the statement required by paragraph (f) of this section with respect to certain holders of regular interests in REMICs described in § 1.67–3T(a)(2)(ii).

(5) *Time for furnishing statements*—(i) *For calendar quarters and calendar years after 1988.* For calendar quarters and calendar years after 1988, each statement required under paragraph (f) of this section to be furnished to any person of a calendar year with respect to amounts includible as interest must be furnished to that person after April 30 of that year and on or before March 15 of the following year, but not before the final interest payment (if any) for the calendar year.

(ii) *For calendar quarters and calendar years prior to 1989*—(A) *In general.* For calendar quarters and calendar years prior to 1989, each statement required under paragraph (f) of this section to be furnished to any person for a calendar year with respect to amounts includible as interest must be furnished to that person after April 30 of that year and on or before January 31 of the following year, but not before the final interest payment (if any) for the calendar year.

(B) *Nominee reporting.* For calendar quarters and calendar years prior to 1989, each statement required under paragraph (f) of this section to be furnished by a nominee must be furnished to the actual owner of a REMIC regular interest or a collateralized debt obligation to which section 1272(a)(6) applies by the later of—

(*1*) 30 days after the nominee receives such information, or

(*2*) January 31 of the year following the calendar year to which the statement relates.

(6) *Special rules*—(i) *Copy of Form 1099 permissible.* The requirements of paragraph (f) of this section for the furnishing of a statement to any person, including the legend requirement or paragraphs (f)(2)(i)(D) and (f)(2)(ii)(H) of this section, may be met by furnishing to that person—

(A) A copy of the Form 1099 filed pursuant to paragraph (b)(2) of this section is respect of that person, plus a separate statement (mailed with the Form 1099) that contains the information described in paragraphs (f)(2)(i)(G), (f)(2)(ii) (E), (F), (I), and (K), (f)(3) and (f)(4), if applicable, of this section, or

(B) A substitute form that contains all the information required under paragraph (f) of this section and that complies with any current revenue procedure concerning the reproduction of paper substitutes of Forms 1099 and the furnishing of substitute statements to forms recipients.

(ii) *Statement furnished by mail.* A statement mailed to the last known address of any person shall be considered to be furnished to that person within the meaning of this section.

(7) *Requirement that nominees furnish information to corporations and certain other specified persons*—(i) *In general.* For calendar quarters and calendar year after 1988, every broker or middleman must provide in writing or by telephone the information specified in paragraph (e)(2) of this section to—

(A) A corporation,

(B) A non-calendar year taxpayer, or

(C) Any other person specified in paragraphs (c)(9) through (14) of this section who requests the information and for whom the broker or middleman holds as a nominee a REMIC regular interest or a collateralized debt obligation. A corporation, non-calendar year taxpayer, or any other person specified in paragraphs (c)(9) through (14) of this section may request the information in writing or by telephone for any calendar quarter and for any class of REMIC regular interest or collateralized debt obligation.

(ii) *Timer of furnishing information.* The statement required in paragraph (f)(7)(i) of this section must be furnished to the corporate or non-calendar year taxpayer within 45 days after receipt of the request. If the request is made, however, for the last calendar quarter in a year, then the information must be furnished by the later of—

(A) 45 days after receipt of request, or

(B) March 15 of the year following the calendar quarter for which the information was requested.

(g) *Information required to be set forth on face of debt instrument.* In the case of any REMIC regular interest or collateralized debt obligation that is issued after April 8, 1988 and that has original issue discount, the issuer must set forth on the fact of the REMIC regular interest or collateralized debt obligation—

(1) The amount of the original issue discount,

(2) The issue date,

(3) The rate at which interest is payable (if any) as of the issue date,

(4) The yield to maturity, including a statement as to the assumption made under section 1272 (a)(6)(B)(iii),

(5) The method used to determine yield where there is a short accrual period, and

(6) The amount of the original issue discount allocable to the short accrual period based on the prepayment assumption determined on the startup day (as defined in section 860G (a)(9)) or the issue date (as defined in section 1275 (a)(2)).

In cases where it is not possible to set forth the information required by this paragraph (g) of the fact of the REMIC regular interest or collateralized debt obligation by the issue date, the issuer must deliver to the holder a sticker containing this information within 10 days after the issue date. For rules relating to the penalty imposed for failure to show the information required by this paragraph (g) on the regular interest or collateralized debt obligation, see section 6706 (a) and the regulations thereunder.

PART 602—[AMENDED]

Par. 6. The authority citation for Part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 7. Section 602.101 (c) is amended by adding to the table in the appropriate place—

"§ 1.67–3T.....1545–1018",

"§ 1.860D–1T.....1545–1018",

"§ 1.860F–4T.....1545–1018", and

"§ 1.6049–7T.....1545–1018".

Fred T. Goldberg, Jr.,

Commissioner of Internal Revenue.

Approved: August 5, 1989.

Kenneth W. Gideon,

Assistant Secretary of the Treasury.

[FR Doc. 89–20916 Filed 9–6–89; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

COTP Western Alaska Regulation 89-04, Safety Zone Regulations: Viekoda Bay, Kodiak Island, Alaska

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a one hundred (100) yard safety zone around the incinerator barge MLC-333, tug MARINE CHALLENGER, and berthing vessel JEANE CANDIES. The zone is needed to protect these vessels from a safety hazard associated with small vessels obstructing movement of vessels transporting oil spill debris to the MLC-333. Entry into this zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation becomes effective at 5:30 p.m., August 18, 1989. It terminates at 12:00 a.m., September 15, 1989, unless sooner terminated by the Captain of the Port.

FOR FURTHER INFORMATION CONTACT: LCDR W.J. Hutmacher, (907) 271-5137.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent damage to the vessels involved, possible loss of oily debris, and injury to vessel crews.

Drafting Information

The drafters of this regulation are LCDR W. J. Hutmacher, project officer for COTP Western Alaska, and CDR R. L. Nelson, project attorney, Commander, Seventeenth Coast Guard District (dl).

Discussion of Regulation

The circumstances requiring this regulation resulted from the citizens of Port Lions stating they planned to demonstrate against the burning of oil spill debris aboard the barge MLC-333 and possibly block the approach of debris-carrying vessels to the incinerator barge. Small boats obstructing the path of debris-carrying vessels can create potential problems for the safe navigation of the debris-carrying vessels that could result in damage to those vessels and the protest vessels, possible loss of oily debris resulting in further oil pollution, and possible injuries to the crews involved. The regulation is necessary to prevent damage and possible injuries from occurring.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, subpart C of part 165 of title 33, Code of Federal Regulations, is amended as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5, 49 CFR 1.46.

2. A new § 165.T1704 is added to read as follows:

§ 165.T1704 Safety zone.

One hundred (100) yards around the incinerator barge MLC-333, tug MARIEN CHALLENGER, and the berthing vessel JEANE CANDIES.

(a) *Location:* The following area is a safety zone: One hundred (100) yards around the incinerator barge MLC-333, tug MARIEN CHALLENGER, and the berthing vessel JEANE CANDIES while anchored in Viekoda Bay, Kodiak Island, Alaska, position 57-51N, 153-05W.

(b) *Effective Date.* This regulation becomes effective at 5:30 p.m., August 18, 1989. It terminates at 12:00 a.m., September 15, 1989, unless sooner terminated by the Captain of the Port.

(c) *Regulations:* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port.

Dated: August 18, 1989.

W.J. Morani, Jr.,

Commander, U.S. Coast Guard, Alternate Captain of the Port, Western Alaska.

[FR Doc. 89-20946 Filed 9-6-89; 8:45 am]

BILLING CODE 4910-14-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900-AD76

Veterans Education; Implementation of the Veterans' Benefits Improvement and Health-Care Authorization Act of 1986

AGENCY: Department of Veterans Affairs.

ACTION: Correction; Final regulations.

SUMMARY: On August 17, 1989, commencing on page 33885 (54 FR 33885-33894), the Department of Veterans Affairs (VA) published a final rule to better acquaint the public with the way in which VA intends to administer the provisions of law contained in the Veterans' Benefits Improvement and Health-Care Authorization Act of 1986 which affect the administration of dependents' educational assistance and benefits provided under the Vietnam-era GI bill. VA inadvertently neglected to show that the introductory text of § 21.4204 contained in the current edition of title 38 Code of Federal Regulations is not removed. The introductory text is published below to avoid any confusion. VA regrets the error and hereby corrects it.

FOR FURTHER INFORMATION CONTACT: Mr. William G. Susling, Jr., Acting Assistant Director for Education Policy and Program Administration (225), Vocational Rehabilitation and Education Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 (202) 233-2092.

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Dated: August 30, 1989.

Charles A. Fountaine III,

Chief, Directives Management Division.

In 38 CFR part 21, Vocational Rehabilitation and Education, the introductory text of § 21.4204 is republished to read as follows:

§ 21.4204 Periodic certification.

Educational assistance allowance is payable on the basis of a required certification concerning the pursuit of a course during the reporting period.

* * * * *

[FR Doc. 89-20957 Filed 9-6-89; 8:45 am]

BILLING CODE 8320-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 88-588; RM-6481]

Radio Broadcasting Services; The Dalles, OR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Nugent Broadcasting Corporation, substitutes Channel 249C2 for Channel 249A at The Dalles, Oregon, and modifies its license for Station KACI(FM) to specify operation on the higher powered channel. Channel 249C2 can be allotted to The Dalles in compliance with the Commission's minimum distance separation requirements with a site restriction of 9.7 kilometer (6.0 miles) northwest to accommodate petitioner's desired transmitter site. The coordinates for this allotment are North Latitude 45–38–54 and West Longitude 121–16–18. With this action, this proceeding is terminated.

EFFECTIVE DATE: October 16, 1989.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 88–588, adopted August 18, 1989, and released September 1, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the FM Table of Allotments is amended by adding Channel 249C2 and removing Channel 249A at The Dalles, Oregon.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21051 Filed 9–6–89; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 88–590; RM–6484; RM–6690]

Radio Broadcasting Services; Ravenel, Barnwell and Blackville, SC

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Coastal Broadcasting, Inc., substitutes Channel 269C2 for Channel 269A at Ravenel, South Carolina, modifies its license for Station WMGL(FM) to specify operation on Channel 269C2, substitutes Channel 256A for Channel 269A at Barnwell, South Carolina, and modifies Station WBAW(FM)'s license to specify the alternate Class A channel. At the request of Aiken Broadcast Group, the Commission allots Channel 250A to Blackville, South Carolina, as its first local FM service. Channel 250A can be allotted to Blackville in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for the Blackville allotment are North Latitude 33–21–48 and West Longitude 81–16–06. Channel 269C2 can be allotted to Ravenel with a site restriction of 17.2 kilometers (10.7 miles) southwest to accommodate Coastal's desired transmitter site. The coordinates for the Ravenel allotment are North Latitude 32–40–40 and West Longitude 80–23–40. Channel 256A can be allotted to Barnwell in compliance with the Commission's minimum distance separation requirements and can be used at Station WBAW(FM)'s present transmitter site. The coordinates for the Barnwell allotment are North Latitude 33–13–25 and West Longitude 81–21–35. With this action, this proceeding is terminated.

DATES: Effective October 16, 1989. The window period for filing applications for Channel 250A at Blackville, South Carolina, will open on October 17, 1989, and close on November 16, 1989.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 88–590, adopted August 18, 1989, and released September 1, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the FM Table of Allotments, is amended as follows: the entry for Barnwell, South Carolina, is amended by removing Channel 269A and adding Channel 256A; an entry for Blackville, South Carolina, Channel 250A, is added; and the entry for Ravenel, South Carolina, is amended by removing Channel 269A and adding Channel 269C2.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21052 Filed 9–6–89; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611 and 672

[Docket No. 81132–9033]

Foreign Fishing; Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of revision of effective date.

SUMMARY: This document revises the "**DATES**" portion of the preamble of a notice of adjustment to the 1989 specification of total allowable catch for pollock for the groundfish fishery of the Gulf of Alaska published August 10, 1989 (54 FR 32819). This action is intended to carry out management objectives contained in the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP).

DATES: This notice of revision is effective September 5, 1989. This notice changes the effective date of the notice published at 54 FR 32819 (August 10, 1989) from September 5, 1989 to September 15, 1989.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg, Fishery Management Biologist, 907–586–7230.

SUPPLEMENTARY INFORMATION: NMFS has been requested by fishermen and processors to delay the opening of directed fishing for pollock in the Gulf of Alaska to September 15. Processors argue that the September 7–8 halibut

opening will produce such a quantity of fish that not less than a week will be required to properly handle the product. Processing of halibut is very different from pollock and requires adjustment in plant operations. Many fishermen have their vessels on contract to Exxon/Veco on oil spill clean-up activities through September 15. Other fishermen, believing the opening would occur in mid-September, have vessels undergoing repair and will not be ready until September 15. An earlier opening would eliminate much of their fishing opportunity and would result in wastage.

In rule document 89–18661, in the issue of August 10, 1989, page 32819, the phrase, "Effective September 5, 1989", should read, "Effective September 15, 1989." In column three, the sentence, "This inseason adjustment takes effect 30 days after the Secretary has filed the proposed adjustment with the Office of the Federal Register," before the Classification Section, should be deleted.

Classification

This action is taken under § 672.22 and Amendment 15 to the FMP. This action is in compliance with Executive Order 12291.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 1, 1989.

Herbert L. Blatt,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–21033 Filed 9–1–89; 3:04 pm]

BILLING CODE 3510–22–M

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50 CFR Parts 611 and 672

[Docket No. 81132–9033]

Foreign fishing; Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure.

SUMMARY: The Secretary of Commerce (Secretary) prohibits trawling for groundfish in the Gulf of Alaska with a fishing vessel that has trawl gear other than pelagic trawl gear attached or on board that vessel, effective September 2, 1989, through the remainder of 1989. This action is necessary to limit the prohibited species catch (PSC) for Pacific halibut to the amount provided for by regulations implementing the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). It is intended to carry out the management objectives of the North Pacific Fishery Management Council.

DATES: This notice is effective at 12:00 noon, Alaska Daylight Time (ADT) on September 2, 1989, until midnight, Alaska Standard Time, December 31, 1989.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg, Fishery Management Biologist, NMFS, 907–586–7230.

SUPPLEMENTARY INFORMATION: The FMP, which governs groundfish fishing in the U.S. exclusive economic zone in the Gulf of Alaska under the Magnuson Fishery Conservation and Management Act, is implemented by rules appearing at 50 CFR 611.92 and part 672. Special consideration is given to the conservation of Pacific halibut (halibut), a valuable species sought in another U.S. fishery, but which are caught as bycatch in the groundfish fishery. Pacific halibut are managed under authority of the International Pacific Halibut Commission; however, bycatches by U.S. fishermen are controlled through prohibited species catch (PSC) limits (50 CFR 672.20(f)).

The current halibut PSC limit for the Gulf of Alaska is an amount that would result in the mortality of no more than 2,000 metric tons (mt). A PSC share allocated to domestic annual processing (DAP) fisheries was not specified numerically, but was defined as the amount that would result in a total mortality inflicted on halibut of 1,485 mt. No JVP operations are planned during the remainder of 1989, and, therefore, the DAP fishery was allowed to continue until the halibut mortality was 2,000 mt. The Regional Director has determined that halibut mortality will equal this number on September 2, 1989. Under § 672.20(f)(1), the Regional Director is prohibiting fishing with trawl gear other than pelagic trawl gear for the remainder of the 1989 fishing year. Fishing with trawl gear is interpreted to include operations at sea in support of, or in preparation for, the use of trawl gear, such as having trawl gear on board.

Classification

Unless this notice takes effect promptly, the halibut PSC for the Gulf of Alaska will be exceeded. Therefore, NOAA finds for good cause that prior opportunity for public comment on this notice is contrary to the public interest and its effective date should not be delayed. This action is taken under 50 CFR 672.20 and is in compliance with Executive Order 12291.

List of Subjects in 50 CFR Parts 611 and 672

Fisheries.

Authority: 16 U.S.C. 1801, *et seq.*

Dated: August 31, 1989.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–21034 Filed 9–1–89; 3:10 pm]

BILLING CODE 3510–22–M

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50 CFR Part 661

[Docket No. 90515–9115]

Ocean Salmon Fisheries Off the Coasts of Washington, Oregon, and California

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of inseason adjustment and closure.

SUMMARY: NOAA announces adjustment to the commercial ocean salmon management measures in the exclusive economic zone (EEZ) as follows: (1) For the subarea from Cape Falcon to Orford Reef Red Buoy, a ration restriction of one chinook for every two coho salmon landed is established and the first two coho salmon may be landed without a chinook salmon, beginning August 14, 1989; (2) the quota for chinook salmon in the commercial fishery from Humbug Mountain, Oregon to Punta Gorda, California, beginning August 18, 1989 is increased from 7,500 to 9,200 fish; and (3) when the commercial fishery from Humbug Mountain to Punta Gorda is open fish taken in this fishery, and only this fishery, may be landed at Port Orford, Oregon, beginning August 18, 1989.

NOAA also announces the closure of four ocean salmon fisheries in the EEZ as follows: (1) The commercial fishery for coho salmon from Cape Falcon, Oregon to Horse Mountain, California, at midnight, August 17, 1989; (2) the recreational fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon, at midnight August 17, 1989; (3) the commercial fishery from Humbug Mountain, Oregon, to Punta Gorda, California, at midnight, August 20, 1989; and (4) the recreational fishery from Cape Falcon to Orford Reef Red Buoy, Oregon, at midnight, August 20, 1989. The Director, Northwest Region, NMFS (Regional Director), has determined that this action is necessary to conform to the preseason notice of 1989 management measures. This action is

intended to allow maximum harvest of ocean salmon quotas established for the 1989 season, to accommodate fishermen's needs without substantially or adversely affecting the implementation of the 1989 management measures, and to ensure conservation of chinook and coho salmon.

DATES: The adjustments were effective as follows: (1) 0001 hours local time, August 14, 1989 for the adjustment to the commercial fishery from Cape Falcon to Orford Reef Red Buoy, Oregon; (2) 2400 hours local time, August 17, 1989 for the closure of the commercial fishery for coho salmon from Cape Falcon, Oregon, to Horse Mountain, California, and closure of the recreational fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon; (3) 0001 hours local time, August 18, 1989 for the revised quota and adjustment to the commercial fishery from Humbug Mountain, Oregon, to Punta Gorda, California; and (4) 2400 hours local time, August 20, 1989 for the closure of the commercial fishery from Humbug Mountain Oregon, to Punta Gorda, California, and closure of the recreational fishery from Cape Falcon to Orford Reef Buoy, Oregon. Actual notice to affected fishermen was given prior to those times through a special telephone hotline and U.S. Coast Guard notice-to-mariners broadcasts as provided by 50 CFR 661.20, 661.21, and 661.23 (as amended May 1, 1989). Public comment on this notice will be accepted through September 22, 1989.

ADDRESSES: Comments may be mailed to Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE., BIN C15700, Seattle, WA 98115–0070; or E. Charles Fullerton, Director, Southwest Region, National Marine Fisheries Service, 300 S. Ferry Street, Terminal Island, CA 90731–7415. Information relevant to this notice has been compiled in aggregate form and is available for public review during business hours at the office of the NMFS Northwest Regional Director.

FOR FURTHER INFORMATION CONTACT: William L. Robinson at 206–526–6140, or Rodney R. McInnis at 213–514–6199.

SUPPLEMENTARY INFORMATION: Regulations governing the ocean salmon fisheries are published at 50 CFR part 661. Management measures for 1989 were effective on May 1, 1989 (54 FR 19798, May 8, 1989). The following adjustments to the commercial management measures are authorized by the ocean salmon regulations at 50 CFR 661.21(b)(1)(i)–(v).

Adjustment to Commercial Fishery From Cape Falcon to Orford Reef Red Buoy, Oregon

In its preseason notice of 1989 management measures, NOAA specified landing limits, landing boundaries, and ratio fisheries (restriction on the ratio of coho to chinook salmon which can be landed) for the 1989 commercial seasons in the subareas from Cape Falcon to Cascade Head, Oregon, and from Cascade Head to Orford Reef Red Buoy, Oregon. These restrictions were modified effective 0001 hours local time, July 18, 1989 (54 FR 31196, July 27, 1989) as follows. For the subarea from Cape Falcon to Cascade Head, a single daily landing limit per vessel or 50 coho salmon was established; for the surbarea from Cascade Head to Orford Reef Red Buoy, a ratio restriction of one chinook salmon for every two coho salmon landed was established and the first two coho salmon could be landed without a chinook salmon.

Based on the most recent catch information, the Regional Director determined that the catch rate should be slowed in the subarea from Cape Falcon to Cascade Head, Oregon, in order to allow maximum harvest of the overall coho quota and subarea coho ceilings established for the area south of Cape Falcon and to provide for equitable distribution of harvest among Oregon ports. Therefore, a landing ratio restriction of one chinook salmon for every two coho salmon landed with the provision that the first two coho salmon may be landed without a chinook salmon was established for the combined subarea from Cape Falcon to Orford Reef Red Buoy, Oregon, effective 0001 hours local time, August 14, 1989.

Adjustment to Commercial Fishery From Humbug Mountain, Oregon, to Punta Gorda, California

The 1989 commercial troll salmon fisheries from Humbug Mountain, Oregon, to Punta Gorda, California, are managed not to exceed an overall quota of 30,000 chinook salmon through August 31. This overall quota is partitioned into three subquotas and seasons. Any overages or underages in meeting a subquota for one time period are subtracted from or added to the next time period prior to August 31.

The commercial fisheries for the first two time periods have been completed. Actual landings indicate that about 20,800 chinook salmon have been caught, and 9,200 fish remain in the overall chinook quota. The third and last season governed by this chinook quota began on August 18, 1989, from Humbug Mountain, Oregon, to Punta Gorda, California. Therefore, the subquota for this fishery should be increased by the number of chinook salmon not harvested in the two earlier fisheries. Accordingly, the subquota for the commercial fishery from Humbug Mountain, Oregon, to Punta Gorda, California, beginning August 18, 1989, was increased from 7,500 to 9,200 chinook salmon.

The preseason notice of 1989 management measures requires that salmon caught in the commercial fisheries from Humbug Mountain, Oregon, to Punta Gorda, California, must be delivered within the area. Commercial fishermen requested to land their catch in Port Orford, Oregon, which is in the closed area between Orford Reef Red Buoy and Humbug Mountain, Oregon. By earlier inseason adjustment (54 FR 24906, June 1989), Port Orford is allowed to receive salmon caught only in the commercial fishery to the north between Cascade Head and Orford Reef Red Buoy, Oregon. In order to allow fishermen to land salmon in Port Orford and to provide proper accounting of catches for each management area, effective 0001 hours local time, August 18, 1989, whenever the commercial salmon fishery between Humbug Mountain, Oregon, and Punta Gorda, California is open, salmon caught in this fishery, and only this fishery, may be landed at Port Orford, Oregon. These landing boundaries, as well as the landing limits, will remain in effect only until this area is closed to commercial fishing.

Closures

Regulations governing the ocean salmon fisheries to 50 CFR 661.21(a)(1) state that "When a quota for the commercial or the recreational fishery, or both, for any salmon species in any portion of the fishery management area is projected by the Regional Director to be reached on or by a certain date, the Secretary will, by notice issued under § 661.23, close the commercial or recreational fishery, or both, for all salmon species in the portion of the fishery management area to which the quota applies as of the date the quota is projected to be reached."

Closure of Commercial Fishery From Cape Falcon, Oregon, to Horse Mountain, California, to Coho Salmon

The 1989 commercial fishery in the area from Cape Falcon, Oregon, to the U.S.-Mexico border is limited to an overall quota of 474,000 coho salmon, of which 5,000 coho salmon were reserved preseason for the commercial fishery south of Horse Mountain, California.

Based on the best available information, the commercial fishery catch south of Cape Falcon was projected to reach the 469,000 coho salmon quota (deducting the 5,000 coho salmon reserved preseason as stated above) by midnight, August 17, 1989. Therefore, the commercial fishery in the subarea from Cape Falcon, Oregon, to Horse Mountain, California, was closed to further fishing for coho salmon effective 2400 hours local time, August 17, 1989. In accordance with the preseason notice of 1989 management measures, the commercial salmon fishery in the subarea from Cape Falcon to Horse Mountain will continue for all salmon species except coho salmon, and the commercial salmon fishery in the subarea from Horse Mountain to the U.S.-Mexico border will continue for all salmon species through the earlier of September 30 or the attainment of a subarea quota of 5,000 coho salmon, effective 0001 hours local time, August 18, 1989.

Closure of Recreational Fishery From Leadbetter Point, Washington, to Cape Falcon, Oregon

The 1989 recreational fishery for all salmon species in the subarea from Leadbetter Point, Washington, to Cape Falcon, Oregon, commenced on June 26, 1989, and was scheduled to continue through the earliest of September 28, 1989, or the attainment of either a subarea quota of 111,400 coho salmon or an overall quota of 47,500 chinook salmon north of Cape Falcon. Based on the best available information, the recreational fishery catch in the subarea was projected to reach the 111,400 coho salmon quota by midnight, August 17, 1989. Therefore, the recreational fishery in this subarea was closed to further fishing effective 2400 hours local time, August 17, 1989.

Closure of Commercial Fishery From Humbug Mountain, Oregon, to Punta Gorda, California

According to the preseason notice, the commercial fishery in the subarea from Humbug Mountain, Oregon, to Punta Gorda, California, opened on August 18, 1989 for all salmon species except coho salmon and was scheduled to continue through the earlier of August 31, 1989 or the attainment of a subarea quota of 9,200 chinook salmon (as described above). Based on the best information available before the fishery opened, the commercial fishery catch in the subarea was projected to reach the subarea quota of 9,200 chinook salmon by midnight, August 20, 1989. Therefore, the commercial fishery in this subarea was closed to further fishing effective 2400 hours local time, August 20, 1989.

Closure of Recreational Fishery From Cape Falcon to Orford Reef Red Buoy, Oregon

The 1989 recreational fishery in the area from Cape Falcon, Oregon, to the U.S.-Mexico border is limited to an overall quota of 285,000 coho salmon. If the recreational coho quota is reached, the recreational fishery from Cape Falcon to Orford Reef Red Buoy, Oregon, is to be closed while the fishery from Orford Reef Red Buoy, Oregon, to the U.S.-Mexico border remains open as regularly scheduled.

The recreational fishery for all salmon species in the subarea from Cape Falcon to Orford Reef Red Buoy, Oregon, commenced on May 1, 1989, and was scheduled to continue through the earlier of September 15 or the attainment of an overall quota of 285,000 coho salmon south of Cape Falcon. The fishing week in this subarea was shortened to Sunday through Thursday only effective 2400 hours local time, July 27, 1989 (54 FR 31841, August 2, 1989) in order to provide a longer recreational fishing season. Based on the best available information, the recreational fishery catch south of Cape Falcon is projected to reach the 285,000 coho salmon quota by midnight, August 20, 1989. Therefore, the recreational fishery in the subarea from Cape Falcon to Orford Reef Red Buoy, Oregon, is closed to further fishing effective 2400 hours local time, August 20, 1989.

The Regional Director consulted with representatives of the Pacific Fishery Management Council, the Washington Department of Fisheries, the Oregon Department of Fish and Wildlife, and the California Department of Fish and Game regarding these closures and inseason adjustments. The States of Washington, Oregon, and California will manage the commercial and recreational fisheries in state waters adjacent to the affected areas of the EEZ in accordance with this federal action. This notice does not apply to other fisheries which may be operating in other areas.

In accordance with the revised inseason notice procedures of 50 CFR 661.20, 661.21, and 661.23, actual notice to fishermen was given prior to the times listed above by telephone hotline number (206) 526-6667 and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 KHz.

Because of the need for immediate action, the Secretary of Commerce has determined that good cause exists for this notice to be issued without affording a prior opportunity for public comment. Therefore, public comments on this notice will be accepted through September 21, 1989.

Other Matters

This action is authorized by 50 CFR 661.23 and is in compliance with Executive Order 12291.

List of Subjects in 50 CFR Part 661

Fisheries, Fishing, Indians.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 1, 1989.

Herbert L. Blott,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89-21048 Filed 9-6-89; 8:45 am]

BILLING CODE 3510-22-M

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50 CFR Part 675

[Docket No. 81131-9019]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of inseason adjustment; notice rescinding and partially rescinding prohibitions on receipt of certain groundfish.

SUMMARY: NOAA announces the apportionment of amounts of Alaska groundfish to the joint venture processing (JVP) portion of the domestic annual harvest (DAH). This action, taken under provisions of the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP), is necessary to assure optimum use of groundfish in that area. It is a conservation and management measure intended to promote fishery objectives of the North Pacific Fishery Management Council.

DATES: Effective noon, September 3, 1989, Alaska daylight time (A.D.T). Comments will be accepted through September 18, 1989.

ADDRESS: Comments should be mailed to Steven Pennoyer, Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802, or be delivered to Room 453, Federal Building, 709 West Ninth Street, Juneau, Alaska.

FOR FURTHER INFORMATION CONTACT: Janet E. Smoker (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION: The FMP is implemented by rules appearing at 50 CFR 611.93 and part 675.

Initial specifications of groundfish for 1989 were published at 54 FR 3605

(January 25, 1989). Initially, 15 percent of the 1989 total allowable catch (TAC) for each species or species group was placed in reserve. Domestic annual processing (DAP) amounts were determined based on NMFS' preseason comprehensive survey of domestic processors. Remaining amounts were provided to domestic fishermen delivering fish to be processed by foreign processors (JVP). No initial specifications were provided for foreign fishing because DAH requirements exceeded the optimum yield. The same notice apportioned amounts from reserve to JVP for arrowtooth flounder, squid, and "other species" in order to provide bycatch amounts for JVP fisheries.

In June, the Regional Director sent another written survey to DAP processors to determine whether information gathered in the initial survey was still valid. The midseason survey was completed on July 28. Respondents indicated actual production for the first and second quarters of 1989 and changes, if any, to amounts requested for the third and fourth quarters. A thorough evaluation of survey returns by NMFS Regional Office staff indicated amounts excess to DAP needs exist within DAH in 1989, as well as DAP amounts that could require supplementation. Amounts that may be needed to supplement DAP are retained in the non-specific reserve, to be apportioned to DAP if the need arises later in the year. Amounts in DAP and reserve which are in excess of DAP requirements are apportioned to JVP.

Earlier this year, NOAA announced prohibitions of receipt by foreign processors of fish taken in several directed fisheries. These included directed fisheries for Bering Sea subarea pollock, effective January 21, 1989 (54 FR 3609, January 25, 1989), Pacific cod, effective February 11, 1989 (54 FR 6934, February 15, 1989), rock sole, effective February 21, 1989 (54 FR 7933, February 24, 1989) and yellowfin sole, effective March 1, 1989 (54 FR 9216, March 6, 1989). This notice reapportions sufficient amounts of pollock and yellowfin sole to permit resumption of JVP directed fisheries for those two species. The prohibitions of receipt by foreign processors of pollock and yellowfin sole taken in directed fisheries are rescinded. However, the amounts of Pacific cod and rock sole reapportioned by this notice are sufficient only to provide bycatch amounts for the directed fishing of other species. The prohibitions of receipt by foreign processors of Pacific cod and rock sole taken by the directed fishing for these species remain in effect.

Reapportionment

The following actions are taken by this notice to reapportion groundfish from DAP and from the non-specific reserve.

The Regional Director has found that the current DAP for Bering Sea subarea pollock may require supplementation by part of the reserve (up to 27,000 mt) later in the year. However, 174,000 mt of the reserve is available and is reapportioned to JVP for Bering Sea subarea pollock. Similarly, 30,000 mt of the nonspecific reserve is available and is reapportioned to JVP for Pacific cod.

The currently specified DAP amounts for yellowfin sole, Greenland turbot, other flatfish, and rock sole are in excess of DAP requirements for 1989. Therefore, excess DAP amounts of these species, along with reserve amounts, are reapportioned to JVP.

These reapportionments will not result in overfishing of any species, since, in each case, the resulting species TAC is less than its acceptable biological catch.

TABLE 1.—BERING SEA/ALEUTIANS REAPPORTIONMENTS OF TAC

[Values are in metric tons]

		Current	This action	Revised
Pollock (Bering Sea subarea)	DAP	1,045,585		1,045,585
TAC=1,313,000; ABC=1,340,000	JVP	93,415	+174,000	267,415
Yellowfin sole	DAP	45,274	−24,000	21,274
TAC=193,952; ABC=241,000	JVP	110,000	+62,678	172,678
Greenland turbot	DAP	6,800	−200	6,600
TAC=6,800; ABC=20,300	JVP	0	200	200
Other Flatfish	DAP	23,906	−15,000	8,906
TAC=63,906; ABC=155,900	JVP	40,000	+15,000	55,000
Pacific cod	DAP	158,613		158,613
TAC=226,079; ABC=370,600	JVP	37,466	+30,000	67,466
Rock Sole	DAP	67,543	−25,000	42,543
TAC=77,148; ABC=171,000	JVP	9,605	25,000	34,605
Total (TAC=2,000,000)	DAP	1,409,514	−64,200	1,345,314
	JVP	295,211	+306,878	602,089
RESERVES		295,275	−242,678	52,597

Classification

This action is taken under the authority of 50 CFR 675.20(b) and complies with Executive Order 12291.

The Assistant Administrator for Fisheries, NOAA finds for good cause that it is impractical and contrary to the public interest to provide prior notice and comment. Immediate effectiveness of this notice is necessary to benefit domestic fishermen who otherwise would be unable to obtain markets for their catch. Interested persons are invited to submit comments in writing to the address above for 15 days after the effective date of this notice.

List of Subjects in 50 CFR Part 675

Fish, Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 1, 1989.

Herbert L. Blatt,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89-21032 Filed 9-1-89; 8:45 am]

BILLING CODE 3510-22-M

50 CFR Part 675

[Docket No. 90407-9170]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of reapportionment and closure.

SUMMARY: The Director, Alaska Region, NMFS (Regional Director), has determined that, (1) previously specified

prohibited species catch (PSC) allowances for Pacific halibut and red king crab are incorrect, and (2) the PSC allowances of red king crab for domestic fisheries in bycatch limitation zone 1 (Zone 1) in the Bering Sea and Aleutian Islands (BSAI) area have been attained. Therefore, the Secretary of Commerce (Secretary) is reapportioning PSC allowances for Pacific halibut and red king crab. In addition, the Secretary is prohibiting any further directed fishing for yellowfin sole, rock sole, and "other flatfish," and directed fishing for pollock and Pacific cod with bottom trawl gear in Zone 1. This action is necessary to prevent excessive bycatch of red king crabs in the trawl fishery for groundfish in an area of particular importance to the red king crab stock. This action is intended to carry out the objectives of recently implemented measures to control the bycatch of prohibited species in the trawl fishery for groundfish.

EFFECTIVE DATES: September 3, 1989 through December 31, 1989.

FOR FURTHER INFORMATION CONTACT: Jay J.C. Ginter (Fishery Management Biologist), NMFS Alaska Region, P.O. Box 21668, Juneau, Alaska 99802–1668, telephone 907–586–7229.

SUPPLEMENTARY INFORMATION: The Secretary approved Amendment 12A to the Fishery Management Plan for the Groundfish Fishery in the Bering Sea and Aleutian Islands Area (FMP) under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). Amendment 12A was implemented by the Secretary with a final rule promulgaed August 9, 1989 (54 FR 32642) and effective September 3, 1989 through December 31, 1990.

The purpose of Amendment 12A is to limit incidental catches of the prohibited species Tanner crab, red king crab, and Pacific halibut by the groundfish fisheries in the BSAI area. Such incidental catches are referred to as bycatches in fisheries targeting other species.

The amendment establishes five prohibited species catch (PSC) limits, each of which are apportioned among four fisheries: The domestic annual processing (DAP) fisheries for (1) flatfish and (2) other species, and the joint venture processing (JVP) fisheries for (3) flatfish and (4) other species. Each of the 20 PSC allowances prescribed for the 1989 groundfish fisheries were specified in the final rule implementing Amendment 12A (50 CFR § 675.21, Table 2, 54 FR 32651, August 9, 1989). Specification of the PSC allowances was based on the anticipated bycatch of prohibited species through the use of a mathematical prediction procedure using statistical information derived from fishery performance in previous years and projected performance for the 1989 fishing year.

Reapportionment

The Regional Director has determined that the prediction procedure has led to incorrect specification of the PSC allowances for Pacific halibut and red king crab. These adjustments of the PSC allowances are based on the best available scientific information concerning the actual groundfish harvest to date and new projections of harvest for the remaining fishing year. The Regional Director has determined that there was insufficient halibut PSC allowance apportioned to the DAP and "JVP flatfish fisheries" and excessive halibut PSC allowance apportioned to the DAP and "JVP other fisheries," and that there was insufficient red king crab PSC allowance apportioned to the "JVP flatfish fishery" and excessive red king crab PSC allowance apportioned to the "JVP other fishery." This adjustment will allow redistribution of uncaught PSC allowances among fisheries. Therefore, the Secretary is adjusting the incorrectly specified halibut and red king crab PSC allowances specified in Table 2, 50 CFR 675.21 as follows:

REAPPORTIONMENT OF 1989 PROHIBITED SPECIES CATCH (PSC) ALLOWANCES OF PACIFIC HALIBUT (IN METRIC TONS) AND RED KING CRAB (IN NUMBERS OF ANIMALS)

Fishery	Original primary PSC allowance for halibut	Change	New primary PSC allowance for halibut
DAP flatfish	181	+50	231
DAP other	3,408	−50	3,358
JVP flatfish	146	+250	396
JVP other	665	−250	415
Primary PSC limit	4,400		4,400

Fishery	Original secondary PSC allowance for halibut (BSAI-wide)	Change	New secondary PSC allowance for halibut (BSAI-wide)
DAP flatfish	220	+50	270
DAP other	4,131	−50	4,081
JVP flatfish	177	+250	427
JVP other	805	−250	555
Secondary PSC limit	5,333		5,333

Fishery	Original PSC allowance for red king crab (zone 1)	Change	New PSC allowance for red king crab (zone 1)
JVP flatfish	111,858	+16,552	128,410
JVP other	16,684	−16,552	132

Closure

The Regional Director has determined that the "DAP flatfish fishery," the "DAP other fishery," the "JVP flatfish fishery" and the "JVP other fishery" have attained their PSC allowances for red king crab in Zone 1 for the 1989 fishing year.

Therefore, the Secretary, by this notice and under authority of § 675.21(c), prohibits for the remainder of the fishing year:

(1) Directed fishing for yellowfin sole, rock sole, and "other flatfish" in the aggregate in Zone 1 by U.S. fishing vessels that process their catch on board or deliver it to U.S. processors;

(2) Directed fishing for pollock and Pacific cod in the aggregate with bottom trawl gear in Zone 1 by U.S. fishing vessels that process their catch on board or deliver it to U.S. processors;

(3) The receipt by foreign vessels of groundfish caught from Zone 1 that is composed of 20 percent or more yellowfin sole, rock sole, and "other flatfish" in the aggregate; and

(4) The receipt by foreign vessels of groundfish caught from Zone 1 with bottom trawl gear that is composed of 20 percent or more pollock and Pacific cod in the aggregate.

Classification

These actions are taken under §§ 675.20 and 675.21 and they comply with Executive Order 12291.

List of Subjects in 50 CFR 675

Fisheries, Reporting and recordkeeping requirements.

(Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 31, 1989.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Services.

[FR Doc. 89-21031 Filed 9-1-89; 2:07 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 54, No. 172
Thursday, September 7, 1989

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 425

[Amendment No. 2; Doc. No. 7089S]

Peanut Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the Peanut Crop Insurance Regulations (7 CFR Part 425), effective for the 1990 and succeeding crop years. The intended effect is to standardize the unit structure and to establish units by share where there is a landlord/tenant relationship.

COMMENT DATE: Written comments, data, and opinions on this proposed rule should be received not later than October 10, 1989.

ADDRESS: Written comments on this proposed rule should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC, 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC, 20250, telephone (202) 447–3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is April 1, 1994.

John Marshall, Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

FCIC proposes to amend the Peanut Crop Insurance Regulations (7 CFR Part 425) to standardize the unit structure and to establish units by share where there is a landlord/tenant relationship.

Changes being proposed herein serve to allow standard policy units currently in existence for all peanut program counties.

FCIC is soliciting public comment on this proposed rule for 30 days following publication in the **Federal Register.** Written comment should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this proposed rule will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 425

Crop insurance; Peanuts

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation proposes to amend the Peanut Crop Insurance Regulations (7 CFR Part 425), proposed to be effective for the 1990 and succeeding crop years, as follows:

PART 425—[AMENDED]

1. The authority citation for 7 CFR Part 425 is revised to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. The Peanut Crop Insurance Regulations (7 CFR part 425) § 425.7 is amended in Section 7(d) by revising subsections 17.c. and 17.n., to read as follows:

§ 425.7 The application and policy.

* * * * *

(d) * * *

17. Meaning of terms. * * *

c. *"County"* means the county shown on the actuarial table and any additional land located in a local producing area bordering on the county, and shown by the actuarial table; and * * *

n. *"Unit"* means all insurable acreage of peanuts in the county on the date insurance attaches for the crop year;

(1) in which you have a 100 percent share; or

(2) which is owned by one entity and operated by another entity on a share basis.

Land rented for cash, a fixed commodity payment, or any consideration other than a share in the insured crop on such land will be considered owned by the lessee. Units will be determined when the acreage is reported and may be adjusted to reflect the actual unit structure when adjusting a loss; however, no further unit division may be made at loss adjustment time.

We may consider any acreage and share thereof reported by or for your spouse or child

or any member of your household to be your bona fide share or the bona fide share of any person having an interest therein.

Peanut acreage that would otherwise be one unit, may be divided into more than one unit, if for each proposed unit you maintain written verifiable records of planted acreage and harvested production for at least the previous crop year. Production reports by unit based on those records must be filed no later than the earlier of the acreage reporting date or 45 days after the sales closing date for the upcoming crop year. The acreage planted to the insured peanut crop, to be divided into units, must be located in separate, legally identifiable sections (except in Florida) or, in the absence of section descriptions (and in Florida) the land is identified by separate ASCS Farm Serial Numbers, provided:

(1) The boundaries of the section or ASCS Farm Serial Number are clearly identified and the insured acreage is easily determined; and

(2) The peanuts are planted in such a manner that the planting pattern does not continue into an adjacent section or ASCS Farm Serial Number,

If you have a loss on any unit, production records for all harvested units must be provided. Production that is commingled between optional units will cause those units to be combined.

* * * * *

Done in Washington, DC on August 16, 1989.

John Marshall,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 89-20953 Filed 9-6-89; 8:45 am]

BILLING CODE 3410-08-M

FEDERAL TRADE COMMISSION

16 CFR Part 307

Smokeless Tobacco

AGENCY: Federal Trade Commission.

ACTION: Extension of time to file comments.

SUMMARY: The Federal Trade Commission has granted several requests to extend the public comment period for all interested parties for 45 days, until October 16, 1989, on the Notice of Proposed Rulemaking for possible amendments to its regulations under the Comprehensive Smokeless Tobacco Act of 1986. The original comment period on the Notice, published on July 31, 1989 (54 FR 31541), ended on August 30, 1989.

DATE: Comments regarding the proposed amendments to the regulations must be filed no later than October 16, 1989.

ADDRESS: Comments should be addressed to Secretary, Federal Trade Commission, 6th & Pennsylvania Ave. NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Anne V. Maher (202) 326-2987. Division of Advertising Practices, Federal Trade Commission, 6th & Pennsylvania Ave. NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: In a Notice of Proposed Rulemaking published on July 31, 1989 (54 FR 31541), the Federal Trade Commission requested public comment on proposed amendments to 16 CFR part 307, the Commission's regulations under the Comprehensive Smokeless Tobacco Act of 1986 ("Act"). Those regulations, which took effect on February 27, 1987, implement the Act's requirements for the display of health warnings in the labeling and advertising of smokeless tobacco products and for the submission of plans for compliance with the Act. The regulations exempt "utilitarian objects for personal use, such as pens, pencils, clothing and sporting goods" from the Act's requirement that all advertising display the warnings. The Commission's decision to exempt utilitarian items was challenged in court, and the court subsequently ordered the Commission to delete the exemption.[1] Consequently, the Notice proposed the deletion of the exemption of utilitarian objects from the regulations, and proposed a method for displaying the required health warnings on utilitarian objects.

The date on which comments would have been due was August 30, 1989. Two organizations, however, have requested a 30-day extension to the time period, while the Smokeless Tobacco Council has requested a 60-day extension. Having considered the requests, the Commission has determined that a 45-day extension period will provide all parties with a sufficient amount of time to prepare comments to the proposed amendments. Accordingly, the comment period will be extended for 45 days, and the Commission will accept written public comments on the Notice until October 16, 1989.

List of Subjects in 16 CFR Part 307

Health warnings, Smokeless tobacco, Trade practices.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 89-20974 Filed 9-6-89; 8:45 am]

BILLING CODE 6750-01-M

[1] *Public Citizen, et al. v. Federal Trade Commission*, No. 88-5209, (D.C. Cir. March 14, 1989), *aff'g*, 688 F. Supp. 667 (D.D.C. 1988).

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Rule Amendments Concerning Trading Cards and Submission of Trade Records

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed Rule Amendments.

SUMMARY: The Commodity Futures Trading Commission proposes several amendments to Regulation 1.35, 17 CFR 1.35. These amendments would (1) require that trading cards prepared by a member of a contract markets showing purchases and sales executed on that contract market, pursuant to paragraph 1.35(d)—(a) contain pre-printed, unique identifying information which would permit the sequencing of such records intra-day, (b) distinguish each member's records from those of other members, and (c) distinguish each such record from all other such records prepared by the member over a period of one week; (2) require that trading cards be timestamped promptly upon completion; (3) require that all contract markets adopt and make effective within 60 days rules which require that trading cards prepared pursuant to Regulation 1.35(d) and customer order tickets prepared pursuant to Regulation 1.35(a-l) be submitted by the executing member to the clearing member or the exchange immediately at the end of intervals not to exceed 30 minutes, commencing with the beginning of the trading session; provided that the time period for submission of trading records after the close not exceed five minutes; (4) require that all contract markets adopt rules providing that the 30-minute period for submission subsequently be shortened to 15 minutes; (5) require that members of contract markets submit the records required by Regulations 1.35(a-1) and 1.35(d) in accordance with exchange rules adopted to implement the 30-minute and 15-minute trade submission requirements; (6) that members be held accountable for all of the trading cards prepared pursuant to paragraph 1.35(d) in exact numerical sequence, regardless of whether that trading cards was voided or otherwise not used for submission of trades to clearing; (7) that members record trades on trading cards in exact chronological order on sequential lines of a trading card with no lines skipped between trades; provided, however, that if lines remain after the last execution recorded on a trading card, the remaining lines

shall be marked through; (8) that all contract markets adopt rules which designate the opening and closing periods upon which the opening and closing trading ranges are based in each of their designated futures or option contracts; (9) that all contract markets adopt rules requiring that members identify on their trading cards prepared pursuant to 1.35(d) the trades executed during designated opening and closing periods, either by drawing a line on the card to separate those trades from others recorded thereon or by other method approved by the Commission.

DATES: Comments on the proposed amendments to Regulation 1.35 must be received on or before October 10, 1989.

ADDRESS: Comments should be sent to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581.

FOR FURTHER INFORMATION CONTACT: Patricia C. Apfelbaum, Assistant Director, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone: (202) 254-8955.

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act Notice

Public report burden for this collection of information is estimated to average 80.83 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Joseph G. Salazar, CFTC Clearance Officer, 2033 K Street NW, Washington, DC 20581; and to, Office of Management and Budget, Paperwork Reduction Project (3038-xxx), Washington, DC 20503.

II. Background

Existing Regulation 1.35 governs the records of cash commodity, futures, and option transactions which must be prepared and maintained for all purchases and sales of commodities for future delivery or commodity options on designated contract markets. Regulation 1.35(d) requires that each member of a contract market executing purchases and sales prepare regularly and promptly a trading card or other record showing such purchases and sales. Those records are made by exchange members with respect to their personal (customer type indicator "CTI" 1) trades, although in some markets those records also are used to reflect trades executed for the benefit of other account types.[1] The contract markets likewise impose on their members a variety of requirements for the preparation of such records and the submission of trade records for clearing, consistent with each exchange's system for assigning a one-minute time of execution to each trade, as required by Commission Regulation 1.35(g). Commission Regulation 1.35(a-1) requires that a written record be prepared of all customer orders both by the futures commission merchant ("FCM") and the member receiving the order on the trading floor, and that the orders be timestamped upon receipt and at the time a report of execution is made from the trading floor.

Commission Regulation 1.35 imposes a variety of obligations on the members of contract markets to keep accurate and complete records of their trading activity. Further, the one-minute trade timing standard of Commission Regulation 1.35(g) is a performance standard which requires an accurate and verifiable time of execution for each trade.[2] The Commission has found that, in many instances, members are not preparing accurate trade records in accordance with their own recordkeeping obligations and, therefore, also are not providing accurate data which will permit an exchange to meet the performance standard as to their trades. Moreover, the exchanges have had sufficient opportunity to address these issues and, although some steps have been taken, have failed to implement adequate measures to address this situation.

For these reasons, the Commission has determined that it is necessary that Commission Regulation 1.35 be amended to provide a variety of means to prevent the above-described source records from being fabricated or altered, to verify the sequence of a member's trading activity, and to enhance surveillance of trades executed during opening and closing periods. These records are source documents from which trade data, particularly for those trades executed for a member's personal account, are taken for entry into clearing and used in the creation of an exchange's trade register. The trade register then is used to conduct trade practice surveillance and to reconstruct trading for various purposes.

Collecting these records more frequently after completion than required now at most exchanges should reduce the potential for a member to alter such records to commit or conceal illegal trading activity. Requiring that trading records be submitted within five minutes after the close also will reduce the potential for members improperly to execute trades after the close of trading. A separate requirement that members comply with those submission requirements would provide the Commission with the authority to enforce these requirements as well.

Timestamping trading cards and including pre-printed sequence information thereon would provide a mechanism by which to verify the sequential order of the trading cards, deter alteration of such trading cards in connection with illegal trading, and help enforce the trade record collection requirements being proposed. Requiring members to be fully accountable for all trading cards will provide more complete written records for surveillance purposes. Requiring that members record trades on trading cards in exact chronological sequence without skipping lines will further reduce the ability of a member to fabricate trades after the fact.[3] Finally, the designation of separate opening and closing periods and identification by members on their trading cards of trades executed during those periods would facilitate the identification of those trades for the purposes of monitoring potential abuses involving customer orders during those periods, which generally have greater volume, and often more price volatility, than other designated time periods during a trading day.[4] A separate requirement that members comply with exchange rules in this regard provide the Commission with the authority to enforce that requirement.

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[1] In some instances, customer orders also may be used to record information specifically required by Regulation 1.35(d) such as opposite clearing member. Such orders are not addressed by the proposed amendments herein that relate to trading cards.

[2] *See*, 49 FR 50190 (December 27, 1984).

[3] The proposed requirement that members record trades on trading cards in exact chronological order on sequential lines of a trading card without skipping lines will not prevent members from recording buys and sells separately on different sides of the trading card or on different cards as long as buys and sells so recorded are in sequential order.

[4] The opening and closing periods referred to herein are the periods which are the basis for establishing the opening and closing ranges and not opening and closing bracket periods. Data collected in connection with the adoption of the amendments to Regulation 1.35 for the timing of trades to the nearest minute indicated that, in some markets the volume of transactions executed during the open ranged from 12-25% and that as much as 12% of the volume of transactions may occur in the closing period.

The Commission believes that timestamping and regular collection of trade records are readily achievable at reasonable expense to the exchanges and their members. With respect to timestamping, order tickets already are required to be timestamped upon report, pursuant to Commission Regulation 1.35(a–1), and trading cards easily could be timestamped upon completion in the same manner. Further, many exchanges already have recognized the benefit of frequent collection of trading records and have imposed such requirements on their members. Likewise, recording trades on trading cards without skipping lines between trades and designating opening and closing periods can be implemented at no cost to exchanges and their members and without a material increase in the time required for the preparation of the required record.

The Commission believes that the proposed requirements would provide several additional benefits. By reducing the opportunity to alter or fabricate source records, the proposed requirements would increase the reliability of audit trail data based on such records and the confidence of public customers in the accuracy of such data. The time stamp and designation of the open and close on trading cards could be used to refine existing exchange audit trail systems. Specifically, the additional timing data would aid verification of the one-minute trade times required under Commission Regulation 1.35(g). Such time stamp data also would provide additional information which could be used in the derivation of one-minute times, for systems which impute trade times, and as such should aid such audit trail systems in imputing reliable one-minute trade times to trades involving a member's personal account (CTI 1 trades), with an increased level of confidence than is the case today. The Commission has identified weaknesses in the exchanges' existing audit trail systems with respect to those trades.[5]

In its review of the implementation of exchange audit trail systems and in its analysis of audit trail proposals preparatory to the adoption of the one-minute timing standard, the Commission previously has identified many of these steps as a means of improving audit trails and made recommendations to the exchanges toward that end.[6] The collection and timestamping requirements combined with additional trading card identification and sequencing information and recording requirements also would address the types and manner of certain abuses allleged in criminal indictments and Commission compliants against a number of traders at the CME and CBT, announced on August 2, 1989. The indictments allege, among other things, that certain traders altered, rewrote, or destroyed trading cards and made false reports of trades to clearing in order to conceal and falsely reflect trading activity which deprived their customers of profits and enabled the traders to avoid liability for trading errors.

In sum, such amendments should result in immediate improvements in the deterrence and detection of illegal trading abuses facilitated by improper fabrication and alteration of trading records and in audit trail data. In particular, such actions would reduce the opportunity for members trading for their personal accounts to participate in illegal trading to defraud customers.

III. Existing Exchange Practices

As noted above, the exchanges already have in place some requirements that address these issues and have indicated that these systems are a valuable tool in their surveillance efforts.[7] Specifically, at the CBT pre-numbered sequential trading cards must be used to record all of a member's personal trades (Regulation 332.04). Trading cards must be used in ascending order each day but need not be used in exact numerical sequence as long as they are used in ascending order on a day-to-day basis. However, CBT has adopted a rule, which will become effective on September 1, 1989, to make members accountable for all trading cards in numerical order, regardless of whether the trading card is used for trade submission (Regulation 332.04).[8] CBT Regulation 332.05 requires that clearing members collect trading cards at designated times throughout the trading day, presently intra-day and once after the close of the market for the day trading session and every half-hour during the evening trading session. The CBT has amended this rule to require that trading cards be timestamped by the clearing member upon collection.[9] CBT has represented the Commission staff that it intends to require the hourly submission of trading cards to clearing members effective September 1, 1989. With respect to designation of opening and closing periods, the CBT currently has no rules establishing such periods.

At the Coffee, Sugar & Cocoa Exchange ("CSC") members are required to record all trades in exact chronological order of execution on pre-printed sequentially numbered trading cards, provided by the CSC. The trading cards are collected by the CSC promptly following the end of each half-hour bracket period, beginning at 10:00 a.m. (Rule 3.18). The traders use three-ply carbon trading cards and submit the top copy of the card to the Exchange. CSC presently employs an opening call procedure for opening its coffee, sugar, and cocoa markets (Rule 3.04), whereby each contract month is "called" for the execution of opening orders for that contract month alone. Typically, the opening call for any particular month lasts one minute or less. There is a similar closing call in the coffee and sugar contracts. The closing period for trading in the cocoa contract is five minutes in length (Rule 3.04(e)). Members are required to place a line on their trading cards to designate trades executed during the opening call (Rule 3.18(d)).

At the New York Futures Exchange ("NYFE") all trades must be recorded on trading cards in the order of execution with each trade on a separate line and no lines skipped. Trading cards are numbered sequentially by the executing member and must be submitted to NYFE no later than 15 minutes after the end of the half-hour bracket period during which those trades were executed (Rule 409 and Regulatory Memorandum 84–11). With respect to the open and close, NYFE has an opening call subject to procedures established by the Floor Committee (Rules 411 and 412). The closing period is set as the last minute of trading (Rule 435(a)). Members are required to draw a line on their trading cards to indicate when the opening call was completed (Rule 409(b)).

At the CME, trades for a member's personal account (CTI 1) and house

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[5] *E.g.*, Rule Enforcement Review of the Chicago Board of Trade ("CBT"), February 17, 1989; Audit Trail Rule Enforcement Review of the Chicago Mercantile Exchange ("CME"), September 19, 1988.

[6] *E.g.*, Letters from the Division of Trading and Markets ("Division") to the exchanges dated February 7 and March 8, 1989; and the Rule Enforcement Review of the CBT.

[7] In its response to the Division's March 8, 1989 letter, the Commodity Exchange, Inc. ("Comex") characterized these procedures as minimizing the opportunity to fabricate or alter source documents and increasing the opportunity for detection of such activities.

[8] The rule was submitted to the Commission pursuant to Commission Regulation 1.41(c). In a letter dated May 24, 1989, the Division notified the Exchange that the rule could be so implemented.

[9] The rule was submitted to the Commission pursuant to Commission Regulation 1.41(c). In a letter dated July 25, 1989, the Division notified the Exchange that the rule could be so implemented. On the same date, the Division informed the Exchange that amendments to CBT Regulation 465.01, which require that all time stamps be affixed by synchronized time clocks, could also be implemented under 1.41(c).

account (CTI 2) trades originated by the member must be recorded on trading cards in the order in which they are executed. All of the member's cards must be numbered sequentially in the order in which they are used, and once a trade has been recorded on a new card, the member may not return to a previous card (Rule 536 B and C). Trading cards are submitted to clearing members twice intra-day and once after the close of the market (Rule 536 A, Memorandum from CME Clearinghouse to All Members re "Intra-day Trade Submission Compliance," August 7, 1989).[10] With respect to opening and closing periods, CME has specified closing periods of 30 seconds for its agricultural, interest rate and S & P futures and 60 seconds for currencies and S & P options.

Comex requires that CTI 1 and 2 trades be recorded on trading cards in the exact order of execution (Rule 4.80(a)(1)). Members also may record CTI 3 and CTI 4 trades on their trading cards. Further, all members submit trading cards and order tickets to their clearing members every half hour beginning at 9:15 a.m. for trades executed during designated half-hour periods (Rule 4.83(a)). Clearing members are required to have full-time representatives on the floor to collect such trading documents (Rule 4.85). Openings at Comex are conducted pursuant to a call procedure (Rule 4.04). The closing period is the last minute of trading (Rule 4.80).

At the Kansas City Board of Trade ("KCBT") all trades must be recorded on trading cards (Rule 1115.00). Further, trades must be submitted to clearing within 90 minutes after the trade was executed (Clearing Corporation Bulletin 88–11, July 27, 1988). In order to comply with these requirements, clearing members must collect trading cards regularly from the executing member. With respect to the open and close, KCBT rules provide that the opening range is set by the Pit Reporter based on all prices at which orders on the open are executed (Rules 1111.00 and 1111.01). The closing period is the last 30 seconds of trading (Rule 1111.02).

At the New York Cotton Exchange ("NYCE") all trades are recorded on numbered carbonized trading cards in the order of execution. Buys and sells are recorded on the left and right sides of the card, respectively, and, except for cross trades and straddles, each buy or sell must be recorded on the line immediately following the prior transaction. A member may, however, skip lines between trades if that is his practice, that practice has been submitted in writing to the Compliance Department, and the practice does not result in trades being recorded out of sequence (Rule 5.10(d)). Trades must be submitted by the clearing member to the clearing house within one-half hour after the bracket in which the trade occurred.[11] The opening period is set at one minute (Rule 5.10(c)).

The existence of these exchange requirements, although less extensive than the proposed regulations, indicate that the exchanges believe that requirements of the type being proposed are important to their audit trail and surveillance capabilities, as well as to the intra-day clearing and reconciliation of trades. These procedures provide an existing structure for the contract markets and their members readily to adopt the necessary changes without disrupting the markets. The proposed regulatory amendments provide a uniform minimum standard for the preparation and submission of trade data and provide additional information to verify the accuracy of that data and enforce existing requirements.

IV. Proposed Rules

In light of the foregoing, the Commission proposes to amend Regulation 1.35 by amending paragraph 1.35(a–1), which pertains to written records of customer orders and paragraph 1.35(d), which pertains to trading cards, and adding a new paragraph (j), which relates to the submission of trading documents to a clearing member or contract market, and designation of opening and closing periods.

1. Proposed Paragraph (a–1) Futures commission merchants, introducting brokers, and members of contract markets: Recording of customers' and option customers' orders.

The Commission proposes to add to subparagraph (a–1)(4) of Regulation 1.35 a new sentence which would require that the members of contract markets comply with exchange rules adopted pursuant to proposed Commission Regulations 1.35(j) (1) and (2), which would require that written records of customer orders be submitted to exchange personnel or the clearing member within certain timeframes.[12] This proposal would give the Commission the authority to enforce such trade date submission requirements independent of any exchange action and thereby would provide the Commission with an additional tool for enforcing the other requirements of Commission Regulation 1.35.

2. Proposed Paragraph (d)—Members of contract markets.

The Commission proposes to add to paragraph (d) of Regulation 1.35 a new sentence which would require that trading cards contain a pre-printed sequence number which would permit the sequencing of such records at least intra-day. The proposed amendments would require further that the trading card contain information to identify the member and to distinguish each of that member's trading cards from other trading cards the member prepares during a period of one week. The Commission further proposes to require that trading cards be timestamped promptly after completion in the same manner as written records of customer orders presently are timestamped upon report. The Commission believes that such identifying and timing information would permit it more effectively to determine whether a member has entered his trades in chronological order and to monitor whether a trader may have altered, fabricated, or destroyed trade records to carry out or conceal illegally trading activity. Likewise, the proposed requirement that members record trades on trading cards in exact chronological order without skipping lines and mark through any lines remaining after the last execution is recorded on a trading card should inhibit the ability of a member to fabricate trades after the fact.

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[10] In a report dated April 19, 1989, the CME's Special Committee to Review Trading Practices recommended that trading cards be collected on an hourly basis and that trading cards have pre-printed numbers. Subsequently, a special Computerized Trade Reconstruction ("CTR") Enhancements Committee ("Committee"), in a report to the Board of Governors dated July 27, 1989, recommended that the Exchange implement the hourly collection of trading cards. The proposal would require that trades executed and recorded prior to 8:00 a.m. would be submitted to the clearing members no later than 8:30 a.m., and that subsequent submissions would take place every hour on the half-hour. Thus, all trades executed and recorded between 8:00 a.m. and 9:00 a.m. would be submitted by 9:30 a.m., and so on throughout the remainder of the trading day. On August 2, 1989, the Board of Governors adopted this requirement, to take effect upon approval by the Commission.

The Committee further recommended that the Exchange require that clearing members timestamp all "locals'" trading cards upon receipt at the firm's floor trading desk. The Committee recommended that the Exchange *not* adopt a requirement that trading cards have pre-printed numbers.

[11] At NYCE trades are submitted to clearing on brokerage submission sheets. Rule 9.10(a) requires trading members to submit brokerage sheets to their clearing members promptly.

[12] The order tickets which must be submitted in accordance with this requirement are any written records of customer orders used on the floor of an exchange, whether prepared on the floor, transmitted via wire, or originating from the FCM or introducing broker.

Further, the timestamping requirement would enable the exchanges to enforce the proposed requirement, discussed below, that trading cards and order tickets be submitted at regular intervals throughout the trading day. The proposed amendments would require members to comply with exchange rules implementing the latter requirement and with rules requiring that they identify trades executed during opening and closing periods on their trading cards, thereby providing the Commission with an additional tool to ensure compliance with other requirements of Regulation 1.35.

The Commission believes that the requirement that trading cards be timestamped upon completion generally could be accomplished in the same manner that order tickets presently are timestamped. At exchanges where trading cards are collected by clearing members, this mechanism for compliance would extend equally to all members. At those exchanges the clearing member already would have the trading cards and simply would have to provide for those trading cards to be timestamped at the floor desk along with order tickets.

As noted above, several exchanges already require that members record trades on pre-printed sequentially numbered trading cards or that sequence numbers be recorded manually. This information is required to be included when trades are submitted for clearing at the CBT, CME, and CSC as part of their computerized systems for deriving one-minute times of execution for each trade. Further, this record enables the exchanges to investigate the sequence of a member's trading activity during a particular trading session and compare the contemporaneous record of the trade to the data submitted for clearing. These exchanges do not, however, require that the trading card numbers be unique except within one trading session. This increases the potential for a member to use a trading card with a duplicate pre-printed number, which ordinarily would be used on a different trade day, to rewrite or fabricate trading records.

For that reason, the Commission is proposing steps to limit the potential for a trader to circumvent the sequence requirement through the use of duplicate printed records. The proposed regulation would require that each trading card contain unique identifying information which would permit the records of each member to be distinguished from those of other members. The trading cards also would have to contain identifiers which would permit the trading cards of a member prepared during one trading session to be distinguished from trading cards the member prepares for other trading sessions during a period of one week.

Compliance with this requirement may be achieved through a variety of means at the election of the member and in accordance with any relevant exchange rules, but any such information must be pre-printed on the trading card. Among the possible methods to achieve this result would be pre-printed dates to distinguish trading days, plus, where applicable, an alpha or other designation to identify the particular trading session during a day. Separate series numbers or letter designations for each group of sequence numbers would be another method by which the trading cards for each trading session could be distinguished from those for other trading sessions during a one-week period. Pre-printed clearing member or floor member identification, which frequently already appear on trading cards, would facilitate further the unique identification of a trading card.

The Commission believes that the flexibility permitted in implementing the proposed amendment recognizes that these types of data presently are used in computerized audit trail systems, and that practical limitations exist on the number of fields and spaces available for data entry. Thus, although the exchanges likely would find it necessary to publish rules or guidelines for their members on the parameters that the unique identifiers must meet, the Commission has determined not to establish more specific criteria for such identifiers or to require that all trading cards be unique indefinitely.

Finally, the amendments to this paragraph would require members of contract markets to comply with exchange rules adopted pursuant to paragraph (j) that require the periodic submission of trading cards, that members be accountable for all trading cards in numerical sequence, and that members identify trades which are executed during designated opening and closing periods. In this manner, the Commission will be able independently to enforce such requirements.

3. Proposed Paragraph (j)—Submission of trading records.

The Commission proposes to add to Regulation 1.35 a new paragraph (j) which would require that contract markets adopt and have in place within 60 days rules requiring that order tickets prepared under paragraph 1.35(a–1) and the trading cards prepared under paragraph 1.35(d) be submitted to the clearing member, or to the exchange, at intervals not to exceed 30 minutes; provided, however, that the time period for submission of such trading records after the close shall not exceed five minutes. The new paragraph further would provide that, effective 90 days after implementation of the 30-minute requirement, the time for submission be reduced to 15 minutes.

Currently, Regulation 1.35(a–1) requires that order tickets be timestamped upon report, which should be as soon as possible after an order has been filled. Nonetheless, order tickets have been included in the proposed amendment to assure that under no circumstances would they be held by a broker longer than the time periods provided for the collection of trading cards.

The purpose of the proposed requirement that trading records be submitted within a particular timeframe to the exchange or clearing member is to remove the record from the trader's control to that of exchange or clearing firm employees and thereby reduce the potential for the member to alter the record or fabricate records in the time which might otherwise intervene between trade execution and the submission of the trades for clearing. In this regard, the Commission intends that the documents remain beyond the member's control at least until after the trades have been entered into clearing.[13]

The timely collection of trade records, together with the requirement that those records be sequentially numbered and otherwise identified, should materially reduce the potential for such abuses. On the other hand, the Commission believes that the proposed collection schedules should be sufficient for traders to fully record and confirm their trades and submit them to the appropriate entity without impeding trade executions.

The proposed regulation also would require that exchanges establish rules subject to Commission approval which designate opening and closing trading periods for each market and require members to identify on their trading cards the trades executed during such periods. This requirement would enhance the ability of exchange and

[13] This requirement is intended to accommodate existing practices whereby the individual member presently is responsible for the direct submission of trades for clearing and retains his own trade records. For example, it could be fulfilled through the use of multi-part trading cards such as those used at the CSC. Both the top copy of such multi-part cards and the carbon copies constitute records which must be retained pursuant to Commission Regulation 1.31.

Commission staff to identify trades executed during those periods and monitor those trades for potential abuse of customer orders at no increased costs to exchanges or their members and with no material increase in the time needed to prepare those records.

Finally, the proposed new paragraph would require that members account for all trading cards required by paragraph (d) in sequence, without gaps, regardless of whether that record is voided or otherwise is not used by the clearing member or member to enter trades for clearing. If, for instance, a member has a clerk rewrite his trades on a new card because of an error discovered upon confirmation to the opposite side, he nevertheless would have to retain the original trading card and submit it to the contract market upon request. If a member's trading cards ordinarily are retained by his clearing member, the clearing member likewise would be responsible for those trading cards not used for trade submission.

V. Proposed Effective Dates

The Commission proposes that proposed Commission Regulation 1.35(j)(1), which would require that trading cards and order tickets be submitted at intervals not to exceed 30 minutes, and that those trading records be submitted within five minutes of the close, be effective 60 days after publication of final rules. After an additional 90 days, the requirement of subparagraph 1.35(j)(2) that such records be submitted at intervals not to exceed 15 minutes would become effective. Further, the requirements in proposed Regulation 1.35(d), that all trading cards be timestamped upon completion, and of Regulation 1.35(j), that exchanges designate open and closing periods and require members to identify trades executed during those periods, also would become effective 60 days after publication of final rules.

The Commission proposes that the additional requirements of proposed Regulation 1.35(d), that trading cards contain certain pre-printed sequence and identifying information, and of proposed Regulation 1.35(j)(3), that members be accountable for all such trading cards, become effective 90 days after the publication of final rules.

VI. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 et seq., requires that agencies, in proposing rules, consider the impact of the rules on small businesses. The Regulation 1.35 amendments proposed here would affect contract markets, clearing members, and contract market members. The Commission previously has determined that contract markets are not "small entities" for the purposes of the RFA, and that the Commission need not, therefore, consider the effect of the proposed amendments on contract markets in relation to the RFA. 47 FR 18618, 18619, April 30, 1982.

The Commission also previously has determined that FCMs should be excluded from the definition of "small entity" based upon the fiduciary nature of the FCM/customer relationships as well as the fact that FCMs must meet minimum financial requirements. 47 FR 18618, 18619, April 30, 1982. The Commission has determined that clearing members are, by exchange or clearing house rule, subject to a minimum capital requirement which is at least as great, and in most cases substantially greater, as that imposed on FCMs, and are not, therefore, small entities for the purposes of the RFA. Further, many clearing members are also FCMs. The Commission need not, therefore, consider the effect of proposed amendments on clearing members in relation to the RFA.

With respect to members of contract markets, the Commission has stated that it is appropriate to evaluate within the context of a particular rule proposal whether some or all floor brokers should be considered small entities and, if so, to analyze the economic impact on such entities at that time. 47 FR 18618, April 30, 1982. The members of contract markets affected by the proposed regulation, other than clearing members, would be floor brokers and floor traders.

Commission Regulation 1.35 imposes requirements on members of contract markets to prepare complete and accurate records of their trades. Commission Regulation 1.35 also establishes a performance standard for accurate and verifiable one-minute times of execution. This standard requires that the trading data recorded by members to be accurate. Moreover, Commission Regulation 1.31 authorizes the Commission to request records for inspection at anytime. The proposed amendments are intended to ensure that the existing requirements of Regulation 1.35 are satisfied.

The Commission believes that the proposed amendments can be implemented without imposing a significant economic burden on a substantial number of small entities. With respect to the requirements that members identify trades executed during the open and close on their trading cards, that they be fully accountable for all trading cards prepared pursuant to Regulation 1.35(d), whether or not those trading cards are used for submitting trades for clearing, and that they record trades in chronological sequence without skipping lines between trades, the Commission believes these requirements would not impose a significant economic burden on members. Notably, there should be very few occasions when a member will have a trading card which is not going to be used for trade submission to clearing, since this only involves trading cards which are rewritten completely due to errors. All other such trading cards already are used directly or indirectly for submitting trade data for clearing.

With respect to the collection of trading records at 30-minute, and ultimately 15-minute, intervals, the Commission again notes that many exchanges already require the frequent collection of those records. For these exchanges, therefore, a mechanism exists to enable members to comply with exchange rules adopted to implement this requirement. At other exchanges compliance with these requirements can reasonably be integrated into existing procedures for the collection of trading information. Although the proposed requirement would require more frequent collection, the Commission believes that existing resources will be sufficient in most cases to meet the requirement. Moreover, the personnel to perform these functions often are employees of clearing members, which are not small entities. Similarly, existing Regulation 1.35(a–1) requires customer order tickets to be timestamped upon report. This means that a procedure for timestamping documents already exists, and trading cards could be timestamped in the same manner. At exchanges where clearing members already are required to collect trading cards, this mechanism for compliance extends equally to all members.

Finally, with respect to the requirement that certain information be pre-printed on trading cards, the Commission believes that the economic impact will not be significant. As noted above, the CBT and the CSC already require that trading cards contain pre-printed sequential numbers. Further, many members at all exchanges already are having their trading cards pre-printed with their member identification. At other exchanges, the Commission believes that these items can be accomplished at reasonable expense. Finally, the timeframe for the implementation of this requirement is expected to reduce further any economic

burden which may incur to the members.

Accordingly, pursuant to section 3(a) of the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1168 (5 U.S.C. 605(b)), based on its initial review of the available data, the Commission certifies the belief that this rule, promulgated, will not have a significant economic impact on a substantial number of small entities. If additional data are provided to the record to suggest that these proposed requirements will have a significant impact on small entities, the CFTC will complete a regulatory flexibility analysis with the fnal rulemaking. The Commission invites specific comment regarding the potential costs of these requirements for small entities and alternative less burdensome means to achieve the Commission's objectives.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, (Act) 44 U.S.C. 3501, *et seq.*, imposes certain requirements on federal agencies, (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act. In compliance with the Act the Commission has submitted this proposed rule and its associated information collection requirements to the Office of Management and Budget. The burden associated with this entire collection, including this proposed rule, is as follows:

Average Burden Hours Per Response: 80.83.

Number of Respondents: 339.

Frequency of Response: on occasion.

Persons wishing to comment on the information which would be required by this proposed rule should contact Gary Waxman, Office of Management and budget, Room 3228, NEOB, Washington, DC 20502, (202) 395–7340. Copies of the information collection submission to OMB are available from Joseph Salazar, CFTC Clearance Officer, 2033 K Street NW., Washington, DC 20581, (202) 254–9735.

List of Subjects

17 CFR Part 1

Commodity futures, Commodity options, Contract markets, Customers, Exchanges of futures for physicals, Futures commission merchants, Introducing brokers, Members of contract markets, Noncompetitive trading, Reporting and recordkeeping requirements.

In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and, in particular, Sections 4, 4g, 5, 5a and 8a thereof, 7 U.S.C. 6, 6g, 7, 7a, and 12a, the Commission hereby proposes to amend 17 CFR part 1 of chapter I of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 7, 7a, 8, 9, 12, 12a, 12c, 13a, 13a–1, 16, 19, 21, 23, and 24, unless otherwise stated.

2. Regulation 1.35 is proposed to be amended by revising paragraph (a–1)(4) to read as follows:

§ 1.35 Record of Cash Commodity, Futures, and Option Transactions.

* * * * *

(a–1) * * *

(4) Each member of a contract market reporting the execution of a customer's or option customer's order from the floor of a contract market shall record on a written record of such order, including the account identification and order number, by time-stamp or other timing device, the date and time, to the nearest minute, such report of execution is made. Each member of a contract market shall submit the written records of customer orders prepared pursuant to this paragraph in accordance with the requirements of exchange rules adopted in accordance with paragraphs (j)(1) and (j)(2) of this section.

3. Regulation 1.35 is proposed to be amended by revising paragraph (d) to read as follows:

* * * * *

(d) *Members of contract markets.* (1) Each member of a contact market who, in the place provided by the contract market for the meeting of persons similarly engaged, executes purchases or sales of any commodity for future delivery or commodity option on or subject to the rules of such contract market, shall prepare regularly and promptly a trading card or other record showing such purchases and sales. Such trading card or record shall show the member's name, the name of the clearing member, transaction date, time (as specified in rules of the contract market which comply with the requirements of this section), quantity, and, as applicable, underlying commodity, contract for future delivery or physical, price or premium, delivery month or expiration date, whether the transaction involved a put or a call and strike price. Such trading card or other record shall also clearly identify the opposite floor broker or floor trader with whom the transaction was executed, and the opposite clearing member (if, in accordance with the rules or practice of the contract market, such opposite clearing member is made known to the member).

(2) Each member of a contract market recording trades on trading cards pursuant to this paragraph shall record such trades in exact chronological order of execution on sequential lines of the trading card without skipping lines between trades; provided, however, that if lines remain after the last execution recorded on a trading card, the remaining lines shall be marked through.

(3) Each trading card prepared pursuant to paragraph (d)(1) of this section also must contain pre-printed sequence numbers, which would permit such records to be sequenced intra-day. The trading cards prepared pursuant to this paragraph also must contain trader identification and other unique identifying information which would permit trading cards of one member to be distinguished from those of other members and would permit each of the tradng cards prepared by the member to be distinguished from other such trading cards prepared by the member for no less than a one week period.

(4) Each member of a contract market reporting the execution of trades on a trading card pursuant to this paragraph shall record, by-time-stamp or other timing device, the date and the earlier of the time, to the nearest minute, such trading card is completed or submitted as required by paragraphs (j)(1) and (j)(2) of this secton.

(5) Each member of a contract market shall be accountable for all trading cards prepared pursuant to this paragraph in exact numerical sequence, whether or not such trading cards are used in the submission of trades for clearing.

(6) Each member of a contract market shall prepare in accordance with exchange rules adopted pursuant to paragraph (j)(4) of this section and submit in accordance with exchange rules adopted pursuant to paragraphs (j)(1) and (j)(2) of this section the trading cards prepared pursuant to this paragraph.

§ 1.35 [Amended]

* * * * *

3. Regulation 1.35 is proposed to be amended by adding paragraph (j) to read as follows:

* * * * *

(j) *Submission of trading records.* Each contract market shall:

(1) Have rules in effect requiring that trading records prepared by members of the contract market pursuant to paragraphs (a–1) and (d) of this section be submitted to contract market personnel or the clearing member at intervals not to exceed 30 minutes, commencing with the beginning of each

trading session; provided, however, that the time period permitted for the submission of trading records after the close of trading in each market shall not exceed five minutes.

(2) Have rules in effect which will require that upon 90 days after the requirements of paragraphs (j)(1) of this section become effective, that the records required to be submitted pursuant to this paragraph be submitted to contract market personnel or the clearing member at intervals not to exceed 15 minutes.

(3) Have rules in effect which provide that members of the contract market shall be accountable for all trading cards prepared pursuant to paragraph (d) of this section in exact numerical sequence, whether or not such records are used in the submission of trades for clearing.

(4) Have rules in effect which designate the opening and closing periods upon which the opening and closing trading ranges are based for each of its markets. The rules also shall provide that members of the contract market identify on the trading cards prepared pursuant to paragraph (d) of this section the trades executed during such opening and closing periods either by drawing a line on the trading card to separate those trades from others recorded thereon or other method approved by the Commission.

Issued in Washington, DC, on this 29th day of August, 1989.

Lynn K. Gilbert,

Deputy Secretary to the Commission.

[FR Doc.89-20928 Filed 9-6-89; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 888

[Docket No. N-89-1983; FR-2656]

Section 8 Housing Assistance Payments Program; Fair Market Rents for New Construction and Substantial Rehabilitation—Chicago, Il

Special Revisions for Fiscal Year 1986 and Fiscal Year 1987

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Proposed notice.

SUMMARY: Section 8(c)(1) of the United States Housing Act of 1937 requires the Secretary to establish Fair Market Rents (FMRs) periodically, but not less frequently than annually. This document proposes to amend the Fiscal Year 1986 and the Fiscal Year 1987 Fair Market Rent Schedules to establish new FMRs for the Chicago, Illinois market area for those fiscal years. These rents are necessary to provide FMRs more comparable to market rents for new construction in this market area.

DATES: Comments due October 10, 1989.

ADDRESSES: Interested persons are invited to submit comments to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection during regular business hours at the above address. (7:30 a.m. to 5:30 p.m. weekdays).

FOR FURTHER INFORMATION CONTACT: Edward M. Winiarski, Chief Appraiser, Valuation Branch, Technical Support Division, Office of Insured Multifamily Housing Development, 451 Seventh Street SW., Washington, DC 20410-0500, telephone (202) 426-7624. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

Section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) (the Act) authorizes a system of housing assistance payments to aid lower income families in renting decent, safe, and sanitary housing. These programs, known collectively as the Section 8 Housing Assistance Payments Program, provide assistance payments for lower income families for a variety of housing options, including new construction and substantial rehabilitation.

Under these programs, HUD or public housing agencies (PHAs) make rental assistance payments on behalf of eligible families to owners. When families lease an eligible unit, the housing assistance payment is made and is based upon the differences between the total housing expense and the total family contribution. Initial contract rents, plus an allowance for utilities generally may not exceed area-wide Fair Market Rents (FMRs) established by the Department. FMRs are based primarily on the level of rentals paid for recently completed or newly constructed dwelling units of modest design within each market area as determined by HUD Field Office staff. For the FY 1987 FMRs previously promulgated by the Department (see the April 26, 1988 **Federal Register**, 53 FR 14954), these rents reflected the Department's cost containment efforts in relation to housing assistance provided in the Section 8 New Construction and Substantial Rehabilitation Programs.

This Document

This document proposes special revisions to the Fiscal Year 1986 and the Fiscal Year 1987 Fair Market Rent schedules applicable to the Chicago, Illinois market area. These FMRs reflected data submitted by the Chicago Office. Where sufficient market rental comparables do not exist, HUD procedures permit the use of an interpolation technique to arrive at indicated FMRs. Although the use of interpolation and adjustments to establish rents are sound principles and techniques, the best data for "market rents" would be that from recently constructed projects, as it would necessarily reflect current conditions in the marketplace with respect to financing, vacancy rates, etc., and would provide a degree of assurance that rents so derived should be adequate to support new projects, all factors being equal.

The Chicago Office requested that the Department establish new rents for the Chicago, Illinois market area. Careful analysis of this request and reanalysis of the FY 1986 and FY 1987 FMRs for this market area indicate that the rents resulting from the application of the aforementioned techniques, when modified to reflect the Department's cost containment policies, are not adequate, even when it is clear that there has been compliance with the Department's cost containment guidelines with respect to project design. Therefore, upward adjustments of the FY 1986 and FY 1987 FMRs for this market area are needed. Accordingly, the Department is proposing revisions of the FY 1986 and FY 1987 schedules applicable to the Chicago, Illinois market area. It is intended that when these schedules are

published for effect, their applicability will be the same as set forth in the preamble to the original FY 1986 and FY 1987 schedules, published on August 7, 1986, at 51 FR 28486, and April 26, 1988, at 53 FR 14954, respectively.

Other Information

HUD regulations in 24 CFR Part 50, implementing section 102(2)(c) of the National Environmental Policy Act of 1969, contain categorical exclusions from their requirements for the actions, activities and programs specified in § 50.20. Since the FMRs established in this Notice are within the exclusion set forth in § 50.20(1), no environmental assessment is required, and no environmental finding has been prepared.

The Catalog of Federal Domestic Assistance Program number and title for the activities covered by this Notice are 14.156, Lower Income Housing Assistance Program (Section 8).

Accordingly, the following amendments to the FY 1986 and FY 1987 Fair Market Rent schedules are proposed for the Chicago, Illinois Market Area:

SCHEDULE A—FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION

REGION 5—CHICAGO REGIONAL OFFICE MARKET; CHICAGO, ILLINOIS

[Including Housing Finance and Development Agencies' Programs]

Structural	Number of Bedrooms				
	0	1	2	3	4+
Special revision of FY 1986 FMRs:					
Detached	.....	.....	786	934	1077
Semi-detached/row	568	639	721	847	939
Walkup	482	600	664	796	836
Elevator 2-4 STY	515	606	714	.....	.....
Elevator 5+ STY	631	759	917	.....	.....
Special revision of FY 1987 FMRs:					
Detached	.....	.....	810	962	1109
Semi-detached/row	585	658	743	962	1109
Walkup	496	618	684	820	861
Elevator 2-4 STY	530	624	735	.....	.....

SCHEDULE A—FAIR MARKET RENTS FOR NEW CONSTRUCTION AND SUBSTANTIAL REHABILITATION—Continued

[Including Housing Finance and Development Agencies' Programs]

Structural	Number of Bedrooms				
	0	1	2	3	4+
Elevator 5+ STY	636	780	934	.....	.....

Authority: Section 8(c)(1), U.S. Housing Act of 1937, 42 U.S.C. 1437f; Section 7(d), Department of HUD Act, 42 U.S.C. 3535(d).

Dated: August 30, 1989.

James E. Schoenberger,

Deputy General Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. 89-21009 Filed 9-6-89; 8:45 am]

BILLING CODE 4210-29-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[FI-27-89]

RIN 1545-AN52

Real Estate Mortgage Investment Conduits; Reporting Requirements and Other Administrative Matters

AGENCY: Internal Revenue Service, Treasury.

ACTION: Amendment of notice of proposed rulemaking and notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains proposed income tax regulations relating to real estate mortgage investment conduits. The relevant provisions in the Internal Revenue Code were added or amended by the Tax Reform Act of 1986 and by the Technical and Miscellaneous Revenue Act of 1988. These regulations prescribe the manner in which an entity elects status as a real estate mortgage investment conduit (REMIC) for Federal income tax purposes and the procedures to be followed when filing a Federal income tax return as a REMIC. The regulations also require REMICs and certain other issuers to file information returns with the Internal Revenue Service and to provide notice to holders of REMIC interests or other debt instruments to which section 1721 (a)(6) applies of income and certain allocable expenses attributable to their interests.

In addition, in the Rules and Regulations portion of this **Federal Register**, the Internal Revenue Service is issuing temporary regulations that relate to the reporting requirements and other administrative matters with respect to interests in REMICs and other debt instruments to which section 1272(a)(6) applies. Except for the amendments to § 1.67-3T and § 1.1275-3T, the text of those temporary regulations and the amendments to § 1.6049-4(b)(2) and to proposed regulation § 1.1275-3 that are proposed in this notice serve as the comment document for this proposed rulemaking.

DATES: These regulations are proposed to be effective after December 31, 1986, except as follows:

With respect to certain reporting requirements, § 1.6049-7(b)(1) and the amendments to § 1.1275-3(b) are proposed to be effective September 7, 1989.

The amendments to § 1.6049-4(b)(2) is proposed to be effective for calendar years after 1990.

Sections 1.6049-7(e)(2)(x) and 1.6049-7(f)(2)(i)(G) and (f)(2)(ii)(K) are proposed to be effective for calendar years beginning after December 31, 1989.

Sections 1.860F-4(e)(1)(ii) (A) and (B), 1-6049-7(c)(6) through (14), 1.6049-7(e)(1), (2)(i) through (ix), (3), (4), and (5), 1.6049-7(f)(3) (i) and (ii), and 1.6049-7(f)(5)(i) and (f)(7) are proposed to be effective for calendar quarters and calendar years beginning after December 31, 1988.

Section 1.6049-7(f)(2)(ii) (E), (F), and (I) are proposed to be effective for calendar quarters and calendar years beginning after December 31, 1987.

Section 1.860F-4(e)(1)(ii)(D) and 1.649-7(f)(3)(iii) are proposed to be effective for calendar quarters and calendar years beginning after December 31, 1987 and ending before January 1, 1990.

Section 1.860F-4(e)(1)(ii)(C) is proposed to be effective for calendar quarters and calendar years beginning after December 31, 1986 and ending before January 1, 1988.

With respect to who may sign a REMIC return, § 1.860F-4(c)(1) is proposed to be effective for REMICs with a startup day on or after November 10, 1988.

Finally, the § 1.6049-7(g) requirement to set forth information on the face of the debt instrument is proposed to be effective for debt instruments issued after April 8, 1988.

Written comments and requests for a public hearing must be mailed or delivered by October 10, 1990.

ADDRESS: Send comments and requests for a public hearing to: Internal Revenue Service, Attn: CC:CORP:T:R (FI–27–89), Room 4429, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Laura Ann M. Lauritzen, 202–566–6624 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Paperwork Reduction Project (1545–1018), Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224.

The collections of information in this regulation are in §§ 1.860D–1(d), 1.860F–4, 1.1275–3(b), 1.6049–4(b)(2), and 1.6049–7 (b)(1), (b)(2), (e), and (f). This information is required by the Internal Revenue Service to provide the Service and investors in REMICs and other debt instruments subject to section 1272(a)(6) with the amount of interest or original issue discount allocable to them. This information will be used to examine the required income tax returns and information returns to ensure compliance with the applicable tax law. The likely respondents are business or other for-profit institutions.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service Individual respondents/recordkeepers may require more or less time, depending on their particular circumstances.

The estimated total annual reporting and/or recordkeeping burden for the requirements contained in §§ 1.60D–1 (d), 1.860F–4, 1.1275–3(b), 1.6049–4 (b)(2), 1.6049–7(b), 1.6049–7(e), 1.6049–7 (f)(1) through (f)(6) of this regulation is reflected on Forms 1066, 1099–INT, 1099–OID, 8281, and 8811.

Estimated total annual reporting and/or recordkeeping burden for the requirements contained in § 1.6049–7(e): *720* hours.

The estimated annual burden per respondent/recordkeeper varies from *0.1* hours to *12.0* hours, depending on individual circumstances, with an estimated average of *1.2* hours.

Estimated number of respondents and/or recordkeepers: *600.*

Estimated annual frequency of responses (for reporting requirements only): *12.*

Estimated total annual reporting and/or recordkeeping burden for the requirements contained in § 1.6049–7 (f)(7): *250* hours.

The estimated annual burden per respondent/recordkeeper varies from *0.1* hours to *20.0* hours, depending on individual circumstances, with an estimated average of *5.0* hours.

Estimated number of respondents and/or recordkeepers: *50.*

Estimated annual frequency of responses (for reporting requirements only): *50.*

Background

The temporary regulations published in the Rules and Regulations portion of this issue of the **Federal Register** amend regulations §§ 1.67–3T and 1.1275–3T, withdraw §§ 1.860D–1T, 1.860F–4T, and 1.6049–7T and add new temporary regulations §§ 1.860D–1T, 1.860F–4T, and 1.6049–7T to part 1 of title 26 of the Code of Federal Regulations (CFR). The final regulations that are proposed to be based on these temporary regulations would be added to part 1 of title 26 of the CFR. The new temporary regulations §§ 1.860–1T, 1.860F–4T, and 1.6049–7T are promulgated as new proposed regulations §§ 1.860D–1, 1.860F–4, and 1.6049–7. The revisions to § 1.67–3T and 1.1275–3T, however, are not being proposed by cross reference.

Those final regulations would provide rules on the reporting requirements and other administrative matters of REMICs and collateralized debt obligations and some additional reporting requirements for debt instruments with original issue discount. For the text of the Temporary Regulations, see T.D. 8259, published in the Rules and Regulations portion of this issue of the **Federal Register**. The preamble to the temporary regulations explains the regulations.

This document also contains a notice of proposed rulemaking which proposes to amend §§ 1.1275–3(b) and 1.6049–4 (b)(2).

The proposed amendments to § 1.1275–3(b) require issuers to provide additional information with the Form 8281. The issuer must provide a schedule showing the amount of original issue discount per unit of original principal amount that accrues for each accrual period and specify the unit of original principal amount if other than $1,000, specify the yield to maturity, and state whether the debt instrument is a variable rate debt instrument.

For debt instruments issued with original issue discount, § 1.6049–4(b)(2) permitted brokers to send Forms 1099–OID to only those persons who were holders of record on the semiannual record date, if any, or on June 30 and December 31. The proposed amendments to § 6049–4(b)(2) require brokers to provide a Form 1099–OID to each person who was a holder of record at any time during the calendar year, even if the person was not the holder of record on June 30 or December 31 of that year, and to report the original issue discount for the period that the person held the debt instrument.

Special Analyses

It has been determined that these proposed regulations will not be major regulations as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, the proposed regulations are being sent to the Administrator of the Small Business Administration for comment on their impact on small business.

Comments and Request for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying in their entirety. A public hearing will be scheduled and held upon written request by any person who submits written comments on the proposed rules. Notice of the time and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Laura Ann M. Lauritzen, Office of the Assistant Chief Counsel (Financial Institutions and Products), Internal Revenue Service. However, personnel from other offices of the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR 1.1271–1 through 1.1297–3

Income taxes, Capital gains and losses, Original issue discount, Applicable federal rate, Market discount, Short-term obligations, Stripped bonds and stripped coupons, Tax-exempt obligations.

26 CFR 1.6001–1 through 1.6109–2

Income taxes, Administration and procedure, Filing requirements.

Proposed Amendments to the Regulations

The proposed amendments to 26 CFR Part 1 are as follows:

PART 1—[AMENDED]

Paragraph 1. The authority for part 1 is amended by adding the following citations:

Authority: 26 U.S.C. 7805; * * * § 1.1275–3(b)(2) also issued under 26 U.S.C. 1275(c).
* * *

Par. 2. Section 1.1275–3(b) of the amendment to the regulations proposed April 8, 1986, (51 FR 12086) is amended as follows:

1. In paragraph (b)(1) by removing the word "and" after the language "(ii) certificates of deposit," in paragraph (b)(1) and by removing the period after the language "(within the meaning of section 1286)" and by adding in place of the period the following language ", and (iv) interests in a REMIC or other debt instrument subject to section 1271(a)(6)."

2. In paragraph (b)(2)(i) by removing the language "address, and" and adding in its place the language "address, telephone number, and".

3. By redesignating paragraphs (b)(2)(iv), (v), (vi), (vii), (viii), and (ix) as paragraphs (b)(2)(v), (vi), (vii), (ix), (x), and (xi) respectively.

4. Redesignated paragraphs (b)(2)(ix)(D) and (E) are further redesignated as paragraphs (b)(2)(ix)(E) and (F) respectively.

5. By adding a new paragraph (b)(2)(iv) immediately after paragraph (b)(2)(iii), a new paragraph (b)(2)(viii) immediately after paragraph (b)(2)(vii), and a new paragraph (b)(2)(ix)(D) immediately after paragraph (b)(2((ix)(C), to read as follows:

§ 1.1275–3 Original issue discount information reporting requirements.

* * * * *

(b) *Information required to be reported to Secretary—*

* * * * *

(2) *Information required to be reported.*

* * * * *

(iv) A schedule of the amount of original issue discount per unit of original principal amount for each accrual period and specify the unit of original principal amount if other than $1,000;

* * * * *

(viii) The yield to maturity;

(ix) * * *

(D) Whether the debt instrument is a variable rate debt instrument described in § 1.1275–5(a);

* * * * *

§ 1.6049–4 [Amended]

Par. 3. Section 1.6049–4 is amended as follows:

1. The first sentence of paragraph (b)(2) is amended by adding a period after the language "aggregating $10 or more" and by removing the parenthetical "(determined, if semiannual record date reporting is being used, under § 1.6049–1(a)(1)(ii)(*b*)(*1*), by treating each holder as holding the obligation on every day it was outstanding during the calendar year)" and adding in its place the following sentence "For calendar years ending before January 1, 1991, semiannual record date reporting under § 1.6049–1(a)(1)(ii)(*b*)(*1*) may be used, and if used, the original issue discount includible in gross income is determined by treating each holder as holding the obligation on every day it was outstanding during the calendar year."

The second sentence in paragraph (b)(2)(iii) is revised to read as follows, "For calendar years ending before January 1, 1991, semiannual record date reporting under § 1.6049–1(a)(1)(ii)(*b*)(*1*) may be used, and if used, the original issue discount includible in gross income is determined by treating each holder as holding the obligation on every day it was outstanding during the calendar year."

3. The flush language that follows paragraph (b)(2)(vi) is revised to read as follows, "Section 1.6049–1(a)(1)(ii)(*b*)(*2*) and, for calendar years ending before January 1, 1991, § 1.6049–1(a)(1)(ii) (*b*)(*1*), and (*c*), apply for purposes of this paragraph."

Fred T. Goldberg, Jr.,

Commissioner of Internal Revenue.

[FR Doc. 89–20917 Filed 9–6–89; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 931

New Mexico Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of comment period on proposed amendments.

SUMMARY: OSM is announcing receipt of a revision pertaining to a previously proposed amendment to the New Mexico permanent regulatory program (hereinafter, the "New Mexico program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment is intended to provide additional safeguards for protection of the hydrologic balance.

This notice sets forth the times and locations that the New Mexico program and proposed amendment to that program are available for public inspection and the reopened comment period during which interested persons may submit written comments on the proposed amendment.

DATES: Written comments must be received by 4:00 p.m., m.d.t. September 22, 1989.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. Robert H. Hagen at the address listed below.

Copies of the New Mexico program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Albuquerque Field Office.

Mr. Robert H. Hagen, Director, Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 625 Silver Avenue, SW., Suite 310, Albuquerque, New Mexico 87102, Telephone: (505) 766–1486.

New Mexico Energy and Minerals Department, Mining and Minerals Division, 525 Camino de los Marquez, Santa Fe, NM 87503, Telephone (505) 827–5970.

FOR FURTHER INFORMATION CONTACT: Mr. Robert H. Hagen, Director, Albuquerque Field Office, (505) 766–1486.

SUPPLEMENTARY INFORMATION:

I. Background on the New Mexico Program

On December 31, 1980, the Secretary of the Interior conditionally approved the New Mexico program. General background information on the New Mexico program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the New Mexico program, can be found in the December 31, 1980, **Federal Register** (45 FR 86489). Subsequent actions concerning New Mexico's program and program amendments can be found at 30 CFR 931.15, 931.16, and 931.30.

II. Proposed Amendment

By letter dated February 21, 1989 (Administrative Record No. NM–474),

New Mexico submitted a proposed amendment to its permanent regulatory program pursuant to SMCRA. New Mexico submitted the proposed amendment at its own initiative. The rule that New Mexico proposed to amend is Coal Surface Mining Commission (CSMC) Rule 80-1-20-41(d)(1). OSM published a notice in the March 14, 1989, **Federal Register** (54 FR 10562) announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (Administrative Record No. NM-482). The public comment period ended April 13, 1989.

During its review of the amendment, OSM identified concerns relating to the protection of the hydrologic balance. OSM notified New Mexico of the concerns by telephone conversation on August 14, 1989 (Administrative Record No. NM-535). New Mexico responded in a letter dated August 17, 1989, by submitting a proposed revision to CSMC Rule 80-1-42(a)(1) (Administrative Record No. NM-534), which is in addition to that revision previously proposed for CSMC 80-1-20-41(d)(1). This additional revision (Administrative Record No. NM-534) is now under consideration.

III. Public Comment Procedures

OSM is reopening the comment period on the proposed New Mexico program amendment to provide the public an opportunity to reconsider the adequacy of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the New Mexico program.

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **"DATES"** or at locations other than the Albuquerque Field Office will not be considered in the final rulemaking or included in the administrative record.

List of Subjects in 30 CFR Part 931

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: August 25, 1989.

Raymond L. Lowrie,

Assistant Director, Western Field Operations.

[FR Doc. 89-20924 Filed 9-6-89; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 934

North Dakota Permanent Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule; withdrawal of proposed amendment.

SUMMARY: OSMRE is announcing withdrawal of a proposed amendment to the North Dakota permanent regulatory program (hereafter referred to as the North Dakota program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment pertains to the reclamation bond liability period for surface coal mining acreage disturbed for sediment ponds and associated access roads, surface water diversions and soil stockpiles.

EFFECTIVE DATE: September 7, 1989.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Ennis, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, 100 East B Street, Casper, Wyoming 82601-1918, Telephone: (307) 261-5776.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program.

On December 15, 1980, the Secretary of Interior conditionally approved the North Dakota program. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 15, 1980, **Federal Register** 45 FR 82246. Subsequent actions concerning North Dakota's program and program amendments can be found at 30 CFR 934.12, 934.13, 934.14, 934.15, and 934.16.

II. Submission of Amendment.

On November 8, 1988, North Dakota submitted a proposed amendment to its program pursuant to SMCRA (Administrative Record No. (ND-H-01). The amendment would revise regulation section at: NDAC section 69-05.2-22-07, which requires, a 10-year bond liability period for a reclamation tract, beginning after the last year of augmented seeding, planting, fertilization, irrigation or other work.

At it's own initiative, for purposes of improving operational efficiency of the State program, North Dakota proposed to amend to section 69-05-2-22-07, to allow for a case-by-case determination of reclamation bond liability periods, for sedimentation ponds and associated disturbances, that would end at the same time as the reclamation bond liability period for the disturbances within the reclamation tract.

OSMRE published a notice in the December 23, 1988, **Federal Register** 53 FR 51845 announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (Administrative Record No. ND-H-11). The public comment period ended on January 23, 1989.

III. Withdrawal of Amendment.

On July 31, 1989, North Dakota requested that the proposed amendment submitted on November 8, 1988, be withdrawn (Administrative Record No. ND-H-13). Therefore, the proposed amendment published in the December 23, 1988, **Federal Register** is withdrawn and 30 CFR Part 934 is not amended.

IV. List of Subjects in 30 CFR Part 934:

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: August 24, 1989.

Raymond L. Lowrie,

Assistant Director, Western Field Operations.

[FR Doc. 89-20925 Filed 9-6-89; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 950

Wyoming Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; Reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is announcing receipt of additional explanatory information and revisions pertaining to a previously proposed amendment to the Wyoming permanent regulatory program (hereinafter, the "Wyoming program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The additional explanatory information and revisions pertain to the entire amendment. The amendment is intended to allow the construction of bluffs as final reclamation features where such features will enhance post-mining land uses for the benefit of wildlife and livestock.

This notice sets forth the times and locations that the Wyoming program and proposed amendment to that program are available for public inspection and the reopened comment period during which interested persons may submit written comments on the proposed amendment.

DATES: Written comments must be received by 4:00 p.m., m.d.t. October 10, 1989.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. Jerry R. Ennis at the address listed below.

Copies of the Wyoming program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Casper Field Office.

Mr. Jerry R. Ennis, Director,
Casper Field Office,
Office of Surface Mining Reclamation and Enforcement,
100 East B Street, Room 2128,
Casper, WY 82602–1918,
Telephone: (307) 261–5776.
Department of Environmental Quality
Land Quality Division
Herschler Building—Third Floor West
122 West 25th Street
Cheyenne, WY 82002
Telphone: (307) 777–7756.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry R. Ennis, Director, Casper Field Office, (307) 261–5776.

SUPPLEMENTARY INFORMATION:

I. Background on the Wyoming Program

On November 26, 1980, the Secretary of the Interior conditionally approved the Wyoming program. General background information on the Wyoming program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Wyoming program can be found in the November 26, 1980 **Federal Register** (45 FR 78637). Subsequent actions concerning Wyoming's program and program amendments can be found at 30 CFR 950.12, 950.15, and 950.16.

II. Proposed Amendment

By letter dated December 13, 1988 (administrative record No. WY–11–1), Wyoming submitted a proposed amendment to its program pursuant to SMCRA. Wyoming submitted the proposed amendment at its own initiative. The proposed amendment defines and provides for approval of bluffs as final reclamation features if it is determined that the bluff-type features will enhance the post-mining land use. Governmental agencies and the public would be provided the opportunity for review of and comment on any applicant's bluff proposal prior to Wyoming approving or disapproving it. Approved bluff-type features would have to be designed and constructed to meet safety, stability, reclamation, and land use planning criteria specified in the proposed amendment.

The proposed amendment requires that approval of bluff-type features be made in accordance with the fish and wildlife protection performance standards of the approved State program.

The regulations that Wyoming proposes to amend are: Wyoming Department of Environmental Quality, Land Quality Division, Rules and Regulations, September 1, 1986.

Chapter I. Section 2. Definitions.

Chapter II. Section 3(b)(i)(B)(VIII) Permit Applications. Special application content requirements for surface coal mining operations.

Chapter IV. Section 2(b)(ii)(A). General environmental protection performance standards. Soft rock surface mining.

Chapter IV. Section 3(a)(v). Special environmental protection performance standards applicable to surface coal mining and reclamation operations. Backfilling, grading, and contouring.

Chapter IV. Section 3(a)(x). Special environmental protection performance standards applicable to surface coal mining and reclamation operations. Backfilling, grading, contouring.

OSM published a notice in the January 13, 1989 **Federal Register** (54 FR 1399) announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (administrative record No. WY–11–5). The public comment period ended February 13, 1989.

During its review of the amendment, OSMRE identified some concerns relating to the definition of bluff, chapter 1, Section 2, and backfilling, grading and contouring requirements, chapter IV, Section 3. OSM notified Wyoming of the concerns by letter dated March 29, 1989 (administrative record No. WY–11–11). Wyoming responded in a letter dated August 21, 1989 by submitting additional explanatory information and a revised amendment package (administrative record No. WY–11–15).

III. Public Comment Procedures

OSM is reopening the comment period on the proposed Wyoming program amendment to provide the public an opportunity to reconsider the adequacy of the amendment in light of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Wyoming program.

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **"DATES"** or at locations other than the Casper Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

List of Subjects in 30 CFR Part 950

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: August 25, 1989.

Raymond L. Lowrie,

Assistant Director, Western Field Operations.

[FR Doc. 89–20926 Filed 9–6–89; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD1 89–040]

Drawbridge Operation Regulations; Bellamy River, NH

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: At the request of the New Hampshire Department of Transportation, the Coast Guard is considering a change to the regulations governing the Route 4 (Scammell) drawbridge across the Bellamy River at mile 0.1, at Dover, New Hampshire to provide that the draw need not open for passage of vessels. Should the needs of navigation warrant, however, the bridge shall be returned to operable condition within six months after notification by the District Commander to do so. This change is being made because no requests have been made to open the draw since August 1958. This action should relieve the bridge owner of the burden of restoring and maintaining the machinery and of having a bridge tender available to open the draw and should still provide for the reasonable needs of navigation.

DATE: Comments must be received on or before October 23, 1989.

ADDRESSES: Comments should be

mailed to Commander (obr), First Coast Guard District, Bldg. 135A, Governors Island, NY 10004–5073. The comments and other materials referenced in this notice will be available for inspection and copying at this address. Normal office hours are between 8 a.m. and 4:30 p.m., Monday through Friday, except federal holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, First Coast Guard District, at (212) 668–7170.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, First Coast Guard District, will evaluate all communications received and determine a course of final action on this proposal. The proposed regulations may be changed in light of comments received.

Drafting Information

The drafters of this notice are Jose M. Arca Jr., project officer, and LT. Robert E. Korroch, project attorney.

Discussion of Proposed Regulation

This drawbridge provides a vertical clearance of 9 feet at mean high water and 16 feet at mean low water. Reportedly, in February 1956, the U.S. Army Corps of Engineers authorized operation of the bridge on 4 hours advance notice during specified hours from April to October, except for emergency openings. However, Title 33 Code of the Federal Regulation Part 117 does not reflect that any special regulations were officially issued. Therefore, operation of the bridge is governed by the general regulation which requires that at all times the draw shall open on signal. The bridge was last opened in August 1958. The present structural and mechanical condition of the bridge precludes opration without the expenditure of substantial funds. However, the proposed regulation would contain provision for restoring the bridge to operation within six months after notification by the District Commander. The New Hampshire Department of Transportation is also investigating replacement of the entire structure.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation, and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979).

The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. The determination is based on the reported information that no requests for openings have been made since 1958. Since the economic impact of this proposal is expected to be minimal, the Coast Guard certifies that if adopted, it will not have a significant economic impact on a substantial number of small entities.

Federalism Implications Assessment

This action has been analyzed under the principles and criteria in Executive Order 12612, and it has been determined that this proposed regulation does not have sufficient federalism implications to warrant preparation of a federal assessment.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 117 of title 33, Code of Federal Regulations as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 449; 49 CFR 1.46; 33 CFR 1.05–1(g); 33 CFR 117.43.

2. A new section 117.695 is added to read as follows:

§ 117.695 Bellamy River.

The draw of the Route 4 drawbridge at mile 0.1 at Dover, New Hampshire need not open for the passage of vessels. However, the bridge shall be returned to operable condition within six months after notification by the District Commander.

Dated: August 21, 1989.

R. I. Rybacki,

Rear Admiral, U.S. Coast Guard Commander, First Coast Guard District.

[FR Doc. 89–20947 Filed 9–6–89; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–3641–5]

Approval and Promulgation of Implementation Plans; Wisconsin

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: USEPA is disapproving a submission by the State of Wisconsin as a revision to the Wisconsin State Implementation Plan (SIP) for ozone. This revision consists of a site-specific reasonably available control technology (RACT) determination for high performance architectural coatings used on miscellaneous metal parts and products at the Masco Corporation (Masco) facility located in Milwaukee, Wisconsin.

USEPA today is disapproving this SIP revision because (1) the Wisconsin Department of Natural Resources (WDNR) has not demonstrated that all sources operated by Masco are in compliance with applicable rules, and (2) NWDNR has not demonstrated that this revision will not jeopardize attainment, maintenance or reasonable further progress (RFP).

DATE: Comments on this revision and on the proposed USEPA action must be received by October 10, 1989.

ADDRESSES: Copies of the SIP revision and technical support documents are available at the following addresses for review. (It is recommended that you telephone Uylaine E. McMahan, at (312) 886–6031, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch (5AR–26), 230 South Dearborn Street, Chicago, Illinois 60604.

Wisconsin Department of Natural Resources, Bureau of Air Management, 101 South Webster, Madison, Wisconsin 53707.

Comments on this proposed rule should be addressed to: (Please submit an original and five copies if possible) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinios 60604 (312) 886–6031.

SUPPLEMENTARY INFORMATION: On November 3, 1988, the WDNR submitted a revision to its ozone SIP, for a site-specific RACT [1] determination for high performance architectural coatings used on miscellaneous metal parts and products for the Masco facility, located in Milwaukee, Wisconsin, an urban nonattainment area for ozone.

Wisconsin's SIP

Under the existing federally approved SIP for Wisconsin, the high performance architectural coatings are subject to the control requirements contained in NR 422.15, Wisconsin Administrative Code. This rule established a VOC emission limit of 4.3 pounds per gallon of coatings, excluding water, for both cured and air dried clear coatings, and 3.5 pounds per gallon of coating, excluding water, for extreme performance cured coatings and all other air-dried coatings. A limit of 3.0 pounds VOC per gallon of coatings, excluding water, is established for all other cured coatings. USEPA approved these rules as meeting the RACT requirement of the Clean Air Act on January 11, 1980 (45 FR 2319), and June 21, 1982 (47 FR 26622).

Analysis

WDNR's November 3, 1988, submittal contains a variance for Masco, whereby the source is subject to the following conditions:

1. Volatile organic compound (VOC) emissions from high performance architectural coatings shall not exceed 6.0 pounds per gallon of coatings, excluding water and exempt solvents, as applied.

2. Masco shall maintain records of the following information for each coating, as it is applied:

a. A unique coating identification name or number
b. Percent solids by volume
c. Percent VOC by volume (excluding exempt VOC)
d. Percent water and exempt VOC by volume
e. Density of the VOC identified in c. (above) in pounds per gallon
f. Pounds of VOC per gallon of coating, excluding water and exempt VOC

3. The department may modify the emission limit in condition 1 in the event coatings capable of meeting the Architectural Aluminum Manufacturer's Association specification 605.2 are developed which have a VOC content lower than that specified in condition 1.

4. High performance architectural coatings may not participate in any internal offset under NR 425.04(3), Wisconsin Administrative Code.

5. This variance shall not become effective until approved by the Administrator of the USEPA or his designee as a source-specific revision to Wisconsin's ozone SIP, pursuant to NR 436.05(5), Wisconsin Administrative Code.

In order for the 6.0 pounds of VOC per gallon of coating emission limit proposed by Masco to be considered RACT, the source must initially demonstrate that it is technically or economically infeasible to meet a lower emission limit using coatings with low VOC content or using add-on control equipment, and then demonstrate it can meet other requirements, involving the impact of the relaxation on attainment and maintenance of the NAAQS.

WDNR also issued an approval to Masco to demonstrate compliance with the applicable rules for the non-high performance architectural coatings through the use of an internal offset with transfer efficient credit. This internal offset has not been submitted to USEPA as a SIP revision.[2]

Masco has demonstrated that it is not feasible to meet the existing SIP limit through the use of currently available coatings alone. The coatings involved in the variance are specialized coatings supplied by a limited number of companies. In addition to the documentation provided by Masco, Region V independently surveyed the coating suppliers and determined that a low-VOC formulation of this type of coating is not currently available.

Masco also evaluated the technical and economic feasibility of add-on control. This evaluation considered controlling emissions to the level required by the SIP, as well as two intermediate alternatives (control of oven exhaust and control of ovens, plus one booth). Masco provided vendor quotes, as well as cost estimates calculated using the procedures outlined in the Economic Analysis Branch Control Cost Manual (EPA 450/5-87-001A). These cost estimates indicate that it is not economically feasible for Masco to meet the existing SIP limit, using add-on control equipment. Masco evaluated the economic feasibility of meeting an intermediate limit using alternative control strategies in the same manner and determined that it is economically infeasible to control bake oven exhaust or to control one spray booth and the bake ovens.

Although Masco has demonstrated that it is not technicallly and economically feasible to meet the existing SIP limit, this revision is still not approvable for two reasons. First, Masco has not met the requirement, contained in NR 436.05, Wisconsin Administrative Code, that the owner or operator of the air contaminant sources for which a revision is requested demonstrates that all direct or portable sources owned or operated in the State by such person and in compliance with all applicable requirements of chapters NR 400 to 499 or are on a schedule for compliance with such requirements.

(The only facility owned or operated by Masco is the subject of this review. Some air-dried and cured coatings (which are not high performance architectural coatings and, therefore, not part of this review) are not in compliance at this time. See footnote 2.)

Second, WDNR has not demonstrated that this revision will not jeopardize attainment and maintenance of the ozone national ambient air quality standards (NAAQS) or reasonable further progress (RFP) towards attainment. WDNR has argued that the revision will not jeopardize attainment because Wisconsin VOC emission summaries indicate the actual emissions for 1986 and 1987 are below target levels in Wisconsin's approved 1982 ozone SIP, and because the increase in emissions allowed by the revision is less than 0.02 percent of the inventory for these years. However, because USEPA recently issued an ozone SIP call to Wisconsin, a demonstration which relies on the previously approved SIP is not acceptable. In additon, USEPA does not consider any increase in VOC emissions to be insignificant.

Proposal

USEPA is disapproving this SIP revision because (1) Masco has not demonstrated that all sources operated by Masco in Milwaukee, Wisconsin, are in compliance with the applicable rules, and (2) WDNR has not demonstrated that this revision will not jeopardize attainment and maintenance of the NAAQS or RFP.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future

[1] A definition of RACT is contained in a December 9, 1976, memorandum from Roger Strelow, former Assistant Administrator for Air and Waste Management. RACT is defined as the lowest emission limitation that a particular sources is capable of meeting by the application of control technology that is reasonably available, considering technological and economical feasibility.

[2] WDNR approved Masco's internal offset request on October 31, 1988. The request has not been submitted to USEPA as a SIP revision. Because USEPA believes that the internal offset and transfer efficiency provisions must be submitted as SIP revisions in order to be effective, USEPA will not consider the non-high performance architectural coatings to be in compliance through the use of an internal offset with transfer efficiency credit, unless it has been approved as a SIP revision.

request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevent statutory and regulatory requirements.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before (30 days from publication) will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V Office address provided at the front of this notice.

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989, (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years.

Under 5 U.S.C. section 605(b), I certify that this SIP disapproval will not have a significant economic impact on a substantial number of small entities because it deals with only one source, Masco Corporation. (See 46 FR 8709).

List of Subjects in 40 CFR Part 52

Environmental Protection
Pollution control
Hydrocarbon
Ozone
Carbon monoxide
Intergovernmental Offices

Authority: 42 U.S.C. 7401–7642

Dated: August 29, 1989.

Frank M. Covington,

Acting Regional Administrator.

[FR Doc. 89–20994 Filed 9–6–89; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 81

[FRL–3641–4]

Designation of Areas for Air Quality Planning Purposes; Oklahoma; Tulsa County Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes to disapprove a request from the Oklahoma State Department of Health (OSDH) to revise the attainment status designation for Tulsa County from nonattainment to attainment for the Ozone National Ambient Air Quality Standard (NAAQS). EPA is proposing to disapprove Oklahoma's request because (1) the area does not have a fully approved State Implementation Plan (SIP) and (2) the ambient air monitoring data do not demonstrate attainment. This notice discusses EPA's review, the State's request, and EPA's proposed action.

DATES: Comments on this action must be received by October 10, 1989.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs at the EPA Regional Office listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region 6, Air Programs Branch (6T–A), 1445 Ross Avenue, Dallas, Texas 75202–2733

Oklahoma State Department of Health, Air Quality Service, 1000 Northeast 10th Street, P.O. Box 53551, Oklahoma City, Oklahoma 73152

FOR FURTHER INFORMATION CONTACT: Gregg Guthrie, Air Programs Branch, U.S. EPA Region 6, telephone (214) 655–7214, or (FTS) 255–7214.

SUPPLEMENTARY INFORMATION: Under section 107(d) of the Clean Air Act (CAA), the Administrator of EPA has promulgated the NAAQS attainment status for all areas within each State. These area designations may be revised whenever sufficient data become available to justify a redesignation.

Background

On March 3, 1978, at 43 FR 8962 EPA identified Tulsa County, Oklahoma as nonattainment for the Ozone NAAQS. In accordance with the requirements of the CAA for such nonattainment areas, the OSDH submitted a SIP revision in April of 1979. The 1979 SIP indicated the Ozone standard would be achieved by December 31, 1982. The 1979 SIP revision for Tulsa County was conditionally approved on February 13, 1980, at 45 FR 9733. After additional submittals by the OSDH, EPA removed the conditions on the 1979 Ozone plan revision on November 28, 1980, at 45 FR 79051. The approved revision included the adoption of the required Set I and Set II stationary source regulations which reflected the application of reasonably available control technology (RACT). Because this revision predicted attainment by December 31, 1982, these regulations were required to represent RACT for major sources only.

Violations of the ozone NAAQS continued during 1983.

Consequently, on February 24, 1984, EPA issued a letter to the Governor of Oklahoma calling for a revision to correct the inadequacy of the existing SIP. As a Post-1982 nonattainment county, EPA required the adoption of regulations specified in the Group I, II and III Control Techniques Guideline (CTG) documents for both major and minor sources located in the County. The State was also required to implement a vehicle Inspection/Maintenance program and submit a demonstration of attainment. On February 20, 1985, the Governor of Oklahoma, submitted a SIP revision designated to achieve the Ozone standard in Tulsa County.

The February 20, 1985, revision predicted attainment by December 31, 1986. The revision has thus far failed to receive EPA approval. EPA intends to act on this revision in the near future, however, approval of that submittal rests on the State's ability to demonstrate that the State's current stationary and mobile source regulations are enforceable and represent RACT and the State's adoption of all regulations required under part D of the CAA.

Because 1984–1986 monitoring data did not demonstrate attainment of the Ozone NAAQS, the Tulsa metropolitan statistical area (MSA) was identified as a potential 1988 SIP Call area in Appendix A of the proposed Post-1987 Ozone/Carbon Monoxide strategy that was published in the **Federal Register** on November 24, 1987. Using the same monitoring data that Oklahoma has submitted to support its redesignation request, EPA issued a Phase I SIP Call for the Tulsa MSA on May 26, 1988. That 1985–1987 ambient monitoring data revealed a calculated expected exceedance rate of 1.1 per year. As a Phase I SIP Call area, the State is required to correct deficiencies and inconsistencies in their existing SIP, complete the adoption of regulations previously required under part D of the CAA, and begin updating their emission inventory to reflect current emission levels in the Tulsa MSA.

Ozone Redesignation Criteria

When considering a redesignation request for ozone, a number of criteria must be met. One of these criteria is achievement of the NAAQS for ozone. The NAAQS for ozone is defined a 0.12 parts per million (ppm) over a one-hour average not to be exceeded more than once per year. An area is determined to be in violation of the standard when the annual average expected number of daily exceedances is greater than one (1.0) at any monitoring site. A daily exceedance occurs when the maximum hourly ozone concentration is greater

than 0.124 ppm during a given day. Ozone daily exceedance is defined at 40 CFR part 50. The expected number of daily exceedances is calculated from the observed number of exceedances by making the assumption that nonmonitored days (invalid or incomplete data) have the same fraction of daily exceedances as those exceedances observed on monitored days.

Specific criteria for ozone redesignation reviews are given in the following policy memoranda: a December 7, 1979, memorandum from Richard G. Rhoads former Director of EPA's Control Programs Development Division; an April 21, 1983, memorandum from Sheldon Meyers, former Director of EPA's Office of Air Quality Planning and Standards (OAQPS); and an April 6, 1987, memorandum from Gerald A. Emison, Director of OAQPS. In summary, those memoranda indicate that the calculated average number of expected exceedances should be determined from the most recent three years of quality assured representative monitoring data and that observed improvements in air quality must be due to implementation of permanent and enforceable emission control measures. Those memoranda also specify that any redesignation request contain evidence that the SIP for the area be fully approved by EPA and finally implemented by the State.

Tulsa Redesignation Request

On August 9, 1988, the OSDH submitted a request to redesignate Tulsa County to an attainment status for the ozone NAAQS. This request was based on the most recent, complete, quality assured three years of monitoring data covering calendar years 1985–1987. These data were collected at three sites within Tulsa County; Site 127 located in 1326 East Mohawk Boulevard, Tulsa, Oklahoma; Site 137 located at 900 South Osage Drive, Skiatook, Oklahoma; and Site 174 located at 502 East 144th Place, South, Glenpool, Oklahoma. These sites are located in a north-south line across the county and all sites have experienced exceedances of the ozone standard during the 1985–1987 time frame. The ozone concentrations showing exceedances are summarized below:

TABLE 1.—OZONE CONCENTRATION EXCEEDANCES PER YEAR (PPM)

Site Number	1985	1986	1987
127	0.13	0.14; 0.13	none.
137	0.13	none	none.
174	0.15	0.13	none.

EPA examined the 1985–1987 air quality data and found that they were collected in accordance with all EPA requirements. Sites 127, 137 and 174 have a calculated annual average expected number of exceedances of 1.1, 0.33 and 0.67 respectively based on the above data. The data collected from Site 127 reveal the area has not reached attainment since EPA requires a 1.0 or lower value for an annual average expected exceedance to demonstrate attainment. In addition, EPA has reviewed the 1988 ozone data and found that more recent exceedances of the ozone standard have occurred. EPA found an expected exceedance rate of 1.1 violations per year based upon 1986–1988 data which reflects continued nonattainment of the area.

Proposed Action

Based on three or more years of monitoring data that fails to demonstrate attainment of the ozone NAAQS and the lack of an EPA-approved control strategy, EPA is proposing to disapprove the State's request to redesignate Tulsa County to attainment. All interested persons are invited to submit written comment on today's proposal. Written comments received by the date specified above will be considered in determining EPA's final action.

Under 5 U.S.C. 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities (See 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401–7642.

Dated: May 15, 1989.

Robert E. Layton, Jr.,

Regional Administrator.

[FR Doc. 89–20995 Filed 9–6–89; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 89–379, RMs–6618; 6657; 6670 and 6793]

Radio Broadcasting Services; Atlantic, Audubon, Fairfield and Newton, IA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on four petitions for rule making. Wireless Communications Corp seeks the allotment of Channel 243C2 to Atlantic, IA, as the community's second local FM service. Christian Family Radio seeks the allotment of Channel 243C1 to Audubon, IA, as its first local FM service. KCOB/KLVN requests the substitution of Channel 241C2 for Channel 240A at Newton, IA, and the modification of its license for Station KLVN–FM accordingly. Galesburg Broadcasting Company seeks the substitution of Channel 240C2 for Channel 240A at Fairfield, IA, and the modification of its license for Station KCMD accordingly by either adjusting the site restriction on proposed Channel 241C2 at Newton or substituting Channel 241A for Channel 240A at Newton and modifying Station KLVN–FM's license accordingly.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: John E. Carl, President, KCOB/KLVN, Inc., 611 First Avenue East, Newton, Iowa 50208 (Petitioner for Newton); James M. Weitzman, Esq., Kaye, Scholer, Fierman, Hayes and Handler, 901 15th Street, NW., Washington, DC 20005 (Counsel to Christian Family); John T. Pritchard, Galesburg Broadcasting Company, 57½ S. Court Street, Fairfield, IA 52556 (Petitioner for Fairfield); and Barry A. Friedman, Esq., Wilner & Scheiner, 1200 New Hampshire Avenue, NW., Suite 300, Washington, DC 20036 (Counsel to Wireless Communications).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No.

89-379, adopted August 18, 1989, and released August 31, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW, Washington, DC The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW, Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

Channel 243C2 can be allotted to Atlantic in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 243C2 at Atlantic are North Latitutde 41-24-00 and West Longitude 90-00-54. Channel 243C1 can be allotted to Audubon with a site restriction of 30.4 kilometers southeast. The coordinates for Channel 243C1 at Audubon are North Latitude 41-30-04 and West Longitude 94-42-09. Channel 240C2 can be allotted to Fairfield with a site restriction of 16.2 kilometers southwest. The coordinates for the Fairfield allotment are North Latitude 40-54-33 and West Longitude 92-05-45. Channel 241C2 can be allotted to Newton with a site restriction of 13.3 kilometers west and Channel 241A can be allotted to Newton for use at Station KLVN-FM's present transmitter site. The coordinates for Channel 241C2 at Newton are North Latitude 41-43-16 and West Longtitude 93-12-22. The coordinates for Channel 241A at Newton are North Latitude 41-41-42 and West Longitude 93-12-22.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89-20982 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 89-369, RM-6847]

Radio Broadcasting Services; Twin Lakes, IA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Twin Lakes. Broadcasting, Inc. seeking the substitution of Channel 290C3 for Channel 288A at Twin Lakes, Iowa, and the modification of its license for Station KTLB accordingly. Channel 290C3 can be allotted to Twin Lakes in compliance with the Commission's minimum distance-separation requirements and can be used at Station KTLB's present transmitter site. The coordinates for this allotment are North Latitude 42-32-09 and West Longitude 94-40-48. In accordance with § 1.420(g) of the Commission's Rules Station KTLB's license may be modified without accepting competing expressions of interest in use of the higher powered channel at Twin Lakes and without requiring the petitioner to demonstrate the availability of an additional equivalent class channel for use by such interested parties.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Francis N. Donnelly, President, Twin Lakes Broadcasting, Inc., North Twin Lakes, S-18, Rockwell City, Iowa 50579 (Petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making MM Docket No. 89-369, adopted August 14, 1989, and released August 31, 1989. The full text of this Commission decision is available for inspection and copying during normal buisness hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing premissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch Policy and Rules Division Mass Media Bureau.

[FR Doc. 89-20984 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 89-378, RM-6823]

Radio Broadcasting Services; Leesville, LA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Stannard Broadcasting Company, Inc., licensee of Station KVVP(FM), Channel 288A, Leesville, Louisiana, proposing the substitution of Channel 289C3 for Channel 288A at Leesville, and the modification of its station's license accordingly. The proposal could provide the community's first wide coverage area FM service. Channel 286C3 can be allotted to Abbeville consistent with the Commission's minimum distance separation requirements with a site restriction of 17.3 kilometers (10.7 miles) south of the city, at coordinates 30-59-30 and 93-13-00.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: James J. Popham, Esquire, 700 Camp Street, New Orleans, LA 70130 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89–378, adopted August 18, 1989, and released September 1, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21053 Filed 9–6–89; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 73

[MM Docket No. 89–374, RM–6870]

Radio Broadcasting Services; Leland, MI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Pyramid Communications Ltd., proposing the substitution of FM Channel 232C3 for Channel 232A at Leland, Michigan, and modification of its construction permit (BPH–850712XY) for Channel 232A to specify Channel 232C3. Canadian concurrence will be obtained for Channel 232C3 at Leland at coordinates 44–51–40 and 85–55–30.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Barbara L. Waite, Venable, Baetjer, Howard & Civiletti, 1301 Pennsylvania Ave. NW., Suite 1200, Washington, DC 20004. (Counsel to the petitioner)

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89–374, adopted August 15, 1989, and released August 31, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contracts. For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–20981 Filed 9–6–89; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 73

[MM Docket No. 89–376, RM–6871]

Radio Broadcasting Services; Aitkin, MN

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Upper Minnesota Broadcasting Corporation, proposing the substitution of FM Channel 232C3 for Channel 232A at Aitkin, Minnesota, and modification of the license for Station KEZZ to specify the new channel. Canadian concurrence will be obtained for Channel 232C3 at coordinates 46–36–15 and 93–39–55.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Timothy K. Brady, P.O. Box 986, Brentwood, Tennessee 37027–0986, (Counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89–376, adopted August 15, 1989, and released September 1, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The Complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are published in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts. For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21054 Filed 9–6–89; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 89-368, RM-6809]

Radio Broadcasting Services; Greenwood, MS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Team Broadcasting, Co., Inc., permittee of Channel 282A Greenwood, Mississippi, proposing the substitution of Channel 282C3 for Channel 282A, and modification of its permit to specify operation on Channel 282C3. The coordinates for Channel 282C3 are 33-35-48 and 90-15-50.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 11, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or its counsel or consultant, as follows: Lawrence Roberts, Mark N. Lipp, Mullin, Rhyne, Emmons and Topel, P.C., 1000 Connecticut Avenue, Suite 500, Washington, DC. 20036 (Counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89-368, adopted August 14, 1989, and released August 31, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC. 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is not longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR Section 1.1204(b) for rules governing permissible *ex parte* contacts For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89-20985 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 89-372, RM-6907]

Radio Broadcasting Services; Clarksdale, MS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by WKDJ Radio, proposing the substitution of FM Channel 243C3 for Channel 243A at Clarkdale, Mississippi, Petitioner also requests modification of its contruction permit for Channel 243A to specify Channel 243C3. The coordinates for Channel 243C3 are 34-06-00 and 90-25-00.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: J. Boyd Irgram, General Partner, P.O. Box 73, Batesville, Mississippi 38606.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89-372, adopted August 15, 1989, and released September 1, 1989. The full text of this Commission decision is available for insepction and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court reveiw, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts. For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89-21055 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-02-M

47 CFR Part 73

[MM Docket No. 89-373, RM-6873]

Radio Broadcasting Services; Lexington, MS

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a proposal filed by J. Scott Communications, Inc. requesting the substitution of FM Channel 290C3 for Channel 292A at Lexington, Mississippi, and modification of its license for Station WLTD(FM) to specify operation on the higher class channel. The coordinates for Channel 290C3 are 33-00-00 and 89-53-30.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Linda J. Eckard, Mark N. Lipp, Mullin, Rhyne, Emmons and Topel, P.C., 1000 Connecticut Avenue NW., Washington, DC 20036, (Counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89-373, adopted August 7, 1989, and released September 1, 1989. The full text of this Commission decision is available

for inspection and copying during normal business hours in the FCC Dockets Branch [Room 230], 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, [202] 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts. For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21056 Filed 9–6–89; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 89–375, RM–6846]

Radio Broadcasting Services; Bozeman, MT

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Northern Sun Corporation, proposing the allotment of FM Channel 260C1 to Bozeman, Montana, as that community's third commercial FM broadcast service. The coordinates for Channel 260C1 are 45–40–54 and 111–02–18.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Dennis F. Begley, Reddy, Begley & Martin, 2033 M Street NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89–375, adopted August 15, 1989, and released September 1, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW,, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts. For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89–21057 Filed 9–6–89; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR 73

[MM Docket No. 89–370, RM–6842]

Radio Broadcasting Services; Wadesboro, NC

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Red Penny Broadcasting seeking the substitution of Channel 228C3 for Channel 228A at Wadesboro, North Carolina, and the modification of its construction permit for a new station there for specify the higher powered channel. Channel 228C3 can be allotted to Wadesboro in compliance with the Commission's minimum distance separation requirements with a site restriction of 4.9 kilometers (3.9 miles) northeast to avoid a short-spacing to Station WZNS, Dillon, South Carolina, Station WCEZ, Columbia, South Carolina, and to an application for Channel 229A at Bishopville, South Caroline (BPH–880519ND). The coordinates for this allotment are latitude 34°59'57" N. and longitude 80°02'34" W. We will not accept competing expressions of interest in use of Channel 228C3 at Wadesboro or require the petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before October 23, 1989, and reply comments on or before November 7, 1989.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Justine Hope Lambert, General Partner, Red Penny Broadcasting, 208 S. Rutherford Street, Wadesboro, North Carolina 28170 (Petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking, MM Docket No. 89–370, adopted August 14, 1989, and released August 31, 1989. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Karl A. Kensinger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 89-20983 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 649

[Docket No. 90809-9209]

RIN 0648-AC28

American Lobster Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: NOAA issues this proposed rule for comment on Amendment 3 to the Fishery Management Plan for the American Lobster Fishery (FMP). Amendment 3 and this proposed rule would: (1) Delay implementation of the increase in the escape vent size scheduled for January 1, 1990 to January 1, 1992; and (2) require that effective January 1, 1992, lobster traps contain an escape panel or equivalent mechanism that would degrade, keeping a trap from ghost fishing after it has been abandoned or lost for 12 months or more. Proposal 2 would become effective only if the New England Fishery Management Council (Council) specifies, and the Regional Director publishes a list of acceptable escape mechanisms at least 12 months prior to January 1, 1992. The purpose of this action is to allow the maximum utilization of the resource through maximum retention of legal sized lobsters during the period of scheduled size increases and to reduce mortality caused by lost or abandoned traps.

DATE: Written comments must be received on or before October 16, 1989.

ADDRESSES: Comments on the proposed rule should be sent to Richard Roe, Rigional Director, National Marine Fisheries Service, Northeast Regional Office, One Blackburn Drive, Gloucester, Massachusetts 01930. Mark the outside of the envelope "Comments on the Lobster Regulations."

Copies of the amendment which incorporates the environmental assessment and the regulatory impact review are available from Douglas G. Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway, Saugus, Massachusetts 01906.

FOR FURTHER INFORMATION CONTACT: Patricia A. Kurkul, Resource Policy Analyst, 508-281-9331.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for the American Lobster Fishery (FMP) and implementing regulations were prepared by the Council in 1983 (48 FR 36266). The objective of the FMP is to support and promote the development and implementation, on a continuing basis, of a unified regional management program for American lobsters (*Homarus americanus*), which is designed to promote conservation, to reduce the possibility of recruitment failure and to allow full utilization of the resource by the United States fishing industry. Efforts to better achieve this objective have resulted in Amendment 1 to the FMP in 1986 (51 FR 19210), Amendment 2 to the FMP in 1987 (52 FR 46088), and this proposed rule to implement Amendment 3.

Amendment 3 contains two proposals: (1) Delay the implementation of the increase in the escape vent size scheduled for January 1, 1990 until January 1, 1992; and (2) require that lobster traps must contain an escape panel or equivalent mechanism that would degrade and allow lobsters to escape after a trap has been abandoned or lost for 12 months or more.

Proposal 1

Amendment 2 to the FMP implemented a schedule of lobster size increases an an escape vent size increase according to the following schedule:

Effective date	Minimum carapace length
January 1, 1988	Increased to 3 2/32 inches.
January 1, 1989	Increased to 3 1/4 inches.
January 1, 1990	No change in carapace length, escape vents compatible with 3 5/16 inches.
January 1, 1991	Increase to 3 9/32 inches.
January 1, 1992	Increase to 3 5/16 inches.

Amendment 3 proposes to delay the scheduled vent size increase until January 1, 1992, in order to ease an unforeseen regulatory burden that the original schedule is likely to impose on the industry.

According to the original schedule, on January 1, 1990, the escape vent size will be increased to one that is compatible with a 3 5/16 inch lobster carapace size. At the time this schedule was published the Council decided that the choice of 1990 for the implementation of the vent size increase was regarded as the most conservative and practical alternative, and that the vent size increase should be compatible with the 3 5/16" carapace size. Since that time, however, the National Marine Fisheries Service provided the Council with scientific guidance concerning the size and timing of the escape vent requirement. This guidance provided the Council with two options (1) a vent size specification of 1 7/8 inches which would maximize the retention of legal size lobsters and (2) a vent size of 1 15/16 which would maximize escapement of lobsters less than the legal size.

Consistent with the objective of the FMP to promote conservation, the Council opted for the vent size that enhances escapement of sublegals, i.e., 1 15/16 inches. However, if this vent size increase were to be implemented in 1990, according to the original schedule, it is estimated that 10-15 percent of lobsters just meeting the minimum legal size could escape until the schedule of lobster minimum size increases is fully implemented in 1992. In short, implementation of a vent size that might allow excessive escapement of legal size lobsters could cause an unintended loss in revenue to the fishery, and erode the cooperation and compliance needed to achieve the objectives of the FMP.

In order to offset the potentially negative economic impacts of the scheduled vent size increase, the Council proposes to postpone the 1 15/16" vent size increase until 1992. This proposal would allow for optimal retention of legal sized lobsters, while ensuring that adequate escapement is achieved consistent with the scheduled increases in minimum carapace length.

Proposal 2

The second proposal would require, effective January 1, 1992, that lobster traps contain an escape panel or equivalent mechanism to keep a trap from ghost fishing after it has been abandoned or lost for 12 months or more. The purpose of this proposal is to reduce fishing mortality caused by lost traps ("ghost fishing") on all sizes of lobster. Every year lobstermen lose about 20-25 percent of their traps due to storms or damage to trap lines caused by trawlers. An unknown number of these traps continue to catch lobsters and cause some level of lobster mortality which is thought to be significant.

Several states already require degradable material in certain types of fish and shellfish traps. For instance, since 1965, Florida has required that spiny lobster traps be made of wood. Other states have a number of fishery regulations similar in purpose which require a range of readily degradable

materials such as cotton twine, soft steel trap hooks and magnesium pins to be used in fish traps.

On January 1, 1988, the state of Connecticut implemented a measure requiring biodegradable escape panels in lobster traps in state waters. Maine is considering a similar regulation that is likely to remain in a pending status until the federal rule is implemented.

Although the potential of time release mechanisms to prevent ghost fishing has been demonstrated in a number of other fisheries, their use is not widespread. Experimentation by individual lobstermen or even academic and scientific institutions is unlikely to lead to a consistent or widely accepted standard for a time release mechanism. In this environment, it is also unlikely that gear manufacturers will develop and distribute the appropriate products to help solve this problem.

This proposal would become effective January 1, 1992, only if the Council specifies, and the Regional Director publishes at least twelve months prior to this date a list of escape mechanisms. Some members of the industry are concerned that the technology of escape mechanisms has not been sufficiently tested. Although the concept of an escape panel is generally supported, a list of acceptable escape mechanisms might not be available one year prior to January 1, 1992. Therefore, implementation will occur at least one year after a list is available and published.

Classification

Section 304(a)(1)(D)(ii) of the Magnuson Act, as amended by Public Law 99–659, 16 U.S.C. 1854 (a)(1)(D)(ii) requires the Secretary of Commerce (Secretary) to publish regulations proposed by the Council within 15 days of receipt of the amendment and proposed regulations. At this time the Secretary has not determined that the amendment these rules would implement is consistent with the national standards, other provisions of the Magnuson Act, and other applicable law. The Secretary, in making that determination, will take into account the information views and comments received during the comment period.

The Council prepared within Amendment 3 an environmental assessment (EA) that discusses the impact on the environment as a result of this rule. A copy of the EA may be obtained from the Council at the address given above and comments on it are requested.

The Under Secretary for Oceans and Atmosphere, NOAA, has determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under E.O. 12291. This proposed rule, if adopted, is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Council prepared within Amendment 3 a regulatory impact review (RIR) which concludes that this rule, if adopted, would have the following economic impacts. Proposal 1 is expected to prevent a reduction in catch of lobsters between 3¼" and 3⁵⁄₁₆" of 8 percent in 1990 and 5 percent in 1991. The net benefits associated with this are unquantifiable because of the lack of data on size distribution of lobsters landed from the exclusive economic zone (EEZ). Proposal 2 is expected to provide an annual net benefit of $1.05–1.52 million in revenues to fishermen in the EEZ. Based on 1987 ex-vessel prices, proposal 2 would provide a gross annual benefit of $1.13–1.59 million in revenues to fishermen because it is expected to increase EEZ lobster landings by 139–196,000 pounds annually. The annual cost of degradable materials, such as hemp, jute, cotton twine or steel wire, is estimated to be $5–6,000 for about 550,000 traps. The opportunity cost of labor to install degradable fasteners annually is estimated to be $55–61,000. The additional cost of slightly larger plastic escape panels needed to cover the escape path opening in the lobster trap is estimated to range from about $11–13,000. A period of one year for an escape release mechanism to work is sufficient to allow a variety of materials and thicknesses to be used without forcing lobstermen to replace escape panel fasteners too frequently. Most inshore lobstermen fish nine months or less. If the material used to secure the escape panels lasts at least this amount of time, then the lobstermen will be able to re-secure the escape panels once a year before putting the gear in the water at the beginning of a new season. Total costs are expected to range from $72–80,000 annually.

Administrative, enforcement, and paperwork and recordkeeping requirements are expected to remain unchanged, thus, there are no impacts on federal, state, or local government agencies. No data on operating costs are currently available for the harvesting sector; however, operating expenses are not expected to increase measurably. Employment impacts are expected to be neutral or very slightly positive because of the small size of the increase in revenues. Impacts on the competitive position of U.S. lobstermen are expected to be neutral or slightly positive. A copy of the RIR may be obtained at the address listed above.

The General Counsel of the Department of Commerce has certified to the Small Business Administration that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities for the reasons stated above in the summary of the RIR. As a result, a regulatory flexibility analysis was not prepared.

This proposed rule is exempt from the procedures of E.O. 12291 under Section 8(a)(2) of that order. Deadlines imposed under the Magnuson Act require the Secretary to publish this proposed rule within 15 days of its receipt. The proposed rule is being reported to the Director, Office of Management and Budget with an explanation of why it is not necessary to follow the procedures of the order.

This rule does not contain a collection of information requirement for the purposes of the Paperwork Reduction Act.

The Council determined that this rule will be implemented in a manner that is consistent, to the maximum extent practicable, with the approved coastal zone management programs of Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Delaware, Maryland and New Jersey. This determination has been submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act.

This rule does not contain policies with federalism implications sufficient to warrant a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Part 649

Fisheries, Reporting and recordkeeping requirements.

Dated: August 31, 1989.

James E. Douglas, Jr.,

Deputy Assistant Administrator For Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 649 is proposed to be amended as follows:

PART 649—AMERICAN LOBSTER FISHERY

1. The authority citation for part 649 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 649.2, the definition of "escape vent" is added in alphabetical order to read as follows:

§ 649.2 Definitions

* * * * *

Escape vent means an opening in a lobster trap designed to allow lobsters smaller than the legal minimum size to escape from the trap.

* * * * *

3. Section 649.20, the table in paragraph (b) is revised to read as follows:

§ 649.20 Harvesting and landing requirements.

* * * * *

(b) *Carapace length.*

* * * * *

Effective dates	Minimum carapace length
January 1, 1985, through December 31, 1987.	3 3/16 inches.
January 1, 1988, through December 31, 1988.	3 7/32 inches.
January 1, 1989, through December 31, 1990.	3 1/4 inches.
January 1, 1991, through December 31, 1991.	3 9/32 inches.
January 1, 1992, and beyond [1].	3 5/16 inches.

[1] By January 1, 1992, escape vents in traps must be compatible with a minimum carapace length of 3 5/16 inches.

* * * * *

4. Section 649.21 is amended by revising paragraph (c)(2) and by adding paragraph (c)(3) to read as follows:

§ 649.21 Gear identification, marking, and escape vent requirements.

* * * * *

(c) * * *

(2) On January 1, 1992, all lobster traps must contain one of the following:

(i) A rectangular escape vent compatible with an unobstructed opening not less than 1 15/16 inches high (49.2 mm) by 6 inches wide (152.2 mm), if the escape vent is made by cutting meshes on a wire mesh trap the width will be measured from center to center on the wires;

(ii) Two circular escape vents with unobstructed openings not less than 2 7/16 inches (61.9 mm) in diameter; or

(iii) Any other type of escape vent which the Regional Director finds to be consistent with paragraphs (c)(2)(i) and (c)(2)(ii) of this section.

(3) On January 1, 1992, lobster traps must contain an escape panel or equivalent mechanism to keep a trap from ghost fishing after it has been abandoned or lost for 12 months or more. This requirement shall become effective on or before January 1, 1991, only if the Council specifies, and the Regional director publishes, a list of acceptable methods for complying with this requirement, including the minimum dimensions of the escape path.

* * * * *

[FR Doc. 89-21035 Filed 9-1-89; 3:32 pm]
BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 54, No. 172
Thursday, September 7, 1989

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Cooperative Agreements Award; Cornell University

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to enter into a Cooperative Agreement with Cornell University to provide partial support funding for collaborative international research on Development of DNA-Probes for Identification Pseudomonas Syringae Pathovar Glycinea.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds in fiscal year 1989 (FY1989) and/or FY1990 to enter into a cooperative agreement with Cornell University to collaborate on international research on Development of DNA-Probes for identification Pseudomonas Syringae Pathovar Glycinea. Cornell University's Department of Plant Pathology will conduct collaborative research with Italy's University of Bologna. Assistance will be provided only to Cornell University's which is contributing resources and experience to conduct the research. Funds provided by OICD will be used to supplement costs for supplies, a research associate, and international travel. Italy's University of Bologna will support their portion of the research.

Based on the above, this is not a formal request for application. It is estimated that $20,000 will be available in FY 1989 and/or FY 1990 to support this work. A total of $40,000 is anticipated to be provided for this cooperative research effort over a three year period, subject to the availability of federally appropriated funds in future fiscal years.

Information on proposed Agreement #58–319R–9–020 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21042 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Cooperative Agreements Award; Cornell University

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to enter into a Cooperative Agreement with Cornell University to provide partial support funding for collaborative international research on Indexing Grape Propagation Material for the Crown Gall Pathogen and Developing Strategies for Disease Control.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds in fiscal year 1989 (FY1989) and/or FY1990 to enter into a cooperative agreement with Cornell University to collaborate in international research on indexing grape propagation material for the Crown Gall Pathogen and developing strategies for disease control. Cornell University's Department of Plant Pathology will conduct collaborative research with Italy's University of Bologna. Assistance will be provided only to Cornell University, which is contributing resources and experience to conduct the research. Funds provided by OICD will be used to supplement costs for a research assistant and international travel. Italy's University of Bologna will support their portion of the research.

Based on the above, this is not a formal request for application. It is estimated $16,250 will be available in FY1989 and/or FY1990 to support this work. A total of $50,250 is anticipated to be provided for this cooperative research effort over a three year period, subject to the availability of federally appropriated funds in future fiscal years.

Information on proposed Agreement #58–319R–9–019 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21043 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Cooperative Agreements Award, Ohio Staten University

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to award a Grant to Ohio Staten University for publication of proceedings from the ISEC Research Committee conference on "International Agricultural Research."

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD anticipates the availability of funds in fiscal year 1989 (FY1989) to provide funding support to Ohio State University for preparation, publication and distribution of the proceedings from the April 10, 1989, conference on International Agricultural Research, sponsored by the International Science and Education Council (ISEC) Research Committee. Assistance will be provided only to Ohio State University which will utilize funds to partially support the publication.

Based on the above, this is not a formal request for application. An estimated $3,720 will be available in FY1989 as partial project support.

Information on proposed Grant #59–319R–9–004 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21044 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Cooperative Agreement Award, University of Florida

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to enter into a Cooperative Agreement with the University of Florida to provide partial support funding for collaborative international research on Evaluating Brassicas as a Cloning Source for Resistance Genes Against Xanthomonas.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds in fiscal year 1989 (FY1989) and/or FY1990 to enter into a cooperative agreement with the University of Florida to collaborate in international research on evaluating Brassicas as a cloning source for resistance genes against Xanthomonas. The University of Florida's Plant Pathology Department will conduct collaborative research with Singapore's National University. Assistance will be provided only to the University of Florida, which is contributing resources and experience to conduct the research. Funds provided by OICD will be used to supplement costs for a research assistant and international travel. Singapore's National University will support their portion of the research.

Based on the above, this is not a formal request for application. It is estimated that $16,000 will be available in FY1989 and/or FY1990 to support this work. A total of $33,500 is anticipated to be provided for this cooperative research effort over a two year period, subject to the availability of federally appropriated funds in future fiscal years.

Information on proposed Agreement #58–319R–9–017 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21045 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Cooperative Agreement Award; Washington State University

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to enter into a Cooperative Agreement with Washington State University to provide partial support funding for collaborate international research on Constraints to the Expansion of Edamame and Azuki Production for the Japanese Market.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds in fiscal year 1989 (FY1989) and/or FY1990 to enter into a cooperative agreement with Washington State University to collaborative in international research on constraints to the expansion of Edamame and Azuki production for the Japanese market. Washington State University's Department of Agronomy and Soils will conduct collaborative research with Iwate and Kokkaido Universities. Assistance will be provided only to Washington State University, which is contributing resources and experience to conduct the research. Funds provided by OICD will be used to supplement costs for a research assistant and international travel. Iwate and Kokkaido Universities will support their portion of the research.

Based on the above, this is not a formal request for application. It is estimated that $19,500 will be available in FY1989 and/or FY1990 to support this work. A total of $59,500 is anticipated to be provided for this cooperative research effort over a three year period, subject to the availability of federally appropriated funds in future fiscal years.

Information on proposed Agreement #58–319R–9–018 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21046 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Cooperative Agreements Awards; William Patterson College

AGENCY: Office of International Cooperation and Development (OICD).

ACTION: Notice of intent.

Activity: OICD intends to enter into a Cooperative Agreement with William Patterson College to provide partial support funding for collaborative international research on Di-Haploid Soybean Plant Induction Via Anther and Inflorescence Culture.

Authority: Section 1458 of the National Agricultural Research, Extension and Teaching Policy Act of 1977, as amended (7 U.S.C. 3291), and the Food Security Act of 1985 (Pub. L. 99–198).

OICD announces the availability of funds in fiscal year 1989 (FY1989) and/or FY1990 to enter into a cooperative agreement with William Patterson College to collaborate in international research on di-haploid soybean plant induction via anther and inflorescence culture. William Patterson College will conduct collaborative research with People's Republic of China's Heilongjiang Academy of Agricultural Science, Harbin. Assistance will be provided only to William College, which is contributing resources and experience to conduct the research. Funds provided by OICD will be used to supplement costs for a research assistant and international travel. People's Republic of China's Heilongjiang Academy of Agricultural Science, Harbin, will support their portion of the research.

Based on the above, this is not a formal request for application. It is estimated that $18,800 will be available in FY1989 and/or FY1990 to support this work. A total of $55,800 is anticipated to be provided for this cooperative research effort over a three year period, subject to the availability of federally appropriated funds in future fiscal years.

Information on proposed Agreement #58–319R–9–021 may be obtained from: USDA/OICD/Management Services Branch, Washington, DC 20250–4300.

Dated: August 30, 1989.

Nancy J. Croft,

Contracting Officer.

[FR Doc. 89–21047 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–DP–M

Soil Conservation Service

South Branch Kawkawlin River Watershed Protection Plan, Michigan

AGENCY: Soil Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines, (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the South Branch Kawkawlin River

Watershed, Bay, Midland and Saginaw Counties, Michigan.

FOR FURTHER INFORMATION CONTACT: Mr. Homer R. Hilner, State Conservationist, Soil Conservation Service, 1405 South Harrison Road, East Lansing, Michigan 48823, telephone 517–337–6702.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will benefit water quality in the South Branch Kawkawlin River Watershed by significantly reducing the amounts of sediment and phosphorus entering the stream. A contact has been made with the State Historical Preservation Officer and concludes that it will have no effect on any cultural resources either eligible for or listed on the National Register of Historic Places. The State Archaeologist will be contacted if any land disturbance associated with this project and archaeological sites, features, or materials are encountered during actual construction. As a result of these findings, Mr. Homer R. Hilner, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

This measure concerns a plan for the installation of practices for water quality improvement. The practices will include: Conservation tillage, critical area planting, grassed waterways, stripcropping, diversions, water and sediment control basins, grade stabilization structures, tree planting, vegetative barriers and field windbreaks. Total financial assistance cost is estimated to be $1,740,300; $973,200 PL–566 funds and $767,100 local funds.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Homer R. Hilner.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904–Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials.)

Dated: August 25, 1989.

Homer R. Hilner,

State Conservationist.

[FR Doc. 89–20908 Filed 9–6–89; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Mid-Atlantic Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Mid-Atlantic Fishery Management Council and its Committees will hold public meetings on September 12–14, 1989, at the Holiday Inn, 3845 Veterans Memorial Highway, Ronkonkoma, NY.

The Council will begin meeting on September 13 at 1 p.m., and will adjourn on September 14 at 3 p.m. The Council will elect officers, recommend 1990 quotas for surf clams and ocean quahogs, as well as discuss other fishery management and administrative matters. The public meeting may be lengthened or shortened depending upon progress on the agenda. The Council also may hold a closed session (not open to the public) to discuss personnel and/or national security matters.

The Habitat Committee will meet on September 12 at 8 a.m.; the Information and Education Committee will meet on September 12 at 10 a.m.; the Coastal Migratory Fisheries Committee will meet jointly with the Atlantic States Marine Fisheries Commission Bluefish Board on September 12 at 1 p.m., to consider the Bluefish Fishery Management Plan, and the Demersal Fisheries Committee will meet on September 13 at 8 a.m.

For further information contact John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19901; telephone: (302) 674–2331.

Dated: August 30, 1989.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–20919 Filed 9–6–89; 8:45 am]

BILLING CODE 3510–22–M

North Pacific Fishery Management Council: Public Meetings

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The North Pacific Fishery Management Council, its Scientific and Statistical Committee (SSC), Advisory Panel (AP), and other Council advisory groups will meet on September 24–29, 1989, at the Sheraton Hotel in Anchorage, AK. Except as noted below, the meetings are open to the public.

The Council will begin meeting on September 26 at 9 a.m. (Also on September 26 the Council will meet at noon in executive session (not open to the public) to discuss employment and litigation matters.) During its open session, the Council will elect officers for the coming year; receive status of stocks reports for groundfish in the Gulf of Alaska and Bering Sea/Aleutian Islands, and set initial harvest quotas and apportionments for domestic and joint venture fisheries for 1990. The Council's administrative process for setting initial and final groundfish specifications will be reviewed and discussed. The Council also will review the performance of domestic harvesters and processors, and receive the results of the survey of crab resources in the Bering Sea and Aleutian Islands. It will receive a status report from the Office of the Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration (NOAA), on efforts to implement a federal domestic observer program. In addition, there will be reports on bycatch management planning, and regulatory and plan amendments in progress.

The Council also will review and approve a formal policy for deadlines for public comments, and will also consider future utility of the Fisheries Obligation Guarantee and the Capital Construction Fund Programs.

The Council will review limited access planning schedules for the sablefish, halibut, groundfish and crab fisheries, and also determine whether they should be modified or abandoned. It will consider approval of a draft sablefish limited access plan for public review and also consider approval of halibut limited access decision points for final staff analysis, as well as review public comments on a draft amendment to fishery management plans (FMPs) to address the issue of roe stripping in the pollock fisheries in the Gulf of Alaska and Bering Sea/Aleutian Islands. It also will consider final approval of this amendment for Secretarial review as well as review options for addressing full utilization and waste issues.

The Council will receive a preliminary analysis for NOAA General Counsel on allocation proposals for allocating resources between at-sea and non-at-sea components of the fishing industry,

and review the Fishery Planning Committee recommendations. The Council will determine how to proceed with further development of any of the alternatives.

The Council will review public comments on the revised FMP for Salmon Fisheries in the Exclusive Economic Zone off Alaska, and consider approval of the plan for Secretarial review. The Council also will review allocative proposals received for the 1990 halibut season, and decide which should be further analyzed and forwarded for public review. It will also consider adjusting the halibut management cycle.

A draft regulatory amendment to prohibit using groundfish pots in the Gulf of Alaska without halibut exclusion mechanisms also will be considered for approval. The Pacific Northwest Crab Industry Advisory Committee will report to the Council on its first meeting under the new Bering Sea and Aleutian Islands King and Tanner Crab FMP. The Council also will consider action to implement a federal observer program for the crab fisheries and initiate discussion on formulating cost recovery programs for the fishing industry.

The Council will review foreign permit applications as available and set priorities for consideration of review of such applications in December. Also, as appropriate, the Council will consider and develop various international issues.

The Council's AP and SSC also will meet during the week of September 24. The AP will begin meeting at 10:30 a.m., on September 24 and the SSC will begin meeting at 10:30 a.m., on September 25. Other meetings scheduled are:

(1) Halibut Management Team, September 24 at 1:30 p.m.
(2) Halibut Regulatory Amendment Advisory Group, September 24 at 7 p.m.
(3) Halibut Bycatch Work Session, September 25 at 7 p.m.
(4) Halibut Committee, September 26 at 7 p.m.

For more information contact the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510; telephone: (907) 271–2809.

Dated: September 1, 1989.

Herbert L. Blatt,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89-21049 Filed 9-6-89; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council and its advisory entities will meet on September 18–21, 1989, at the Red Lion Inn-Downtowner, 1800 Fairview, Boise, ID. Except as noted below, the meetings are open to the public.

The Council will meet on September 20 at 8 a.m., to address groundfish management issues, including but not limited to: (1) Inseason management measure adjustments for rockfish and sablefish; (2) preliminary management specifications for 1990; (3) Canadian management proposals for 1990; (4) sablefish management in 1990; (5) a preliminary report on measures to extend the whiting venture season; (6) Council guidance on the draft plan amendment; and (7) proposed regulations governing domestic offshore processors. Also on September 20 the Council will hear a status report on the Pacific halibut fisheries in 1989, and discuss the schedule of meetings to develop the 1990 allocations. On September 20 at 4 p.m., the Council will receive public comments on any issue not on the agenda. Public comments on agenda items will be considered before Council action on each item.

The Council will convene on September 21 at 8 a.m., in closed session (not open to the public), to discuss litigation and personnel matters. The open session will start at 9 a.m., to address salmon management, habitat and administrative matters. Salmon management agenda items include, but are not limited to, (1) the sequence of events and current status of the 1989 fisheries; (2) approval of the draft plan amendment for public hearings; (3) a report from council on penalties for barbless hook violations and legality of multiple landings of the same fish, and (4) a discussion on management implications of the decision to classify Sacramento River winter chinook as a threatened species.

The Scientific and Statistical Committee will meet on September 18 at 8 a.m., to address scientific issues on the Council's agenda, and will reconvene on September 19 at 8 a.m.

The Groundfish Select Group will meet on September 19 at 8 a.m., to address groundfish issues on the Council's agenda.

The Budget Committee will meet on September 19 at 1 p.m., to review the status of the 1989/90 Council budgets.

The Habitat Committee will meet on September 19 at 3 p.m., to consider timely and relevant habitat matters impacting fisheries in the Council's jurisdiction.

Detailed agendas for the above meetings will be made available to the public after September 1, 1989. For further information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 S.W. First Avenue, Room 420, Portland, OR 97201; telephone: (503) 326–6352.

Dated: August 30, 1989.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–20920 Filed 9–6–89; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council's Anchovy Plan Development Team will hold a public meeting on September 14, 1989, at 9 a.m., at the National Marine Fisheries Service, Southwest Fisheries Center, 8604 La Jolla Shores Drive, La Jolla, CA. The Team will continue developing a plan amendment to the Council's anchovy fishery management plan, which would provide for a mininal reduction fishery under specified conditions.

For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 SW. First Avenue, Portland, OR 97201; telephone: (503) 326–6352.

Dated: August 30, 1989.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–20921 Filed 9–6–89; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council's Scientific and Statistical Committee salmon subcommittee will hold a public meeting on September 14–15, 1989, at the General Administration Building, Director's Conference Room, Olympia, WA. On September 14 the meeting will begin at 11 a.m., and on September 15 the meeting will adjourn by 4:30 p.m. The subcommittee will review the methods used to estimate

wild coho returns to Washington State coastal streams.

A detailed agenda is available from the Pacific Council's office. For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 SW. First Avenue, Portland, OR 97201; telephone: (503) 326–6352.

Dated: August 30, 1989.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–20922 Filed 9–6–89; 8:45 am]

BILLING CODE 3510–22–M

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The South Atlantic Fishery Management Council will hold a public meeting of the Bluefish Advisory Panel at the Council's headquarters (address below), beginning on September 25, 1989, at 1 p.m., and concluding on September 26 at noon. The advisory panel will review the Bluefish Fishery Management Plan and consider comments received at recent public hearings concerning the plan. It will also formulate recommendations to the Council regarding management measures contained in the proposed plan. A detailed agenda will be available to the public on or about September 8, 1989.

For more information contact Carrie R. F. Knight, Public Information Specialist, South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407; telephone: (803) 571–4366.

Dated: September 1, 1989.

Herbert L. Blatt,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 89–21050 Filed 9–6–89; 8:45 am]

BILLING CODE 3510–22–M

Marine Mammals; Permit Program Review; Permits for Taking Marine Mammals for Public Display Purposes

AGENCY: National Marine Fisheries Service (NOAA Fisheries), NOAA Commerce.

ACTION: Notice.

SUMMARY: The National Marine Fisheries Service (NOAA Fisheries) will hold a working session to solicit input on a definition of public display consistent with the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361–1407) (MMPA). This working session is part of a comprehensive review of NOAA Fisheries' permit program to take marine mammals for purposes of public display and scientific research. Note that this working session is not a hearing. Participants should be prepared to contribute substantively to the permit program review.

DATES: Persons wishing to participate in the working session must notify the Information Contact listed below by September 22, 1989. The working session will be held on Tuesday, October 3, 1989, at 9:30 a.m.

ADDRESS: Office of Protected Resources and Habitat Programs, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Art Jeffers, Permits Division, address above; telephone 301/427–2289.

SUPPLEMENTARY INFORMATION: NOAA Fisheries is conducting a review of its program and policies for issuing permits to take marine mammals for purposes of scientific research, public display, or enhancing the survival or recovery of a species or stock pursuant to the MMPA, and for scientific research and enhancement pursuant to the Endangered Species Act (See 54 FR 13099, March 30, 1989 and 54 FR 27663, June 30, 1989). One of the objectives of the permit program review is the development of a definition of public display consistent with the policies and the purposes of the MMPA. The need for such a definition and the issues and concerns regarding whether certain activities or types of facilities constitute public display, as that term is used in the MMPA, are presented in a Discussion Paper released as part of the permit program review.

This working session is being held to give interested members of the public an opportunity to participate in group discussions to: identify, consistent with the MMPA, the elements that should enter a definition of public display; develop and examine alternative definitions of public display; and discuss the role of education in public display. The results of the working session together with the comments received on the Discussion Paper will be considered by NOAA Fisheries in the development of revised permit regulations and an Advance Notice of Proposed Rulemaking will be issued at that time. This working session is not a hearing. Participants are encouraged to: be prepared to contribute substantively and constructively to group discussions; have a working knowledge of the relevant sections of the MMPA: and be familiar with the applicable chapters of the Discussion Paper.

Separate working sessions will be held on other topics as part of the permit program review, including but not limited to the following: care and maintenance of captive marine mammals; scientific research permits; effects on wild populations; permits and the National Environmental Policy Act. Dates and locations will be published in the Federal Register.

Dated: August 30, 1989.

Nancy Foster,

Director, Office of Protected Resources and Habitat Programs, National Marine Fisheries Service.

[FR Doc. 89–20923 Filed 9–6–89; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Defense Manufacturing Board; Meeting

AGENCY: Under Secretary of Defense (Acquisition).

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Office of the Under Secretary of Defense for Acquisition announces a forthcoming planning meeting for a Defense Manufacturing Board project on concurrent engineering.

Date and Time: September 25, 1989, 0900–1500.

Address: Institute for Defense Analysis, 1801 N. Beauregard, Room 218S, Alexandria, VA 22311.

The agenda for the meeting will include an overview of Department of Defense activity in the general area of concurrent engineering.

FOR FURTHER INFORMATION CONTACT: Ms. Sherry Fitzpatrick of the DMB Secretariat, (202) 697–0957.

Dated: August 31, 1989.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89–20939 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–01–M

Defense Science Board Task Force on Low Observable Technology

ACTION: Change in Location of Advisory Committee Meeting Notice.

SUMMARY: The meeting of the Defense Science Board Task Force on Low

Observable Technology scheduled for August 23–24, 1989 as published in the **Federal Register** (Vol. 54, No. 96, Page 21648, Friday, May 19, 1989, FR Doc. 89–12018) will be held on August 23–24, 1989 at the Institute for Defense Analyses. This notice supercedes the change previously submitted in **Federal Register** (Vol. 54, No. 117, Page 25892, Tuesday, June 20, 1989, FR Doc. 89–14508).

Dated: August 31, 1989.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89–20940 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–01–M

Defense Science Board Task Force on Follow-on Forces Attack

ACTION: Change in Date of Advisory Committee Meeting Notice.

SUMMARY: The meeting of the Defense Science Board Task Force on Follow-on Forces Attack scheduled for September 6–7, 1989 as published in the **Federal Register** (Vol. 54, No. 134, Page 29769, Friday, July 14, 1989, FR Doc. 89–16483) will be held on September 14–15, 1989.

Dated: August 31, 1989.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 89–20941 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–01–M

Department of the Navy

Extension of Public Review Period for the Draft Environmental Impact Statement for Electronic Installations in the Western Pacific

The public review and comment period for the Draft Environmental Impact Statement for Electronic Installations in the Western Pacific is hereby extended to October 5, 1989. All comments must be postmarked on or before that date and sent to: E.C. Rushing, Jr., Commander, CEC, USN, Head, Facilities Planning Department, Pacific Division, Naval Facilities Engineering Command, Pearl Harbor, Hawaii 96860–7300.

Dated: September 1, 1989.

Sandra M. Kay,

Department of the Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 89–20951 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–AE–M

CNO Executive Panel Advisory Committee Space Task Force; Closed Meeting

Notice was published on August 21, 1989, at 54 FR 34547–8 that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee Space Task Force will meet September 26–27, 1989 at 4401 Ford Avenue, Alexandria, Virginia. This meeting has been canceled. In accordance with 5 U.S.C. section 552b(e)(2), the meeting cancellation is publicly announced at the earlier practical time.

Dated: September 1, 1989.

Sandra M. Kay,

Department of the Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 89–20949 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–AE–M

CNO Executive Panel Advisory Committee on Superconductivity; Closed Meeting

Notice was published on August 16, 1989, at 54 FR 33759 that the Chief of Naval Operations (CNO) Executive Panel Advisory Committee on Superconductivity will meet on September 5–6, 1989 at 4401 Ford Avenue, Alexandria, Virginia. This meeting has been canceled. In accordance with 5 U.S.C. section 552b(e)(2), the meeting cancellation is publicly announced at the earliest practical time.

Dated: September 1, 1989.

Sandra M. Kay,

Department of the Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 89–20950 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–AE–M

Performance Review Board Membership; Correction

Volume 54, No. 154 of the **Federal Register** at pages 33053 and 33054 which was issued on August 11, 1989 contained the names of individuals who were nominated for the Department of the Navy's Senior Executive Service Performance Review Boards. That list was not complete as one entire page of names was not published. The following is the list of names omitted in the previous publication.

Addendum to Department of the Navy PRB Membership

Storey, R. C. Mr.
Swofford, F. W. Mr.
Tarbell, W. A. Mr.
Taussig, J. K. Mr.
Thomas, R. O. Mr.
Thompson, R. H. Mr.
Tobin, P. E. RADM
Topping, R. RADM
Tupaz, J. B. Capt
Turner, D. Mr.
Turnquist, C. J. Mr.
Urban, R. G. Mr.
Weiss, A. R. Mr.
Wilcox, H. J. Mr.
Wilgenbusch, R. RADM
Williams, J. F. Mr.
Willoughby, W. J. Mr.
Wineglass, R. J. MGEN
Winokur, R. S. Dr.
Wood, A. D. Dr.
Wyant, F. E. Mr.
Zanfagna, P. E. Mr.
Zimmerman, Jr, H. H. Mr.

Dated: September 1, 1989.

Sandra M. Kay,

Department of the Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 89–20952 Filed 9–6–89; 8:45 am]

BILLING CODE 3810–AE–M

DEPARTMENT OF EDUCATION

Office of Bilingual Education and Minority Languages Affairs

Applications Submitted Under Direct Grant Programs

AGENCY: Department of Education.

ACTION: Notice for individuals interested in reviewing applications submitted under direct grant programs administered by the Office of Bilingual Education and Minority Languages Affairs.

SUMMARY: The Director of the Office of Bilingual Education and Minority Languages Affairs (OBEMLA), Department of Education, invites interested individuals to apply to serve as field readers for programs administered by OBEMLA. OBEMLA administers programs authorized by the Bilingual Education Act, 20 U.S.C. 3281–3341 as amended by Public Law 100–297 (April 28, 1988), and 34 CFR parts 500, 501, 524, 525, 526, 561, 573, and 574.

Each year the Secretary selects field readers to evaluate grant applications based upon criteria published in program regulations and, where applicable, additional criteria published in the application notices in the **Federal Register.**

Expertise is desirable in such areas as evaluation, curriculum and materials development, personnel and parent training, education administration, research, bilingual education, English as a second language, teaching English to speakers of other languages (TESOL),

second language acquisition, adult education, special education, and vocational education. This list is not intended to be all inclusive and individuals with expertise in related fields are encouraged to apply. Individuals selected as reviewers will be compensated for their services as needed. Individuals interested in serving as field readers for the fiscal year 1990 funding cycle should contact OBEMLA no later than September 29, 1989.

FOR FURTHER INFORMATION CONTACT: Ms. Carolyn Craig, Office of Bilingual Education and Minority Languages Affairs, U.S. Department of Education, 400 Maryland Avenue, SW. (Room 5086, Switzer Building), Washington, DC 20202–6642. Telephone: (202) 732–5722.

Dated: August 17, 1989.

Rita Esquivel,

Director, Office of Bilingual Education and Minority Languages Affairs.

Catalog of Federal Domestic Assistance (CFDA) No. 84.003, Bilingual Education

I. Transitional Bilingual Education Program
II. Developmental Bilingual Education Program
III. Special Alternative Instructional Program
IV. Academic Excellence Program
V. Family English Literacy Program
VI. Special Populations Program
VII. Educational Personnel Training Program
VIII. Training Development and Improvement Program
IX. Short-Term Training Program

[FR Doc. 89–20937 Filed 9–6–89; 8:45 am]
BILLING CODE 4000–01–M

[CFDA No. 84.158N]

Office of Special Education Programs

Application for New Awards under the Training and Employment Models for Youth with Handicaps

AGENCY: Department of Education.

ACTION: Correction notice.

SUMMARY: This notice corrects an error made in the application notice published in the **Federal Register** on July 21, 1989 (54 FR 30656). The deadline for transmittal of applications is corrected to read December 18, 1989. The deadline for Intergovernmental Review is corrected to read February 16, 1990.

FOR FURTHER INFORMATION CONTACT: Joseph Clair, Division of Educational Services, Office of Special Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW., (Switzer Building, Room 4620–2644), Washington, DC 20202. Telephone (202) 732–4503.

Program Authority: 20 U.S.C. 1425

Dated: August 30, 1989.

Michael E. Vader,

Acting Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 89–20938 Filed 9–6–89; 8:45 am]
BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. GP88–26–000]

Northern Pump Co., Danner No. A–1 Well; Order Vacating Final Well Category Determination

Issued August 3, 1989

Before Commissioners: Martha O. Hesse, Chairman; Charles G. Stalon, Charles A. Trabandt, Elizabeth Anne Moler and Jerry J. Langdon.

On February 17, 1988, and May 23, 1988, the Kansas Corporation Commission (Kansas) issued orders revoking its prior determinations under section 108 of the Natural Gas Policy Act of 1978 (NGPA) [1] that the Danner No. A–1 well (the well), located in Finney County, Kansas and formerly owned and operated by Northern Pump Company (Northern Pump), was qualified as a stripper well and that production from the well was seasonally affected.[2] On July 11, 1988, Hawley Management Company (Hawley) [3] filed a protest to Kansas' orders. The Commission took no action to reverse or remand the Kansas determination revoking the seasonally affected determination and that determination became final on July 21, 1988.

On March 27, 1989, the Commission reopened the final well determination that the well qualified as stripper well under section 108.[4] In the March 27, 1989 order reopening the stripper well determination, the Commission found that it appeared that in making the subject determination untrue statements of material fact were relied upon or necessary material facts were omitted. Kansas, in its February 17, 1988 order noted that testimony had revealed that it was Northern Pump's practice to partially close the valve on the well. Further, Williams Natural Gas Company, Larson Family Farms, and Randal K. Loder (purchasers of the gas) argued that the record showed that Northern Pump read the irrigation meters only once a month and estimated the number of irrigation gas days of production each month by dividing this monthly amount by an estimated daily volume which it assumed an irrigation pump would use during one day of operation.

Section 108(b) of the NGPA provides that a well qualifies as a stripper well if:

(A) During the preceding 90-day production period, such well produced nonassociated natural gas at a rate which did not exceed an average of 60 Mcf per production day during such period; and

(B) During such period such well produced at its *maximum efficient rate of flow* [MER], determined in accordance with recognized conservation practices designed to maximize the ultimate recovery of natural gas. [Emphasis added.]

Section 271.803(d) of the Commission's regulations provides that a production day means:

(1) Any day during which gas is produced; and

(2) Any day during which gas is not produced if production during such day is prohibited by a State law or a conservation practice recognized or approved by the State agency having regulatory jurisdiction over the production of natural gas.

On April 26, 1989, the purchasers filed the only comments received in response to the March 27, 1989 order. The purchasers request that the Commission vacate the section 108 stripper well determination based upon the record in this proceeding. The purchasers argue that the production figures submitted by Northern Pump in support of its section 108 application did not reflect the true maximum efficient rate of flow of the well as required by NGPA section 108(b)(1), because the valve was restricted. The purchasers further argue that the production records submitted in Northern Pump's section 108 application were also tainted by the use of estimated irrigation gas production days which creates the possibility of the double counting of production days. Finally, purchasers contend that state

[1] 15 U.S.C. 3318 (1982).

[2] On May 21, 1986, the Commission issued an order reopening and remanding to Kansas a determination that the well is a seasonally affected stripper gas well. 35 FERC ¶61,207.

[3] Hawley states that it is serving as manager of liquidation and dissolution of Northern Pump Company and acting as agent for the Estate Trust of Roseta H. Wright, the owner of Northern Pump Company. Hawley further states that the current operator and partial owner of the well is Ensign Operating Company (Ensign), which purchased the well in November 1986, and that Amoco Production Company also owns an interest in the well.

[4] 46 FERC ¶61,367 (1989). The Commission found that the May 26, 1986 order had only reopened and remanded the seasonally affected determination. 46 FERC at 62,153.

flow tests demonstrate that the well's MER exceeded 60 Mcf per day in 1978.

Northern Pump in the course of the stripper well determination made no statement concerning the operating practice of restricting the valve on the well and failed to explain its method of estimating production days to show its compliance with § 271.803(d) of the regulations. Section 275.205(d) of the Commission's regulations provides that the Commission shall vacate any reopened determination if it finds that the grounds for reopening the determination exist.[5] Accordingly, we find good cause under section 503(d) of the NGPA to vacate the final section 108 determination of natural gas produced from the subject well.

Ensign and all working interest owners and first resellers that have collected proceeds from first sales of gas from the subject well, if they have not already done so, must refund, with interest calculated under § 154.102(c) of the Commission's regulations, all amounts collected in excess of the otherwise applicable maximum lawful price.

The Commission orders:

(A) The stripper well determination under section 108 for the Danner No. A–1 well is hereby vacated pursuant to section 503(d) of the NGPA and § 275.205 of the Commission's regulations.

(B) Within ten days from the date of this order, Ensign shall serve a copy of this order on all working interest owners or all purchasers/resellers of gas from the well and must give the Commission a list of the owners or purchasers.

(C) Within 60 days from the date of this order, Ensign and any other working interest owners and purchasers/resellers of the gas from the well must refund with interest all amounts collected in excess of the applicable maximum lawful price.

(D) Within ninety days from the date of this order, anyone who collected proceeds from first sales of gas from the well shall file a refund report. The refund report must show (1) the amount of overcharges and interest refunded, (2) the dates the refunds were paid, and (3) a statement of concurrence by the purchasers that all refunds were made, or, alternatively, a statement that no refunds are due.

(E) This order shall not prejudice any enforcement action that may be warranted.

[5] 18 CFR 275.205 (1988).

By the Commission.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 89–20942 Filed 9–6–89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM89–5–1–000]

Alabama-Tennessee Natural Gas Co.; Proposed Changes in FERC Gas Tariff

August 30, 1989.

Take notice that on August 24, 1989, Alabama-Tennessee Natural Gas Company (Alabama-Tennessee), Post office Box 918, Florence, Alabama 35631, tendered for filing Alternate Second Revised Sheet No. 4A to its FERC Gas Tariff, First Revised Volume No. 1. Such tariff sheet is proposed to become effective July 1, 1989.

Alabama-Tennessee states that the filing is to adjust the currently effective take-or-pay surcharge rates to its customers to reflect decreases in the amount being billed to it by Tennessee Gas Pipeline Company, and to adjust the computation of carrying charges for one customer, in compliance with the Commission's July 7, 1989 order in Docket No. TM89–3–1–000. Alabama-Tennessee asserts that the allocation methodology utilized is that approved by the Commission in Docket Nos. RP88–205–001 and TM89–1–1–000. Alabama-Tennessee further states that such filing is being made pursuant to § 26.1(a) of its tariff.

Alabama-Tennessee has requested any necessary waivers of the Commission's Regulations in order to permit the tariff sheets to become effective as proposed.

Alabama-Tennessee states that copies of the tariff filing have been mailed to all of its jurisdictional customers and affected State Regulatory Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 or Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before September 7, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspections.

Lois D. Cashell,

Secretary.

[FR Doc. 89–20943 Filed 9–6–89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89–220–000]

CNG Transmission Corp.; Proposed Changes in FERC Gas Tariff

August 30, 1989.

Take notice that CNG Transmission Corporation on August 25, 1989 tendered for filing proposed changes in its FERC gas tariff Volume No. 1. The purpose of the filing is to implement new rates for Outer Continental Shelf interruptible transportation service. The proposed tariff sheets being filed are Second Revised Sheet No. 1, Superseding First Revised Sheet No. 1; Original Sheets No. 81A, 81B, 81C, 81D, 81E and 81F; Sixth Revised Sheet No. 32, and First Revised Sheets No. 226, 227, 228, 229, 230 231, and 232.

The Federal Energy Regulatory Commission, in Orders 509 and 509A, issued to CNG a blanket certificate for off-shore transportation. CNG initially filed to continue use of its current TF and TI rates for off-shore transportation under this blanket certificate, but by this filing proposes to use new rates designed specifically for interruptible off-shore transportation.

Copies of the filing were served upon the company's jurisdictional customers and interested state commissions.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426 in accordance with §§ 385.214 and 385.211 of the Commission's rules and regulations. All such motions or protests should be filed on or before September 7, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants party to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 89–20944 Filed 9–6–89; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP89-221-000]

North Penn Gas Co.; Proposed Changes in FERC Gas Tariff

August 30, 1989.

Take notice that North Penn Gas Company (North Penn) on August 25, 1989, pursuant to Ordering paragraph (G) of the Commission Order dated August 3, 1989, filed the following tariff sheets to First Revised Volume No. 1 of its FERC Gas Tariff:

Substitute Ninety-third Revised Sheet No. PGA—Effective August 1, 1989
Substitute Ninety-fourth Revised Sheet No. PGA—Effective September 1, 1989
Second Revised Sheet No. 15H(1)—Effective September 1, 1989
Original Sheet No. 15H(1)(a)—Effective September 1, 1989
Original Sheet No. 15H(6)—Effective September 1, 1989

North Penn states these sheets establish procedure by which it recovers from its customers FERC Order 473 Compression Allowance Charges and LNG Charges for which North Penn's pipeline suppliers have received Commission approval to bill and which are being billed to North Penn.

The tariff sheets in which North Penn proposes the pass-through of these charges are as follows:

(1) Second Revised Sheets No. 15H(1) and Original Sheet No. 15H(1)(a). These tariff sheets establish procedures (Section 18) by which North Penn will recover from its customers the FERC Order 473 Compression Allowance and the LNG Charges which North Penn's pipeline suppliers bill North Penn.

(2) Original Sheet No. 15H(6). This tariff sheet (as well as Appendix A) sets for each category of up-stream cost, the allocation of amounts billed to North Penn through July 1989; the amount of any such costs paid by North Penn's customers through a PGA surcharge; any related account 191 credit (off-set); and the net amount of each charge to be billed to North Penn's customers. The allocation methodology utilizes the same procedure utilized by North Penn's pipeline suppliers in their allocation of costs to North Penn.

As per Section 18, the amounts billed to North Penn after July 1989 will be billed by North Penn as incurred to its customers and Corning Natural Gas Corporation (Corning).

(3) Substitute Ninety-third, and Substitute Ninety-fourth Revised Sheet No. PGA-1. These revised tariff sheets eliminate the PGA surcharge for Order 473 and LNG Costs currently in effect, so that the net amount of these charges can be billed effective September 1, 1989 under tariff sheet No. 15H(6).

In the August 3, 1989 Commission order (page 15, footnote 48), the Commission states that "for purposes of determining the Corning-related portion of the Account No. 191 balance, the balance as of October 31, 1988 should be used. During the deferral period ended on that date, North Penn received several large refunds from Tennessee relating to the period when Corning was a customer of North Penn."

North Penn states it has difficulty implementing the above-passage as to refunds associated with Corning's past purchases, which refunds were reflected in Account 191 after October 31, 1988. To avoid prejudice to Corning or any customer, North Penn has designated and reserved such amounts pending Commission clarification.

Copies of this filing were served upon North Penn's sales customers as well as interested state commissions.

Any person desiring to be heard or to protest said filing should file a protest or motion to intervene with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.214 and 385.211. All motions or protests should be filed on or before September 7, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 89-20945 Filed 9-6-89; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3641-9]

Agency Information Collection Activities Under Office of Management and Budget Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATE: Comments must be submitted on or before October 10, 1989.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 382-2740.

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: Phase 3 of the Pesticide Reregistration Process (EPA ICR #1543.01). This ICR requests clearance for a new information collection.

Abstract: Under Phase 3 of the pesticide reregistration process, registrants responsible for submitting generic data to support reregistration of certain active ingredients must provide the following information to EPA: an update on their commitment to comply with reregistration data requirements; summaries of studies previously submitted to the Agency; reformatted versions of toxicology and residue chemistry reports submitted prior to 1982; information on unreasonable adverse effects; and any other information that might support reregistration.

Burden Statement: The public reporting burden for this collection of information is estimated to average 1360 hours per response, including 346 hours to summarize an average of 34 studies, 976 hours to reformat an average of 12 studies, 25 hours to complete the "Phase 3 Chemical Response Worksheet," 14 hours to identify unreasonable adverse effects, and 15 minutes to complete the "Phase 3 Report and Worksheet on Project Status." These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Respondents: Pesticide manufacturers

Estimated No. of Respondents: 1220

Estimated Total Annual Burden on Respondents: 1,659,803 hours

Frequency of Collection: One time.

Send comments regarding the burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street, SW., Washington, DC 20460, and

Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, (Telephone 395-3084).

Dated: August 30, 1989.

Paul Lapsley

Director, Information and Regulatory Systems Division.

[FR Doc. 89-20991 Filed 9-6-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3641-6]

Agency Information Collection Activities Under Office of Management and Budget Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATE: EPA is requesting emergency processing of this ICR by September 11, 1989.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202 382-2740).

SUPPLEMENTARY INFORMATION:

Office of Water

Title: Pesticides in Groundwater GIS Case Study (EPA ICR# 1512).

Abstract: Respondents will be asked to voluntarily answer questions concerning pesticide usage and the proximity of application points to water supplies. Data will be used to demonstrate techniques for identifying vulnerable water supplies needed in developing State Pesticide in Groundwater Management Plans. This collection is essential to the mission of the agency and statutory deadlines may be missed if normal procedures are followed.

Burden Statement: The estimated public reporting burden for this collection of information is one hour per respondent, per year. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Respondents: Farmers, County Agriculture Agents

Estimated No. of Respondents: 151

Estimated Total Annual Burden on Respondents: 156 hours

Frequency of Collection: One-time only.

To obtain a copy of the ICR package contact Sandy Farmer on (202) 382-2740.

Send comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street, SW., Washington, DC 20460, and

Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, (Telephone (202) 395-3084).

Dated: August 30, 1989.

Paul Lapsley,

Director, Information and Regulatory Systems Division.

[FR Doc. 89-20993 Filed 9-6-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3641-7]

Workshop on Environmental and Occupational Asthma

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of workshop.

SUMMARY: A scientific workshop, sponsored by the Federal Task Force on Environmental Cancer and Heart and Lung Disease, will be held at the Hyatt Regency Long Beach, 200 South Pine Avenue, Long Beach, California.

DATES: The workshop will begin at 5:00 p.m. on Tuesday, November 28, 1989 and conclude at 12:00 p.m. on December 1, 1989.

ADDRESSES: Preregistration is required and attendance will be limited to 150 persons (including observers from the public). To register as an observer for the workshop, contact Ms. Willie Sanderson, Technical Resources Inc., 3202 Tower Oaks Boulevard, Rockville, Maryland, 20852, Tel. (301) 231-5250. Registration will be closed on October 20, 1989.

FOR FURTHER INFORMATION CONTACT: Thomas O. Miller, U.S. Environmental Protection Agency, RD-683, 401 M Street SW., Washington DC, 20460, Tel. (202) 382-5893 (FTS: 382-5893).

SUPPLEMENTARY INFORMATION: The Federal Task Force on Environmental Cancer and Heart and Lung Disease is an interagency group established by Congress to promote cooperation and coordination among Federal agencies on environmental health issues and to recommend research needed to understand the relationship between environmental factors and human disease. The purpose of the workshop is to identify research needs on environmentally and occupationally related asthma and to promote communication linkages between pulmonary medicine specialists and primary care providers.

Dated: August 25, 1989.

John H. Skinner,

Acting Assistant Administrator for Research and Development.

[FR Doc. 89-20992 Filed 9-6-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

August 31, 1989.

The Federal Communications Commission has submitted the following information collection requirements to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act, as amended (44 U.S.C. 3501-3520).

Copies of the submissions may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street NW., Suite 140, Washington, DC 20037. Persons wishing to comment on these information collections should contact Eyvette Flynn, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-3785. Copies of these comments should also be sent to the Commission. For further information contact Jerry Cowden, Federal Communications Commission, (202) 632-7513.

OMB Number: 3060-0228

Title: Section 80.59, Compulsory ship stations

Action: Extension

Respondents: Individuals or households, state or local governments, businesses (including small businesses), and non-profit institutions

Frequency of Response: On occasion

Estimated Annual Burden: 200 respondents; 400 hours total annual burden; 2 hours average burden per response

Needs and Uses: Rule is needed to permit vessels to operate for up to 30 days beyond expiration of safety certificate when annual inspection required by treaty or statute cannot be performed in time.

OMB Number: 3060-0265

Title: Section 80.868, Card of instructions

Action: Extension

Respondents: Individuals or households, state or local governments, businesses (including small businesses), and non-profit institutions

Frequency of Response: Recordkeeping requirement

Estimated Annual Burden: 3,000 recordkeepers; 300 hours total annual burden; 6 minutes average burden per recordkeeper

Needs and Uses: Rule needed to ensure that radiotelephone distress procedures are readily available on board certain ships required by statute or treaty to be equipped with radio.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 89-20979 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

Application for Consolidated Hearing; Longhorn Broadcast Limited Partnership, et al

1. The Commission has before it the following mutually exclusive applications for 1 new FM station and 2 new AM stations:

I.

Applicant	File No.	MMDocket No.
A. Longhorn Broadcast Limited Partnership; Elgin, Texas.	BPH-871124MD	89-380
B. Johnny L. Crain and Richard J. Martinez, d/b/a Elgin Broadcasting; Elgin, Texas.	BPH-871124ML	
C. Dynamic Radio Broadcasting Corporation; Elgin, Texas.	BPH-871124MR	
D. Austin Broadcasting Company; Elgin, Texas.	BPH-871124MX	
E. William Robert Lundgren; Elgin, Texas.	BPH-871124MB (Previously Dismissed)	

Issue heading and applicants

1. & 2. Real Party-in-Interest, A
3. Qualifications, A
4. Comparative, A,B,C,D
5. Ultimate, A,B,C,D

II.

Applicant	File No.	MMDocket No.
A. William W. Muench; Willard, Missouri.	BPH-880126NO	89-371
B. MW Multicom Inc.; Willard, Missouri.	BPH-880126OI	

Issue heading and applicants

1. Air Hazard, A,B
2. Comparative, A,B
3. Ultimate, A,B

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

3. If there is any non-standardized issue in this proceeding, the full text of the issue and the applicants to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington, DC 20037. (Telephone (202) 857-3800).

W. Jan Gay,

Assistant Chief, Audio Service Division, Mass Media Bureau.

Appendix (Elgin, Texas)

1. To determine whether Sonrise Management Services, Inc. is an undisclosed party to the application of (A) Longhorn.

2. To determine whether (A) Longhorn's organizational structure is a sham.

3. To determine, from the evidence adduced pursuant to Issues 1 through 2 above, whether (A) Longhorn possesses that basic qualifications to be a licensee of the facilities sought herein.

[FR Doc. 89-20980 Filed 9-6-89; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10220. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-003155-009.

Title: Port Authority of New York and New Jersey Terminal Agreement.

Parties: Port Authority of New York and New Jersey (Port Authority), Maersk Container Service Company, Inc.

Synopsis: The Agreement provides for the removal on or after September 1, 1989, of the Port Authority's termination right associated with Building No. 186, Port Newark (Paragraph 12 of Agreement No. 224-003155-008) which is used as an equipment maintenance facility.

Agreement No.: 224-200235-001.

Title: Port of Palm Beach District Terminal Agreement.

Parties: Port of Palm Beach District, Palm Beach Steamship Agency (Agency).

Synopsis: The Agreement provides that if the Agency exercises its renewal option in the basic lease agreement, it is to be evidenced in writing and filed with the Federal Maritime Commission to become effective pursuant to the provisions of the Shipping Act of 1984. All other terms and conditions of the basic agreement remain the same.

By Order of the Federal Maritime Commission.

Dated: August 31, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 89-20910 Filed 9-6-89; 8:45 am]

BILLING CODE 6730-01-M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance) to Neckermann Und Reisen et al.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3,

Pub. L. 89–777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR part 540):

Nur Touristic GmbH (d/b/a Neckermann Und Reisen)/Trans World Cruises, Inc./and Arcalia Shipping Company, c/o Freehill, Hogan & Mahar, 80 Pine Street, New York, New York 10005–1759.

Vessel: VASCO DA GAMA.

Dated: September 1, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 89–20986 Filed 9–6–89; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of July 5–6, 1989

In accordance with § 271.5 of its Rules Regarding Availability of Information (12 CFR 271, *et seq.*), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on July 5–6, 1989.[1] The directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting tends to confirm earlier indications that economic growth has slowed this year. Gains in total nonfarm payroll employment have moderated substantially in recent months, but the civilian unemployment rate, at 5.2 percent in May, remained close to its average level in earlier months of the year. Industrial production increased on balance in April and May at about the reduced rate experienced earlier in the year. Growth in consumer spending has weakened considerably this year. Housing starts declined slightly further in May. Recent indicators of business captial spending suggest a substantial additional increase in the second quarter after a rebound in the first quarter. The nominal U.S. merchandise trade deficit narrowed in April from a substantially reduced average value in the first quarter. Broad measures of prices have risen more rapidly this year than in 1988, reflecting sharp increases in energy and food prices.

Interest rates have fallen since the Committee meeting on May 16, with the largest declines generally occurring on long-term markets. In foreign exchange markets, the trade-weighted value of the dollar in terms of the other G–10 currencies rose sharply earlier in the intermeeting period but subsequently more than retraced that rise in often volatile trading.

M2 and M3 declined in May, primarily because of sizable reductions in transaction and other liquid balances arising from the clearing of unusually large tax payments; data through mid-June point to a rebound in these measures of money. Thus far this year, expansion of M2 has been at a rate below the Committee's annual range, while growth of M3 has been around the lower bound of the Committee's range.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability, promote growth in output on a sustainable basis, and contribute to an improved pattern of international transactions. In furtherance of these objectives, the Committee reaffirmed at this meeting the ranges it had established in February for growth of M2 and M3 of 3 to 7 percent and 3½ to 7½ percent, respectively, measured from the fourth quarter of 1988 to the fourth quarter of 1989. The monitoring range for growth of total domestic non-financial debt also was maintained at 6½ to 10½ percent for the year. For 1990, on a tentative basis, the Committee agreed to use the same ranges as in 1989 for growth in each of the monetary aggregates and debt, measured from the fourth quarter of 1989 to the fourth quarter of 1990. The behavior of the monetary aggregates will continue to be evaluated in the light of movements in their velocities, developments in the economy and financial markets, and progress toward price level stability.

In the implementation of policy for the immediate future, the Committee seeks to decrease slightly the existing degree of pressure on reserve positions. Taking account of indications of inflationary pressures, the strength of the business expansion, the behavior of the monetary aggregates, and developments in foreign exchange and domestic financial markets, somewhat greater reserve restraint or somewhat lesser reserve restraint would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with growth of M2 and M3 over the period from June through September at annual rates of about 7 percent. The Chairman may call for Committee consultation if it appears to the Manager for Domestic Operations that reserve conditions during the period before the next meeting are likely to be associated with a federal funds rate persistently outside a range of 7 to 11 percent.

By order of the Federal Open Market Committee, August 31, 1989.

Normand Bernard,

Assistant Secretary, Federal Open Market Committee.

[FR Doc. 89–20961 Filed 9–6–89; 8:45 am]

BILLING CODE 6210–01–M

[1] Copies of the record of policy actions of the Committee for the meeting of July 5–6, 1989, are available upon request to The Board of Governors of the Federal Reserve System, Washington, DC 20551.

Change in Bank Control Notice; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 21, 1989.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President), 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Dan B. Kyle*, Richwood, Ohio; to retain up to 15 percent of the voting shares of The Citizens Savings Bank Company, Richwood, Ohio.

Board of Governors of the Federal Reserve System, August 31, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89–20963 Filed 9–6–89; 8:45 am

BILLING CODE 6210–01–M

Intercounty Bancshares, Inc. Employee Stock Ownership Plan; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (14 U.S.C. 1842) and 225.14 of the Board's Regulation Y (12 CFR 225.24) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than September 28, 1989.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *InterCounty Bancshares, Inc. Employee Stock Ownership Plan,* Wilmington, Ohio; to become a bank holding company by acquiring 25 percent of the voting shares of InterCounty Banshares, Inc., Wilmington, Ohio.

B. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Bank Maryland Corp.,* Towson, Maryland; to acquire 100 percent of the voting shares of Universal Bank of Maryland, Lanham-Seabrook, Maryland.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Lemens Banking Investments, Ltd.,* Austin Texas; to become a bank holding company by acquiring 61.8 percent of the voting shares of First Bank & Trust Co. Bartlett, Bartlett, Texas, and Eagle Bank, Jarrell, Texas.

2. *The Plains Corporation,* Wilmington, Delaware; to become a bank holding company by acquiring 98.02 percent of the voting shares of the Plains Corporation, Lubbock, Texas, and thereby indirectly acquire Plains National Bank of Lubbock, Lubbock, Texas.

Board of Governors of the Federal Reserve System, August 31, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-20964 Filed 9-6-89; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Report to Congress on the Costs of Operating Privately Owned Vehicles

The Travel Expense Amendments Act of 1975 (Pub. L. 94-22, May 19, 1975) requires the periodic investigation of the operating costs of privately owned vehicles (airplanes, automobiles, and motorcycles) to Government employees while engaged on official business. Further, the Act requires that the results of these investigations be reported to the Congress and published in the Federal Register.

The following report is being published to comply with the requirements of the Act.

Dated: August 23, 1989.

Richard G. Austin,

Acting Administrator of General Services.

The Travel Expense Amendments Act of 1975 (Pub. L. 94-22, May 19, 1975), 5 U.S.C. 5707(b), requires that the Administrator of General Services, in consultation with the Comptroller General of the United States, the Secretaries of Defense and Transportation, and representatives of Government employee organizations, conduct a periodic investigation of the costs of operating privately owned vehicles to Government employees while engaged on official business and report the results to the Congress at least once a year. The Act further requires that a determination of the average, actual cost per mile be made based on the results of the investigation. Such figures must be reported to the Congress within 5 working days after the determinations have been made.

The General Services Administration (GSA) conducted an automobile cost investigation based on calendar year 1988 data and consulted with representatives of employee organizations, the General Accounting Office, and the Departments of Defense and Transportation on the results. As required, GSA is reporting the results of that investigation and the cost per mile determination.

GSA's investigation of the costs of operating privately owned automobiles revealed an average cost of 24 cents per mile. GSA is currently processing an amendment to the Federal Travel Regulation increasing the automobile mileage reimbursement rate from the current level of 22.5 cents to 24 cents.

The investigation of the cost of operating privately owned motorcycles and airplanes is still in process. The results of that investigation will be reported upon completion of the investigation and the consultation process.

This report on the cost of operating privately owned automobiles will be published in the Federal Register.

[FR Doc. 89-20970 Filed 9-6-89; 8:45 am]

BILLING CODE 6820-24-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

[Announcement No. 948]

Availability of Funds for Fiscal Year 1989 for a Cooperative Agreement for an Epidemiologic Study to Determine the Incidence and Extent of Human Immunodeficiency Virus (HIV) Infection in American Blood Donors

Introduction

The Centers for Disease Control (CDC) proposes to continue assistance to the American Red Cross (ARC) through a cooperative agreement for an epidemiologic surveillance study to determine the incidence and extent of infection with Human Immunodeficiency Virus (HIV) and related retroviruses in American blood donors and to monitor trends over time using computer software developed by ARC and CDC.

Authority

This program is authorized under section 317(k)(3) of the Public Health Service Act (42 U.S.C. 247(b)), as amended.

Eligible Applicant

The American Red Cross (ARC) is the major collector of blood for transfusion in the United States, with about six million units collected annually. This number comprises approximately half the nation's blood supply. The other half is collected by numerous independent local blood banks and the military. ARC is national in scope, with collection in at least parts of most States in the continental United States. Because the prevalence of HIV infection, and especially the incidence of new infection, in blood donors is low (due to the self-deferral process), very large numbers of donors need to be studied to obtain meaningful results. Additionally, HIV infection levels vary considerably by geographic area. It is essential to obtain HIV infection data from across the entire United States.

The ARC, funded through cooperative agreement U64/CCU302659, awarded by the Centers for Disease Control in Fiscal Year 1986 has 3 years in experience in epidemiologic surveillance studies of HIV infection. It has developed a system to collect, manage, and analyze at least 6 million records a year on donations that have been tested for HIV infection. There is no other organization that is known to have already collected, managed, and analyzed millions of blood donation records which would enable to monitoring of trends in HIV infection from as early as 1986. Therefore, the intent of this announcement is to provide funding to the American Red Cross for an additional five years to continue this study.

Availability of Funds

Approximately $203,000 is available in fiscal year 1989 to fund this award. The award will be funded with 12-month annual budget periods within a 5-year project period, which will begin September 29, 1989. Continuation awards within the project period will be made on the basis of satisfactory

progress and the availability of funds. The funding estimate outlined above may vary and is subject to change. No other applications are being accepted for this project.

Purpose

The purpose of this cooperative agreement is to continue assistance to the American Red Cross for: (1) Determining and monitoring the extent of HIV infection in blood donors, (2) analyzing the characteristics of infected donors to strengthen the effectiveness of the donor deferral and screening process, (3) analyzing the socio-demographic characteristics of donors to assess the degree of representativeness of the general population, and (4) monitoring for emergence of additional Acquired Immunodeficiency Syndrome (AIDS) viruses as well as other viruses relevant to the epidemiology of AIDS.

Program Requirements

1. Recipient Agency Activities

a. Collect and analyze, on a national scale, serologic and demographic data on first-time and repeat blood donors to determine the prevalence of HIV infection by person, place, and time.

b. Continue to refine the data management system for the study.

c. Provide training for data management personnel at the ARC regional level.

d. Identify areas experiencing appreciable percentage of true seropositives which would permit ARC to determine reasons why the self-deferral process was not fully effective in screening these donors.

e. Analyze the socio-demographic characteristics of blood donors to assess the degree of their representativeness of the general U.S. population.

f. Using the computerized surveillance software developed by ARC and CDC, prepare summary data to be used for other epidemiologic studies of HIV infection in blood donors.

g. Develop and implement CDC/ARC collaborative studies for national surveillance of HIV–2 and other viruses relevant to the epidemiology of AIDS.

h. Collaborate with CDC in the presentation and dissemination of study results.

2. Centers for Disease Control Activities

a. Provide technical assistance in designing a data management system.

b. Monitor trends in the prevalence of HIV infection in first-time donors and the incidence of new HIV infection in repeat donors.

c. Evaluate and validate trend findings by comparison with trend data from other national and regional sentinel surveillance activities.

d. Collaborate in the analysis of the socio-demographic characteristics of blood donors to assess the degree of their representativeness of the general U.S. population.

e. Provide technical collaboration to the applicant in the data analyses, the evaluation of the self-deferral process and socio-demographic studies.

f. Collaborate in the presentation and dissemination of study results.

Evaluation Criteria

The application will be reviewed and evaluated based on the following criteria:

1. The extent to which the proposed objectives are measurable, specific, time-phased, and related to required recipient activities and program purpose.

2. The quality of the applicant's plan for conducting program activities and the potential effectiveness of the proposed methods in meeting its objectives.

In addition, consideration will also be given to the extent that the budget request and proposed use of project funds are appropriate and reasonable.

Funding Priorities

The intent of this announcement is to renew the cooperative agreement U64/CCU302659 between the American Red Cross and the Centers for Disease Control.

E.O. 12372 Review

The application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 13.118.

Application Submission and Deadline

The American Red Cross must submit an original and two copies of application form PHS–5161–1 (Rev 3/89) to Candice Nowicki, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Atlanta, Georgia 30305, on or before September 8, 1989.

Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please refer to Announcement Number 948 and contact the following: Business: Carole J. Tully, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Atlanta, Georgia 30305, or by calling (404) 842–6575 or FTS 236–6575. Technical: Lyle Peterson, M.D., AIDS Program, Center for Infectious Diseases, Centers for Disease Control, Atlanta, Georgia 30333, (404) 639–2082 or FTS 236–2082.

Dated: August 31, 1989.

Robert L. Foster,

Acting Director, Office of Program Support Centers For Disease Control

[FR Doc. 89–20956 Filed 9–6–89; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 85F–0477]

INI Agrico, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 5M3882) proposing that the food additive regulations be amended to provide for the safe use of a source of gamma radiation to control insect infestation and to inhibit growth and maturation in fresh papaya at doses not to exceed 1 kiloGray (kGy).

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 13, 1985 (50 FR 46834), FDA published a notice that it had filed a petition (FAP 5M3882) submitted by INI Agrico, Inc., 1000 Elwell Ct., Suite 232, Palo Alto, CA 94303, that proposed to amend the food additive regulations to provide for the safe use of a source of gamma radiation to control insect infestation and to inhibit growth and maturation in fresh papaya at doses not to exceed 1 kGy (100 kilorad).

The agency concludes that the petitioned amendment is not necessary because of a broader regulation issued in 1986. In the **Federal Register** of April 18, 1986 (51 FR 13376), FDA issued a regulation based on a 1984 proposal that, among other things, permits the use of ionizing radiation to inhibit the growth and maturation of fresh foods

and to disinfest food of arthropod pests at a dose not to exceed 1 kGy. Thus, the agency concludes that the use of radiation requested by the petitioner is already permitted and that the petition should be withdrawn.

On February 14, 1989, the agency requested the petitioner to concur that the petitioned amendment is no longer necessary and that the petition be withdrawn without prejudice (21 CFR 171.7) within 30 days. The agency has not received a response to this request and has been unable to contact the petitioner. Therefore, FDA is withdrawing the petition without prejudice. The agency will refile the petition if the petitioner so requests within 30 days.

Dated: August 24, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-20969 Filed 9-6-89; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Establishment; AIDS Research Advisory Committee

Pursuant to the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86, Stat. 770-776), and sec. 2304 of the Public Health Service Act, (42 U.S. Code 300cc-3) as amended, the National Institutes of Health, announces the establishment by the Director, National Institutes of Allergy and Infectious Diseases of the AIDS Research Advisory Committee, NIAID.

The AIDS Advisory Committee shall advise the Director of the National Institutes of Allergy and Infectious Diseases, and Director, Division of AIDS, on all aspects of research of HIV infection and AIDS related to the mission of the Division of AIDS, including pathogenesis, epidemiology, vaccine development, and treatment research.

Authority for this Committee shall terminate on August 23, 1991, unless renewed by appropriate action as authorized by law.

Dated: August 29, 1989.

William F. Raub,

Acting Director, NIH.

[FR Doc. 89-20911 Filed 9-6-89; 8:45 am]

BILLING CODE 4140-01-M

Meeting; National Heart, Lung, and Blood Institute

Notice is hereby given of the meeting of the National Cholesterol Education Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Tuesday, October 3, 1989, from 9 a.m. to 3:00 p.m., at the Old Colony Inn, 625 First Street, Alexandria, Virginia 22314, (703) 548-6300.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National Cholesterol Education Program. Attendance by the public will be limited to space available.

For the agenda, list of participants, and meeting summary, contact: Dr. James I. Cleeman, Coordinator, National Cholesterol Education Program, Office of Prevention, Education and Control, National Heart, Lung, and Blood Institute, National Institutes of Health, C-200, Bethesda, Maryland 20892, (301) 496-0554.

Dated: August 30, 1989.

William F. Raub,

Acting Director, NIH.

[FR Doc. 89-20912 Filed 9-6-89; 8:45 am]

BILLING CODE 4140-01-M

Meeting; National Diabetes Advisory Board

Pursuant to Public Law 92-463, notice is hereby given of the National Diabetes Advisory Board's meeting date which will be October 1-2, 1989. The meeting will begin at approximately 5:30 p.m. October 1, 1989, and recess at approximately 10:00 p.m. The meeting will reconvene at 8:00 a.m. on October 2, 1989, and conclude by 3:30 p.m. The Board will meet at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, Virginia 22032. The purpose of the meeting is to discuss the Board's activities and to continue evaluation of the implementation of the long-range plan to combat diabetes mellitus. Although the entire meeting will be open to the public, attendance will be limited to space available. Notice of the meeting room will be posted in the hotel lobby.

For any further information, please contact Mr. Raymond M. Kuehne, Executive Director, National Diabetes Advisory Board, 1801 Rockville Pike, Suite 500, Rockville, Maryland 20852, (301) 496-6045. His office will provide, for example, a membership roster of the Board and an agenda and summaries of the actual meetings.

Dated: August 29, 1989.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 89-20913 Filed 9-6-89; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Health Resources and Services Administration

Final Project Specifications, Review Criteria, Funding Preference and Funding Priorities for Grants for Podiatric Primary Care Residency Training Programs

The Health Resources and Services Administration announces the final Project Specifications, Review Criteria, Funding Preference and Funding Priorities for Grants for Podiatric Primary Care Residency Training Programs.

Section 788(e) authorizes the award of grants to accredited schools of podiatric medicine and public and nonprofit private hospitals to meet the costs of projects to: (1) Plan and implement projects in primary care training for podiatric physicians in approved or provisionally approved residency training programs; and (2) provide financial assistance in meeting costs of supporting trainees who participate in such programs and who plan to specialize in primary care.

Proposed Project Specifications, Review Criteria, Funding Preference and Funding Priorities were published in the **Federal Register** May 11, 1989, (54 FR 20440) for public comment. Four comments were received from three respondents during this 30-day comment period.

Proposed Project Specifications

Three of the comments were related to the Proposed Project Specification (a) which states that each project is expected to have a project director who is employed by the grantee institution and has completed at least one year of podiatric residency training and has at least one year of clinical teaching experience.

The three respondents recommended that a person who is certified by one of the recognized specialty boards within the profession, i.e., the American Board of Podiatric Surgery, the American Board of Podiatric Public Health, or the American Board of Podiatric Orthopedics, and who has a minimum of five years of clinical teaching experience in a college or approved post-graduate program, also be eligible to serve as project director for the program.

One respondent also recommended that an alternative qualification be added following ". . . clinical teaching experience" in specification "a" to read as follows: "or hold certification in a recognized specialty area in podiatric

medicine and has at least five years of clinical teaching experience."

The respondents presented the following rationale for the recommendations. Many of the existing podiatric residency training programs have been established by or are under the direction of podiatrists who have not completed a residency training program themselves, since these podiatrists graduated during the 1960s and early 1970s when postdoctoral training opportunities in podiatric medicine were minimal. If the Proposed Project Specification (a) were to remain unchanged, many experienced and qualified leaders in the field of podiatric medicine would be prohibited from serving as project directors.

The Department accepts the rationale for the recommended changes to Project Specification (a) and has revised this requirement accordingly.

Specification "a" stipulates that the project director must complete at least one year of podiatric residency training. It was also suggested to insert "approved" between "podiatric" and "residency training" to ensure the educational integrity of the proposed program. The Department has accepted this suggestion and has revised the requirement accordingly.

Proposed Funding Preference

A comment was also received in support of the Proposed Funding Preference regarding the establishment of a new residency program. The respondent recommended that an alternate method for achieving preference status be added: namely, the addition of a minimum of three new positions to an already established and approved residency program. These three new positions would constitute a separate training track with its own educational program designed to meet applicable requirements.

No change will be made in the Proposed Funding Preference since the Department interprets the phrase "new podiatric primary care residency training program with a minimum of three new residency positions" to include the addition of a podiatric primary care residency training track to an existing approved podiatric residency training program, provided that the addition to an existing program results in a net increase of three podiatric residency positions.

The following final project specifications, review criteria, funding preference and funding priorities will be used in making grant awards in Fiscal Year 1989:

Final Project Specifications

Each project should have:

a. A project director who is employed by the grantee institution and: (1) Has completed at least one year of approved podiatric residency training and has at least one year of clinical teaching experience; or (2) is board certified in a recognized specialty area in podiatric medicine and has had at least five years of clinical teaching experience.

b. An appropriate administrative and organizational plan and appropriate faculty, staff and facility resources for the achievement of stated objectives.

c. A systematic evaluation of the educational program, including the performance and competence of trainees and faculty, the administration of the program, and the degree to which program and educational objectives are met.

d. Use of ambulatory care settings where podiatric primary care is practiced and where an adequate portion of the clinical training is conducted.

e. A curriculum which:

1. Is appropriate for the academic level of the trainees and the specific length and nature of the educational program;

2. Supplements any practical (including clinical) experiences with related educational activities; and

3. Includes: A minimum of 20 percent of curriculum time devoted to supervised instruction in ambulatory clinical settings; instruction in behavioral sciences and the development of psychosocial skills and topics; and a supervised clinical experience in a family medicine or general internal medicine ambulatory care setting;

f. A sufficient number of residents to provide an adequate collegial environment for the educational program and to enhance cost-efficiency.

g. An adequate number of qualified faculty with training and experience in podiatric medicine, and behavioral sciences and liaison faculty in related program areas for the number of residents in the program. The faculty in the program are expected to engage in periodic faculty development activities to improve their teaching skills.

h. Adequate facilities for the provision of the educational activities and, in particular, have ambulatory care space the residents with a broad clinical experience.

Final Review Criteria

Approval of all applications will be based on an analysis of the following factors:

1. The degree to which the proposed project provides for the project specifications;

2. The administrative and management capability of the applicant to carry out the proposed project in a cost effective manner;

3. The degree to which the proposed training program emphasizes podiatric primary care; and

4. The potential of the project to continue on a self-sustaining basis.

Final Funding Preference

Applications that propose to start a new podiatric primary care residency program with a minimum of three new residency positions will be placed ahead of other approved applications in the funding order.

Final Funding Priorities

In determining the order of funding of approved applications, a funding priority will be given to:

1. Applications which demonstrate an affiliation with a college of podiatric medicine that will serve to enrich the educational experience of participating residents.

2. Applications which demonstrate a realistic plan for the recruitment of underrepresented minorities (i.e. Black, Hispanic and American/Alaskan Native) into the program.

3. Applications which meet at least two of the following curriculum initiatives:

a. Applications proposing to develop and implement curricula concerning ambulatory and inpatient care of those with HIV infection-related diseases.

b. Applications which are innovative in their educational approaches to quality assurance/risk management activities: monitoring and evaluation of health care services and utilization of peer-developed guidelines and standards.

c. Applications proposing to provide substantial multidisciplinary geriatric training experiences in multiple ambulatory settings and inpatient and extended care facilities.

the *Catalog of Federal Domestic Assistance*. It is not subject to the provisions of Executive Order 12372 Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

This program will be listed at 13.181 in sufficient to provide an adequate clinical experience for the residents.

i. A sufficient number of patients with a variety of health care needs to provide

Dated: August 31, 1989.

John H. Kelso,

Acting Administrator.

[FR Doc. 89-20966 Filed 9-6-89; 8:45 am]

BILLING CODE 4160-15-M

Health Resources and Services Administration

Final Funding Preference for Scholarships for the Undergraduate Education of Professional Nurses Grant Program

The Health Resources and Services Administration announces the Final Funding Preference for Scholarships for the Undergraduate Education of Professional Nurses Grant Program.

Section 843 of the Public Health Service Act, as amended authorizes scholarships to provide financial assistance to individuals who are enrolled or accepted for enrollment as undergraduate nursing students in diploma, associate, or baccalaureate degree programs or in programs of nursing education leading to first degrees in professional nursing and who are in financial need with respect to attending these schools. A scholarship recipient must agree to serve full time upon graduation as a registered nurse for a period of not less than 2 years in an Indian Health Service Center, or a Native Hawaiian Health Center, or a public hospital, or a Migrant Health Center, or a Community Health Center, or a certified nursing facility, or a rural health clinic, or in a health facility determined by the Secretary to have a critical shortage of nurses.

A Proposed Funding Preference was published in the **Federal Register** on June 16, 1989 (54 FR 25629) for public comment. Comments were received from 10 respondents during this 30-day comment period. One comment was received that supported the definition of undergraduate nursing student, which was not part of the **Federal Register** notice.

Proposed Funding Preference

One comment suggested an alternative method of achieving the outcome of the preference by requiring schools to give preference in awarding scholarships to students from disadvantaged and minority backgrounds.

The purpose of the preference is to attract those schools that, by virtue of their enrollment, already have an 11.4 percent minority representation. These schools represent students most in need of scholarship support.

Several respondents indicated their intention to withdraw from applying for the scholarships because they did not meet the minority enrollment requirement to obtain the funding preference. The requirement of minority enrollment is to receive a funding preference. The preference is a bonus which does not preclude from consideration those applicants who do not qualify for the preference. There are instances where applicants who meet the requirements of the law but do not qualify for the preference are funded. Conversely, because of a limited appropriation of funds some applicants might qualify for a funding preference and not get funded because of the large number of approved applicants.

All comments received have been carefully considered.

No change will be made in the Proposed Funding Preference. The following final funding preference will be used in making grant awards in Fiscal Year 1989.

Final Funding Preference

For Fiscal Year 1989, preference in the award of the scholarship grants will be given to applicants which show evidence that they exceed the 3-year average enrollment of underrepresented minority students (i.e., Black, Hispanic, American Indian, Alaskan Native, Native Hawaiian, Asian/Pacific Islander), in undergraduate nursing programs. For the 1985-86 school year underrepresented minorities reflected 11.4 percent of undergraduate nursing students. The Administration has determined that these population groups continue to be underrepresented in the nursing profession. Their representation should be increased to ensure equitable opportunities to a career in nursing.

This program is listed at 13.182 in the *Catalog of Federal Domestic Assistance.* It is not subject to the provision of Executive Order 12372, Intergovernment Review of Federal Programs (as implemented through 45 CFR Part 100).

Dated: August 31, 1989.

John H. Kelso,

Acting Administrator.

[FR Doc. 89-20965 Filed 9-6-89; 8:45 am]

BILLING CODE 4160-15-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-89-2045]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESS: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the

proposal and the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: August 25, 1989.

John T. Murphy,

Information Policy and Management Division.

Proposal: Financial Statement (Claims Collection)

Office: Administration

Description of the Need for the Information and its Proposed Use: Each office in the Department is authorized to have a claims collection officer to establish and maintain a file regarding each claim for which collection activities are made. This information will be used by the claims collection officer to make judgements concerning the likelihood of being able to collect a claim.

Form Number: HUD–27041

Respondents: Individuals or Households

Frequency of Submission: On Occasion

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD-27041 6,000		1		1		

Total Estimated Burden Hours: 6,000

Status: Reinstatement

Contact: Ronald A. Nelson, HUD, (202) 755–1446; John Allison, OMB, (202) 395–6880

Date: August 25, 1989.

[FR Doc. 89–21010 Filed 9–6–89; 8:45 am]

BILLING CODE 4210–01–M

Office of Administration

[Docket No. N–89–2044]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The department is soliciting public comments on the subject proposal.

ADDRESS: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755–6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: August 30, 1989.

John T. Murphy,

Director, Information Policy and Management Division.

Proposal: Housing and Urban Development (HUD) Act of 1987, Preservation of Low Income Housing, Prepayment of a HUD-Insured Mortgage By an Owner of Low Income Housing, Title II

Office: Housing

Description of the Need for the Information and its Proposed Use: This rule gives regulatory effect to legislative provisions governing prepayment of HUD insured mortgages. These provisions will assure that affordable multifamily housing units are preserved to the maximum extent practicable for lower-income families and that displacement of such families are minimized while public and private sectors find long term remedies to the potential loss of affordable housing.

Form Number: None

Respondents: State or Local Government, Businesses or Other For-Profit, Federal Agencies or Employers

Frequency of Submission: Other

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information Collection 120		1		100		

Total Estimated Burden Hours: 12,000

Status: Revision

Contact: James J. Tahash, HUD, (202) 426–3944, John Allison, OMB, (202) 395–6880

Date: August 30, 1989

[FR Doc. 89–21011 Filed 9–6–89; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA–650–4143–02]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for collection of information listed below has been submitted to the Office of Managment and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1004–0121), Washington, DC 20503, telephone (202) 395–7340.

Title: 43 CFR parts 3500, 3510, 3520, 3530, 3540, 3550, 3560, 3570 and 3580 Leasing of Solid Minerals Others than Coal and Oil Shale.

OMB Approval Number: (1004–0121).

Abstract: Respondents supply information relevant to the identification, location and quality of the specific non-energy mineral under application for prospecting, leasing or

exploration and their qualifications for holding Federal mineral permits, leases and exploration licenses. This information allows the Bureau to determine the availability of the lands under application and to assure that prospective permittees, lessees and licensees are in compliance with applicable statutory and regulatory requirements.

Bureau Form Numbers: 3104–3, 3104–5, 3504–1, 3504–3, 3504–4 and 3510–2.

Estimated completion times:

Competitive lease bid: 1 hr.
Preference right lease application: 10 hrs.
Fringe acreage/lease modification: 2 hrs.
Assignment/sublease: 2 hrs.
Lease renewal/adjustment: 2 hrs.
Exploration license: 3 hrs.
Development contract: 3 hrs.
Prospecting permit extension: 1 hr.
Exploration plan for prospecting permit: 10 hrs.
Prospecting permit application: 5/6 hr.
Use permit application (Bureau Form 3510–2): 2 hrs.
Bonding requirements (Bureau Form Nos. 3504–1, 3504–3, 3504–4, 3104–3 and 3104–5): 5/6 hr.

Description of Respondents: Prospective holders of Federal non-energy prospecting permits, leases, use permits and exploration licenses.

Annual Responses: 1,246

Annual Burden Hours: 3,722

Bureau clearance officer: Rick Iovaine (202) 653–8853

Dated: April 14, 1989.

Hillary A. Oden,

Assistant Director, Energy and Mineral Resources.

[FR Doc. 89–20972 Filed 9–6–89; 8:45am]

BILLING CODE 4310–84–M

[AZ–020–09–4213–01]

Phoenix District Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Meeting of the Phoenix District Advisory Council.

DATE: October 5–6, 1989, 9:00 a.m.

ADDRESS: 2015 West Deer Valley Road, Phoenix, Arizona 85027.

SUMMARY: The Phoenix District Advisory Council of the Bureau of Land Management meets October 5–6, 1989. A tour of the Kingman Resource Area will occur on October 5. The formal meeting will be held at the Kingman Resource Area Office, 2475 Beverly Avenue Kingman, Arizona at 9:00 a.m. on October 6.

The Council has been established by and will be managed according to the Federal Advisory Committee Act of 1972, the Federal Land Policy and Management Act of 1976, and the Public Rangelands Improvement Act of 1978.

The agenda for the meeting includes:

—Kingman Resource Management Plan
—BLM Management Updates
—Business form Floor
—Public Comments and Statements
—Futures Meetings and Agenda Topics

SUPPLEMENTARY INFORMATION: This is a public meeting and the presentation of oral statements or the submission of written statements that address the issues on the meeting agenda or related matters are welcome.

Dated: August 31, 1989.

Henri R. Bisson,

District Manager.

[FR Doc. 89–20955 Filed 9–6–89; 8:45 am]

BILLING CODE 4310–32–M

[NV–930–09–4212–13; N–51436]

Realty Action; Exchange of Public Lands, Clark County, Nevada

The following described federal lands are being considered for disposal by exchange pursuant to Section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Mount Diablo Meridian, Nevada

T. 19 S., R. 60 E.,
Sec. 5, NW¼;
Sec. 6, N½, NE¼SW¼, W½NE¼ NW¼SW¼, W½SE¼NW¼SW¼, W½NW¼SW¼, SW¼SW¼, E½SE¼ SW¼, SE¼;
Sec. 7, N½, SW¼, W½SE¼;
Sec. 17, N½, SW¼, N½SE¼, SW¼SE¼;
Sec. 20, NE¼NE¼;
Sec. 21, SW¼NW¼;
Sec. 28, W½NE¼, E½NW¼, SW¼NW¼, N½SE¼.
Total acres 2,290

Final determination on disposal will await completion of an environmental analysis.

In accordance with the regulations of 43 CFR 2201.1(b), subject to valid existing rights, publication of this Notice shall segregate the affected public lands from appropriation under the public land laws, including the mining laws, but not the mineral leasing laws, and from any subsequent land exchange proposals filed by any proponent other than Metroplex Properties or their nominee.

The segregation of the above-described lands shall terminate upon issuance of a document conveying such lands or upon publication in the Federal Register of a notice of termination of the segregation; or the expiration of two years from the date of publication, whichever occurs first.

For a period of forty-five days, interested parties may submit comments to the District Manager, Las Vegas District Office, 4765 Vegas Drive, Las Vegas, Nevada 89126.

Dated: August 30, 1989.

Gary Ryan,

Acting District Manager, Las Vegas, Nevada.

[FR Doc. 89–21019 Filed 9–6–89; 8:45 am]

BILLING CODE 4310–HC–M

[UT–943–09–4212–13; U–61686]

Issuance of Land Exchange Conveyance Document; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Exchange of public and private lands.

SUMMARY: This action informs the public of the conveyance of 1,673.72 acres of public lands out of Federal ownership and the acquisition of 12,596.52 acres into Federal ownership.

FOR FURTHER INFORMATION CONTACT: Mike Barnes, BLM Utah State Office, 324 South State Street, Salt Lake City, Utah 84111, 801–439–4119.

SUPPLEMENTARY INFORMATION: Notice is hereby given that in exchange of lands made pursuant to section 206 of the Act of October 21, 1976, 90 Stat. 2756, 43 U.S.C. 1716, a patent has been issued transferring 1,673.72 acres of land in Tooele County, Utah, from Federal to private ownership.

1. In exchange, the following described lands have been reconveyed to the United States:

Salt Lake Meridian, Utah

T. 10 N., R. 4 W.,
Sec. 19, lots, 1,2,3,4, E½, E½W½;
Sec. 29, all;
Sec. 31, lots 1,2,3,4, E½, E½W½.
T. 10 N., R. 16 W.,
Sec. 3, lots 1,2,3,4, S½N½, S½.
T. 11 N., R. 16 W.,
Sec. 29, all;
Sec. 33, all.

3. The mineral estate for the lands described in paragraph 1 were not acquired by the Bureau of Land Management.

4. The following described lands have been reconveyed to the United States but will remain closed to surface and mineral entry until a notice of opening is given in the Federal Register:

Salt Lake Meridian, Utah

T. 9 S., R. 18 W.,

Dewey No. 2, Dewey No. 3, and Dewey No. 4 patented mining claims, within section 8 and 17, of Mineral Survey #6311.

T. 9 S., R. 18 W.,

Roy No's. 1, 2, 3, 4, and 5 patented mining claims, within section 27, 28, 33, and 34, Mineral Survey #3697.

containing 135.46 acres.

5. The purpose of the exchange was to acquire non-federal land that will allow blocking the land into better management units. The public interest was best served through the completion of the exchange.

Dated:

Ted D. Stephenson,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 89-21020 Filed 9-6-89; 8:45 am]

BILLING CODE 4310-DQ-M

Fish and Wildlife Service

Klamath River Basin Fisheries Task Force; Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meetings.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Klamath River Basin Fisheries Task Force, established under the authority of the Klamath River Basin Fishery Resources Restoration Act (16 U.S.C. 460ss et seq.). The meeting is open to the public.

DATES: The Klamath River Basin Fisheries Task Force will meet from 9:00 a.m. to 4:00 p.m., Thursday, September 7, 1989, and from 8:00 a.m. until noon on Friday, September 8th. A public scoping meeting will be held from 7:00 p.m. to 9:00 p.m., September 7, 1989.

PLACE: The meeting will be held at the Eureka Inn, 7th and C Streets, Eureka, California 95501.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald A. Iverson, Project Leader, U.S. Fish and Wildlife Service, P.O. Box 1006 (1030 South Main), Yreka, California 96097-1006, telephone (916) 842-5763.

SUPPLEMENTARY INFORMATION: For background information on the Task Force, please refer to the notice of their initial meeting that appeared in the **Federal Register** on July 8, 1987 (52 FR 25639).

Reports will be provided to the Task Force on current projects of the Klamath River Basin Fishery Restoration Program. Schedules and procedures for carrying out the long-range planning of the Restoration Program will be discussed. The Task Force will make final recommendations on the Restoration Program work plan for Fiscal Year 1990. Status of appointing a sport fishery representative to the Task Force will be reported. The evening scoping meeting will permit members of the public to offer comments and suggestions for developing the long-range plan and environmental assessment for the Restoration Program.

Dated: August 21, 1989.

W.E. Martin,

Acting Regional Director, U.S. Fish and Wildlife Service.

[FR Doc. 89-20971 Filed 9-6-89; 8:45 am]

BILLING CODE 4310-55-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-297]

Commission Decision not to Modify or Vacate Initial Determination Granting Temporary Relief, and Issuance of a Limited Temporary Exclusion Order and Temporary Cease and Desist Orders, Subject to Posting of Bond by Complainant

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has determined not to modify the presiding administrative law judge's (ALJ) initial determination (ID) granting temporary relief in the above-referenced investigation, and has issued a limited temporary exclusion order and temporary cease and desist orders, subject to posting of a bond by complainant.

FOR FURTHER INFORMATION CONTACT: Judith M. Czako, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-252-1093.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), as amended by the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 (Aug. 23, 1988) and in sections 210.24 and 210.58 of the Commission's Interim Rules of Practice and Procedure (53 FR 33034, Aug. 29, 1988, and 53 FR 49118, Dec. 6, 1988).

On April 17, 1989, Motorola, Inc. filed a complaint and a motion for temporary relief with the Commission alleging violations of section 337 in the importation and sale of certain cellular radiotelephones and subassemblies and component parts thereof. Motorola's complaint alleged infringement of seven U.S. patents. The motion for temporary relief was limited to 4 claims of 3 patents: claims 62 and 77 of U.S. Letters Patent 4,523,155; claim 18 of U.S. Letters Patent 4,636,593; and the sole claim of U.S. Letters Patent Des. 269,873.

Pursuant to Commission interim rule 210.24(e)(8), the Commission provisionally accepted Motorola's motion for temporary relief at the Commission meeting on May 23, 1989. The Commission also instituted an investigation into the allegations of Motorola's complaint and published a notice of investigation in the **Federal Register**. 54 FR 23292-93 (May 31, 1989). The notice named the following respondents: (1) Nokia Corporation of Helsinki, Finland; (2) Nokia-Mobira Oy of Salo, Finland; (3) Nokia, Inc. of Basking Ridge, New Jersey; (4) Nokia-Mobira, Inc. of Largo, Florida; (5) Tandy Mobira Communications Corporation of Masan, The Republic of Korea; (6) Tandy Corporation of Fort Worth, Texas; and (7) A & A International of Fort Worth, Texas.

The presiding administrative law judge (ALJ) held an evidentiary hearing on Motorola's motion for temporary relief from July 7 to July 12, 1989. All respondents actively participated in the hearing. The Commission received submissions on the issues of remedy, the public interest, and bonding, from all parties on July 31, 1989, in accordance with Commission interim rule 210.24(e)(18)(ii).

On August 9, 1989, the ALJ issued his ID granting Motorola's motion for temporary relief. All parties filed written comments or responses to comments on the ID.

The Commission, having considered the ID, the comments and responses to comments of the parties, and the record in this investigation, determined that there are no errors of law or policy reasons to vacate or modify the ID. Consequently, pursuant to Commission interim rule 210.24(e)(17)(ii), the ID became the Commission's determination.

The Commission having determined that there is reason to believe that there is a violation of section 337 in the importation, sale for importation, or sale in the United States of the accused cellular radiotelephones, subassembles thereof, or component parts thereof, and having determined that temporary relief is warranted, considered the issues of the appropriate form of such relief, whether the public interest precludes issuance of such relief, complainant's

bond, and respondents' bond during the period such relief is in effect.

The Commission has determined that a temporary limited exclusion order and temporary cease and desist orders directed to all U.S. respondents are the appropriate form of temporary relief. The Commission has further determined that the statutory public interest factors do not preclude the issuance of such relief, and that respondents' bond under the temporary limited exclusion order and the temporary cease and desist orders shall be in the amount of twenty-five (25) percent of the entered value of the imported articles.

Commission interim rule 210.58(b)(3) sets forth the requirements for posting of complainant's bond. Commission interim rule 210.58(b)(7) requires that all bonds posted by complainant must be approved by the Commission Secretary before the temporary relief which the bond will secure will be issued. Consequently, the issuance of temporary relief described in the preceding paragraph is subject to the posting and approval of complainant's bond in the amount of five (5) percent of complainant's 1988 revenues from the products in question. Complainant is to file its bond with the Commission Secretary within seven (7) business days of publication of this notice in the **Federal Register**.

Copies of all nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–252–1000. Hearing-impaired are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

By order of the Commission.

Issued: August 29, 1989.

Kenneth R. Mason,

Secretary.

[FR Doc. 89–21012 Filed 9–6–89; 8:45 am]

BILLING CODE 7020–02–M

[TA–503(a)–18 and 332–279]

President's List of Articles Which May Be Designated or Modified as Eligible Articles for Purposes of the U.S. Generalized System of Preferences

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on August 16, 1989, of a request from the U.S. Trade Representative, the Commission instituted investigation No. TA–503(a)–18 and 332–279 under sections 503(a) and 131(a) of the Trade Act of 1974 (19 U.S.C. 2463(a) and 2151(b)) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g))—

(1) Pursuant to sections 503(a) and 131(a) of the Trade Act, and the authority of the President delegated to the U.S. Trade Representative by sections 4(c) and 8(c) and (d) of Executive Order 11846, as amended, to advise the President, with respect to each article listed in Part A of the attached Annex, as to the probable economic effect on U.S. industries producing like or directly competitive articles and on consumers of the elimination of U.S. import duties under the U.S. Generalized System of Preferences (GSP). In providing its advice, the USTR requested the Commission to assume that benefits of the GSP would not apply to imports that would be excluded from receiving such benefits by virtue of the "competitive need" limits specified in section 504(c)(1) of the 1974 Act.

(2) Under authority delegated by the President, pursuant to section 332(g) of the Tariff Act, to advise the President—

(A) With respect to each article listed in Part B of the attached Annex, as to the probable economic effect on U.S. industries producing like or directly competitive articles and on consumers of the removal of the articles in Part B from eligibility for duty-free treatment under the GSP;

(B) With respect to the article listed in Part C of the attached Annex, as to the probable economic effect on U.S. industries producing like or directly competitive articles and on consumers of the removal of Brazil from eligibility for duty-free treatment under the GSP;

(C) In accordance with section 504(c)(3)(A)(i) of the Trade Act, as to the probable economic effect on domestic industries producing like or directly competitive articles and on consumers of waiving the competitive need limits for countries specified with respect to the articles listed in Part D of the attached Annex and for Malaysia with respect to the articles provided for in HTS 8541.40.9060;

(D) As to the probable economic effect on domestic industries producing like or directly competitive articles and on consumers of restoring the competitive need limits specified in section 504(c)(1) of the 1974 Act for Mexico with respect to the articles listed in Part F of the attached Annex, all of the foregoing articles for which Mexico currently is subject to the reduced competitive need limits specified in section 504(c)(2)(B) of the 1974 Act;

(E) In accordance with section 504(d) of the 1974 Act, which exempts from one of the competitive need limits in section 504(c) of the 1974 Act articles for which no like or directly competitive article was being produced in the United States on January 3, 1985, as to whether products like or directly competitive with the articles in Part A or Part E of the attached Annex were being produced in the United States on January 3, 1985.

EFFECTIVE DATE: August 29, 1989.

FOR FURTHER INFORMATION CONTACT:

(1) Agricultural products, Mr. C. B. Stahmer (202–252–1321)
(2) Textiles and apparel, Mr. Larry Butler (202–252–1470)
(3) Chemical products, Ms. Elizabeth Nesbitt (202–252–1355)
(4) Minerals and metals, Ms. Deborah McNay (202–252–1425)
(5) Machinery and equipment, Ms. Kathleen Lahey (202–252–1409)
(6) General manufactures, Mr. Eric Langer (202–252–1497)

All of the above are in the Commission's Office of Industries. For information on legal aspects of the investigation contact Mr. William Gearhart of the Commission's Office of the General Counsel at 202–252–1091.

BACKGROUND: The USTR announced the items which have been sent to the Commission for probable economic effect advice in the **Federal Register** of August 10, 1989.

Public Hearing: A public hearing in connection with the investigation will be held in the Commission Hearing Room, 500 E Street SW., Washington, DC 20436, beginning at 9:30 a.m. on October 3, 1989 and continuing as required on October 4 and 5. All persons shall have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file requests to appear and should file prehearing briefs (original and 14 copies) with the Secretary, United States International Trade Commission, 500 E St. SW., Washington, DC 20436, not later than noon, September 22, 1989. Posthearing briefs must be filed by October 11, 1989.

Written Submissions: In lieu of or in addition to appearances at the public hearing, interested persons are invited to submit written statements concerning the investigation. Written statements should be received by the close of business on October 2, 1989. Commercial or financial information which a submitter desires the

Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of § 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). All written submissions, except for confidential business information, will be made available for inspection by interested persons. All submissions should be addressed to the Secretary at the Commission's office in Washington, DC.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 252–1810.

By order of the Commission.

Dated: August 31, 1989.

Kenneth R. Mason,

Secretary.

Annex I (HTS Item Numbers) [1]

A. Petitions to add products to the list of eligible articles for the Generalized System of Preferences.

0710.22.30(pt.)	3407.00.00(pt.)	7005.29.0510
0811.90.40	3812.30.10(pt.)	7005.29.15
0811.90.60(pt.)	5503.40.00	7005.29.25
1102.90.40(pt.)	6116.10.4505	7013.99.50(pt.)
1104.29.00	6216.00.2505	7614.90.10(pt.)
1512.11.0040	6216.00.3005	8528.10.8055
2004.10.00(pt.)	6216.00.4805	8532.10.00
2007.99.55	6304.99.20(pt.)	8532.25.00
2007.99.65	6911.10.50(pt.)	8532.29.00
2309.90.60(pt.)	6912.00.49(pt.)	8541.40.9060
2924.29.40(pt.)	7005.21.10	9607.11.00
2935.00.45(pt.)	7005.21.20	9607.19.00

B. Petitions to remove products from the list of eligible articles for the Generalized System of Preferences.

2827.51.00	3912.20.00	7312.10.70
2905.44.00	7312.10.50	7312.10.90
3503.00.50	7312.10.60	8507.10.0060
3506.99.00		

C. Petition to remove duty-free status from a beneficiary developing country for a product on the list of eligible articles for the Generalized System of Preferences.

2905.43.00 (Brazil) [2]

[1] See USTR Federal Register notice of August 10, 1989 (54 FR 32891), for article descriptions.

[2] The country named is the beneficiary developing country specified by the petitioner. The TPSC reserves the right to address removal of GSP status for countries in addition to those specified by the petitioner.

D. Petitions for waiver of competitive need limit for a product on the list of eligible products for the Generalized System of Preference.

0711.90.60(pt.) (Mexico)	8421.23.00 (Mexico)	8605.00.00 (Mexico)
2001.90.40(pt.) (Mexico)	8421.31.00 (Mexico)	8606.10.00 (Mexico)
2001.90.40(pt.) (Mexico)	8471.20.00 (Mexico)	8606.20.00 (Mexico)
2005.90.90(pt.) (Mexico)	8471.91.00 (Mexico)	8606.30.00 (Mexico)
2203.00.00 (Mexico)	8471.99.30 (Malaysia)	8606.91.00 (Mexico)
3903.19.00 (Mexico)	8504.40.00 (Malaysia)	8606.92.00 (Mexico)
3904.10.00 (Mexico)	8505.19.00 (Mexico)	8606.99.00 (Mexico)
4818.10.00 (Mexico)	8511.30.00 (Mexico)	9503.70.80 (Mexico)
4818.20.00 (Mexico)	8523.20.00 (Mexico)	9503.90.50 (Mexico)
4818.30.00 (Mexico)	8525.20.30 (Malaysia)	9503.90.60 (Mexico)
7314.19.00 (Mexico)	8541.40.9060 (Malaysia)	

E. Petitions to determine an eligible article as not like or directly competitive with any article produced in the United States on January 3, 1985.

1515.30.00(pt.)
2001.90.40(pt.)
2005.90.90(pt.)
9405.91.20(pt.)

F. Restoring the competitive need limits is being considered for the following articles from Mexico.

2005.90.90(pt.)	8421.23.00	9503.70.80
2203.00.00	8421.31.00	9503.90.50
3904.10.00	8505.19.00	9503.90.60
7314.19.00	8523.20.00	

[FR Doc. 89–21015 Filed 9–6–89; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 731–TA–424 (Final)]

Martial Arts Uniforms From Taiwan

Determination

On the basis of the record [1] developed in the subject investigation, the Commission determines,[2] pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act that an industry in the United States is not materially injured, or threatened with material injury, nor is the establishment of an industry in the United States materially retarded, by reason of imports from Taiwan of martial arts uniforms, provided for in subheadings 6203.22.10, 6203.23.00, 6203.29.20, 6204.22.10, 6204.23.00, and 6204.29.20 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less their fair value (LTFV).

[1] The record is defined in § 207.2(h) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(h)).

[2] Commissioner Eckes and Commissioner Newquist dissenting.

Background

The Commission instituted this investigation effective May 1, 1989, following a preliminary determination by the Department of Commerce that imports of martial arts uniforms from Taiwan were being sold at LTFV within the meanings of section 735 of the Act (19 U.S.C. 1673d(a)). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of May 31, 1989 (54 FR 23205). The hearing was held in Washington, DC, on July 25, 1989, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on August 28, 1989. The views of the Commission are contained in USITC Publication 2216 (August 1989), entitled "Martial Arts Uniforms From Taiwan: Determination of the Commission in Investigation No. 731–TA–424 (Final) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation."

Dated: August 29, 1989.

By Order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 89–21013 Filed 9–6–89; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–296]

Certain Phenylene Sulfide Polymers and Polymers Compounds and Products Containing Same; Commission Decision not To Review an Initial Determination Amending the Complaint and Notice of Investigation To Add an Additional Respondent

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the United States International Trade Commission has determined not to review an initial determination (ID) (Order No. 16) issued by the presiding administrative law judge (ALJ) granting the motion of complainant Phillips Petroleum Company (Phillips) to add Polyplastics Co., Ltd. of Osaka, Japan (Polyplastics) as a respondent to the above-captioned investigation.

ADDRESSES: Copies of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E. Street, SW., Washington, DC 20436, Telephone 202–252–1000.

FOR FURTHER INFORMATION CONTACT: Craig L. McKee, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E. Street SW., Washington, DC 20436, telephone 202–252–1117.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission TDD terminal on 202–252–1810.

SUPPLEMENTARY INFORMATION: On July 13, 1989, the presiding ALJ issued an ID amending the complaint and notice of investigation to add Polyplastics as a respondent. No petitions for review of the ID or government agency comments were received. These actions are taken under authority of the Tariff Act of 1930 (19 U.S.C. 1337) and Commission interim rule § 210.53(h).

By order of the Commission.

Dated: August 30, 1989.

Kenneth R. Mason,

Secretary.

[FR Doc. 89–21014 Filed 9–6–89; 8:45 am]

BILLING CODE 7020-02-M

[332-278]

United States-Canada Free-Trade Agreement: Probable Economic Effects on U.S. Industries and Consumers of Accelerated Elimination of U.S. Tariffs on Certain Articles From Canada

AGENCY: United States International Trade Commission.

ACTION: Notice of receipt from the U.S. Trade Representative (USTR) of supplemental information; notice of availability of annotated list prepared by the Commission of articles in USTR **Federal Register** notice of July 17, 1989 (54 FR 29959).

Background

In her letter to the Commission on July 17, 1989, the USTR provided a list of subheadings in the U..S Harmonized Tariff Schedule which may be considered for acceleration of tariff removal under the United States-Canada Free-Trade Agreement and requested the Commission's advice as to the probable economic effect of such accelerated elimination on domestic industries producing like or directly competitive articles and on consumers.

Ambassador Hills indicated in her letter that a number of the petitions received by the Governments of the United States and Canada requested acceleration only for selected products within a subheading, and that to the extent possible separate additional advice was desired on the effect of acceleration of tariff elimination on the narrow product coverage specified in such petitions.

On August 4, 1989, the Commission received from the USTR a list of such selected products within subheadings contained in petitions to the USTR. The Commission was advised that it will receive a simlar list of products contained in petitions submitted to the Government of Canada.

Upon request, a copy of an annotated Commission list of HTS subheadings included in Annex I of the USTR notice of July 17, 1989, showing for each subheading a brief products description, may be obtained from the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436 (202–252–1802). Also available is a copy of the selected products within subheadings contained in petitions to the USR.

The original notice of the Commission's institution of investigation and scheduling of hearing was published in the **Federal Register** on August 9, 1989 (54 FR 32701).

FOR FURTHER INFORMATION CONTACT: Carl Seastrum, (202–252–1493), or any of the other persons named in the Commission's original notice of investigation.

Hearing-impaired persons can obtain information of this study by contacting our TDD terminal on (202–252–1810).

By order of the Commission

Dated: August 31, 1989.

Kenneth R. Mason,

Secretary.

[FR Doc. 89–21016 Filed 9–6–89; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 31519 (Sub-No. 1)]

Norfolk and Western Railway Co.—Trackage Rights Exemption—Chicago Rail Link and Chicago Short Line Railway Co.

In Finance Docket No. 31519, Chicago Rail Link (CRL) has agreed to grant overhead trackage rights to Norfolk and Western Railway Company (NW) over 2,730 feet of its Illinois Central Railroad Company (IC) connection track and number 14 track in Chicago, IL. In Finance Docket No. 31519 (Sub-No. 1), CRL and Chicago Short Line Railway Company have agreed to grant overhead trackage rights to NW over 1,320 feet of their track number 14 in Chicago, IL.[1] The proposed transactions were to have been consummated on or about August 17, 1989.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Pleadings must be filed with the Commission and served on: Robert J. Cooney, Three Commercial Place, Norfolk, VA 23510–2191.

As a condition to the use of this exemption, any employees affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified by *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Dated: August 29, 1989.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 89–20989 Filed 9–6–89; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 31521]

North Carolina Railroad Co. Merger Exemption—Atlantic and North Carolina Railroad Co.

North Carolina Railroad Company (NCR) and Atlantic and North Carolina Railroad Company (ANCR) have filed a

[1] In Finance Docket No. 31520, *Norfolk and Western Railway Company—Trackage Rights Exemption—Illinois Central Railroad Company*, IC agreed to grant overhead trackage rights to NW over its line between milepost 12, at 95th Street in Chicago, IL, and milepost 110, at Gibson City, IL. There is no connection between 95th Street and NW's Calumet Yard. The purpose of these trackage rights is to provide such a connection.

notice of exemption to merge ANCR into NCR. The merger is expected to be consummated by September 30, 1989.

NCR and ANCR are Class III rail carriers, whose lines and properties are leased to affiliates of Norfolk Southern Corporation. The State of North Carolina owns 75 percent and 74 percent, respectively, of the outstanding common stock of NCR and ANCR.

This is a transaction within a corporate family of the type specifically exempted from prior approval under 49 CFR 1180.2(d)(3).[1] It will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family. The proposed transaction is intended to effect operating efficiencies.

To ensure that all employees who may be affected by the transaction are given the minimum protection afforded under 49 U.S.C. 10505(g)(2) and 49 U.S.C. 11347, the labor conditions set forth in *New York Dock Ry.—Control—Brooklyn Eastern Dist.*, 360 I.C.C. 60 (1979), are imposed.

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: E. Stephen Stroud, North Carolina Railroad Company, 300 S. Salisbury Street, P.O. Box 1550, Raleigh, NC 27602; and Frank A. Rouse, Atlantic and North Carolina Railroad Company, 131 S. Queen Street, P.O. Box 3557, Kinston, NC 28502.

Decided: August 31, 1989.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 89-20988 Filed 9-6-89; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-3 (Sub-No. 84)]

Missouri Pacific Railroad Co.; Abandonment of Railroad Between Centralia and Hoyleton in Clinton and Washington Counties, IL; Findings

The Commission has found that the public convenience and necessity permit Missouri Pacific Railroad Company to abandon its approximately 8-mile line of railroad between milepost 15.025 near Centralia and milepost 23.0 at Hoyleton, IL.

A certificate will be issued authorizing abandonment unless within 15 days after this publication the Commission also finds that: (1) A financially responsible person has offered financial assistance (through subsidy or purchase) to enable the rail service to be continued; and (2) it is likely that the assistance would fully compensate the railroad.

Any financial assistance offer must be filed with the Commission and served on the applicant no later than 10 days from publication of the Notice. The following notation must be typed in bold face on the lower left-hand corner of the envelope: **"Rail Section, AB-OFA."** Any offer previously made must be remade within this 10-day period.

Information and procedures regarding financial assistance for continued rail service are contained in 49 U.S.C. 10905 and 49 CFR 1152.27.

Decided: August 29, 1989

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Andre, Lamboley, and Phillips. Vice Chairman Simmons concurred in the result with a separate expression. Commissioner Lamboley dissented with a separate expression.

Noreta R. McGee,

Secretary.

[FR Doc. 89-20990 Filed 9-6-89; 8:45 am]

BILLING CODE 7035-01-M

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[1] Normally, the intercorporate family class exemption would be available only if common control had been previously approved or an exemption from the common control provisions had been previously granted. Here it appears that control over these carriers by the State of North Carolina pre-dated the Interstate Commerce Act and that, therefore, Commission approval for control is not required. Publication of the notice is not a ruling by the Commission on this issue.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 88-90]

Nathan Beckman, D.D.S.; Denial of Application

On September 6, 1988, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Nathan Beckman, D.D.S., (Respondent) of 2301 Collins Avenue, Mez. Suite 101, Miami Beach, Florida 33139, proposing to deny his application, executed on September 1, 1987, for registration as a practitioner under 21 U.S.C. 823(f). The Order to Show Cause alleged that Respondent's registration would be inconsistent with the public interest.

Respondent requested a hearing on the issues raised by the Order to Show Cause and the matter was docketed before Administrative Law Judge Francis L. Young. Following prehearing procedures, a hearing session was held on January 18, 1989, in Miami, Florida. Due to civil disturbances in the Miami area, the Government's witness was unable to attend the hearing. As a result, Respondent presented his case and another hearing session was scheduled for March 15, 1989, in West Palm Beach, Florida. At that session, the Government presented its case and Respondent was permitted to testify with respect to the evidence presented by the Government.

On April 12, 1989, the Administrative Law Judge issued his opinion and recommended ruling, findings of fact, conclusions of law and decision. Pursuant to 21 CFR 1316.66, on May 2, 1989, the Government filed exceptions to Judge Young's opinion and recommended decision. On May 26, 1989, the Administrative Law Judge transmitted the record of these proceedings, including the Government's exceptions, to the Administrator. The Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues his final order in this matter based upon findings of fact and conclusions of law as hereinafter set forth.

During 1981, the Metro-Dade Police Department initiated an undercover investigation of an individual who was interested in purchasing large quantities of cocaine. Undercover conversations with the individual in early September 1981, included negotiations for the delivery of one kilogram of cocaine for $43,000. The individual told the undercover detective that his buyer was Respondent, a Miami Beach dentist. The individual further told the detective that Respondent and his partner, a Miami Beach attorney, bought and sold 21 kilograms of cocaine per month. This individual introduced the undercover detectives to a second individual. The second individual told the detectives that he was negotiating with them on behalf of Respondent, who was interested in purchasing large amounts of cocaine. This individual subsequently requested and received from the detective a sample of cocaine (½ gram) to give to Respondent. The individual stated that if Respondent liked the cocaine, Respondent would purchase one to five kilograms of it for $43,000 per kilogram. The individual later contacted the undercover detectives and advised them that Respondent liked the quality of cocaine and wanted to talk to the detectives.

On September 11, 1981, the individual took the undercover detectives to Respondent's office in Miami Beach, Florida. Upon entering Respondent's office, the detectives observed Respondent freebasing cocaine with a group of people. During a conversation

with the undercover detectives, Respondent acknowledged that he had received and tested the cocaine sample which was given by the undercover detectives to the individual for Respondent. Respondent also stated that he was interested in purchasing three to five kilograms of cocaine from the detectives. During further negotiations, Respondent discussed the price per kilogram of cocaine and admitted to trafficking in approximately 21 kilograms of cocaine per month. Respondent also advised the detectives that he could supply large quantities of Quaaludes. On this occasion, Respondent gave the individual one gram of cocaine to give to the undercover detectives.

On September 15, 1981, the undercover detectives met with Respondent at his office where he gave them another gram of cocaine and negotiated to purchase cocaine from the detectives. Subsequent undercover conversations with Respondent on September 15 and 17, 1981, concerned the delivery of Quaaludes by Respondent through the first individual. On September 18, 1981, undercover detectives met the individual at his residence where the detectives agreed to purchase 50,000 Quaalude tablets for $40,000. The individual delivered approximately 20,000 Quaalude tablets to the detectives stating that the Quaaludes belonged to Respondent. The individual was then arrested.

On September 22, 1981, Respondent was arrested as a result of the Metro-Dade Police Department investigation. At the time of the arrest, officers seized six pounds of Quaalude tablets, approximately one-quarter ounce of cocaine and approximately 270 amphetamines ("black beauties") which were in plain view.

On October 6, 1981, Respondent was charged in a Florida State court with one count of trafficking in methaqualone, one count of possession with intent to sell methaqualone, two counts of delivery of cocaine, one count of conspiracy to traffic in methaqualone and one count of conspiracy to traffic in cocaine. On October 14, 1981, Respondent was also charged with offenses relating to the drugs seized at his office at the time of his arrest. Respondent was specifically charged with one count of trafficking in methaqualone, one count of actual or constructive possesson of cocaine and one count of possession with the intent to sell methaqualone.

Respondent entered a guilty plea to all charges and was adjudged convicted. On January 19, 1982, the Court withheld imposition of sentence, placed Respondent on ten years probation and fined him $10,000. The period of probation was suspended after three years.

On October 12, 1982, the State of Florida, Department of Professional Regulation, Division of Professions, Board of Dentistry, suspended Respondent's license to practice dentistry for five years with the possibility of reinstatement after one year. The Board also ordered that Respondent's DEA registration be suspended for at least five years. On January 25, 1988, Respondent's dental license was reinstated without any restrictions.

Testimony at the hearing indicated that Respondent suffered from attacks of depression from 1975 through 1981. Specifically, Respondent experienced attacks of endogenous depression in 1975 and in 1979 or 1980, which were professionally treated. These attacks of depression were caused by a chemical imbalance in Respondent's brain. During the 1980 attack, Respondent began abusing cocaine; however, Respondent's treating psychiatrist was not aware of Respondent's drug abuse until after his arrest. Respondent's psychiatrist testified that he treated Respondent for his second bout of depression. The psychiatrist stated that Respondent's depression drove him to cocaine abuse. The psychiatrist further stated that he felt that Respondent had made a complete recovery from the 1980 attack of endogenous depression, but stated that there was a possibility that Respondent could experience further attacks of depression. Respondent's psychiatrist testified that Respondent may become depressed because some internal biochemical mechanism goes off. The psychiatrist further stated that this sort of chemical imbalance in the brain does not go away by itself; however, a person with such an imbalance may exist for five to ten years without another attack of depression. Respondent's psychiatrist stated that he did not believe that Respondent would resort to drug abuse as a result of future attacks of depression.

In his opinion, Judge Young states that three aspects of this case call for careful consideration: First, circumstances that led Respondent to become involved with drug abuse and cocaine dealers; second, the extent of his involvement as a dealer; and third, his present situation. The Administrative Law Judge noted that although Respondent was arrested and charged with conspiracy and drug dealing, there was no trial since he pled guilty to the charges against him. Judge Young concluded that the Government's evidence contained much hearsay testimony as to what other persons, apparent drug dealers, said about Respondent's participation with them. The Administrative Law Judge conceded that Respondent seemed to be talking as a member of a group that was dealing in large quantities of drugs; however, Judge Young did not believe that the record supported a conclusion that Respondent was, in fact, a "big-time" and long-time cocaine-world figure. The Administrative Law Judge also conceded that Respondent did indeed agree to sell officers a large quantity of Quaaludes, but, Judge Young stated, the delivery of the Quaalude tablets was actually effected by someone other than Respondent. Judge Young concluded that there is no question that Respondent was guilty of the offenses with which he was charged; however, Judge Young stated that the extent of his involvement was not shown to be as great as the Government implied. The Administrative Law Judge believed that Respondent's involvement in drugs resulted from a physical and mental impairment and that this impairment is not present in Respondent at the present time. The Administrative Law Judge concluded that based on the evidence presented, Respondent can be trusted to responsibly handle controlled substances and recommended that Respondent's application be granted.

The Administrator may deny an application for registration if he determines that such registration would be inconsistent with the public interest. The factors which are considered in determining whether the registration would be in the public interest are enumerated in 21 U.S.C. 823(f). Three of the factors to be considered include the applicant's conviction record under Federal or state laws relating to controlled substances, the applicant's compliance with Federal, state or local laws relating to controlled substances and such other conduct which may threaten the public health and safety. All factors need not be present for the Administrator to deny an application for registration. Instead, the Administrator may accord each factor the weight he deems appropriate in determining the public interest. See, *Neveille H. Williams, D.D.S.*, Docket No. 87–47, 53 FR 23465 (1988); *Paul Stepak, M.D.*, 51 FR 17556 (1986).

In this instance, there is no question that Respondent has been convicted of controlled substance-related felony offenses. Although the illegal activities which resulted in Respondent's conviction fell outside the scope of his professional practice and did not

involve the use of his DEA registration, the conviction constitutes a suffcient basis for finding that his registration is not in the public interest. See, *Gordon Acker, M.D.*, Docket No. 86–41, 52 FR 9962 (1987), aff'd *sub nom Acker v. DEA*, No. 87–1160 (D.C. Cir. January 19, 1988); and *Walker L. Whaley, M.D.*, Docket No. 85–12, 51 FR 15556 (1986).

Based upon Respondent's felony convictions relating to controlled substances, the facts underlying those convictions and Respondent's history of mental illness, the Administrator concludes that Respondent's registration would not be in the public interest. Respondent was involved in the trafficking of large quantities of cocaine and methaqualone. Respondent admitted to undercover detectives that he was involved in trafficking approximately 21 kilograms of cocaine per month. He negotiated the delivery of a large quantity of methaqualone and actually delivered two grams of cocaine to the undercover detectives. Respondent's methaqualone negotiations with the detectives ultimately resulted in the seizure of a significant quantity of the drug as well as the arrest of Respondent and his associates. During Respondent's arrest, detectives seized large quantities of methaqualone and amphetamines, which in no way, given the quantities, could have been intended for personal use. The Administrator concludes that the evidence supports a finding that Respondent was not only personally abusing controlled substances, but he was also trafficking in significant quantities of drugs.

The Administrator further concludes that Respondent's behavior may very well have been caused by his attack of endogenous depression in the early 1980s; however, the likelihood of a recurrence of such a bout of depression causes the Administrator to conclude that Respondent cannot be trusted with a DEA registration. Respondent's attacks of depression were caused by a chemical imbalance in his brain. Respondent's psychiatrist testified that there is a 30–40% chance that Respondent will suffer another bout of depression in the future. The psychiatrist further testified that this sort of chemical imbalance in the brain does not go away by itself; however, a person with such an imbalance may exist for five to ten years without another recurrence of the depression.

A DEA registration carries with it a serious responsibility for the proper use of controlled substances. The Administrator requires assurance that the registrant will uphold his responsibility to handle controlled substances with sufficient care to protect the public interest. Respondent has yet to provide the Administrator with that degree of assurance. As a result, the Administrator concludes that Respondent's registration is inconsistent with the public interest and his application for registration must be denied.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823(f), hereby orders that the application for registration, executed by Nathan Beckman, D.D.S., on September 1, 1987, be, and it is, denied. This order is effective September 7, 1989.

Dated: August 30, 1989.

John C. Lawn,

Administrator.

[FR Doc. 89–21021 Filed 9–6–89; 8:45 am]

BILLING CODE: 4410–09–M

[Docket No. 89–14]

Thomas E. Brewer, Jr., M.D. High Point, NC; Hearing

Notice is hereby given that on February 13, 1989, the Drug Enforcement Administration, Department of Justice, issued to Thomas E. Brewer, Jr., M.D. an Order to Show Cause as to why the Drug Enforcement Administration should not deny your application for a DEA Certificate of Registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, September 19, 1989, commencing at 10:00 a.m., at the United States Court of Appeals for the Federal Circuit, Courtroom one, second floor, 717 Madison Place, N.W., Washington, DC.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89–21022 Filed 9–6–89; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 89–9]

Charles Christian Briggs, III, Nantucket, MA; Hearing

Notice is hereby given that on January 23, 1989, the Drug Enforcement Administration, Department of Justice, issued to Charles Christian Briggs, III, an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, AB5392802, and deny any pending applications for registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, September 26, 1989, commencing at 10:00 a.m., at the United States Tax Court, Boston Federal Building, 10 Causeway Street, Courtroom 1013, Boston, Massachusetts.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89–21023 Filed 9–6–89; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 89–20]

Butler Drug Store, Inc., Lafayette, TN; Hearing

Notice is hereby given that on April 5, 1989, the Drug Enforcement Administration, Department of Justice, issued to Butler Drug Store, Inc., an order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, BB0761836, and deny any pending applications for registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, October 3, 1989, commencing at 9:30 a.m., at the United States District Court, 801 Broadway, Courtroom A–826, Nashville, Tennessee.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89–21024 Filed 9–6–89; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 89–25]

Ozie T. Faison, Jr., Smith Discount Drugs, New Bern, NC; Hearing

Notice is hereby given that on March 23, 1989, the Drug Enforcement Administration, Department of Justice, issued to Ozie T. Faison, Smith Discount Drugs, an Order to Show Cause as to why the Drug Enforcement

Administration should not deny your application for a DEA Certificate of Registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Friday, October 13, 1989, commencing at 10:00 a.m., at the United States District Court of Appeals for the Federal Circuit, Courtroom one, second floor, 717 Madison Place, NW., Washington, DC.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89-21025 Filed 9-6-89; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 89-29]

Sidney Lesser, D.D.S., Detroit, MI; Hearing

Notice is hereby given that on March 23, 1989, the Drug Enforcement Administration, Department of Justice, issued to Sidney Lesser, D.D.S., an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, AL2745000, and deny any pending applications for registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Thursday, September 21, 1989, commencing at 10:00 a.m., at the United States Court of Appeals for the Federal Circuit, Courtroom one, second floor, 717 Madison Place, NW., Washington, DC.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89-21026 Filed 9-6-89; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 89-42]

The Medicine Shoppe, Donelson, TN; Hearing

Notice is hereby given that on June 15, 1989, the Drug Enforcement Administration, Department of Justice, issued to The Medicine Shoppe, an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration, BT1385877, and deny any pending applications for registration.

Thirty days have elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Thursday, October 5, 1989, commencing at 9:30 a.m., at the United States District Court, 801 Broadway, Courtroom A-826, Nashville, Tennessee.

Dated: August 29, 1989.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 89-21027 Filed 9-6-89; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 88-55]

Wayne Nichols, D.V.M.; Revocation of Registration

On April 21, 1988, the Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to Wayne Nichols, D.V.M., 3505 Mt. Tabor Road, West Liberty, Ohio (Respondent), proposing to revoke his DEA Certificate of Registration, AN2871451. The statutory predicate for the Order to Show Cause was that Respondent's continued registration with DEA was inconsistent with the public interest as set forth in 21 U.S.C. 823(f) and 824(a)(4). Additionally, citing his preliminary finding that Respondent's continued registration posed an imminent danger to the public health and safety, the Administrator ordered the immediate suspension of the registration pending the outcome of these proceedings. 21 U.S.C. 824(d).

Respondent requested a hearing on the issues raised in the Order to Show Cause in a letter dated May 23, 1988. The matter was placed on the docket of Administrative Law Judge Francis L. Young. Following prehearing procedures, a hearing was held in Columbus, Ohio on February 9 and 10, 1989. On May 11, 1989, the Administrative Law Judge issued his opinion and recommended ruling, findings of fact, conclusions of law and decision. No exceptions were filed. On June 20, 1989, Judge Young transmitted the record of these proceedings to the Administrator of DEA. The Administrator has considered the record in its entirety and, pursuant to 21 CFR 1316.67, hereby enters his final order in this matter based upon findings of fact and conclusions of law as hereinafter set forth.

The Administrative Law Judge found that Respondent was a veterinarian first inspected by DEA in April 1976, because of his unusual purchases of cocaine and codeine sulfate. Investigators noted that Respondent failed to note the date of receipt and amount received on his DEA 222 order forms, which are the documents Respondent is required to keep to record his purchases of Schedule II controlled substances. Respondent also failed to keep any records of dispensing of controlled substances, and failed to note dates of receipt on invoices for Schedule III-V controlled substances. Respondent was verbally advised of these violations by Investigators, and was also sent a registered letter advising him of the violations on August 27, 1976. This letter was signed for by a member of Respondent's household. Respondent did not respond to the letter and was sent another registered letter in November 1976. While Respondent maintains that he responded to this letter, the DEA has no record of any such response.

In 1977, DEA Investigators returned to Respondent's registered location. They found that Respondent continued to fail to note the amount and date of receipt on his DEA 222 order forms; that he failed to produce for Investigators some of the order forms for which he was accountable; that he failed to maintain complete and accurate records of dispensing of controlled substances; and that he failed to take a May 1, 1977, biennial inventory. Respondent was again advised of these violations both verbally and in writing. He was sent a Notice of Hearing dated September 12, 1977, by registered mail. Respondent failed to appear at the hearing and the matter was referred to the Ohio State Board of Veterinary Examiners. The Veterinary Board later advised DEA that the Executive Secretary of the Board had spoken with Respondent, who assured him that he would keep more efficient records.

A review of summaries from DEA's ARCOS System showed that Respondent was one of the largest practitioner purchasers of Dilaudid and cocaine in the United States for the years 1985, 1986, and 1987. In fact, Respondent was the number one practitioner purchaser of cocaine in the country in 1986, purchasing 1,745 grams; and the second largest practitioner purchaser of Dilaudid in the country for 1986, purchasing 14,750 4mg. tablets. DEA Investigators again conducted an investigation of Respondent's dispensing

of controlled substances in January 1987. Using a zero balance as the beginning inventory, Investigators audited four controlled substances, including Dilaudid and cocaine for an 18-month period. During the audit period, Respondent received 117.28 ounces of cocaine and 12,437 Dilaudid tablets. Investigators again noted that Respondent failed to maintain proper receiving records and failed to properly dispose of controlled substances. During the audit period Respondent reported a loss of 1,600 Dilaudid tablets which he had stored in an unlocked refrigerator in an unlocked camper parked at a racetrack in Kentucky. These highly abused Schedule II controlled substances were stored in a manner that failed to comply with DEA security regulations and at a location not registered with DEA. At the conclusion of the investigation, the DEA Investigators advised Respondent of the violations noted and provided him with a booklet outlining the DEA regulations applicable to practitioners.

In March 1988, DEA Investigators conducted yet another audit of Respondent's controlled substance records. The Investigators again noted the same recordkeeping violations and conducted an audit of selected controlled substances. Two audits were conducted of Respondent's controlled substance records. One utilized patient records, one utilized Respondent's log book. The results of the audits were widely disparate. While both audits showed significant shortages of Dilaudid 4mg. tablets, one set of records showed an overage of more than 12 ounces of cocaine, the other records showing a shortage of 34 ounces. Respondent had no explanation for these differences. In addition, Respondent noted a loss of 1,200 Dilaudid tablets which he said disintegrated when he spilled chloral hydrate on them. He did not report this loss to DEA as required.

On April 27, 1988, DEA Investigators and Agents returned to Respondent's registered address, executed a search warrant and served Respondent with an Order to Show Cause and Immediate Suspension of Registration. A short audit was conducted using two separate sets of records. There were discrepancies in the audit figures and Respondent continued to keep incomplete records.

The Administrative Law Judge also found that commonly used veterinary references do not list cocaine and Dilaudid as drugs commonly used in veterinary medicine. The American Association of Equine Practitioners and the American Veterinary Medical Association have both issued policy statements discouraging the use of controlled substances such as Dilaudid in veterinary practice. The Administrative Law Judge concluded that the evidence is undisputed that Respondent has continually failed to comply with the recordkeeping and security requirements of the Controlled Substances Act and the implementing regulations. He did so even though he had been specifically advised and notified by DEA that there were deficiencies in his recordkeeping and security practices. Although there was no direct evidence of intentional diversion of the unusually large amounts of cocaine and Dilaudid purchased by Respondent, Respondent's lax security and inadequate records provided the opportunity for diversion to occur. In fact, 1,600 Dilaudid tablets, with a street value of approximately $64,000, were stolen from Respondent's trailer due to his careless and improper storage of the drug. The Administrative Law Judge found that Respondent's continued registration was inconsistent with the public interest in that he continually failed to comply with applicable State, Federal, or local laws relating to controlled substances; and that his conduct threatened the public health and safety by allowing diversion of controlled substances into the illicit traffic. The Administrator adopts the opinion and recommended ruling of the Administrative Law Judge, and concludes that Respondent's DEA Certificate of Registration should be revoked.

Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that DEA Certificate of Registration, AN2871451, previously issued to Wayne Nichols, D.V.M., be, and it hereby is, revoked. It is further ordered that any pending applications for renewal of that registration be, and they hereby are, denied.

At the time the Order to Show Cause and Immediate Suspension of Registration was served on Respondent, all controlled substances possessed by Respondent under the authority of his then-suspended registration were placed under seal until the time for disposition of this proceeding and taking appeals had elapsed, or until all appeals had been concluded. Accordingly, these controlled substances shall remain under seal until October 10, 1989, or until any appeal of this order has been concluded. At that time, all such controlled substances shall be forfeited to the United States and shall be disposed of pursuant to 21 U.S.C. 881(e).

This order is effective September 7, 1989.

Dated: August 29, 1989.

John C. Lawn,

Administrator.

[FR Doc. 89-21028 Filed 9-6-89; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Advisory Committee on Construction Safety and Health; Full Committee Meeting

Notice is hereby given that the Advisory Committee on Construction Safety and Health, established under section 107(e)(1) of the Contract Work Hours and Safety Standard Act (40 U.S.C. 333) and section 7(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) will meet on September 13 and 14, 1989, in Room N-3437 B and C of the Francis Perkins Building, Department of Labor, Washington, DC. The meeting is open to the public and will begin at 9:00 a.m.

The agenda for this meeting includes reports by the Bureau of Labor Statistics on recordkeeping requirements, the work group on cadmium, OSHA's Technical Data Center Staff, the voluntary protection programs, the work group on steel erection, and the departmental legislative affairs staff. Written data, views or comments may be submitted, preferably with 20 copies, to the Division of Consumer Affairs. Any such submissions received prior to the meeting will be provided to the members of the Committee and will be included in the record of the meeting. Anyone wishing to make an oral presentation should notify the Division of Consumer Affairs before the meeting. The request should state the amount of time desired, the capacity in which the person will appear and a brief outline of the content of the presentation.

For additional information contact: Tom Hall, Division of Consumer Affairs, Occupational Safety and Health Administration, Room N-3647, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone 202-523-8615. An official record of the meeting will be available for public inspection at the Division of Consumer Affairs.

Alan C. McMillan,

Acting Assistant Secretary.

[FR Doc. 89-20962 Filed 9-6-89; 8:45 am]

BILLING CODE 4510-26-M

LEGAL SERVICES CORPORATION

Request for Comments on a Grant Award to Single Parents United 'N Kids (SPUNK)

AGENCY: Legal Services Corporation.

ACTION: Correction.

FOR FURTHER INFORMATION CONTACT: Victoria O'Brien, Counsel to the Director, or Charles T. Moses, Associate Director, Legal Services Corporation, Office of Field Services, 400 Virginia Ave., SW., Washington, DC 20024–2751, (202) 863–1837.

SUPPLEMENTARY INFORMATION: The Legal Services Corporation's article in the **Federal Register** Notice, dated Wednesday, August 30, 1989, Vol. 54, No. 167, page 35953, announced its intention to award a grant in the amount of $32,380 to SPUNK. However, in one instance, in the second sentence of the first paragraph under **SUPPLEMENTARY INFORMATION,** it was referred to as SUPPORT. It should have read "SPUNK".

Dated: September 5, 1989.

Ellen J. Smead,

Acting Director, Office of Field Services.

[FR Doc. 89–21133 Filed 9–6–89; 8:45 am]

BILLING CODE 7050–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (89–60)]

NASA Advisory Council (NAC), Space Systems and Technology Advisory Committee (SSTAC); meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Systems and Technology Advisory Committee, Ad Hoc Review Team on Technology Requirements for Human Performance on Long Space Missions.

DATES: September 19, 1989, 12:15 p.m. to 5 p.m.

ADDRESSES: National Aeronautics and Space Administration, Federal Building 10B, Room 647, 600 Independence Avenue, SW, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. James P. Jenkins, Office of Aeronautics and Space Technology, National Aeronautics and Space Administration, Washington, DC 20546, 202/453–2750.

SUPPLEMENTARY INFORMATION: The NAC Space Systems and Technology Advisory Committee (SSTAC) was established to provide overall guidance to the Office of Aeronautics and Space Technology (OAST) on space systems and technology programs. Special ad hoc review teams are formed to address specific topics. The Ad Hoc Review Team on Technology Requirements for Human Performance on Long Space Missions, chaired by Dr. Gerald P. Carr, is comprised of eight members. The meeting will be open to the public up to the seating capacity of the room (approximately 25 persons including the team members and other participants). It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the participants.

Type of Meeting: Open.

Agenda:

September 19, 1989

12:15 p.m.—Review Existing Studies of Human Space Explorations.

5 p.m.—Adjourn.

Dated: August 30, 1989.

John W. Gaff,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 89–20959 Filed 9–6–89; 8:45 am]

BILLING CODE 7510–01–M

[Notice (89–61)]

NASA Advisory Council (NAC), Space Systems and Technology Advisory Committee (SSTAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Systems and Technology Advisory Committee and the Aerospace Research and Technology Subcommittee.

DATES: September 25, 1989, 8:30 a.m. to 5:30 p.m.; September 26, 1989, 8 a.m. to 4 p.m.; and September 27, 1989, 8:30 a.m. to 3 p.m.

ADDRESSES: National Aeronautics and Space Administration, Langley Research Center, Building 1222, H.J.E. Reid Conference Center, Hampton, VA 23665.

FOR FURTHER INFORMATION CONTACT: Ms. Catherine L. Smith, Office of Aeronautics and Space Technology, National Aeronautics and Space Administration, Washington, DC 20546, 202/453–2367.

SUPPLEMENTARY INFORMATION: The NAC Space Systems and Technology Advisory Committee was established to provide overall guidance of direction to the space research and technology activities in the Office of Aeronautics and Space Technology (OAST). The Aerospace Research and Technology Informal Subcommittee (ARTS) was formed to provide technical support for the SSTAC and to conduct ad hoc interdisciplinary studies and assessments. The Committee, chaired by Dr. Joseph F. Shea, is comprised of 20 members. The subcommittee is comprised of 26 members. The meeting will be open to the public up to the seating capacity of the room (approximately 150 persons including the Committee members and other participants).

Type of Meeting: Open.

Agenda:

September 25, 1989

8:30 a.m.—Opening Remarks.

8:45 a.m.—Overview of Langley Research Center Activities.

9:45 a.m.—Space Overview and Current Planning.

11 a.m.—Parallel Discipline Sessions.

5:30 p.m.—Adjourn.

September 26, 1989

8 a.m.—Continue Parallel Discipline Sessions.

1:30 p.m.—Discipline Reports.

3:30 p.m.—OAST Responses to Ad Hoc Review Team Recommendations.

4 p.m.—Adjourn.

September 27, 1989

8:30 a.m.—Opening Remarks.

8:35 a.m.—OAST Overview.

10 a.m.—Task Force Activities.

12:45 p.m.—SSTAC Report Summaries.

2:15 p.m.—Closing Remarks.

3 p.m.—Adjourn.

Dated: August 30, 1989.

John W. Gaff,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 89–20960 Filed 9–6–89; 8:45 am]

BILLING CODE 7510–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-295 and 50-304]

Commonwealth Edison Co.; Environmental Assessment and Finding of no Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. DPR-39 and DPR-48, issued to Commonwealth Edison Company, (the licensee) for Zion Station, Units 1 and 2, located in Lake County, Illinois.

Environmental Assessment

Identification of Proposed Action

The proposed amendments would permit temporary one-time changes to Zion Technical Specifications regarding the Auxiliary Electric Power that would allow performing extensive preventive maintenance, in accordance with the manufacturer's recommendation, on the diesel generator that is shared between the two units. Because the common diesel generator is shared, extended maintenance periods have not been available under present Technical Specifications, even during scheduled refueling outages of either of the two units. The proposed changes would extend the present allowable out-of-service period for the common diesel from 7 days to 45 days during which, with one unit in cold shutdown, two diesel generators would be required to satisfy the standby AC on-site power requirements for Unit 2. In addition, the remaining two diesels for Unit 1 will also be available while the shared diesel is out of service.

This revision to the licenses of Zion Station, Units 1 and 2, would be made in response to the licensee's application for amendment dated July 6, 1989, as supplemented August 4, August 10 and August 24, 1989.

The Need For The Proposed Action

Pursuant to 10 CFR 50.90, the licensee has proposed amendments to Facility Operating Licenses DPR-39 and DPR-48 for Zion Station, Units 1 and 2, respectively. The proposed amendments, would extend the allowable out-of-service period for a one-time maintenance overhaul of the "0" diesel generator.

The "0" diesel generator is shared between Units 1 and 2, and the existing Technical Specification Section 3.15.2.C permits reactor operation for 7 days, if the "0" diesel generator becomes inoperable. This amendment request would modify Section 3.15.2.C of the Technical Specifications to permit the allowable out-of-service period for the "0" diesel generator to be extended from 7 days to 45 days for a one-time maintenance overhaul. The proposed extension to 45 days is necessary in order to perform the extensive maintenance overhaul to the diesel generator in conformance with the manufacturer's recommendation that such overhaul be performed at 5 year intervals.

Environmental Impacts of the Proposed Action

The Commission has evaluated the radiological impact of the proposed amendments and determined that for any of the core melt sequences to be influenced by the "0" diesel outage one must first have a complete loss of offsite power, which has never occurred at Zion station since its criticality in 1973. The outage of "0" diesel may have some influence in case of a small break loss of coolant accident concurrent with complete loss of all offsite power and an additional failure of one of the remaining diesels. However, the staff has concluded that a simultaneous loss of all offsite power (i.e., 6 offsite lines and 4 paths to ESF buses) and a loss of coolant accident concurrent with additional single failure of a diesel generator is a very unlikely event over the 45-day period while the "0" DG is out for maintenance. The licensee has reviewed and verified their existing emergency operating procedures (EOP) for its applicability during LOCA with only one emergency safety feature bus available. The licensee stated that their EOP procedures allow for unit shutdown following a LOCA using either a single charging pump or single safety injection pump. Thus, the risk and likelihood of core melt are not significantly affected by Unit 2 operation while the "0" DG is out for maintenance.

The staff finds that the proposed extension of the allowable out-of-service period to allow for maintenance of the "0" diesel generator poses no undue risk to the public health and safety. This conclusion is based upon numerous compensatory actions planned by the licensee during this outage (e.g., removal of fuel from Unit 1 for most of the time the "0" diesel is unavailable and performance of maintenance on emergency safeguards features buses only when the "0" diesel is operable), and the likelihood of the event that may cause a significant damage to the core.

The proposed amendments involve a change to a requirement with respect to the installation and use of a facility component located within the restricted area as defined in 10 CFR part 20.

With regard to nonradiological impacts, the proposed amendments involve systems located entirely within the restricted area as defined in 10 CFR part 20. They do not affect non-radiological plant effluents and have no other environmental impact. Therefore, the Commission also concludes that there are no significant nonradiological environmental impacts associated with the proposed amendments.

Accordingly, the Commission findings in the "Final Environmental Statement related to the operation of Zion Station, Units 1 and 2 dated December 1972, regarding radiological environmental impacts from the plants during normal operation or after accident conditions, are not adversely altered by this action.

The Notice of Consideration of Issuance of Amendment and Opportunity for Hearing in connection with this action was published in the **Federal Register** on July 20, 1989 (54 FR 30485). No request for hearing or petition for leave to intervene was filed following this notice.

Alternative to the Proposed Actions

Since the Commission has concluded that no adverse environmental effects are associated with this proposed action, any alternatives with equal or greater environmental impact need not be evaluated.

The principal alternative would be to deny the requested amendment. This would not reduce environmental impacts of plant operation and would result in reduced operational flexibility.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the Nuclear Regulatory Commission's Final Environmental Statement for the Zion Nuclear Power Station, Units 1 and 2, dated December 1972.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's submittals of July 6, 1989, August 4, August 10 and August 24, 1989 and did not consult other agencies or persons.

Finding of no Significant Impact

The Commission has determined not to prepare an environmental impact statement of the proposed license amendment.

Based upon this environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the request for amendments dated July 6, 1989, as supplemented August 4, 1989, August 10, 1989, and August 24, 1989, and the Final Environmental Statement for Zion, dated December 1972, which are available for public inspection at the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555; and at the Local Public Document Room, Waukegan Public Library, 128 N. County Street, Waukegan, Illinois 60085.

Dated at Rockville, Maryland, this 1st day of September 1989.

For the Nuclear Regulatory Commission.

Paul C. Shemanski,

Acting Director, Project Directorate III–2, Division of Reactor Projects—III, IV, V and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 89–21001 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–445A]

Texas Utilities Electric Co., Comanche Peak Steam Electric Station, Unit 1; Reevaluation of Antitrust Funding

Notice is hereby given that counsel for Cap Rock Electric Cooperative, Inc. has requested a reevaluation by the Director of the Office of Nuclear Reactor Regulation of the "Finding of No Significant Change" pursuant to the operating license antitrust review of the captioned nuclear unit. After further review, I have decided not to change my finding.

A copy of my finding, the request for reevaluation, and my reevaluation are available for public examination and copying, for a fee, at the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555.

Dated at Rockville, Maryland, this 29th day of August 1989.

For the Nuclear Regulatory Commission.

Thomas E. Murley,

Director, Office of Nucler Reactor Regulation.

[FR Doc. 89–21002 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–361 and 50–362]

Southern California Edison Co., et al.; Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (Commission) has issued Amendment No. 76 to Facility Operating License No. NPF–10 and Amendment No. 64 to Facility Operating License No. NPF–15, issued to Southern California Edison Company, San Diego Gas and Electric Company, The City of Riverside, California and the City of Anaheim, California (the licensees), which revised the Technical Specifications for operation of the San Onofre Nuclear Generating Station, Units 2 and 3, located in San Diego County California.

The amendments were effective as of the date of issuance.

These amendments revised the following Technical Specifications (TS):

a. TS 3/4.3.3.5, "Remote Shutdown Instrumentation." (Unit 2 only)

b. TS 3/4.3.3.6, "Accident Monitoring Instrumentation." (Unit 2 only)

c. TS 3/4.7.6, "Snubbers."

TS 3/4.3.3.5 and TS 3/4.3.3.6 are revised to allow a one-time extension of the surveillance interval for channel calibration of pressurizer level instruments used for remote shutdown monitoring and accident monitoring. TS 3/4.7.6 is revised to increase the interval for functional testing of snubbers to at least once per refueling interval, which is defined as 24 months. Also, TS 3/4.7.6 is revised to provide an extension of the visual inspection interval requirements for snubbers inspected during the Cycle 4 refueling outage. These amendments are in response to applications for amendments designated as PCN 246 and PCN 290, dated May 19, 1988 and March 10, 1989.

The applications for amendments comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations, the Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which is set forth in the license amendments.

Notices of Consideration of Issuance of Amendments and Opportunity for Hearing in connection with this action were published in the **Federal Register** on February 27, 1989 (54 FR 8250) and April 24, 1989 (54 FR 16438–D). No request for a hearing or petition for leave to intervene was filed following the notices.

The Commission has prepared an Environmental Assessment related to the action and has determined that an environmental impact statement will not be prepared and that issuance of the amendment will have no significant adverse effect on the quality of the human environment.

For further details with respect to the action see (1) the applications for amendments dated May 19, 1988 and March 10, 1989, (2) Amendment No. 76 to License No. NPF–10 and Amendment No. 64 to License No. NPF–15, (3) the Commission's related Safety Evaluation and (4) the Commission's Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555, and the General Library, University of California, P.O. Box 19557, Irvine, California 92713. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects III, IV, V and Special Projects.

Dated at Rockville, Maryland this 30th day of August, 1989.

For the Nuclear Regulatory Commission.

Charles M. Trammell,

Senior Project Manager, Project Directorate V, Division of Reactor Projects III, IV, V and Special Projects, Office of Nuclear Regulatory Regulation.

[FR Doc. 89–20998 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–362]

Southern California Edison Co., et al.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–15 issued to Southern California Edison Company (SCE), San Diego Gas and Electric Company, the City of Riverside, California and the City of Anaheim, California (the licensees), for operation of San Onofre Nuclear Generating Station, Unit 3, located in San Diego County, California. The request for amendment was submitted by letter dated July 26, 1989, and identified as Proposed Change PCN–294.

The proposed change would revise Technical Specification 3/4.7.6, "Snubbers." Surveillance Requirement 4.7.6.b requires a visual inspection of all snubbers on a regular basis. The interval for visual inspections is decreased as a function of the number of inoperable snubbers is discovered. With no inoperable snubbers found, a maximum interval of 18 months plus or minus 25 percent is allowed. With one inoperable snubber per inspection period, the interval is 12 months plus or minus 25 percent. The proposal change would allow a one-time extension of the 12 month interval to 20 months plus or minus 25 percent, for the case where one inoperable snubber was found.

Before issuance of the proposed license amendments, the Commission

will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By October 10, 1989, the licensees may file a request for a hearing with respect to issuance of the amendments to the subject facility operating licenses, and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for hearing and petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition, and the Secretary or the designated Atomic Safety Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition with requesting leave of the Board up to fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendments under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-600 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to George W. Knighton: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Mr. Charles R. Kocher, Esq., Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, California 91770 and Orrick, Herrington and Sutcliffe, Attention: David R. Pigott, Esq., 600 Montgomery Street, San Francisco, California, 94111, attorneys for the licensees.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

If a request for hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendments which is available for public inspection at the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, and at the General Library, University of California at Irvine, Irvine, California 92713.

Dated at Rockville, Maryland, this 30th day of August, 1989.

For the Nuclear Regulatory Commission.

George W. Knighton,

Director, Project Directorate V, Division of Reactor Projects III, IV, V and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 89-20999 Filed 9-6-89; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-361 and 50-362]

Southern California Edison Co., et al.; Consideration of Issuance of Amendments to Facility Operating Licenses and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. NPF-10 and NPF-15 issued to Southern California Edison Company (SCE), San Diego Gas and Electric Company, the City of Riverside, California and the City of Anaheim, California (the licensees), for operation of San Onofre Nuclear Generating Station, Units 2 and 3, located in San Diego County, California. The request for amendment was submitted by letter dated July 31, 1989, and identified as Proposed Change PCN-295.

The proposed change would revise Technical Specification 3/4.1.3.4, "CEA Drop Time," and its Bases, to use both an arithmetic average Control Element Assembly (CEA) drop time and a maximum individual CEA drop time. The maximum individual CEA drop time restriction would be used to limit the CEA drop time distribution from the arithmetic average.

The requirements of Technical Specification 3/4.1.3.4 ensure that actual drop times for full length CEAs are consistent with the drop time assumed in the accident and transient analyses. The drop times for full length CEAs, from the fully withdrawn position until the CEA reaches its 90 percent insertion position, are measured with the reactor

coolant average temperature greater that 520 °F and all reactor coolant pumps running. CEA drop times are measured following each removal and reinstallation of the reactor vessel head; following any maintenance on, or modification to the CEA drive system which could affect the drop time of those specific CEAs; and at least once per refueling interval.

Prior to SONGS Unit 2 Cycle 4 start-up, CEA drop times were measured individually using a visicorder to simultaneously monitor CEA position (from the reed switch position transmitter) and power to the upper gripper coil. The CEA was withdrawn from the core to its full out position and dropped by opening its individual circuit breaker. From the visicorder chart, the time from the interruption of power to 90 percent CEA insertion could be determined.

Beginning with the SONGS Unit 2 Cycle 4 start-up, a new method of measuring CEA drop times was instituted. This method uses special software (CEA Drop Time Test or CDTT software) loaded into one of the Control Element Assembly Calculators (CEACs). The CDTT software initiates a Core Protection Calculator (CPC) trip and simultaneously monitors the positions of all 91 CEAs (83 full length and 8 part length) as a function of time. The data obtained is then analyzed to determine individual CEA drop times. Under this method, it is important to note that power is interrupted at the reactor trip breakers rather than at the individual breakers as in the previous method. This new method more accurately reflects the operation of the reactor protection system during a scram.

The CEA drop times measured using the new method during SONGS Unit 2 Cycle 4 start-up were unexpectedly longer than those measured by the visicorder method. This is due to the longer time constant for dissipation of the gripper coil stored energy when tripped by the reactor trip breakers than when tripped by the individual circuit breakers. Subsequently, SCE requested a Technical Specification change to revise the drop time to the current limit of 3.2 seconds. In addition, Core Operating Limits Supervisory System (COLSS) and CPC penalty factors were installed to account for the increased CEA drop time. All the design basis events were re-analyzed at that time to support the change to 3.2 seconds.

The SONGS Unit 3 Cycle 4 CEA drop time test found that the margin between the slowest CEA and the Technical Specification limit of 3.2 seconds was small. To increase the margin between the Technical Specification value and the measured time, the licensees have proposed to amend the CEA drop time specification to incorporate the use of an arithmetic average CEA drop time with a restriction on the maximum individual CEA drop time. In addition, the proposed amendment would expand the Technical Specifications to have a range of average and maximum individual drop times.

The proposed specification would provide three average CEA drop times of 3.0, 3.2, and 3.4 seconds, with corresponding maximum individual CEA drop times of 3.2, 3.4, and 3.6 seconds. It would also provide COLSS margin and CPC margin-to-trip adjustment factors, and a penalty would be applied (adjustment factor greater than 1.0) if the average time is longer than 3.2 seconds. The plant would not enter either Mode 2 or 1 if either the average CEA drop time is greater than 3.4 seconds or the maximum individual CEA drop time is greater than 3.6 seconds.

Before issuance of the proposed license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By October 10, 1989 the licensees may file a request for a hearing with respect to issuance of the amendments to the subject facility operating licensees, and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for hearing and petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition, and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendments under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly inform the Commission by a toll-free telephone call to Western Union at 1–(800)325–6000 (in Missouri 1–(800)342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to George W. Knighton: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition

should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Mr. Charles R. Kocher, Esq., Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, California 91770 and Orrick, Herrington and Sutcliffe, Attention: David R. Pigott, Esq., 600 Montgomery Street, San Francisco, Califorina 94111, attorneys for the licensees.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

If a request for hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendments which is available for public inspection at the Commission's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, and at the General Library, University of California at Irvine, Irvine, California 92713.

Dated at Rockville, Maryland, this 30th day of August, 1989.

For the Nuclear Regulatory Commission.

George W. Knighton,

Director, Project Directorate V, Division of Reactor Projects III, IV, V and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 89–21000 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

Docket No. 50–271–OLA (Spent Fuel Pool Amendment)

Appointment of Adjudicatory Employee; Vermont Yankee Nuclear Power Corp.

Commissioners: Kenneth M. Carr, Chairman, Thomas M. Roberts, Kenneth C. Rogers, James R. Curtiss.

In accord with the requirements of 10 CFR 2.4, notice is hereby given that Dr. Harold VanderMolen, a Commission employee in the Office of Nuclear Reactor Regulation, has been appointed as a Commission adjudicatory employee within the meaning of § 2.4 to advise the Commission on issues in the above-captioned proceeding related to consideration under the National Environmental Policy Act of the proposed spent fuel pool reracking.

Dr. VanderMolen has not been engaged in the performance of any investigative or litigating function in connection with the Vermont Yankee facility or in any factually-related proceeding.

Until such time as a final decision is issued in the above-captioned matter, interested persons outside the agency and agency employees performing investigation or litigating functions in the Vermont Yankee operating license amendment proceeding are required to observe the restrictions of 10 CFR 2.780 and 2.781 in their communications with Dr. VanderMolen.

It is so *ordered.*

Dated at Rockville, Maryland this 30th day of August, 1989.

For the Commission,

Samuel J. Chilk

Secretary of the Commission.

[FR Doc. 89–20909 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–320]

Meeting of the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 GPU Nuclear Corporation

Notice is hereby given pursuant to the Federal Advisory Committee Act that the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 (TMI–2) will be meeting on September 21, 1989, from 7:00 p.m. to 10:00 p.m. at the Holiday Inn, 23 S. Second Street, Harrisburg, Pennsylvania. The meeting will be open to the public.

At this meeting, the Panel will receive a status report on the progress of defueling from the licensee, GPU Nuclear Corporation. The licensee will also discuss the radiation monitoring program around TMI–2, and the schedule and proposed funding for the remainder of the cleanup. The NRC staff will summarize the findings of Final Supplement 3 to the Programmatic Environmental Impact Statement related to decontamination and disposal of radioactive wastes resulting from the March 28, 1979 accident at TMI–2. Final Supplement 3 evaluates the licensee's proposal to place the facility in long term storage following defueling.

Further information on the meeting may be obtained from Dr. Michael T. Masnik, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–1373.

Dated: September 1, 1989.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Advisory Committee, Management Officer.

[FR Doc. 89–21194 Filed 9–6–89; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Request for Approval of RI 20–1 Application for Minimum Annuity Submitted to OMB for Clearance

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980, (title 44, U.S. Code, chapter 35) this notice announces a request to extend the use of RI 20–1 (Application for Minimum Annuity). OPM currently uses RI 20–1 to determine if an annuitant qualifies for the minimum annuity, repealed under Section 305 of Public Law 99–251 (Federal Employees Benefits Improvement Act of 1986). Annuitants who were entitled to the minimum annuity prior to the repeal date of February 27, 1986 continue to receive the minimum annuity in accordance with Section 305.

Approximately 300 Civil Service annuitants complete the form, which requires approximately 15 minutes, for a total public burden of 75 hours. For copies of this proposal, call Larry Dambrose (632–0199) or Grace Butler (632–0259).

DATES: Comments on this proposal should be received within 10 working days from the date of this publication.

ADDRESSES: Send or deliver comments to—

C. Ronald Trueworthy, Agency Clearance Officer, U.S. Office of Personnel Management, 1900 E Street, NW., Room 6410, Washington, DC 20415.

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW., Room 3235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mary Beth Smith-Toomey, 202–632–5472.

U.S. Office of Personnel Management.
Constance Newman,
Director.
[FR Doc. 89-21041 Filed 9-6-89; 8:45 am]
BILLING CODE 6325-01-M

PENSION BENEFIT GUARANTY CORPORATION

Request for Exemption From Bond/Escrow Requirement Relating To Sale of Assets by an Employer

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of pendency of request.

SUMMARY: This notice advises interested persons that the Pension Benefit Guaranty Corporation has received a request from The Orioles, Inc. for an exemption from the bond/escrow requirement of section 4204(a)(1)(B) of the Employee Retirement Income Security Act of 1974, as amended. Section 4204(a)(1) provides that the sale of assets by an employer that contributes to a multiemployer pension plan will not constitute a complete or partial withdrawal from the plan if certain conditions are met. Two of these conditions are that the purchaser post a bond or deposit money in escrow for a five plan year period beginning after the sale, and that the contract of sale between the seller and the purchaser provide that the seller will be secondarily liable for its withdrawal liability if the purchaser withdraws from the plan within five years after the sale and does not pay its withdrawal liability. The PBGC is authorized to grant exemptions from these requirements. Prior to granting an exemption, the PBGC is required to give interested persons an opportunity to comment on the exemption request. The effect of this notice is to advise interested persons of this exemption request and to solicit their views on it.

DATES: Comments must be submitted on or before October 23, 1989.

ADDRESSES: All written comments (at least three copies) should be addressed to: Pension Benefit Guaranty Corporation, Office of General Counsel (22510), 2020 K Street, NW., Washington, DC 20006. The request for an exemption and the comments received will be available for public inspection at the PBGC's Communication and Public Affairs Department, Suite 7100, at the above address, between the hours of 9:00 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: J. Ronald Goldstein, Senior Counsel, Office of General Counsel (22510), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; (202) 778-8850; (202-778-8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Background

Section 4204(a)(1) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA") provides that a bona fide arm's length sale of assets to an unrelated party by an employer that contributes to a multiemployer pension plan will not result in a withdrawal if three conditions are met. These conditions, listed in section 4204(a)(1)(A)-(C), are that—

(A) The purchaser has an obligation to contribute to the plan for substantially the same number of contribution base units for which the seller was obligated to contribute;

(B) The purchaser obtains a bond or places an amount in escrow, for a period of five plan years after the sale, in an amount equal to the greater of the seller's average required annual contribution to the plan for the three plan years before the year of sale or the seller's required annual contribution for the plan year before the year of sale; and

(C) The contract of sale provides that if the purchaser withdraws from the plan within the first five plan years beginning after the sale and fails to pay its liability to the plan, the seller will be secondarily liable for the liability it (the seller) would have had but for section 4204.

The bond or escrow described above would be paid to the plan if the purchaser withdraws from the plan or fails to make any required contributions to the plan within the first five plan years beginning after the sale.

Additionally, section 4204(b)(1) provides that if a sale of assets is covered by section 4204, the purchaser assumes by operation of law the contribution record of the seller for the plan year in which the sale occurred and the preceding four plan years.

Section 4204(c) of ERISA authorizes the Pension Benefit Guaranty Corporation ("PBGC") to grant individual or class variances or exemptions from the purchaser's bond/escrow requirement of section 4204(a)(1)(B) and the sale-contract requirement of section 4204(a)(1)(C). The legislative history of section 4204 indicates a Congressional intent that the sales rules be administered in a manner that assures protection of the plan with the least practicable intrusion into normal business transactions. The granting of an exemption or variance from the requirements of section 4204(A)(1)(B) or (C) does not constitute a finding by PBGC that the transaction satisfies the other requirements of section 4204(a)(1).

Under the PBGC's regulation on variances for sales of assets (29 CFR Part 2643), requests for waivers of the bond/escrow and contract/provision requirements are normally made to the multiemployer plan in question. However, under § 2643.2 of the regulation, a waiver of these requirements may be sought from the PBGC, if the transaction does not satisfy any of the criteria in Subpart B of the regulation and the parties assert some other basis for granting the waiver. Under § 2643.3(a) of the regulation, the PBGC will approve a variance or exemption request if it determines that approval of the request—

(1) Would more effectively or equitably carry out the purposes of Title IV of the Act; and

(2) Would not significantly increase the risk of financial loss to the plan.

Section 4204(c) of ERISA and § 2643.3(b) of the regulation require the PBGC to publish a notice of the pendency of a request for a variance or exemption in the **Federal Register**, and to provide interested parties with an opportunity to comment on the proposed variance or exemption.

The Request

The PBGC has received a request from the purchaser, The Orioles, Inc. (the "Buyer"), a corporation formed under the laws of Maryland, for an exemption from the requirements of section 4204(a)(1)(B) of ERISA with respect to its purchase of the Baltimore Orioles baseball team from The Baltimore Orioles, Inc. (the "Seller"). In the request, the Buyer represents among other things that:

1. The Major League Baseball Players Benefit Plan (the "Plan") is established and maintained pursuant to a collective bargaining agreement between the 26 professional major league baseball teams and the Major League Baseball Players Association.

2. The Seller was a participating employer in the Plan.

3. The major league clubs have established the Major Leagues Central Fund (the "Central Fund") pursuant to the "Major League Agreement in re Major Leagues Central Fund." Under this Agreement, contributions to the Plan for all participating employers are paid by the Office of the Commissioner of Baseball from the Central Fund on behalf of the clubs in satisfaction of their pension liability arising under the

Plan's funding agreement. The monies in the Central Fund, which fund the Plan, are derived directly from (i) gate receipts from All-Star games, (ii) radio and television revenues from World Series, League Championships, intra-division play-offs and All-Star games, and (iii) certain other radio and television revenue (including foreign broadcasts) from regular and exhibition games.

4. In 1988, the major league clubs contributed the sum of $33,000,000 per year to cover both pension and welfare benefits, approximately $28,000,000 of which was remitted to the Plan. Each major league club is responsible the 1/26 of that amount. In 1988, the Central Fund paid approximately $1,000,000 as pension contributions to the Plan on behalf of the Seller.

5. The Buyer and the Seller entered into an agreement on March 16, 1989 for the sale of the Baltimore Orioles baseball team. The final closing occurred on or about May 26, 1989.

6. The contract of sale provides that the Buyer will have an obligation to contribute to the Plan for substantially the same number of contribution units as the Seller.

7. The sales agreement further provides that:

> If the Buyer hereafter, but prior to the end of the fifth plan year commencing after closing, partially or completely withdraws * * * Seller shall remain secondarily liabile for any withdrawal liability it would have had to the Plan but for the operation of ERISA § 4204.

8. In support of the variance request, the Buyer states that:

> [b]ecause the Plan is funded directly from the revenues which are paid from the Central Fund directly to the [Plan's trust fund] without first passing through the hands of any of the Employers, the Plan enjoys adequate security * * *. A change in ownership * * * does not in any way affect the obligation to fund the Plan * * * nor create the possibility that there will be difficulty in collecting Plan contributions from any new owner * * *.

9. The Buyer has sent by certified mail, return receipt requested, a complete copy of this request to the Plan and the collective bargaining representative of the Orioles baseball team.

Comments

All interested persons are invited to submit written comments on the pending exemption to the above address on or before [insert date 45 days after publication]. All comments will be made a part of the record. Comments received, as well as the application for exemption, will be available for public inspection at the address set forth above.

Issued at Washington, DC on this 30th day of August 1989.

James B. Lockhart III,

Executive Director Pension Benefit Guaranty Corporation.

[FR Doc. 89-21030 Filed 9-6-89; 8:45 am]

BILLING CODE 7708-01-M

POSTAL RATE COMMISSION

[Order No. 843, Docket No. C89-4]

MOAA Catalog Subclass Proposal; Order on Filing of Complaint of Mail Order Association of America

Issued August 31, 1989.

Before Commissioners: Henry R. Folsom, Vice-Chairman; John W. Crutcher; W.H. "Trey" LeBlanc, III; Patti Birge Tyson.

Notice is hereby given that on August 18, 1989, a document entitled "Complaint of Mail Order Association of America Seeking the Creation of a Subclass for Catalogs Sorted to the Carrier Route" was filed with the Commission and assigned Docket No. C89-4. MOAA's complaint alleges that under the current classification, the Postal Service is charging third-class rates which do not conform to the policies of the Postal Reorganization Act and claims that creation of a subclass would remedy this allegedly inequitable situation.

The statutory basis set forth in the complaint is MOAA's assertion that the current classification system results in violations of the requirements of sections 3623(c)(1), 3622(b)(1), 3622(b)(3) and 3622(b)(6) of the Postal Reorganization Act, which generally relate to considerations of fairness and equity, costing, and mail preparation.[1] In support of its position, MOAA cites several factors which it believes have led to "overcharging" catalogs sorted to the carrier route level. These include the alleged failure of the current schedule to recognize cost differences between carrier and non-carrier route mail, the Commission's allegedly misplaced confidence that rate category treatment for carrier route pieces produces fair rates and the impact of the minimum-per-piece/per pound rate structure on heavier (pound-rated) pieces. *See* Complaint at pp. 3-5.

Relationship to Docket Nos. R80-1, R87-1 and C89-3. MOAA asserts (at pp. 5-8) that its complaint requires a review of the evidentiary basis for Commission action in Docket No. R80-1 eliminating a distinction between catalogs and circulars and argues against the ability of the existing three-tier rate structure, based on presortation, to reflect adequately cost savings. In addition, MOAA criticizes the Commission's decision, in Docket No. R87-1, not to recommend a carrier route subclass for bulk third class mail, specifically questioning the conclusion that there must be intrinsic differences for a type of mail to be given subclass status. It nonetheless argues that catalogs meet this criterion in that they are intrinsically different from the balance of third-class mail in terms of physical makeup, purpose, use and nature of the mailing customer. At the same time, MOAA claims that catalogs have intrinsic similarities in, among other things, their handling and cost characteristics, their use as a marketing tool, and their preparation. Complaint at pp. 9-13. Accordingly, MOAA argues in favor of a carrier route subclass for catalogs or, in the alternative, for a catalog subclass encompassing all three levels of sortation. Complaint at pp. 12-13.

Procedural matters. MOAA acknowledges the Complaint of Advo-System, Inc. (Docket No. C89-3) seeking a separate subclass for local saturation mail and urges consolidation of this and any related complaints. In addition, in conformance with the Commission's rules of practice, MOAA identifies "persons affected" as all those making use of third-class mail for the purpose of effecting delivery of their catalogs, particularly those persons entering their catalogs sorted to the carrier route level.

It is ordered:

(1) The Postal Service's answer to the MOAA Complaint is to be filed by September 18, 1989.

(2) Stephen A. Gold, Director of the Office of the Consumer Advocate, is appointed to represent the interests of the general public.

By the Commission.

Charles L. Clapp,

Secretary.

[FR Doc. 89-20978 Filed 9-6-89; 8:45 am]

BILLING CODE 7710-FW-M

[1] In MOAA's view, violations of the requirements of section 3623(c)(1) arise in that the current classification system fails adequately to reflect the cost differences for the various types of mail within the class. Violations of 3622(b)(1) allegedly occur because the current classification system results in a rate schedule which is not "fair and equitable." With respect to section 3622(b)(3), MOAA claims carrier route mail, particularly carrier route catalogs, bear a portion of non-attributable costs exceeding that which is "reasonably assignable." MOAA also claims that the classification fails to comply with the section 3622(b)(6)'s requirement that the schedule recognize "the degree of preparation of mail * * * and its effect upon reducing costs of the Postal Service."

PRESIDENTIAL COMMISSION ON CATASTROPHIC NUCLEAR ACCIDENTS

Meeting

The Presidential Commission on Catastrophic Nuclear Accidents, pursuant to its authority under Subsection 170(1), of Public Law 100–408, the Price-Anderson Amendments Act of 1988, will hold a meeting on September 27, 1989, from 10:00 a.m.–5:00 p.m., in the Potomac Rooms at the Wyndham-Bristol Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037. The Commission was created to conduct a comprehensive study of appropriate means of fully compensating victims of a catastrophic nuclear accidents and to submit a final report to Congress not later then August 20, 1990.

The purpose of the meeting is to receive a briefing from Joseph B. Knotts, Jr. of the law firm Bishop, Cook, Purcell and Reynolds on the present status, pursuant to the Price-Anderson Act, of persons injured as a result of an accident at a nuclear power plant in the United States; from representatives of the nuclear insurance pools on their claims experience with respect to the Three Mile Island accident in Pennsylvania; and from Kenneth R. Feinberg, a member of the Commission, on the American Bar Association's recent report on mass torts. The Commission will also discuss its plans for future meetings and activities and will be briefed by respresentatives of the General Services Administration on standards of conduct.

Further information on these meetings can be obtained from Jerome Saltzman whose temporary address is c/o Department of Energy, 1000 Independence Avenue, NW., RW–20, Washington, DC 20585, (202) 586–9692.

The public will be permitted to attend this meeting as observers. The meeting will be transcribed and procedures to obtain transcripts will be provided at the meeting. Members of the public wishing to attend the Commission should notify Jerome Saltzman on (202) 586-9692 by close of business, September 22, 1989.

Dated: September 1, 1989.

Jerome Saltzman,

Executive Director Presidential Commission on Catastrophic Nuclear Accidents.

[FR Doc. 89–20954 Filed 9–6–89; 8:45 am]

BILLING CODE 6820–SP–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–27202; File No. SR–PSE–89–16]

Self-Regulatory Organizations; Notice of Filing of Amendment to Proposed Rule Change by the Pacific Stock Exchange, Inc. Relating to a One-Year Pilot Which Requires the Trading Crowd to Make Ten-Up Markets

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on August 15, 1989, the Pacific Stock Exchange, Inc. ("PSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") an amendment to the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization.[1] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its earlier rule filing, changing Rule VI, section 87, as set forth below (Amendments are indicated with brackets for deletions, and italics for new language.)

Rule VI, Section 87—Trading Crowd Firm Disseminated Market Quotes

Sec. 87. Each trading crowd is required to provide a depth of ten (10) option contracts for all non-broker/dealer customer orders, at the bid/offer which is displayed as the Disseminated market quote at the time such orders are announced or displayed at the trading post designated for trading the subject option class.

(a) The member/member organization entering an order for execution pursuant to this Rule is responsible for ascertaining the account origin of such order and for providing notation on the subject order ticket of such order's account origin.

(b) The Rule shall be in effect at all times other than during a trading rotation at the subject trading post and a reasonable period of time immediately following a trading rotation, not to exceed five (5) minutes.

(c) [Should the executing Floor Broker attempt to split the disseminated market quotes, or] *A trading crowd shall be exempt from the provisions of this rule* upon the declaration of a "fast market" pursuant to Rule VI, Section 38 [, the trading crowd shall be exempt from the provisions of this rule.]

(d) Should the response of members present at a trading post be insufficient to provide a depth of ten (10) contracts, the Order Book Official shall allocate among the Market Makers present at the trading post the balance of contracts necessary to provide an execution on ten contracts. The Order Book staff shall record and maintain lists of the individual Market Makers who were allocated contracts, and consider such allocations when similar occasions arise within the same trading session. The Order Book Official shall seek, as reasonably as possible, to equalize such allocations.

(e) The enforcement of this Rule, and the *determination of the* expiration months and strike prices subject to the provisions of this Rule shall be [determined by] *within the jurisdiction of* the Options Floor Trading Committee. Two Options Floor Officials may grant exemptions to the provisions of this Rule for either a class or series within a class of option contracts if, in their determination, the individual situation warrants such action, or upon their determination that an error occurred in the dissemination of a market quote.

(f) This Rule is effective on (approval by Commission) and shall continue in effect to and including [date one year after approval.] Any extension of the effectiveness of this Rule shall require further approval by the Securities and Exchange Commission.

Commentary:

.01 If a bid/offer displayed as a disseminated market quote is on behalf of an order represented by a Floor Broker or the Order Book Official and is for less than ten (10) contracts, the trading crowd is obligated to buy/sell the balance of contracts necessary to provide a depth of ten (10) contracts at the disseminated bid/offer.

.02 Should a Floor Broker cause a bid/offer to be disseminated and the order is subsequently executed or cancelled, the Floor Broker shall be responsible for causing the removal of such disseminated bid/offer. Failure to remove such bid/offer may result in the Floor Broker being held responsible for providing a depth of ten (10) contracts. A Market Maker who has caused a bid/offer to be disseminated is equally

[1] The original proposed rule change was published for comment in Securities Exchange Act Release No. 26957 (June 22, 1989), 54 FR 27445.

responsible for causing the removal of such bid/offer upon leaving a trading post.

.03 Market Maker orders for less than ten (10) contracts that are represented at a trading post by a Floor Broker shall not be disseminated. Floor Brokers shall remain obligated to use due diligence in the representation of orders pursuant to Rule VI, Section 62(a).

.04 [Options Floor Officials, pursuant to Rule VI, Section 39, and Commentary .05 thereunder, may issue Floor Citations for v] *Violations of this Section and its Commentary shall be subject to formal disciplinary action* pursuant to Rule XX.

Rule VI, Section 1

Applicability, Definitions and References.

Sec. 1(a)(29). No Change.

Rule VI, Section 39

Admission to and Conduct on the Trading Floor.

Sec. 39. Commentary .05. No change.

Rule VI, Section 62

Responsibilities of Floor Brokers.

Sec. 62. Commentaries .04 and .05. No change.

Rule VI, Section 79

Obligations of Market Makers.

Sec. 79. Commentary .08. No change.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B) and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

The Exchange proposes to amend the proposed Rule VI, section 87, to remove the exemption set forth in paragraph (c) that provides for a trading crowd's exemption from its "ten-up" obligation in the event a floor broker attempts to "split" the disseminated market quotes, to specifically state, in paragraph (e), that the enforcement of Section 87 is within the jurisdiction of the Options Floor Trading Committee ("OFTC"), and to require, in Commentary .04, that violations of Section 87 would be subject to formal disciplinary action, as opposed to disposition via floor citation.

The OFTC reconsidered the exemption with regard to a trading crowd's obligation in the event a floor broker attempts to split the market by announcing a bid or offer which betters the displayed market. The purpose of the exemption had been to preclude floor brokers from using the provisions of Section 87 as a leverage to obtain executions at better prices than those disseminated at the time an order is announced at the trading post. The OFTC determined that while this leverage activity should be discouraged, the exemption essentially provided that the "ten-up" requirement extend only to the market quotes caused to be disseminated by market makers, substantially limiting any benefit to public customers.

The Exchange proposes to amend Commentary .04 of section 87 to reflect that violations of Section 87, which would include the refusal by a market maker to accept an allocation of contracts by an Order Book Official pursuant to paragraph (d), and the failure of a floor broker to provide a "ten-up" execution as a result of his failure to remove a disseminated bid or offer for which he is responsible, would be subject to formal disciplinary action, as opposed to disposition via floor citation, pursuant to the Exchange's Minor Rule Plan. The Exchange believes that the formal disciplinary procedures as set forth in Rule XX would be more appropriate, due to the serious nature of these violations. The sanction amounts for these violations would be based on the premium value of the refused allocations or executions.

The Exchange believes that the proposed rule change will protect investors and promote the public interest by assuring a minimum ten contract execution of public customer orders at the displayed bid or offer.

The proposed rule changes are consistent with section 6(b)(5) of the 1934 Act, which provides, in pertinent part, that the rules of the Exchange be designated to promote just and equitable principles of trade and to protect the investing public.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of the publication of this notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding; or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposes rule change; or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file a six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by September 28, 1989.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: August 31, 1989.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 89-21003 Filed 9-6-89; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-27204; File No. SR-PSE-88-07]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by Pacific Stock Exchange, Inc. Relating to Arbitration Procedures and Filing Fees

I. Introduction

On June 3, 1988, the Pacific Stock Exchange, Inc. ("PSE" or "Exchange") submitted to the Securities and Exchange Commission ("Commission" or "SEC") pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b-4 thereunder,[2] a proposed rule change designed to simplify arbitration procedures for claims up to $10,000, to provide for three or five arbitrators in certain matters, to update the filing fees, and to increase the amount retained from the deposit where a matter is settled or withdrawn prior to the first arbitration session. Amendment No. 1, submitted by the PSE on August 25, 1989, makes additional changes to the Exchange's rules under the proposed rule change and the statements of purpose concerning the proposed rule change.

Notice of the proposed rule change was provided by the issuance of a Commission release (Securities Exchange Act Release No, 26832, May 18, 1989), and by publication in the Federal Register (53 FR 27254, July 19, 1988). The Commission received no comments on the proposed rule change.

II. Description of the Proposal

A Uniform Arbitration Code (the "Uniform Code") has been developed by the Securities Industry Conference on Arbitration ("SICA"), to establish a uniform system of arbitration procedures throughout the securities industry. The proposed rule changes are intended to conform certain provisions of PSE Rule XII of PSE with the Uniform Code. In general, the changes are intended to simplify arbitration procedures for claims up to $10,000, to provide for three or five arbitrators in certain matters, to update the filing fees, and to increase the amount retained from the deposit where a matter is settled or withdrawn prior to the first arbitration session.

Section 2(a) of PSE Rule XII currently provides that claims of less than $5,000 may be decided by a single arbitrator pursuant to expedited and simplified arbitration procedures. The proposed amendment would increase the limit on the size of claims for which the simplified arbitration procedures are available from $5,000 to $10,000, in order to increase substantially the number of cases processed under the expedited procedures. The proposal would also establish a filing fee of $200 in cases where the amount in controversy is more than $5,000 but does not exceed $10,000.

Section 2(d) PSE Rule XII currently provides that, in a simplified arbitration, if a counterclaim exceeding $5,000 is filed, the arbitrator may refer the claim, counterclaim, and/or third party claim, if any, to a panel of three or five arbitrators. The proposed amendment to section 2(d) would provide for an increased threshold of $10,000.

Section 8(a)(1) of PSE Rule XII currently provides that in all matters involving public customers where the claim does not exceed $500,000, or where the claim does not involve or disclose a monetary claim, the Director of Arbitration shall appoint a panel of no fewer than three nor more than five arbitrators.

Moreover, section 8(a)(2) currently provides that in all matters involving public customers where the claim is $500,000 or more, a panel of five arbitrators is required, unless the parties agree to have three arbitrators. In order to alleviate administrative delays and costs frequently encountered in such cases, an amendment would eliminate the requirement that the Director of Arbitration appoint five-member panels for large cases. The amended rule would allow the Director of Arbitration to exercise discretion in appointing panels of three or five arbitrators, as appropriate, in all cases not heard under the simplified arbitration procedures.

The proposed rule change amending section 31(a) of Rule XII would increase the deposit required for claims over $500,000 from $750 to $1,000. The proposed rule amendment to section 31(a) establishes a non-refundable filing fee of $500 imposed on all member firms for each arbitration Submission Agreement filed with PSE against a non-member. In the case of non-monetary claims, the proposed rule would amend section 31(c) to provide a maximum deposit of $1,000, rather than $750. The proposed rule change amending section 31(d) of Rule XII would provide that the administrative fee retained in an arbitration case which is settled or withdrawn prior to the first hearing session be increased from $25 to $100.

PSE has adopted the proposed rule change pursuant to section 6(b)(5) of the Securities Exchange Act of 1934, which requires that the PSE's rules be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and, in general, protect investors and the public interest. The fee increases represented by these changes are reasonable and provide for an equitable allocation of fees among SRO members and investors using the arbitration facilities consistent with section 6(b)(4) of the Act.

III. Discussion and Conclusion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of sections 6(b) (4) and (5) of the Act,[3] which require that national securities exchanges and registered securities associations have rules designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, provide for an equitable allocation of fees, and, in general, protect investors and the public interest. In accordance with the guidelines provided by SICA's recent revisions to the Uniform Code of Arbitration,[4] the Commission finds that the proposed amendments will streamline the Exchange's procedural rules governing arbitration, provide for more efficient arbitration proceedings involving smaller claims, and help defray the expenses associated with the Exchange's administration of the arbitration forum.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[5] that the above mentioned proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Dated: August 31, 1989.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 89-21004 Filed 9-6-89; 8:45 am]

BILLING CODE 8010-01-M

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[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] 15 U.S.C. 78f(b) (4) and (5).

[4] *See, e.g.*, Securities Exchange Act Release No. 26315 (November 28, 1988), 53 FR 48995 (December 5, 1988) (approval of SEC File No. SR-AMEX-88-17). *See also*, Securities Exchange Act Release No. 26605 (May 10, 1989), 54 FR 21144 (May 16, 1989) (approval of SEC Files No. SR-NYSE-88-08, SR-NYSE-88-29, SR-NASD-88-51, SR-NYSE-88-19, and SR-AMEX-88-29), and Securities Exchange Act Release No. 27093 (August 2, 1989), 54 FR 32713 (August 9, 1989) (accelerated approval of SEC File No. SR-CBOE-89-06).

[5] 15 U.S.C. 78s(b)(2) (1982).

[6] 17 CFR 200.30-3(a)(12) (1989).

[Release No. 34-27205; File No. SR-Phlx-89-17]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Crossing Agency Orders

I. Introduction

On March 27, 1989, the Philadelphia Stock Exchange, Inc. ("Exchange" or "Phlx") submitted to the Securities and Exchange Commission ("Commission" or "SEC"), pursuant to Section 19(b)(1) of the Securities and Exchange Act of 1934 ("Act") [1] and Rule 19b-4 thereunder,[2] a proposed rule change designed to clarify the rights and obligations of market participants in executing agency cross transactions. Amendment No. 1, submitted by the Exchange on July 31, 1989,[3] amends the operation of the proposed rule change as it applies to specialists and alternate specialists and addresses concerns raised by the proposal at it relates to customer priority rules.

Notice of the proposed rule change was provided by the issuance of a Commission release (Securities Exchange Act Release No. 26832, May 18, 1989), and by publication in the Federal Register (54 FR 22513, May 24, 1988). The Commission received no comments on the proposed rule change.

II. Description of the Proposal.

Rule 126 of the Rules of the Exchange's Board of Governors generally requires that when a member is holding an order to buy and an order to sell the same security, the member must offer the security at a price which is higher than his bid by the minimum variation permitted in the security before making a transaction with himself. The proposed rule change amends Phlx Rule 126 to codify a policy that, as a general matter, a specialist or alternate specialist may not interfere with the customer side of a cross by buying or selling for his own account at that price. For the limited purposes of Exchange Rule 126, the proposal would generally define a "customer order" as any order which a broker represents in an agency capacity, including any order of a market maker or other broker-dealer not affiliated with the executing broker or of any associated person of such broker-dealer is excluded from the rule's definition of "customer order".

The proposal would allow the participation of a specialist or alternate specialist in a cross transaction executed on the Exchange in certain specified circumstances. When a member organization has both a customer's order to buy and a customer's order to sell the same security at the same price, or when one member organization has a customer's order on one side and another member organization has a customer's order on the other side, the proposed rule change will allow a specialist or alternate specialist to participate in the cross by buying or selling for his own account at that price only to the extent that the specialist had previously made a bid or offer at the same price as the cross and that bid or offer had been publicly disseminated. Similarly, where a member organization has a customer's order on one side only and the member organization (or another member organization) is acting as principal on the other side, a specialist or alternate specialist may participate on the customer side of the trade by buying or selling securities for his own account only to the extent that the specialist or alternate specialist had entered a publicly disseminated bid or offer at that price. In addition, specialists and alternate specialists are not required to yield priority to the member organization on the principal side of such a cross. Finally, the Phlx states that the specialist or alternate specialist could participate in the cross on behalf of any customer orders to buy or sell at the cross price.

The rule also specifies that a specialist cannot seek to avoid the operation of the rule by placing an order in one of his specialty stocks with another member in order to have that order placed on the specialist's own book. A specialist would not, however, be prevented from entering orders in securities traded by an unaffiliated specialist unit.

The proposal clarifies that an agency cross is entitled to priority over a member's proprietary bids or offers. Where a specialist or alternate specialist has exposed himself to market risk by publicly disseminating a bid or offer at a specified price, however, he will be protected from yielding priority to an agency cross up to the size of his disseminated market. In addition, because the specialist or alternate specialist can participate in the cross on behalf of any customer orders to buy or sell at the cross price, the proposal ensures that customer orders entrusted to Phlx specialists will not be disadvantaged by priority being granted to agency crosses.

The Exchange contends that the proposed rule change addresses concerns raised by the existence of multiple exchange markets in a trading environment increasingly characterized by substantial block positioning in a manner consistent with auction market principles, and that the proposal strikes a balance between the competing needs of various groups of customers and between the varying interests of equity specialists, options market makers and floor brokers.

III. Discussion and Conclusion.

In response to concerns raised by Commission staff about how the proposed rule change could affect customer priority rules,[4] the Exchange emphasized that the proposed rule change does not operate in a manner inconsistent with traditional auction market concepts of customer priority embodied in Section 11(a) of the Act.[5] For purposes of the proposed rule change, the Exchange stated that the term "customer order" would not include any transactions circumscribed by Section 11(a) of the Act, as it does not extend to any order for the account of a broker-dealer affiliated with the executing broker, or any associated person of the broker-dealer.[6]

In recognition of the fact that most principal trading activity originating on the Exchange's equity floor, other than facilitation crosses, is undertaken by the specialist or alternate specialist acting in that capacity, the proposed rule change would impose limitations on specialists or alternate specialists seeking to trade in such capacity while one or more member organizations are seeking to effect cross transactions. The Exchange believes that the proposed rule change does not permit a transaction, or give parity, priority, or precedence to the order of a member, in a manner inconsistent with the operation of section 11(a)(1)(G) of the Act.[7] Moreover, consistent with section

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[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] *See* Letter from Richard T. Chase, Executive Vice-President, PHLX, to Howard Kramer, Assistant Director, Division of Market Regulation, SEC, dated July 28, 1989.

[4] *See* note 3, *supra*.

[5] 15 U.S.C. 78k(a)(1) (1989). *See also* Commission Rule 11a1-1(T)(a)(3), which provides that customer orders must be given priority over orders of an exchange member at the same price. 17 CFR 240.11a1-1(T)(a)(3) (1989).

[6] *See* letter from Richard T. Chase, *supra* note 3. The Commission notes that in order to comply with Section 11(a), the term "customer order" must not include any order for an account with respect to which a broker-dealer or an associated person of the borker-dealer exercises investment discretion.

[7] *Id.*

11(a)(1)(A) of the Act, to the extent a specialist or alternate specialist had made a publicly disseminated bid or offer at the cross price, the proposed rule change does not limit his or her ability to participate along with the customer side of the cross up the size of his or her disseminated market.

The Commission finds the proposed rule change to be consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds the proposed rule change to be consistent with the requiremetns of section 6(b)(5) [8] in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and protect investors and the public interest by assuring that agency cross transactions are executed in a fair and orderly auction market environment. In addition, the proposal is consistent with section 11A(a)(1)(C) (ii) and (iv) of the Act [9] because it should promote fair competition among brokers and dealers and the practicability of brokers executing investors' orders in the best market.

The Commission believes the proposed rule change strikes an appropriate balance between the competing needs of various customers' orders represented for execution on the Phlx and the proprietary trading operations of Exchange members and member organizations. The proposal clarifies that an agency cross is entitled to priority over a member's proprietary bids of offers, except where a specialist or alternate specialist had publicly disseminated a bid or offer at the cross price. The proposal will continue to afford price protection to customer limit orders entered on a specialist's book and prevent such orders from being disadvantaged by priority being granted to agency crosses. Orders on the book that coincide with the cross price will benefit by generally being assured of receiving an execution at the cross price. Finally, the proposed rule change does not limit the ability of customer orders to receive price improvement, since the proposed rule change covers only the proprietary trading activity of a member at the cross price, and therefore does not restrict the ability of a member to interfere with the execution of a cross at a better price.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[10] that the proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Dated: August 31, 1989.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 89-21005 Filed 9-6-89; 8:45 am]

BILLING CODE 8010-01-M

[8] 15 U.S.C. 78f(b)(5) (1982).

[9] 15 U.S.C. 78k-1(a)(1)(C) (ii) and (iv) (1982).

[10] 15 U.S.C. 78s(b)(2) (1982).

[11] 17 CFR 200.30-3(a)(12) (1989).

[Release No. 34-27203; File No. SR-PHLX-89-37]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Half Point Strike Prices

On June 26, 1989, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Act of 1934 ("Act") [1] and Rule 19b-4 thereunder,[2] a proposed rule change to provide for the addition of half point (.005) strike price intervals for the Deutsche Mark, Japanese Yen, and Swiss Franc currency options.

The proposed rule change was published for comment in Securities Exchange Act Release No. 27014 (July 10, 1989), 54 FR 30123 (July 18, 1989). No comments were received on the proposed rule change.

The PHLX proposes to adopt a pilot program, pursuant to Exchange Rule 1011(a)(ii), to provide for the addition of half point (.005) strike price intervals for the Deutsche Mark (CFM/XDM), Japanese Yen (CJY/XJY) and Swiss Franc (CSF/XSF) currency options. In order to minimize any potential operational burdens that may result from the proliferation of options series, the pilot program would be limited to no more than the first three expiration cycles and the nearest four half point strike price intervals to the currency spot market (*i.e.*, two above the two below spot).

The Exchange believes that the additional half point strike prices will enable investors in Deutsche Mark, Japanese Yen, and Swiss Franc options contracts to manage and hedge their currency risk more effectively. Moreover, the Exchange believes that establishing these additional options series in both American and European style foreign currency options will provide foreign currency options market participants with competitive alternative products to the other foreign currency markets, particularly the over-the-counter options market and the forward market.

The PHLX believes that the proposed rule changes is consistent with section 6(b) of the Act in that it is designed to facilitate the trading of the Deutsche Mark, Japanese Yen and Swiss Franc foreign currency options contracts. In addition, the PHLX believes the proposal promotes the protection of investors and the public interest.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6.[3] By introducing half point intervals, the proposal provides investors in a non-volatile currency with greater flexibility in managing their currency risk, thereby promoting the mechanism of a free and open market and protecting investors and the public interest. Moreover, to avoid the proliferation of options series, the PHLX will add half point strikes only for at-or near-the-money strikes and for no more than the first three expiration cycles. Finally, the strike price revision is similar to others the Commission has approved in options for other non-volatile currencies traded on the PHLX.[4]

It is therefore ordered, pursuant to section 19(B)(2) of the Act,[5] that the proposed rule change (SR-PHLX-89-37) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Dated: August 31, 1989.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 89-21006 Filed 9-6-89; 8:45 am]

BILLING CODE 8010-01-M

[1] 15 U.S.C. 78s(b)(12) (1984).

[2] 17 CFR 240.19b-4 (1988).

[3] 15 U.S.C. 78f (1984).

[4] *See* Securities Exchange Act Rel. No. 23986 (December 12, 1986), 51 FR 45979; Securities Exchange Act Rel. No. 24103 (February 13, 1987), 52 FR 5605 (February 25, 1987); and Securities Exchange Act Rel. No. 25685 (May 10, 1988), 53 FR 17524 (May 17, 1988).

[5] 15 U.S.C. 78s(b)(2) (1984).

[6] 17 CFR 200.30-3(a)(12) (1988).

[Rel. No. IC-17122; File No. 812-7300]

Golden American Life Insurance Co., et al.

August 31, 1989.

AGENCY: The Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: Golden American Life Insurance Company ("Golden American" or "Company"), Golden American Knox Funds Separate Account B of Golden American Life Insurance Company (the "Account"), and Directed Services, Inc. ("DSI").

RELEVANT 1940 ACT SECTIONS: Exemption requested under section 6(c) from sections 26(a)(2)(C) and 27(c)(2).

SUMMARY OF APPLICATION: Applicants seek an order to the extent necessary to permit the deduction of a mortality and expense risk charge from the assets of the Account under a deferred variable annuity contract (the "Deferred Annuity") and an immediate variable annuity certain contract (the "Annuity Certain") (collectively, the "Contracts") and to permit the deduction of a guaranteed death benefit charge from the accumulation value in the Account under the Deferred Annuity.

FILING DATE: The application was filed on April 18, 1989 and amended on August 4, 1989.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the requested exemption will be granted. Any interested person may request a hearing on this application, or ask to be notified if a hearing is ordered. Any request must be received by the SEC by 5:30 p.m., on September 25, 1989. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, in the case of an attorney-at-law, by certificate. Request notification of the date of hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, c/o Golden American Life Insurance Company, 909 Third Avenue, 19th Floor, New York, New York 10022.

FOR FURTHER INFORMATION CONTACT: Cindy J. Rose, Financial Analyst, at (202) 272-2058 or Clifford E. Kirsch, Acting Assistant Director, at (202) 272-2061.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicants' Representations

1. Golden American is a stock life insurance company organized under the laws of the State of Minnesota. From January 2, 1973 through December 31, 1987, the name of the company was St. Paul Life Insurance Company. On December 31, 1987, after all of St. Paul Life Insurance Company's business was sold, the name was changed to Golden American Life Insurance Company. The Account is a separate investment account of Golden American established to act as a funding vehicle of variable annuity contracts. The Account is registered with the Commission as a unit investment trust and a registration statement on Form N-4 has been filed with the Commission.

2. The Account is divided into divisions, each division investing in shares of a designated series of the Knox Funds (the "Fund"). The Fund is registered with the Commission as an open-end management investment company and has filed a registration statement on Form N-1A. The Fund is a series-type mutual fund that contains four series, each of which will pursue different investment objectives and policies.

3. Pursuant to a Distribution Agreement between Directed Services, Inc. (a wholly owned subsidiary of the Golden Financial Group, Inc.) and Golden American, DSI will solicit sales of the Contracts through registered representatives who are licensed to sell securities and variable insurance products including variable annuities. The registered representatives will be appointed by Golden American to sell the Company's Contracts. The offering of the Contracts will be continuous.

4. The Contracts provide for the accumulation of values on a variable basis except to the extent that a portion of the accumulation value is allocated to the Guaranteed Interest Division of the general account. Payment of annuity benefits will be on a fixed or variable basis. The variable aspects of the Contracts differ significantly from the fixed aspects in that the Contract owner and the Annuitant assume the risk of investment gain or loss under a Contract rather than Golden American. A Contract owner directs the allocation of premium payments and accumulation value to the Account.

5. The Deferred Annuity is an individual flexible premium payment contract which provides for an initial premium payment and for additional premium payments if the Contract owner so desires. There is, however, no obligation to make additional payments. In the Deferred Annuity, the Company guarantees a minimum death benefit payable to the beneficiary if the Contract owner or the Annuitant (when there is no Contingent Annuitant) dies prior to the annuity commencement date. The Company will pay the greater of: (1) The accumulation value or (2) the lesser of the guaranteed death benefit or the maximum guaranteed death benefit. The guaranteed death benefit is the accumulated value of the premiums paid adjusted at an annual interest rate of 5% minus the accumulated value of the partial withdrawals taken adjusted at an annual interest rate of 5%. The Company reserves the right to modify this interest rate structure to one which approximately yields equivalent results over the life of a contract. The maximum guaranteed death benefit is two times the sum of premiums paid minus two times the sum of partial withdrawals taken. The charge for the guaranteed death benefit will be no greater than $1.20 per $1,000 of guaranteed death benefit per contract year. In the future, the Account may offer other variable annuity contracts that may make a guaranteed death benefit charge of up to $1.20 per $1,000 of guaranteed death benefit per year. This charge is not an asset-based charge. Rather it is a contract charge imposed to compensate the Company for the risk that the minimum guaranteed death benefit due under a Deferred Annuity when the annuitant dies during the accumulation phase may exceed the normal death benefit otherwise payable. Expressed as an asset charge (assuming a hypothetical gross return of 5%), it would effectively increase the mortality and expense risk charge by approximately 0.10%. For higher hypothetical gross returns, this charge, when expressed as an asset charge, would be less; and for lower hypothetical gross returns, it would be more. In the Applicants' view, assessment of this risk charge in this manner will benefit Contract owners because it provides a better match of the charge and the risk than does assessing it as a daily percentage of assets charged against assets in each division of the Account.

6. The Annuity Certain is an immediate annuity which provides for a single premium payment and variable annuity payments to be paid to the Annuitant over a fixed period of time.

7. The Contracts provide for partial withdrawals. In the Deferred Annuity,

the cash surrender value may be applied at any time before the annuity commencement date to an income plan and, on the annuity commencement date, the accumulation value may be applied to an income plan. In the Annuity Certain, the cash surrender value may be applied to an income plan at any time during the certain period.

8. Sales loading at a maximum rate of 1.5% of each premium is deducted from each premium payment. This charge is allocated to cover distribution expenses. All sales loading applicable to initial, single or additional premium payments is deducted by Golden American at the time of payment.

9. The Contracts provide that a maximum mortality and expense risk charge equal to 0.002477% of the asset values in each division of the Account will be deducted on a daily basis (equivalent to an annual charge of 0.90%). In the Deferred Annuity, approximately 0.55% of the maximum charge is for assuming the mortality risk and 0.35% is for assuming the expense risk. In the Annuity Certain, approximately 0.45% of the maximum charge is for assuming the mortality risk and 0.45% is for assuming the expense risk. The mortality risk assumed by the Company arises from its obligations to continue to make annuity payments under the Contracts or income plan provisions of the Contracts, determined in accordance with the guaranteed annuity tables and other provisions of the Contracts, regardless of how long each annuitant lives and regardless of how long all payees as a group live. The particular mortality risk assumed by the Company under the Deferred Annuity is the risk that, after annuitization or upon selection of an annuity option with a life contingency, annuitants will live longer than the Company's actuarial projections indicated, resulting in higher than expected payments during the payout phase, since the payment options are guaranteed not to be less than the tables discussed in the Deferred Annuity. The particular mortality risk assumed by the Company under the Annuity Certain relates to the fact that, at all times, the Company will offer the option to convert the Annuity Certain, which does not provide for payments based on life contingencies, to one or more annuity contracts that provide for payments based on life contingencies. The mortality risk assumed by the Company is the risk that annuitants, or beneficiaries after the death of the annuitant, will choose one such option and will possibly live longer than the Company's actuarial projections indicate, resulting in higher than expected payments during the payout phase, since any payment option is guaranteed not to be less than the tables discussed in the Annuity Certain. In addition, the Company assumes a risk that the charges for the administrative expenses may not be adequate to cover such expenses. In the Deferred Annuity, Golden American also assumes a risk to pay out a guaranteed death benefit in excess of the accumulation value. Golden American is compensated for this risk by the guaranteed death benefit charge. The guaranteed death benefit charge is based on the amount of the guaranteed death benefit and is less than 0.10% of net assets (assuming a hypthetical gross return of 5%).

10. Applicants represent that they have reviewed publicly available information regarding the level of the mortality and expense risk and guaranteed death benefit charges under comparable variable annuity contracts currently being offered in the industry, taking into consideration such factors as current charge level or annuity rate guarantees and the markets in which the Contracts will be offered. Based upon the foregoing, Applicants represent that the maximum charges under the Contracts are within the range of industry practice for comparable contracts. Applicants will maintain and make available to the Commission, upon request, a memorandum outlining the methodology underlying this representation.

11. Applicants do not believe that the sales loading imposed under the Contracts will necessarily cover the expected costs of distributing the Contracts. Any "shortfall" will be made up from the general account assets which includes amount derived from risk charges. The Company has concluded that there is a reasonable likelihood that the distribution financing arrangement being used in connection with the Contracts will benefit the Account and the Contract owners. The Company will keep and make available to the Commission, upon request, a memorandum setting forth the basis for this representation.

12. Applicants further represent that the Account will only invest in underlying funds which have undertaken to have a board of directors/trustees, a majority of whom are not interested persons of such funds, formulate and approve any plan under Rule 12b–1 under the 1940 Act to finance distribution expenses.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 89–20997 Filed 9–7–89; 8:45am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Region I Advisory Council, Connecticut; Public Meeting

The U.S. Small Business Administration Region I Advisory Council, located in the geographical area of Hartford, will hold a public meeting at 8:00 a.m., on Monday, October 2, 1989, at the Days Inn, 900 East Main Street, Meriden, Connecticut, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration or others present.

For further information, write or call Henry A. Povinelli, District Director, U.S. Small Business Administration, 330 Main Street, Hartford, Connecticut 06106, phone (203) 240–4670.

Jean M. Nowak,

Director, Office of Advisory Councils.

August 28, 1989.

[FR Doc. 89–20930 Filed 9–6–89; 8:45 am]

BILLING CODE 8025–01–M

New York Advisory Council Meeting Region II; Public Meeting

The United States Small Business Administration Region II Advisory Council, located in the geographical area of New York City, will hold a public meeting on Wednesday, September 27, 1989, at 9:30 am in the Board Room of Pfizer, Inc., located at 235 East 42nd Street, New York City. To be discussed are such matters as may be presented by members, staff of the Small Business Administration or others present.

For further information, write or call Mr. Bert X. Haggerty, District Director New York, U.S. Small Business Administration, 26 Federal Plaza, Room 3100, New York NY 10278, telephone (212) 264–1318.

Jean M. Nowak,

Director, Office of Advisory Councils.

August 28, 1989

[FR Doc. 89–20931 Filed 9–6–89; 8:45 am]

BILLING CODE 8025–01–M

Region I Advisory Council, Vermont; Public Meeting

The U.S. Small Business Administration Region I Advisory Council, located in the geographical area of Montpelier, will hold a public meeting at 10:00 a.m., Thursday, September 21, 1989, at the Holiday Inn, Rutland, Vermont, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration or others present.

For further information, write or call Ora H. Paul, District Director, U.S. Small Business Administration, Federal Building, 87 State Street, P.O. Box 605, Montpelier, Vermont 05602, phone (802) 828–4422.

Jean M. Nowak,

Director, Office of Advisory Councils.

August 25, 1989

[FR Doc. 89–20932 Filed 9–6–89; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; San Benito County, California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this Notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project in San Benito County, California.

FOR FURTHER INFORMATION CONTACT: Mr. John R. Schultz, District Engineer, Federal Highway Administration, P.O. Box 1915, Sacramento, California 95812–1915. Telephone: (916) 551–1307.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the California Department of Transportation, San Benito County, and the City of Hollister, will prepare an Environmental Impact Statement (EIS) on a proposal to improve highway facilities on State Highway Route 156 in San Benito County. The 7-mile section of highway to be improved is comprised of contiguous segments of 2–lane, 4-lane, and 4-lane divided highway beginning in the vicinity of the Union/Mitchell Road/Route 156 intersection, west of Hollister, passing through downtown Hollister and terminating in the vicinity of the San Felipe Road/Route 156 intersection, north of Hollister. Some intersections in Hollister are now operating at or near capacity during peak hours. The highway carries both through and local traffic, including large trucks which add to the congestion (especially when they don't follow the signed truck route). A Route 156 bypass is proposed to allow through trucks, recreational vehicles and cars to go around, instead of through, downtown Hollister.

The alternates under consideration are the "no-build," "upgrade" the existing facility, and construct a "bypass" around the north and west sides of town. The no-build alternate is not considered viable at this time since traffic volume is now very heavy and will continue to increase. It is not considered practicable to widen the existing highway through town since this would require taking many residential and commercial buildings. Several bypass alternates are being considered. All start west of town near the Union/Mitchell Road/Route 156 intersection, and end either just south of the City Airport near the Flynn Road/Route 156 intersection, or north of the airport near the San Felipe Road/Route 156 intersection. The selected bypass alternate could be constructed as a 2-lane limited access highway, but sufficient right-of-way would be purchased to accommodate an ultimate 4-lane divided highway.

The project would be partially funded by a County sales tax measure, which would provide $6,250,000 toward the cost of constructing a Route 156 bypass around the City of Hollister.

Advertised public meetings and community advisory committee meetings have been held to discuss the project and obtain public input. More such meetings will be held prior to the formal public hearing planned for early 1990. These meetings, and the comments to be received from this Notice of Intent (and the Notice of Preparation), will constitute the scope process for this project.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address previously provided in this document.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning, and Construction. The regulations implementing Executive Order 12472 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: August 29, 1989.

Susan E. Klekar,

District Engineer, Sacramento, California.

[FR Doc. 89–20973 Filed 9–6–89; 8:45 am]

BILLING CODE 4910–22–M

National Motor Carrier Advisory Committee

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of public meetings.

SUMMARY: The FHWA announces that the National Motor Carrier Advisory Committee will hold a meeting on September 26, and 17, 1989, in Ann Arbor, Michigan. The meeting on September 26 will begin at 9:15 a.m. and will be held in Room 1443 of the Chrysler Engineering Center on Bonisteel Boulevard on the North Campus of the University of Michigan. On September 27 the meeting will reconvene at 9:00 a.m. at the Ann Arbor Marriott, 3600 Plymouth Road, Ann Arbor Michigan. The meeting on both days will be open to the public.

The agenda will include discussion of the National Transportation Policy, possible revisions to streamline the Federal Motor Carrier Safety Regulations, proposed changes to the definition of a "commercial motor vehicle" regarding the weight of such vehicles, proposed actions of the Commercial Motor Vehicle Safety Regulatory Review Panel regarding uniformity of State motor carrier safety requirements, alcohol testing of commercial motor vehicle operators, the biometric identification of commercial motor vehicle operators, and intelligent Vehicle/Highway Systems. Recommendations will also be presented from the Subcommittee on Safety. The Committee will also tour the University of Michigan's Transportation Research Institute (UMTRI).

In conjunction with the full committee meeting, the Subcommittee on Safety will meet on September 25, 1989, to discuss the issue referenced above regarding the definition of a "commercial motor vehicle" and the appropriate weight threshold for the Federal regulation of those vehicles and their operators. The meeting will also be held at the Ann Arbor Marriott and will begin at 1:30 p.m. This Subcommittee meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph S. Toole, Executive Director, National Motor Carrier Advisory Committee, Federal Highway Administration, HOA–1, Room 4218, 400 7th Street, SW., Washington, DC 20590, (202) 366–2238, office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

Dated: August 30, 1989.

Thomas D. Larson,

Federal Highway Administrator.

[FR Doc. 89-20927 Filed 9-6-89; 8:45 am]

BILLING CODE 4910-22-M

Maritime Administration

Approval of Applicant as Mortgagee; Bank of the West

Notice is hereby given that Bank of the West, having offices at 2 West Santa Clara Street, San Jose, California 95113, has been approved as Mortgagee pursuant to Public Law 100-710 and 46 CFR 221.43.

Dated: August 31, 1989.

By Order of the Maritime Administrator.

James S. Saari,

Secretary.

[FR Doc. 89-20996 Filed 9-6-89; 8:45 am]

BILLING CODE 4910-81-M

Sunshine Act Meetings

Federal Register
Vol. 54, No. 172
Thursday, September 7, 1989

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, September 11, 1989.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: September 1, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89–21109 Filed 9–1–89; 8:45 am]

BILLING CODE 6210–01–M

NUCLEAR REGULATORY COMMISSION

DATE: Monday, September 11, 1989.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Monday, September 11—Tentative

10:00 a.m.

Affirmation/Discussion and Vote (Public Meeting)

a. Amendments to 10 CFR Part 34: Safety Requirements for Industrial Radiographic Equipment
b. Motion by Joseph J. Macktal to Reconsider CLI–89–14 (Tentative)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for reaffirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (301) 492–0292

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 492–1661.

Dated: September 1, 1989.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 89–21195 Filed 9–5–89; 2:30 pm]

BILLING CODE 7590–01–M

Corrections

Federal Register
Vol. 54, No. 172
Thursday, September 7, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 Parts 52 and 81

[FRL-3627-7]

Approval and Promulgation of Implementation Plans; and Designation of Areas for Air Quality Purposes; State of Iowa

Correction

In rule document 89-18998 beginning on page 33536 in the issue of August 15, 1989, make the following corrections:

§ 52.827 [Corrected]

1. On page 33539, in § 52.827, in the table, footnote g should read "October 16, 1992."

2. On page 33541, in the first column, in the file line at the end of the document, "FR Doc. 89-18996" should read "FR Doc. 89-18998".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 12

Proposed Customs Regulation Amendment to the Definition of Switchblade Knives

Correction

In proposed rule document 89-19492 beginning on page 34186 in the issue of, Friday, August 18, 1989, make the following correction:

On page 34187, in the first column, in the 27th line, "not" should read "now".

BILLING CODE 1505-01-D

federal register

Thursday
September 7, 1989

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 410
Medicare; Catastrophic Outpatient Benefit; Proposed Rule

42 CFR Part 414
Medicare; Payment for Covered Outpatient Drugs; Proposed Rule

42 CFR Parts 400, 417, 485, and 489
Medicare; Conditions of Participation for Home Intravenous Drug Therapy Providers; Proposed Rule

Medicare; Outpatient Prescription Drugs; List of Covered Home IV Drugs; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

[BPD-613-P]

RIN 0938-AD91

Medicare Program; Catastrophic Outpatient Drug Benefit

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

ACTION: Proposed rule.

SUMMARY: These proposed regulations would implement, in part, section 202 of the Medicare Catastrophic Coverage Act of 1988 (MCCA), which establishes a new catastrophic drug benefit under Medicare Part B. The new benefit would be added to the drug coverage already available under Medicare, which would continue largely unchanged.

The MCCA provides for payment of a catastrophic level of beneficiary expenditures for "covered outpatient drugs". The payment aspect of this benefit will be implemented in separate regulations. The MCCA defines the items and services included as "covered outpatient drugs" to include coverage of outpatient prescription drugs on a much broader scope than is now available under Part B. These proposed regulations describe that new benefit.

These regulations also describe the bases that HCFA would use to implement the statutory requirement for establishing standards for the prescribing of each "covered outpatient drug". These standards would be used to identify inappropriate drug prescribing and dispensing and adverse drug reactions and to educate physicians and pharmacists about them. They would not be used to define coverage or payment of covered outpatient drugs.

The regulations also describe limits on the supply of a "covered outpatient drug" that Medicare would pay for, and reflect other related changes in Medicare created by MCCA.

DATE: To assure consideration, comments must be received at the appropriate address, as provided below, no later than 5:00 p.m. on November 6, 1989.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-613-P, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code BPD-613-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (Phone 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Walter Rutemueller, (301) 966-6849.

SUPPLEMENTARY INFORMATION: In this proposed rule, we explain in much detail, current Medicare coverage of drugs, as well as the expansion of drug coverage set forth in the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360, enacted on July 1, 1988). To assist readers in referencing sections contained in this proposed rule, we are providing a table of contents below:

Table of Contents

I. Background

The Medicare program was established by Congress in 1965 with the enactment of title XVIII of the Social Security Act (the Act). The program provides payment for certain medical services and supplies for persons 65 years of age or over, disabled beneficiaries, and persons with end-stage renal disease. The program currently covers approximately 26.8 million aged, 3 million disabled individuals, and 100,000 persons with end-stage renal disease.

Medicare consists essentially of two complementary insurance programs, the Hospital Insurance program (known as Part A) and the Supplementary Medical Insurance program (known as Part B). Although Part A is called Hospital Insurance, covered benefits also include services furnished in skilled nursing facilities (SNFs) or by home health agencies and hospices.

Part B covers a wide range of medical services and supplies such as those furnished by physicians or others in connection with physicians' services, outpatient hospital services, and outpatient physical and occupational therapy services. Physicians' services covered under Part B include visits to patients in the home, office, hospital, and other institutions. Part B also currently covers certain drugs and biologicals that cannot be self-administered, diagnostic x-ray and laboratory tests, and purchase or rental of durable medical equipment, ambulance services, prosthetic devices, and certain medical supplies.

The Medicare program was not designed to cover the total cost of providing medical care for its beneficiaries. Under current law, beneficiaries are liable for specified cost-sharing charges, in the form of deductibles and coinsurance amounts, and the cost of the first 3 pints of whole blood (unless replacement blood is furnished). Part B of Medicare pays for Part B services according to formulae established by statute; generally 80 percent of the reasonable charge is paid for physicians' services and other covered medical services (including drugs used in immunosuppressive therapy furnished within 1 year of a

covered organ transplant) after the beneficiary has met the $75 deductible. The beneficiary is then liable for the remaining amount of the charge for the services, which is usually 20 percent of the reasonable charge (known as coinsurance). In addition, if a physician does not accept assignment (that is, does not agree to accept Medicare's determination of the reasonable charge amount as payment in full for covered services), the beneficiary may be liable for the difference between Medicare's reasonable charge and the physician's actual charge, subject to certain limits on that charge.

II. Pre-existing Drug Benefit

The Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360, enacted on July 1, 1988) established a new catastrophic outpatient drug benefit under Part B. For purposes of coverage, payment, deductibles and coinsurance, the new Part B catastrophic outpatient drug benefit is distinct and separate from the current Medicare coverage of drugs that existed before the enactment of Public Law 100–360. The current Medicare drug benefit, to which we will refer in this preamble as the "pre-existing drug benefit", includes both Part A and Part B coverage. For the most part the pre-existing drug benefit has not been changed by Public Law 100–360. In this section of the preamble, we discuss both the Part A and Part B coverage requirements of the pre-existing drug benefit.

Pre-existing Medicare coverage of drugs is based on title XVIII of the Act; Medicare regulations at 42 CFR, Chapter IV; and the Medicare Carriers Manual (Part 3, Chapter II, section 2050.5).

A. General Statutory Provisions

• The Medicare statute, at section 1861(t)(1) of the Act, defines "drugs" and "biologicals", except for purposes of home health services, to include only those drugs and biologicals, respectively, as are included (or approved for inclusion)—

—In the U.S. Pharmacopoeia, the National Formulary, or the U.S. Homeopathic Pharmacopoeia;

—In New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein); or

—As approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of a hospital furnishing the drugs and biologicals for use in the hospital.

• In addition, in accordance with section 1862(c)(1) of the Act, payment may not be made under Part B for any expenses incurred for a drug product if all of the following conditions are met:

—The drug product—

+ Meets the requirements of section 107(c)(3) of the Drug Amendments of 1962, that is, generally stated, was approved by the Secretary as safe before October 10, 1962;

+ May be dispensed only upon prescription;

+ Is one for which the Secretary has issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug and Cosmetic Act (FFDCA) on a proposed order of the Secretary to withdraw approval of an application for the drug product under that section, because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling; and

+ Is one for which the Secretary has not determined that there is a compelling justification for its medical need.

—Any other drug product that is identical, related, or similar (as determined in accordance with 21 CFR 310.6(b)(1)) to a drug product described above and for which the Secretary has not determined that there is a compelling justification for its medical need.

B. Part A Statutory Provisions

Pre-existing Medicare Part A coverage of drugs and biologicals is provided for in section 1861 of the Act as follows:

• Drugs and biologicals used in the hospital that are ordinarily furnished by the hospital for the care and treatment of patients (paragraph (b)(2));

• Drugs and biologicals furnished for use in a SNF that ordinarily are furnished by the facility for the care and treatment of inpatients (paragraph (h)(5));

• Drugs and biologicals furnished to terminally ill individuals under a written plan as part of a hospice program (paragraph (dd)(1)(E)).

C. Part B Statutory Provisions

All Medicare Part B coverage of drugs is derived from the scope of benefits provided for in section 1832 of the Act. Section 1861 of the Act defines the coverage provisions specified in section 1832 of the Act.

Pre-existing Medicare Part B coverage of outpatient drugs and biologicals is provided for in section 1861 of the Act, as follows:

• Drugs and biologicals that cannot be self-administered and that are furnished as incident to a physician's service (subsections (s)(2) (A) and (B));

• Diagnostic services furnished by a hospital to outpatients, including drugs and biologicals required in the performance of these services (subsection (s)(2)(C));

• Dialysis supplies, including drugs and biologicals (subsection (s)(2)(F));

• Antigens that are prepared by a physician for a particular patient and that are administered by or under the supervision of a physician (subsection (s)(2)(G));

• Blood clotting factors, for hemophilia patients competent to use those factors to control bleeding without medical or other supervision (subsection (s)(2)(I));

• Immunosuppressive drugs and drugs that are needed for effective immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under Medicare, and that are furnished within 1 year after the date of the transplant procedure (subsection (s)(2)(J), as it was in effect before the enactment of Pub. L. 100–360).

• Supplies that are incident to a physician assistant's services furnished under the supervision of a physician, including drugs and biologicals (subsection (s)(2)(K)(ii));

• Pneumococcal, influenza, and hepatitis B vaccines (subsection (s)(10));

• Drugs and biologicals that cannot be self-administered and that are furnished to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility (subsection (cc)(1)(F));

• Drugs and biologicals furnished as part of or incident to the provision of covered rural health clinic services (subsection (aa)(1)), partial hospitalization services (subsection (ff)(2)(D)), certified nurse-midwife services (subsection (gg)(1)), and qualified psychologist services (subsection (ii)).

Drugs and biologicals also are covered as part of or incident to services furnished in qualified ambulatory surgical centers as provided in section 1832(a)(2)(F)(i) of the Act.

Public Law 100–360 expanded Medicare coverage of prescription outpatient drugs and biologicals by creating a new drug benefit. Pre-existing coverage, as discussed above, will continue unchanged except for drugs used in immunosuppressive therapy. As discussed below, coverage for these drugs would be expanded under the provisions of Public Law 100–360 and would be included as part of the new catastrophic drug benefit.

D. Instructions

The Medicare Carriers Manual (HCFA Pub. 14–3) (Part 3, Chapter II, § 2050.5) provides instructions on the pre-existing Part B coverage of drugs and biologicals specified in the statute and in regulations (42 CFR 410.10 and 410.26 through 410.29).

• The drugs and biologicals that Medicare covers meet the definition of "drugs" or "biologicals" in section 1861(t)(1) of the Act and are not unfavorably evaluated in either the American Medical Association's Drug Evaluations or Accepted Dental Therapeutics. If a drug is excluded from coverage because it is unfavorably evaluated in either of these compendia, the exclusion applies only to those uses for which the drug or biological was so unfavorably evaluated.

• The drugs and biologicals are not covered if they are excluded as immunizations (section 1862(a)(7) of the Act). As stated in section 2050(c) of the Medicare Carriers Manual, vaccinations or inoculations are excluded as "immunizations" unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globlin. We note that coverage of the following vaccines has been specifically provided for by Congress.

—Pneumococcal vaccinations.

With the enactment of the Social Security Act Amendments of 1980 (section 1 of Pub. L. 96–611) on December 28, 1980, Part B pays 100 percent of the reasonable charges for pneumococcal vaccine and its administration to a patient if it is ordered by a physician who is a doctor of medicine or osteopathy (section 1861(s)(10) of the Act).

—Hepatitis B vaccine.

With the enactment of the Deficit Reduction Act of 1984 (section 2323 of Pub. L. 98–369), coverage under Part B was extended to hepatitis B vaccine and its administration furnished to a Medicare beneficiary who is at high or intermediate risk of contracting Hepatitis B (section 1861(s)(10) of the Act).

—Influenza vaccine.

The Omnibus Budget Reconciliation Act of 1987 (section 4071 of Pub. L. 100–203) provides for the coverage of influenza vaccine and its administration by either November 1, 1990 or April 1, 1993 contingent upon the Secretary demonstrating that the use of influenza vaccine is cost-effective.

• The drugs and biologicals are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (section 1862(a)(1)(A) of the Act). In making national coverage decisions, HCFA interprets the terms "reasonable" and "necessary" contained in section 1862(a)(1)(A) of the Act to mean that a service is safe, effective, non-investigational, and appropriate as evidenced by available scientific and medical information. We published a proposed rule on January 30, 1989 (54 FR 4302) that would establish in regulations generally applicable criteria and procedures for determining whether a service is "reasonable" and "necessary" under the Medicare program, and to set forth the coverage decisionmaking process that we propose to include in regulations. The January 30, 1989 rule proposes to include cost-effectiveness considerations in addition to the other criteria we currently use when determining whether a service is reasonable and necessary. However, we note that not all of the criteria announced in the January 30, 1989 rule would apply to the Medicare catastrophic drug benefit. Public Law 100–360 added section 1834(c)(5)(C)(ii) to the Act, which prohibits the denial of coverage of or payment for any specific use of a covered outpatient drug for a specific indication except for those instances in which the Secretary determines under section 1862(a)(1) of the Act that use of the drug for that indication is not safe or not effective. (Accordingly, as discussed in greater detail below, except for exclusions based on section 1861(t)(4)(A) of the Act, which pertains to the definition of "covered home IV drugs", or section 1862(c)(2) of the Act, which pertains to prescriptions in excess of a 30-day supply, we would use only considerations concerning safety and effectiveness to make decisions to exclude from coverage or to deny payment for a specific covered outpatient drug or class of drugs under the Medicare catastrophic drug benefit.)

Under the current program, we have determined as a matter of national policy that drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are generally considered safe and effective for purposes of meeting the reasonable and necessary criteria when used for indications specified in their labeling (section 2050.5(D) of the Medicare Carriers Manual). In addition, except for drugs used in immunosuppressive therapy, FDA-approved drugs also may be covered when used for indications other than those specified on their labeling unless such use is contraindicated on the drugs' labels or is specifically not covered by HCFA.

• Drugs that are considered by the FDA to be experimental or investigational are not covered except for certain cancer drugs distributed by the National Cancer Institute (NCI).

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment within NCI, distributes certain drugs for use in terminally ill cancer patients. One group of these drugs, designated by FDA and NCI as Group C drugs, unlike other drugs distributed by the NCI, is not limited to use in clinical trials for the purpose of testing their efficacy. In view of NCI controls on their distribution and use, Group C drugs are covered by Medicare under current rules if all other applicable coverage requirements are met.

• In accordance with section 1861(s)(2)(J) of the Act, as added by section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), we covered, effective January 1, 1987, immunosuppressive drugs furnished to an individual who receives a Medicare covered organ transplant, for a period of up to 1 year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed. Section 4075 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) amended section 1861(s)(2)(J) of the Act to expand Medicare coverage to include prescription drugs used in immunosuppressive therapy. We have restricted coverage of drugs used in immunosuppressive therapy to those specifically labelled by the FDA as immunosuppressive drugs and to those whose approved labels indicate they are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen. We restricted coverage of these drugs to labelled indications to ensure that we did not allow coverage of these drugs beyond the scope of section 1861(s)(2)(J) of the Act, which before the enactment of Public Law 100–360 specifically authorized payment only for prescription drugs used in immunosuppressive therapy. Coverage of non-labeled uses for other drugs is ordinarily determined by our contractors taking into consideration the generally accepted medical practice in the community. The statutory changes mentioned above specified that the 1-year period during these drugs could be covered would begin with the date of a transplant. We issued manual instructions to our Medicare contractors

in April 1987 (Carriers Manual, section 2050.5, paragraph G). We interpreted the statutory phrase, "within one year after the date of the transplant procedure," to mean 365 days from the day on which the inpatient is discharged from the hospital. We believe the term "transplant procedure" can be interpreted to mean something broader than just the surgery itself, and for the reasons set forth below, we consider the procedure to end at the date of discharge. If the date of surgery was used instead of the date of discharge, the immunosuppressive drug benefit would vary from one Medicare beneficiary to another, depending upon the beneficiary's post-operative recovery period while an inpatient. For example, if one patient's hospital stay was 30 days longer than another patient's stay, one of the patients would receive less coverage under Part B. Further, the conference report accompanying Public Law 99–509 (H.R. Rept. 99–1012, page 337) indicates that Congress was aware that immunosuppressive drugs are already covered while a beneficiary is in the hospital.

Nonetheless, Congress added this coverage by amending section 1861(s)(2) of the Act, which is a listing of "medical and other health services" covered under Part B. By amending this section, Congress made immunosuppressive drugs a specific Part B benefit, which extends explicitly for 1 year. Since inpatient immunosuppressive drugs are covered already under Part A, and since the date of discharge is later than the date of surgery, to use the actual transplant date would require us to either shorten the coverage under Part B to less than 1 year or pay for inpatient hospital services with Part B funds. The former is inconsistent with Congressional intent. If we were to furnish Part B benefits beginning at the time of surgery, we would have to adjust the diagnosis related group weights to exclude the costs of post-operative immunosuppressive drugs. This would be cumbersome. Further, it is administratively more difficult for a carrier to determine the date of surgery rather than the date of discharge.

III. FDA Responsibilities and Categories of Prescription Drugs Resulting From Amendments to the Federal Food, Drug and Cosmetic Act

For purposes of discussing later in this preamble the expanded coverage of drugs mandated by Congress, we are providing a summary of the responsibilities of the FDA in approving drugs and licensing biologicals for marketing and of the statute that controls FDA approval of drugs and biologicals for marketing.

FDA protects the public health of the nation by regulating foods, drugs, biological products, cosmetics, medical devices, radiological products, poisons, pesticides, and food additives. FDA's regulatory functions are to assure that: foods are safe, pure, and wholesome; drugs, medical devices, and biological products are safe and effective; cosmetics are harmless; all of the above are honestly and informatively packaged, and that exposure to potentially injurious radiation is minimized. The role of FDA is critical to the Medicare coverage process since, as discussed earlier, FDA approval of drugs and devices precedes Medicare coverage in most cases.

The FDA's current role as it relates to approval of drugs is controlled by the Federal Food, Drug and Cosmetic Act of 1938 (FFDCA) (Pub. L. 75–717, 21 U.S.C. 301, et seq.). Before enactment of the FFDCA, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The FFDCA first established the requirement that a manufacturer has to prove the safety of a drug before it could market it in the United States. In accordance with the FFDCA, drugs marketed before passage of the 1938 Act were "grandfathered" so that manufacturers, if they did not change the representations on the drugs' labels, were allowed to continue to market them unless evidence was developed to indicate that they were not safe. However, once a manufacturer changed the representation on a drug's label, that drug was considered a "new drug" and the manufacturer was required to prove that the drug was safe for its intended use.

In 1962, the FFDCA was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the Drug Amendments of 1962 (Pub. L. 87–781, enacted on October 10, 1962), all new drugs must be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962. These drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established to review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program. The pre-1962 drugs that are subject to review under this program are referred to as the "DESI" drugs. If the FDA decides that a DESI drug lacks substantial evidence of effectiveness for the condition(s) it is intended to treat, it publishes a notice of opportunity for a hearing in the Federal Register concerning its proposal to withdraw approval for marketing. This process afforded the manufacturer an opportunity for a hearing before a final determination is made. Drugs for which a notice of opportunity for hearing has been issued but the hearing has not been completed are considered by the FDA to be less than effective.

Biologicals were first required to be licensed under the Biologics Control Act of 1902, which was recodified in 1944 as section 351 of the Public Health Service Act (PHS Act, 42 U.S.C. 262). To be licensed under section 351 of the PHS Act, a biological must be shown to be safe, pure, and potent. The majority of biological products also meet the drug definitions in the FFDCA subject to the drug adulteration, misbranding, and registration provisions of the FFDCA.

When the Bureau of Biologics (currently the Center for Biologics Evaluation and Research) became a part of FDA in 1972, biologicals licensed before July 1972 were reviewed for efficacy by expert advisory review panels. Similar to the DESI program described above, manufacturers of biologicals with inadequate evidence of effectiveness are offered an opportunity for a hearing on proposals to revoke product licenses.

When a manufacturer submits an application for the approval of a new drug, it indicates on the application the proposed uses for the drug. The FDA requires the manufacturer to submit clinical data and scientific information to prove the safety and effectiveness of the drug for these proposed uses. The FDA requires the manufacturer to submit clinical data and scientific information to prove the safety and effectiveness of the drug for these proposed uses and determines for which of the proposed uses the manufacturer has proven that the drug is safe and effective. If a drug is approved, it may be labeled, promoted, and advertised by the manufacturer only for those specific proposed uses of the drug that have been approved by the FDA as safe and effective. The labeling includes a description of the drug, its action, clinical pharmacology, and indications and usage for the drug. In addition, sections with the headings, contraindications, warnings, precautions, and adverse reactions are included when applicable. All labels conclude with sections on dosage and administration and how the drug is supplied.

After a drug is approved, additional medical and scientific information may be developed by the medical community that indicates there are other appropriate uses for the drug besides those specified on a drug's label. As previously stated, we may cover FDA-approved drugs for uses other than those specified on their labeling if the available medical and scientific information indicates that additional uses are appropriate and accepted in the medical community, unless the uses are contraindicated on a drug's label.

IV. The Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360, enacted on July 1, 1988) made a number of significant changes to the Medicare program. Generally, the statute provides for—

- Expanded hosptial, SNF, and hospice care coverage under part A of the program beginning January 1, 1989;
- A cap on the amount a beneficiary must spend on specified services under part B before Medicare will assume the full part B payment beginning January 1, 1990;
- Coverage of screening mammography and in-home respite care benefits, and improved home health benefits beginning January 1, 1990; and
- Coverage of drugs used in immunosuppressive therapy without regard to the duration of that therapy or whether the organ transplant procedure was covered by Medicare and home intravenous (IV) therapy services beginning January 1, 1990, and for coverage of other outpatient prescription drugs, biologicals, and insulin beginning on January 1, 1991.

Specifically, section 202 of Public Law 100–360 amended the Act to include "covered outpatient drugs" as part of the "medical and other health services" benefit under sections 1832 (a)(1) and (a)(2)(B) of the Act. Pre-existing coverage of drugs, as described in section II of this preamble, would continue unchanged except for drugs used in immunosuppressive therapy. As discussed below, coverage for these drugs would be expanded and extended under the provisions of Public Law 100–360, and these drugs would be included as part of the new catastrophic drug benefit. A discussion of the specific provisions of section 202 of Public Law 100–360 that this proposed rule would implement follows.

A. Definition of Covered Outpatient Drugs

Section 202(a) of Public Law 100–360 amended sections 1861(s)(2)(J) and added section 1861(t)(2) of the Act. As revised, section 1861(s)(2)(J) provides coverage of "covered outpatient drugs", which is primarily defined in section 1861(t)(2). Section 1861(t)(2) defines the term to include a broad range of drugs, biological products, and insulin.

1. Drugs

A drug is covered if it may be dispensed only upon prescription and meets one of the following requirements:

a. The drug is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the FFDCA, or approved under section 505(j) of the FFDCA.

b. The drug was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 (October 10, 1962) or it is identical, similar or related to such a drug, as defined by 21 CFR 310.6(b)(1). Nevertheless, these drugs will not be covered if the Secretary has made a final determination that they are "new drugs" and have not been approved under sections 505 or 507 of the FFDCA, or if they are subject to certain actions brought by the Secretary to enforce provisions of section 502(f) or 505(a) of the FFDCA (21 U.S.C. 352(f), or 355(a)).

c. The drug is described in section 107(c)(3) of the Drug Amendments of 1962 and is one for which the Secretary has determined there is compelling justification for its medical need, or it is identical, similar, or related to such a drug. Also, the drug must be one for which the Secretary has not issued a notice to withdraw approval for marketing, because the Secretary has determined that the drug is less than effective for all conditions of use represented, recommended, or suggested on its labeling. These are the "DESI" drugs. (We note that the conference report that accompanied Public Law 100–360 indicates, apparently in error, that the only DESI drug that would be covered under Medicare because a notice for an opportunity for hearing has not been issued, is nitroglycerin patches (H.R. Rep. No. 100–661, 100th Congress, 2d Session 185–186 (1988)).

2. Biological Products

A biological product is considered a "covered outpatient drug" if it is one that may be dispensed only upon prescription, is licensed under section 351 of the PHS Act (42 U.S.C. 262), and is produced at an establishment licensed under that Act to produce that product.

3. Insulin

Insulin is covered if it is certified under section 506 of the FFDCA (21 U.S.C. 356) for the strength, quality, and purity necessary to ensure adequate safety and efficacy of use. In accordance with section 1861(t)(2)(C) of the Act, insulin would be considered a "covered outpatient drug" whether or not it is dispensed under a prescription.

B. Covered Home IV Drugs

Section 202(a)(2)(C) of Public Law 100–360 added sections 1861(t)(4) (A) and (B) to the Act to specify the following:

- "Covered home IV drugs" are defined as covered outpatient drugs that are dispensed to an individual and intravenously administered to an individual in a place of residence used as the individual's home, and that are—

—Antibiotic drugs unless the Secretary has determined, for a specific drug or for the indication for which it is applied, that the drug cannot generally be administered safely and effectively in a home setting; or

—Drugs that are not antibiotics, but only if the Secretary has determined for a specific drug and the indications for which the drug is being applied that it can generally be administered safely and effectively in a home setting.

- By January 1, 1990 and periodically thereafter, the Secretary is required to publish a list of covered home IV drugs, and indications for the drugs, with respect to which home IV drug therapy may be furnished under Medicare.

C. Drugs Excluded From Catastrophic Coverage

In enacting the expanded drug coverage under Public Law 100–360, Congress specified in section 202(a)(2)(C) several restrictions on which drugs can be included under the new benefit. Thus, section 1861(t)(3)(A) of the Act excludes from the new benefit certain drugs, biologicals, or insulin that were covered by Medicare before the enactment of Public Law 100–360 from the definition of "covered outpatient drugs". Coverage for any drug, biological, or insulin furnished as one of the following benefits or, as part of, or as incident to, any of the following benefits, for which payment may be made under Medicare, would continue but would not be included as part of this new catastrophic drug benefit. These items would not be subject to the same coverage standards and coinsurance and deductible requirements that apply to drugs covered as part of the catastrophic drug benefit.

- Inpatient hospital services (section 1861(b)(2)).
- Extended care services (section 1861(h)(5)).

- Physicians' services (section 1861(s)(2) (A) or (B)).
- Dialysis supplies (section 1861(s)(2)(F)).
- Antigens (section 1861(s)(2)(G)).
- Blood clotting factors for hemophiliacs (section 1861(s)(2)(I)).
- Services of a physician assistant (section 1861(s)(2)(K)(ii)).
- Pneumococcal, hepatitis B, or influenza vaccines (section 1861(s)(10)).
- Rural health clinic services (section 1861(aa)(1)).
- Comprehensive outpatient rehabilitation facility services (section 1861(cc)(1)(F)).
- Hospice care (section 1861(dd)(1)(E)).
- Certified nurse-midwife services (section 1861(gg)(1)).
- A covered surgical procedure in an ambulatory surgical center (section 1832(a)(2)(F)(i)).

The purpose of section 1861(t)(3)(A) of the Act is to preserve and keep separate from the catastrophic drug benefit the coverage of drugs authorized by the benefits listed above. The coverage of drugs authorized by these benefits would remain unchanged and would not be duplicated or replaced by the catastrophic drug benefit. For example, section 1861(t)(3) of the Act specifies, in part, that the term "covered outpatient drug" does not include any drug, biological, or insulin furnished as, as part of, or as incident to extended care services if payment for these drugs or biologicals may be included under Medicare. The term "extended care services" is defined at section 1861(h)(5) of the Act as including drugs and biologicals that may be ordinarily furnished by SNFs for the care and treatment of inpatients.

Therefore, drugs and biologicals furnished to beneficiaries who qualify for Part A covered inpatient care in a participating SNF would be excluded from the covered outpatient drug benefit since payment could be made for these drugs and biologicals as part of the extended care services benefit under section 1861(h)(5) of the Act. However, in those instances where Part A coverage is exhausted, or not available to a particular beneficiary who is eligible for Part B only, the catastrophic Part B drug benefit would apply. Therefore, except for drugs already included under a pre-existing Part B benefit (such as antigens) and covered home IV drugs, drugs furnished in a hospital or a SNF to a beneficiary who is not eligible for Medicare Part A services could be covered as part of the new catastrophic drug benefit. This individual could either be a beneficiary who is eligible for Part B only or one who has exhausted his or her Part A benefit. Consistent with this policy, drugs furnished to residents of a long term care facility would be eligible for payment under the catastrophic drug benefit if the nursing home stays does not qualify for Part A payment for inpatient services and the drugs are not otherwise payable under a pre-existing Part B benefit.

D. Phase-in of Coverage

While section 202(m)(1) of Public Law 100–360 specifies that the amendments made by section 202 shall apply to items dispensed on or after January 1, 1990, the provisions of section 1861(t)(3)(B) of the Act (as added by section 202(a)(2)(C) of Pub. L. 100–360) limit covered outpatient drugs dispensed in 1990 to the following drugs:

1. Immunosuppressive Drugs

Effective January 1, 1987, immunosuppressive drugs were covered if furnished within 1 year after the beneficiary's date of discharge from an inpatient hospital stay during which a covered organ transplant was performed (section 1861(s)(2)(J) of the Act, as in effect before the enactment of Pub. L. 100–360). (Medicare currently covers heart, kidney, and bone marrow transplants. Liver transplants in limited circumstances for children under age 18 are also covered.) The coverage of immunosuppressive drugs was expanded by section 4075 of Public Law 100–203, effective December 22, 1987, to include prescription drugs used in immunosuppressive therapy. Section 202(a) of Public Law 100–360, effective January 1, 1990, extends the coverage of drugs used in immunosuppressive therapy to include those drugs furnished in subsequent years after the first year following a covered transplant and those following a noncovered transplant irrespective of any prescribed time limitations.

2. Covered Home IV Drugs as Defined in Section 1861(t)(4) of the Act

Accordingly, in 1990, the new drug benefit would only include drugs used in immunosuppressive therapy and covered home IV drugs. It would not include all covered outpatient drugs described in section 1861(t)(2) of the Act until January 1, 1991.

E. Ensuring Appropriate Prescribing and Dispensing Practices

Section 202(b)(4) of Public Law 100–360 added section 1834(c)(5) to the Act, which requires the Secretary—

- To establish a program to identify (and educate physicians and pharmacists concerning)—
  - —Instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered outpatient drugs,
  - —Instances or patterns of substandard care with respect to covered outpatient drugs, and
  - —Potential adverse reactions with respect to covered outpatient drugs.
- To establish standards for the prescribing of each covered outpatient drug for purposes of the program identified above. The standards must be based on accepted medical practice. In establishing these standards, we must incorporate standards from authoritative compendia we select; however, we may modify a standard through rulemaking on the basis of scientific and medical information that the standard is not consistent with the safe and effective use of a drug. Congress intended that we rely only on those compendia that base their standards on a review of published scientific and medical information and that employ a review process that allows public comment. The compendia should also provide adequate assurances that the panelists who establish the standards are free of financial (or other) conflicts of interest (H. R. Rept. No. 100–661, 100th Congress, 2d Session 192 (1988)).
- To provide for the coverage and payment of every specific covered outpatient drug, and specific class of covered outpatient drugs. However, the Secretary may exclude a specific use of a covered outpatient drug for a specific indication if he has found under section 1862(a)(1) of the Act that the use is not safe or effective. Also, the Secretary may exclude from coverage or payment certain drugs under section 1862(c)(2) of the Act (which relates to prescriptions in excess of a 30-day supply, unless a greater supply is authorized by the Secretary) or section 1861(t)(4)(A) of the Act (which relates to the definition of covered home IV drugs).

F. Limitations on the Length of Prescriptions

Section 202(d) of Public Law 100–360 added a new section 1862(c)(2) to the Act to prohibit payment under Part B for any expense incurred for a covered outpatient drug if the drug is dispensed in a quantity exceeding a 30-day supply or a longer period of time as the Secretary may authorize. Under this provision of the law, we may authorize payment for more than a 30-day supply, but not for more than a 90-day supply except in exceptional circumstances as determined by the Secretary. This

extended supply policy may apply to specific drugs or classes of drugs.

G. Study and Report on Experimental Drugs

Finally, we note that in accordance with section 202(k)(1)(A) of Public Law 100–360, we are required to conduct a study and submit a report to Congress by January 1, 1990, on the possibility of covering certain experimental drugs and biologicals (for example, those used in the treatment of cancer or in immunosuppressive therapy) as covered outpatient drugs under the Medicare program. We received public comments on the issue of Medicare coverage of experimental or investigational drugs under the pre-existing drug benefit when we published a proposed rule on January 30, 1989 (54 FR 4302), pertaining to making Medicare coverage decisions. We are currently considering those comments and we will respond to them in the rule that finalizes our policies on Medicare coverage decisions.

V. Provisions of this Proposed Rule

To implement the provisions of section 202 of Public Law 100–360 described above, we are proposing in this rule to amend 42 CFR part 410, Subpart B as discussed below.

- We would add a new § 410.29 to expand coverage under Medicare Part B to include catastrophic expenses for covered outpatient drugs. We would use the statutory language to define "covered outpatient drugs". The definition would indicate that, except for insulin, "covered outpatient drugs" would be limited to those drugs and biologicals that may be dispensed only upon prescription. Therefore, except for insulin, drugs that can be purchased without a prescription, even if they are prescribed, would not be included in the definition of "covered outpatient drugs".

We would define the term "covered home IV drug" to mean a covered outpatient drug that is furnished by a qualified home IV drug therapy provider to an individual and that is intravenously administered in a place of residence used as that individual's home. The definition would include the requirement that a home IV drug, to be covered and reimbursed, must be furnished directly or under arrangements by a qualified home IV drug therapy provider. The statute at 1861(jj)(3)(i) of the Act requires, in part, that a qualified home IV drug therapy provider be capable of furnishing or arranging for covered home IV drugs. We believe that it is implicit in the statute that Congress intended that covered home IV drugs be furnished only by these providers. This requirement is consistent with the standards that Congress established in section 1861(jj) of the Act to ensure that covered home IV drugs are furnished as part of a safely and effectively administered home IV therapy benefit. We believe we would be undermining the intent of this section of the statute, if we did not require that covered home IV drugs be furnished directly or under arrangements by a home IV drug therapy provider that we have determined, in accordance with section 1861(jj) of the Act, is capable of furnishing or arranging for the services needed to conduct safely and effectively an IV drug therapy program.

There are many hazards associated with furnishing home IV drug therapy. The furnishing of home IV drugs may result in complications that could cause permanent damage or threaten the life of the patient. A patient could be afflicted with a possibly life-threatening condition such as anaphalaxis (severe allergic reaction), IV infiltration (accumulation of the IV drug in tissue surrounding the vein), or site infection, as a result of receiving home IV drug therapy. Also, these drugs may cause one or more other serious side effects such as diarrhea, fever, nephrotoxicity (destructive effect to kidney cells), coagulapathy (blood clotting disorder), and phlebitis (inflammation of the vein). Thus, while receiving home IV drug therapy, the patient must be carefully monitored to discern the presence of signs or symptoms of impending problems.

All home IV drug therapies involve the separate functions of mixing and administering potentially dangerous drugs. The preparation of IV drugs for administration is a specialty that has evolved over the years as the profession of pharmacy has expanded. It is a subspecialty of hospital pharmacy, and requires special training and education.

All IV drugs require special conditions for their preparation, including asceptic work areas, specific lighting requirements, and special equipment such as laminar flow hoods, pumps, tubing, needles, and syringes. Individual drug labels have specific requirements dealing with all aspects of preparation and storage before administration. These requirements include cautions concerning special needles and syringes necessary for reconstitution, inspection for particulate matter after reconstitution, temperature ranges at which the reconstituted drugs must be stored, as well as a whole range of other precautions. Because of the cost factors involved, as well as the specialization necessary on the part of the pharmacist to prepare these drugs, the local chain or community pharmacist could not be expected to have the expertise, equipment, or work area necessary to prepare these drugs in a manner to ensure their sterility and stability, a factor that is necessary to guarantee their safety for use in the home.

Additional complications associated with home IV drug therapy result from factors related to the patients, such as disease progression, combinations of disease processes and their therapies, and the aging process in general. Often, Medicare beneficiaries have several concurrent medical problems, and they are often in need of long-term, interrelated therapies. Frequently, these beneficiaries may lack visual acuity and manual dexterity. Psychoses or neuroses of patients can present additional problems for safe and effective home IV drug therapy. Also, patient safety might be affected by noncompliance with the drug therapy regimen, poor living conditions, or high stress levels of both a patient and the spouse or other caregiver, or a combination of these factors. Therefore, to prevent morbidity and mortality, and to achieve the desired therapeutic effect, it is critical that the provider be skilled in carefully screening and evaluating patients initially, and on a continuing basis.

Some home IV drugs have the potential to be toxic and to cause lethal consequences even when administered in the proper dosages. This potential exists because some drugs have undesired side effects on certain organs or body systems and a particular patient's organs or body systems may already be compromised by aging or specific disease processes. For example, antibiotics have the potential to cause anaphylaxis in patients who may be allergic to the drug, and morphine can cause respiratory depression, which can be life threatening.

In addition, the rate of infusion of some drugs is problematic. For example, if a drug such as aminophyline is administered at a rapid infusion rate, it can cause severe cardiovascular problems, which could lead rapidly to death from arrythmia. Furthermore, the site of infusion must be closely monitored, not only for infections or blood clot formation, but also for extravasation (leaking of the medication from the vein into the tissue).

Because of the risks and dangers associated with home IV drug therapy, it is critical that providers who furnish these drugs possess the expertise to evaluate patient signs and symptoms and to discern the potential for toxic reactions, such as renal or hepatic failure. In addition, the provider must be

able to teach and reinforce teaching about necessary safety precautions to be taken by its employees and patients.

Section 1862(a)(1)(A) of the Act prohibits payment under the Medicare program for an expense incurred for services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." In considering whether an IV drug is reasonable and necessary for coverage and payment purposes, we have to determine if the drug is being used safely and effectively. Additionally, the statute at section 1861(t)(4)(A) of the Act requires that we determine which drugs can or cannot be safely and effectively administered in a home setting. To make these determinations in a meaningful way, we had to use as a basis the expectation that the drugs would be furnished by a provider qualified to conduct a safe and effective home IV drug program. We believe that any rational determination that a drug can be safely and effectively administered in the home setting would have to be based on the premise that the drug would be furnished by a provider that meets our conditions of participation and is therefore qualified to furnish the services necessary to ensure that the drug is administered safely and effectively. Section 1861(jj)(3) of the Act describes the requirements that a home IV drug therapy provider must meet to qualify to furnish the services, including pharmacy and nursing services, "as are necessary to conduct safely and effectively an intravenously administered drug regimen through use of a covered home IV drug * * *." We believe it was the intent of Congress in using this language that covered home IV drugs be furnished only by providers who meet these requirements.

In addition, in compiling the list of IV drugs that should be included on the required list of covered home IV drugs, we determined that, to ensure that we would have a safe and effective home IV drug program, it would be necessary to require that each home IV drug be furnished by a qualified home IV drug therapy provider. Moreover, for the drugs included on the list, we determined that they could only be safely and effectively administered in a home setting if they were furnished by a qualified home IV drug therapy provider. We chose this approach because of the potentially serious or life threatening side effects of these drugs, the precautions that must be taken to ensure that IV drug therapy administered in a home setting is safe and effective, and the importance of proper patient selection when serving an older and more frail population.

In deciding upon the proposed policy that a covered home IV drug must be furnished directly or under arrangements by a qualified home IV drug therapy provider, we considered as an alternative also making Medicare payments directly to pharmacies that dispense these drugs. However, we rejected this alternative for the following reasons that relate to ensuring that covered home IV drugs are safely and effectively administered in a home setting.

If the Medicare program paid pharmacies directly for the covered home IV drugs they dispensed, we would lose the controls established by Congress in section 1861(jj) of the Act to ensure that these drugs would be safely and effectively administered in a home setting. These controls include requirements pertaining to the following:

a. Patients being under a plan of care established and periodically reviewed by a physician.

b. Patients receiving the items and services such as nursing, pharmacy, and related services (including medical supplies, IV fluids, proper delivery and equipment) that are necessary to conduct safely and effectively an IV administered drug regimen.

c. Patients having services available 7 days a week on a 24-hour basis and procedures being in place to handle their emergencies.

d. Patients being provided with drug regimen review and coordination of care.

e. Patients having services furnished by properly trained personnel.

If the Medicare program paid pharmacies directly for the covered home IV drugs they dispensed, we would be treating these drugs the same as other "covered outpatient drugs." However, Congress clearly singled-out these home IV drugs and treated them differently because of its concerns about ensuring the safety and effectiveness of home IV drug therapy. This is evidenced by sections 1861(t)(4) (A) and (B), 1834(d)(3), 1835(a)(2)(G), and 1861(jj) of the Act. Congress has included in the Act several provisions that involve certain precautions to ensure the safety and effectiveness of the covered home IV drug therapy program. It was because of the dangers associated with the use of home IV drugs for the treatment of the elderly that Congress established these precautions. We do not want these regulations to allow these precautions to be circumvented. We believe that one of the most important of these precautions is the link that Congress has established between covered home IV drugs and covered home IV therapy services furnished by a qualified provider.

If we paid pharmacies directly for the covered home IV drugs that they dispensed, we believe we would be undermining the purpose for which Congress enacted section 1861(jj) of the Act. In section 1861(jj) of the Act, Congress authorized home IV drug therapy services and established a new class of providers to ensure that covered home IV drugs are administered safely and effectively. The Act also stipulates that covered home IV drug therapy services must be furnished by a qualified home IV drug therapy provider. If we paid pharmacies directly for these drugs, we would possibly be allowing home IV drugs to be furnished to individuals who would receive them without the involvement of a qualified home IV drug therapy provider and without any assurance that they would receive the home IV drug therapy services, as defined in section 1861(jj) of the Act, that are necessary for safe and effective home IV drug therapy. The home IV drug therapy services were intended by Congress as means to an end. The ultimate concern is to ensure the safe and effective use of home IV drugs. Thus, we do not believe it was the intent of Congress to place restrictions on who can be paid by the Medicare program for furnishing covered home IV drug therapy services without at the same time intending that similar restrictions be placed on who can be paid by the Medicare program for furnishing covered home IV drugs.

Of course, a pharmacy can qualify as a provider of home IV drug therapy services by meeting the requirements applicable to such a provider in section 1861(jj)(3) of the Act and implementing regulations. However, if we directly paid pharmacies that dispensed covered home IV drugs, this practice would be contrary to the intent of section 1861(jj)(3) of the Act, which stipulates that certain requirements must be met by qualified home IV drug therapy providers. The purpose of these requirements is to ensure that those entities that furnish the services necessary to conduct home IV drug therapy safely and effectively in a home setting are qualified to do so. This is another step that Congress has taken as a result of its concerns about the safety and effectiveness of home IV drug therapy. However, if covered home IV drugs were available from other sources besides qualified home IV drug therapy providers, we would not be able to ensure that the services necessary for

safe and effective home IV drug therapy are furnished by an entity that is qualified to do so.

While we have proposed to limit coverage and payment to "covered home IV drugs" that are furnished directly by or under arrangements with a qualified home IV therapy provider, we specifically invite comments concerning this proposal. (As defined in section 1861(w)(1) of the Act, the term "under arrangements" means that the Medicare payment for a service procured by a Medicare provider of services by contract with an outside entity may be made only to the Medicare provider of services, not to the outside entity. Further, the term "under arrangements" also means that this Medicare payment to the provider discharges the beneficiary's legal obligation to pay the bill for those services, whether the bill is from the provider or the outside entity.)

As illustrated by the statutory provisions relating to home IV therapy services, the definition of a qualified home IV therapy provider, and the requirement that covered home IV drug therapy services must have prior approval by a Peer Review Organization, Congress intended that the use of covered home IV drugs be strictly controlled and regulated. As set forth in section 1861(jj) of the Act, Congress established high standards to ensure the safety and effectiveness of IV drugs used in the home setting. We do not believe we can ensure the safe and effective use of these drugs in the home unless we require that these drugs be furnished by qualified home IV therapy providers. We believe that, were we to propose otherwise, we would be undercutting the high safety and effectiveness standards established by Congress for covered home IV drugs. Moreover, without this requirement, the purpose for which the statute established qualified home IV therapy providers as a special and separate type of Medicare provider would be seriously weakened and easily circumvented. Thus, we have included in the definition of a "covered home IV drug" the restriction that the drug must be furnished directly or under arrangements made by a qualified home IV therapy provider.

In essence, the totality of the home IV benefit as it is constructed by Congress in sections 1154(a)(16), 1834(d), 1816(k), 1835(a)(2)(G), 1861(t)(4), and 1861(jj) of the Act, anticipates close monitoring not only of the home IV therapy services in terms of use and administration of the drug but also of the quality of the preparation of the drug, its delivery to the home of a beneficiary, its proper maintenance, and storage. The home IV therapy legislation establishes a completely new class of providers that will be dealing with frail beneficiaries who, in many cases, will be self-administering home IV drugs or who will have caregivers perform the administration. A primary consideration is that the drugs involved will be dangerous, toxic substances that must be carefully prepared, delivered timely to a beneficiaries home by an entity that can ensure proper handling so that the stability of the drug is not compromised (for example, is properly refrigerated) and maintained in a manner that will ensure viability at the time of its use. We think that these considerations support the view that it was the intent of Congress that home IV drugs be furnished to beneficiaries only by qualified home IV providers.

We also believe that the statute reflects the intent of Congress that only qualified home IV therapy providers submit claims and receive payment for covered home IV drugs. Section 1816(k) of the Act authorizes the Secretary to use intermediaries to pay for home IV drugs and home IV drug therapy services. Thus, claims for covered home IV drugs and home IV drug therapy services would be processed by intermediaries. Traditionally, under the Medicare program only providers submit claims to intermediaries. In authorizing the use of intermediaries to process these claims, therefore, we believe it was the intent of Congress that only providers, rather than suppliers or beneficiaries, be allowed to bill for covered home IV drugs and home IV drug therapy services.

In addition, section 1834(c)(1)(A)(ii) of the Act exempts from the catastrophic drug deductible "covered home IV drugs dispensed in conjunction with home intravenous drug therapy services which are part of a continuous course of such therapy initiated while the individual was an inpatient in a hospital." Since all claims for home IV drug therapy services would be processed by intermediaries, only an intermediary would know if a home IV drug was dispensed in conjunction with home IV drug therapy services begun in a hospital. Thus, administratively we believe it would be impractical for other entities besides intermediaries to process claims for home IV drugs. Traditionally, as stated above, suppliers and beneficiaries do not submit claims to intermediaries.

It is important to note that qualified home IV therapy providers could either furnish covered home IV drugs directly or arrange for them. Accordingly, there is no reason for any outside entity to bill the Medicare program for the drug. Instead, the entity would seek payment from the provider. In fact, to permit splintering of services would be undesirable from both a medical and an administrative point of view.

The definition of "covered home IV drugs" would include antibiotics except for specific antibiotics or specific indications that we determine are not safe and effective for home use. We would include those non-antibiotics that we determine can be safely and effectively administered in the home. Also, as required by section 1861(t)(4)(B) of the Act as added by section 202(a) of Public Law 100-360, we will publish by January 1, 1990 in the **Federal Register** a list of home IV drugs that can generally be administered safely and effectively in a beneficiary's home, and the indications for which those drugs may be used. We are in the process of developing this list based on a review of available medical and scientific information, and consultations with providers of home IV drugs and publishers of authoritative compendia. Home IV drug therapy services could be covered under Medicare only for those listed drugs.

In new § 410.29(c)(1), we would specify that we will update the list (that is, in terms of additions or deletions) at least annually. Updates may occur more frequently as necessary, possibly semi-annually, contingent upon the information we receive about IV drugs that might safely and effectively be used in the home. We specifically request comments about the frequency of these updates. As we understand it, there may be only 10 to 20 new drugs approved for marketing by the FDA during the course of a year that might be administrable through the IV route. However, we would determine whether these newly approved drugs can be safely and effectively administered in the home. In addition, we would specify that home IV drugs would be covered irrespective of whether there was a prior inpatient hospital stay. We are including this clarification to ensure that it is understood that coverage of home IV drugs does not require a prior inpatient hospital stay. (The list of drugs proposed for the home IV benefit was published separately in the **Federal Register**. We will also be publishing separate proposed rules concerning a payment methodology for covered outpatient drugs; coverage requirements for home IV drug therapy services; conditions of participation for home IV drug therapy providers; drug deductible and

coinsurance amounts; the fee schedule for home IV drug therapy services; requirements for participating pharmacies and drug bill processors; and coverage of catastrophic Part B expenses, outpatient drug expenses, and respite care benefits for beneficiaries enrolled in pre-pay health plans, such as health maintenance organizations. We will propose a definition of "home" for purposes of the home IV benefit in the proposed rule on the general coverage requirements for home IV drug therapy services.)

We would specify in new § 410.29(c)(2) that a home IV drug would be covered separately under Medicare. Therefore, beginning on January 1, 1990, those drugs appearing on the list of home IV drugs promulgated by HCFA under the authority of section 1861(t)(4)(B) of the Act would be available as "covered home IV drugs" only through the covered home IV drug benefit under the authority of section 1861(t)(4)(A) of the Act. (We note that this does not mean that outside of the covered home IV drug benefit these drugs would not continue to be covered under the pre-existing drug coverage specified in section 1861(t)(3)(A) of the Act.) Considering all of the separate provisions in sections 202 and 203 of Public Law 100–360 regarding the safety and effectiveness of covered home IV drugs, we believe it was the intent of Congress that these drugs be covered only as part of the specifically identified pre-existing benefits or the covered home IV drug benefit and not as part of another benefit. Accordingly, these drugs would no longer be available as part of the durable medical equipment benefit, under which it is now possible for Medicare payment to be made for IV administered drugs.

• We would redesignate existing § 410.29 as § 410.30 and add the following limitations that pertain to the new drug coverage benefit under Public Law 100–360:

—For the period January 1, 1990 through December 31, 1990, "covered outpatient drugs" would be limited to the drugs that are used in immunosuppressive therapy, and covered home IV drugs for appropriate indications identified in the final list of covered home IV drugs to be published after we evaluate public comments on the proposed list mentioned above.

—The regulations would identify those categories of drugs that are currently covered by Medicare and that would be excluded from the definition of a "covered outpatient drug" under Public Law 100–360. As indicated earlier, section 1861(t)(3) of the Act specifies which currently covered categories of drugs would be excluded from the definition of "covered outpatient drugs." These drugs would continue to be covered but not as part of the new drug benefit.

—Initially, we are proposing to limit payment for covered outpatient drugs to those drugs dispensed in a 34-day supply or less under an original prescription or under a refill. Generally, the statute limits payment for a covered outpatient drug to a 30-day supply or a longer period as the Secretary may authorize up to 90 days, and beyond in exceptional circumstances. Although, as discussed in greater detail below, we are considering exceptions to this policy, we believe that by limiting the supply of prescription drugs to 34 days, we would accomplish certain objectives as follows:

+ We would provide a means of controlling excessive prescribing and stockpiling of drugs for the period of the next year before the deductible is met.

+ Physicians and pharmacists would be provided frequent and regular opportunities to review patients' drug utilization.

+ We would reduce wastage of prescription drugs when a patient discontinues a drug therapy because of successful treatment of the condition for which the medication had been prescribed, because of an unsatisfactory or adverse outcome, or because a drug has reached its expiration date.

We have decided that 34-days is a more appropriate limit than 30 days for the following reasons:

+ Many tablets and capsules are packaged in quantities of 100 by pharmaceutical manufacturers and distributors. Also, the dosage for many tablets and capsules is one taken three times a day. Thus, under a 30-day limit, if a physician orders 100 tablets or capsules, the pharmacist could dispense only 90 tablets or capsules at one time and 10 tablets or capsules (10%) would remain. The cost of the remaining quantity would not be recouped until another prescription for the same medication is dispensed. If the limit is set at a 34-day supply, the pharmacist could dispense the full quantity of 100 tablets or capsules.

+ Many nursing homes receive pharmaceuticals under a unit dose system. The pharmacy usually bills the nursing home once a month, regardless of the dosage or the quantity of medication. In this circumstance, the closing date for the billing could be the first of the month or any other date of the month, but in those months in which there are 31 days, because the pharmacy bills on the basis of a calendar month, it would bill for a 31-day supply of medication.

+ Many patients see their physicians "once a month". This does not always mean every 30 days. Because of weekends and holidays, appointments may not always be scheduled every 28 or 30 days. Setting the allowed upper limit quantity to a 34-day supply might alleviate the need for patients to call for authorization to refill medication just before an appointment when the medication might be discontinued by the prescriber.

For these reasons, we believe that a 34-day limit on the length of prescriptions is a more practical approach than to propose a 30-day drug limit.

Section 1862(c)(2) of the Act stipulates that no payment may be made under Part B for *any expense* incurred for a covered outpatient drug if the drug is dispensed in a quantity exceeding a supply authorized by the Secretary. In accordance with this limitation, we would not pay for any portion of a prescription, not even for a 34-day supply or less, that is dispensed for a supply of more than 34 days. This limitation would apply after the drug deductible is met. It also would apply to the drug claim by which an individual exceeds the deductible. Therefore, payment for these drugs would be the total responsibility of the beneficiary or another health insurer. We would notify Medicare providers of services of this limitation to discourage the prescribing of drugs for more than a 34-day supply.

For drugs prescribed for use on a "take as needed" basis, the pharmacist would be asked to calculate the number of days supply for which a drug is prescribed based on the physician's indicated dosage range if that range is known. If the range is unknown, the calculation would be based on the manufacturer's recommended maximum daily dosage specified in the drug's approved labeling. For drugs, such as creams and ointments, whose approved labeling does not include a manufacturer's recommended maximum daily dosage, the pharmacist would be asked to estimate, based on the patient's condition, the number of days supply for which a drug is prescribed.

The 34-day limitation would pertain to the quantity of drugs dispensed at one time. Therefore, payment could be made for a prescription that authorizes a 34-day supply or less of a drug, even if the prescription authorizes refills. Nevertheless, neither a prescription nor an authorized refill could be paid for if it was dispensed for more than a 34-day supply.

As noted earlier, the statute permits the Secretary to authorize payment for prescriptions up to 90 days and for exceptions beyond a 90-day supply. In proposing the 34-day limitation, we recognize that its application to all prescription drugs could be burdensome to some beneficiaries on maintenance drugs, especially those living in rural areas. Also, a 34-day limit would result in more claims being processed and a greater number of dispensing fees. Therefore, we are considering exceptions to the 34-day limit for certain types of maintenance drugs (for example, insulin, digitalis, antiarthritics, anticoagulants, hormones, antiarhythmics) for which more than a 34-day supply may be appropriate. One exception we are including in this proposed rule is for those covered outpatient drugs that are marketed only in an amount that exceeds a 34-day supply. For these covered outpatient drugs, payment would be allowed for the smallest supply in which the drugs are marketed. We invite comments to identify other specific drugs or categories of drugs we should consider paying for in excess of a 34-day supply. Also, we note that at the point of sale, the contractors that will be processing the drug bills (referred to as "drug bill processors") will ordinarily not know the beneficiary's diagnosis. For this reason, we ask commenters to base recommendations for exceptions to the 34-day limit on names of drugs or therapeutic categories of drugs rather than on types of diagnoses. In the final rule, we will identify any exceptions to this limit that we believe are appropriate based on the comments we receive.

• In § 410.31, we would expand the coverage requirements for drugs used in immunosuppressive therapy to provide for payment of all covered outpatient drugs used in immunosuppressive therapy, beginning January 1, 1990, irrespective of whether the beneficiary received a Medicare covered or noncovered organ transplant and irrespective of a prescribed time limit.

• We would add a new § 410.32 to establish standards based on accepted medical practice for the prescribing of each covered outpatient drug. Section 1834(c)(5) of the Act, as amended by section 202(b)(5) of Pub. L. 100-360, requires the Secretary to establish, for each covered outpatient drug, standards for the prescribing of the drug that are based on accepted medical practice. This section of the law indicates that these standards are for the purpose of carrying out the program required by section 1834(c)(5)(A) of the Act. This program must identify (and educate physicians and pharmacists concerning)—

—Unnecessary or inappropriate prescribing or dispensing practices for covered outpatient drugs,
—Instances or patterns of substandard care with respect to these drugs, and
—Potential adverse reactions with respect to covered outpatient drugs.

In establishing the standards that would be used to implement this program, the statute requires us to incorporate standards from those authoritative compendia that we select. The conference report that accompanied Public Law 100-360 states that the conferees expect that we would use only those compendia that base their standards on a review of published scientific and medical information, that provide for a public comment and review process, and that provide adequate assurances that the panelists who establish standards are free of financial (or other) conflicts of interest (H. R. Rep. No. 100-661, 100th Congress, 2d Session 192 (1988)).

We believe it is essential for a compendium to meet at least these three criteria to ensure that its standards are based on accepted medical practice. Therefore, we propose to incorporate drug standards only from compendia that meet these three criteria. Information included in an authoritative compendium should be based on a review of published scientific and medical information to ensure that it is consistent with accepted current medical practice and verified by the latest research and published literature in the field of pharmacology. We also believe that an authoritative compendium should provide for a comment and review process that allows experts who are directly responsible for developing the compendium to review and comment on its content. This process is needed to ensure that the compendium presents a consensus view based on the published literature and the advice of experts from the scientific and medical community. It is also essential that an authoritative compendium provide adequate assurances that the panelists who establish standards are free of financial (or other) conflicts of interest. It is crucial that a compendium be as unbiased as possible. Therefore, an authoritative compendium must ensure that those who establish its standards are free of conflicts of interest.

Additionally, the conference report states that the conferees expect that among the compendia we would consider for use would be the U.S. Pharmacopoeia Dispensing Information, volume 1 (Drug Information for the Health Care Professional), the American Medical Association's Drug Evaluations, and the American Hospital Formulary Service Drug Information. We have considered these three compendia and believe that all three meet the selection criteria described in the committee report and discussed above. Therefore, for purposes of certain provisions of the drug utilization review program; that is, the identification and education of physicians and pharmacists about inappropriate prescribing and dispensing practices and substandard care with respect to drugs and potential adverse reactions, we propose to adopt as our standards the standards established in these three compendia. These standards would not be used to define coverage or payment of covered outpatient drugs under the Act.

These standards together with the standards derived from accepted medical practice, medical literature, advice obtained from medical consultants and experts in the field (some of whom we expect would be under contract), would be used to develop criteria for purposes of drug utilization review. In conducting a drug utilization review program, we also would apply the requirements in the statute and regulations that govern the coverage of and payment for covered outpatient drugs. Parts of the drug utilization review program would serve as the basis for the program required by section 1834(c)(5)(A) of the Act to identify and educate physicians and pharmacists concerning inappropriate prescribing and dispensing practices. We intend to publish a separate proposed rule concerning the drug utilization review program when we have more information. That proposed rule will describe how, as part of retrospective drug utilization review, we would use data collected through the electronic point-of-sale claims processing system required by section 1842(o)(4) of the Act, as amended by Public Law 100-360. The data on covered outpatient drugs would be used to identify and educate physicians and

pharmacists concerning in apropriate prescribing and dispensing practices.

Section 1834(c)(5)(C)(ii) of the Act authorizes the Secretary to exclude from coverage or to deny payment for a specific use of a covered outpatient drug for a specific indication if the Secretary determines the use is not safe or is not effective. We anticipate that the use of this authority would be necessary only in a limited number of circumstances. The criteria mentioned above together with the statute and regulations would be used to identify those exceptional circumstances that warrant the use of this authority. Since diagnostic information will not be included on the prescription, ordinarily it would not be known by the drug processor at the time a claim is received either electronically or by mail. Therefore, in order to deny payment or exclude coverage for a specific use of a covered outpatient drug for a specific indication that we have determined is not safe or is not effective, as authorized by section 1834(c)(5)(C)(ii) of the Act, we would establish a pre-authorization review process. For those drug uses and indications for which we have determined that a pre-authorization review process is needed, we would require that information from the prescribing physician regarding the beneficiary's diagnosis and the purpose for which the drug has been prescribed must accompany the claim, or if it is a participating pharmacy that the pharmacist must have the information on file before payment could be approved. For example, beneficiaries using a nonparticipating pharmacy, would be required to submit this information directly to the drug bill processor as part of submitting a paper claim. For beneficiaries using a participating pharmacy, it would be sufficient for the pharmacist to have the required information on file. An override of an alert transmitted by the drug bill processor could be the means used by the participating pharmacy to indicate that the information is on file. The beneficiary would be obligated either to obtain the additional documentation from the physician, or if he or she is unwilling or unable to do so, to submit a paper claim for the drug. Of course, if the pharmacist in a participating pharmacy chooses to do so, he or she may call the physician to ascertain the diagnosis for which the physician prescribed the drug and then document the information in the pharmacy files.

Even though sections 1834(c)(5)(C)(ii) and 1861(t)(2) of the Act both refer to the safety and effectiveness of drugs, they pertain to two completely separate and distinct administrative processes. Thus, the words "safe" and "effective" as used in section 1834(c)(5)(C)(ii) have a different application and relate to a different purpose than the words "safety" and "effectiveness" that appear in section 1861(t)(2). Therefore, even though a drug may have been approved for "safety" and "effectiveness" by the FDA, the Secretary may determine that a specific use of the drug for a specific indication is not safe or is not effective.

Section 1834(c)(5)(C)(ii) pertains to determinations made by the Secretary to exclude coverage of or deny payment for specific uses of covered outpatient drugs for specific indications under Medicare. It gives the Secretary authority to deny payment or exclude coverage under the Medicare program if the Secretary determines that a specific use of a drug for a specific indication, which might not be limited to the labeled usages, is not safe or is not effective.

Section 1861(t)(2) of the Act refers to the process (described in section III of this preamble), whereby the FDA determines before a new drug can be marketed that the drug is safe and effective for certain specific indications identified on the drug's approved label. According to this process, before the FDA will approve a new drug for marketing, it has to be shown to be safe and effective for its proposed uses. The purpose of this process is to determine whether a drug is safe and effective for marketing for its labeled uses.

Thus, section 1834(c)(5)(C)(ii) authorizes exclusion of Medicare coverage or denial of Medicare payment for specific uses of covered outpatient drugs for specific indications, while the FDA process referred to in section 1861(t)(2) relates to the uses for which an approved drug may be marketed.

We are considering what the specific elements of a drug utilization review program should be. One of the elements under consideration is therapeutic drug utilization review. We propose to include this element as part of our drug utilization review program. Its purpose would be to identify prescribed drugs that may interact harmfully with either an existing disease or medical condition of a beneficiary. We specifically invite comments concerning the feasibility of including therapeutic drug utilization review as part of either prepayment or postpayment drug utilization review.

We plan to begin implementing the drug utilization review program in January 1991. At this time, we believe that a drug utilization review program should consist minimally of the following elements:

—Prepayment Review and Denial.

Claims for Medicare drug payments ordinarily would be submitted to drug bill processors directly by participating pharmacies through an electronic point-of-sale claims processing system or by beneficiaries who receive drugs from a nonparticipating pharmacy. (Claims for home IV drugs would be submitted to intermediaries. The drug utilization review program described here would only apply to claims submitted to drug bill processors, thus, it would not pertain to covered home IV drugs.) Before payment is approved, the drug claim would be reviewed by the drug bill processor regarding the following items:

+ Does the drug meet the definition of a "covered outpatient drug" as defined in section 1861(t) (2) through (4) of the Act? For example, a drug that may be dispensed without a prescription would not be covered.
+ Was the drug dispensed for more than a 34-day supply? If the drug was dispensed for more than a 34-day supply, it would not be paid for by Medicare unless Medicare regulations authorize an exception for that drug. Payment would not be approved for any portion of a supply of drugs if the supply exceeds the limitations set forth in regulations on the length of prescriptions.
+ Is the drug prescribed for a use that is not safe or is not effective? In accordance with section 1834(c)(5)(C)(ii) of the Act, the Secretary may determine that the specific use of a drug for a specific indication is not safe or effective for the diagnosis or treatment of an illness or injury as required by section 1862(a)(1)(A) of the Act. Drugs prescribed for cosmetic purposes (for example, those used to treat conditions such as wrinkles or balding) would not be covered. However, if these conditions are caused by a medical problem, covered outpatient drugs prescribed for the treatment of the medical problem would be covered. Similarly, we are considering whether other drugs (such as oral contraceptives) should be subject to this same exclusion.

• Under section 1834(c)(5)(C)(ii) of the Act, payment may be denied for a drug if the Secretary determines that it is not safe or effective for the particular beneficiary for whom it is prescribed. For purposes of safety and efficacy, payment for duplicate prescriptions for a drug would be denied, unless in the judgement of the pharmacist, after conferring with the beneficiary or

prescribing physician, or in the judgement of the drug bill processor, there is a justifiable reason for filling the prescription. By the term "duplicate prescriptions" we mean prescriptions for the same drug and for the same patient that are prescribed for the same time period. A duplicate prescription could result from two different physicians unknowingly prescribing the same drug for the same patient. An example of a reason why payment for a duplicate prescription may be justifiable would be that the drugs obtained from a previous prescription might have been lost or stolen. Also, some allowance would be made to permit an individual to refill a prescription before all of the previously dispensed quantity of drugs has been consumed (that is, when there are 10 or fewer days of a supply remaining on the previous dispensing of that prescription). If prescriptions include refills, for purposes of convenience or to ensure that their medication is continued as directed, individuals do not ordinarily completely exhaust a current supply of drugs before having a prescription refilled. Therefore, we do not believe it would be warranted to alert pharmacies about a potential duplication of a prescription if the drug bill processor's records indicate that if the beneficiary had taken the drug as directed there would be a drug supply of 10 or fewer days remaining from the previous dispensing of that prescription. The drug bill processor would know how many days' supply would be remaining, since at the time the drug was dispensed the pharmacist would have informed the drug bill processor of the number of days for which the drug was prescribed. We decided on 10 or fewer days, because we believe this would give the beneficiary sufficient time to obtain a refill before his or her supply of drugs was exhausted. In addition, we believe it is a reasonable benchmark for identifying those instances when it is not necessary to alert a pharmacy about a possible situation in which an individual may be inappropriately having a prescription duplicated.

+ Does the beneficiary's medication profile indicate that a prescribed drug may interact harmfully with a drug in the profile? We anticipate that the pharmacy would be alerted regarding the possible need for counseling or some other type of intervention before filling a particular prescription if the drug bill processor's records indicate there is a risk of a significant drug interaction between a newly prescribed drug and a drug that has previously been dispensed to the beneficiary.
+ Was the drug prescribed in an amount that exceeds the recommended maximum daily dose? Pharmacies would be alerted by the drug bill processors concerning claims for drugs that are prescribed in amounts that are likely to cause severe adverse effects. Pharmacies would be expected to take what they consider to be appropriate action.

—Post-payment Review.

For purposes of implementing a post-payment drug review program, we plan to use expert consultants to help develop drug utilization review criteria. As mentioned above, these criteria would, in part, be based on the compendia whose standards we have adopted. These criteria would be used to identify and educate physicians and pharmacists concerning potential or possible inappropriate prescribing or dispensing practices or substandard care. In conducting post-payment drug utilization review, Medicare contractors would analyze and study the following data on beneficiaries:

+ A beneficiary's age, sex, and reason for entitlement (that is, by reason of disability or age).
+ The total number of prescriptions used by a beneficiary, particularly drug dosage form, and strength, including therapeutic class, doses per day, number of treatment drugs and remedial drugs and increases in the use of these drugs.
+ The number of different prescribing physicians and different pharmacies.
+ Diagnostic information reported on physician claims for services, number of physician visits, and increases in visits.
+ Other relevant information requested by our consultants.

—Education.

We would establish a program to educate physicians and pharmacists about inappropriate prescribing and dispensing practices. This program would educate physicians and pharmacists about the criteria that we use for drug utilization review and the findings that result from drug utilization review. The program would include the following educational aspects:

+ If post-payment utilization review indicates that, in accordance with our criteria, drugs may have been inappropriately prescribed or dispensed to a particular beneficiary, the individual's physician or pharmacist would be informed of the drug utilization review findings. For example, a physician may be informed that one of his or her patients with diabetes is taking a drug that raises blood sugar. The physician would be advised of this information for his or her evaluation and action, if appropriate.
+ We would utilize educational materials and continuing education programs to inform and advise physicians and pharmacists about unnecessary and inappropriate prescribing and dispensing of drugs.

We specifically request public comment regarding the establishment of standards for a covered drug that is not included in any of the three compendia we propose to adopt. Also, since we were not able to review all compendia before publishing this rule, we invite comments regarding other compendia whose standards may be appropriate for our use.

If we would decide to change our selection of any of the compendia after this rule is issued in final form, we would publish a proposed rule to announce the change(s). If we would wish to modify any of the standards in a selected compendia, we would publish a notice in the **Federal Register** describing the modification(s).

In accordance with section 1834(c)(5)(C) of the Act, we would base all decisions to exclude coverage or deny payment for any specific use of a covered outpatient drug for a specific indication on a finding under section 1862(a)(1) of the Act that the use of the drug for the particular indication was not safe or was not effective. Section 1862(a)(1)(A) of the Act precludes Medicare from paying for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. However, as explained earlier, Congress specified in section 1834(c)(5)(C) of the Act (as amended by section 202(b)(4) of Pub. L. 100–360) that under section 1862(a)(1) of the Act, payment or coverage of covered outpatient drugs can be denied only if the Secretary has determined they are not safe or effective for a particular indication. Hence, under section 1862(a)(1) of the Act, payment would be denied for a covered outpatient drug only when we determine, or in accordance with our guidelines, an authorized Medicare agent determines, that a specific use of a drug is not safe or effective for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Our guidelines would

explain, for example, that if a prescription is issued in the presence of a clear contraindication, the use of a drug would not be considered safe or effective and would not be covered. Also, a prescription for a drug that is not medically necessary or appropriate for a particular beneficiary would not be covered because of safety and effectiveness considerations. Therefore, carriers would be authorized to deny payment for a covered drug in specific situations and for particular beneficiaries, if scientific and medical information indicates that the use of the drug in those circumstances is not safe or effective for the treatment of a particular patient.

As stated above, in accordance with the requirements of section 1862(a)(1)(A) of the Act, services are not covered by Medicare unless they are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We do not consider cosmetic changes that occur as part of the natural aging process to constitute illness or injury for purposes of Medicare coverage. Therefore, drugs prescribed for the treatment of cosmetic conditions that result from the natural process of aging (for example, wrinkles and balding) would not meet the requirements of section 1862(a)(1)(A) of the Act and would be excluded from coverage.

We would allow Medicare payment for uses of covered drugs even if those uses are not included in the official FDA approved label unless the use is contraindicated by the drug's label. (We note, however, that we would cover home IV drugs only for the indications set forth in the published list of home IV drugs discussed earlier in this preamble.) Also, if we determine on the basis of scientific and medical information that a use of a covered drug is not safe or effective, we would deny payment.

VI. Regulatory Impact Statement

A. Executive Order 12291

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

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

The central purpose of this proposed rule would be to bring our existing regulations into conformity with the definition of a "covered outpatient drug" contained in section 1861(t) of the Act. With respect to the provisions of section 1834(c)(5)(B) of the Act as added by section 202(b)(4) of Public Law 100-360, which require the Secretary to establish standards for the use of covered drugs, as described in section V of this preamble, we propose to adopt as our standards, the standards in the U.S. Pharmacopoeia Dispensing Information, volume 1 (Drug Information for the Health Care Professional), the American Medical Association's Drug Evaluations, and the American Hospital Formulary Service Drug Information. Since these compendia are to be used only as part of a program established under section 1834(c)(5)(A) to identify and educate physicians and pharmacists about instances or patterns of inappropriate prescribing or dispensing of covered outpatient drugs, substandard care or potential adverse drug reactions, their adoption as part of a monitoring and educational program would have only an indirect effect on physicians and pharmacists. Furthermore, in proposing to adopt these compendia, we would be utilizing standards that are widely and commonly accepted by physicians, pharmacists, and other health care professionals. Consequently, we believe that our proposed use of these compendia as part of the basis on which we would develop prescribing standards would not alter, to any significant degree, current prescribing patterns or practices.

Section 1862(c)(2) of the Act (which was added by section 202(d) of Pub. L. 100-360) requires the Secretary to deny payment for a covered outpatient drug, including any portion of the prescription, if a drug is dispensed in a quantity exceeding a specified number of days. The Act permits the Secretary to set limits from 30 days to 90 days (and for periods longer than 90 days under exceptional circumstances).

In section V of the preamble, we have explained our reasons for proposing a limit on the amount of a covered outpatient drug for which we would make payment to a 34-day supply (§ 410.30). Although we are considering exceptions to the proposed 34-day dispensing limit for certain types of maintenance drugs (we have specifically requested comments in section V of this proposed rule on which drugs to grant an exception), nevertheless, many drugs may be subject to the proposed limit and as a consequence, there may be some adverse effects resulting from this proposal.

For example, Medicare beneficiaries living in rural areas may find this proposed policy particularly onerous and costly. In addition, the proposed 34-day limitation on dosage supply could result in higher program costs. When we pay for a covered outpatient drug on the basis of the drug's average wholesale price (in accordance with section 1834(c)(3) of the Act that was added by section 202(b)(3) of Pub. L. 100-360), we are required to pay the dispensing pharmacy an administrative allowance of $4.50 to a participating pharmacy and $2.50 to another pharmacy. The proposed 34-day supply dispensing limit may result in more prescriptions being refilled than might occur under a policy that would permit the statutorily mandated maximum 90-day supply of a drug to be dispensed at one time. Consequently, the administrative allowance might be paid more frequently under the proposed policy. Also, we may incur additional administrative costs as a result of the higher volume of bills that would be processed. However, these additional costs for pharmacy administrative allowances and bill processing may be offset by savings generated from reducing the volume that might have been dispensed but, subsequently was never used. The proposed 34-day limit on the supply of drugs that may be dispensed at one time may reduce this kind of waste and produce savings for both the Medicare program and beneficiaries (the Medicare program would achieve savings by avoiding payment for unused drugs, and Medicare beneficiaries would save by not incurring the out-of-pocket expenses for the purchase of the unused drugs).

In conclusion, balancing possible higher payments for pharmacy administrative allowances and bill processing against savings resulting from reducing the unnecessary purchase of drugs, we believe that the total economic impact of the proposed 34-day limitation on the dispensing of covered outpatient drugs should be less than $100 million per year compared to a policy that would cover the maximum number of days permitted under the statute.

Thus, for the reasons we have given, we do not believe this rule would meet any of the criteria of a major rule under E.O. 12291 and a regulatory impact analysis is not required.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all pharmacists, most pharmacies, and some pharmaceutical manufacturers qualify as small entities.

As stated in the discussion on the applicability of E.O. 12291 to this proposed rule, we believe that the central provision of this rule, which specifies which drugs would be considered covered outpatient drugs under the Medicare program, is prescribed by the Act as amended by section 202 of Public Law 100–360. Thus, we view any benefits or adverse consequences that may affect small entities as a result of the applicable statute rather than of this proposed rule. Also, as explained in our discussion of the effects of this proposed rule under the E.O., we believe that adoption of the U.S. Pharmacopoeia Dispensing Information, volume 1 (Drug Information for the Health Care Professional), the American Medical Association's Drug Evaluations, or the American Hospital Formulary Service Drug Information as standards for drug utilization review and education purposes would have a minimal effect on the behavior of physicians and other health professionals licensed to prescribe medication.

Although our proposal in § 410.30 to limit the amount of a covered outpatient drug that may be dispensed at one time to a 34-day supply for either a prescription or a refill may provide substantial revenue increases to some pharmacies in the form of more frequent dispensing fees, we do not expect the provisions in § 410.30 to have a substantial effect on a significant number of small entities; given the projected dollar amount of national retail sales of covered outpatient drugs; the comparatively small increase in Medicare payments caused by requiring refills of a covered outpatient prescription drug every 34 days compared with the cost of paying for drugs which would have been dispensed in larger amounts; and the actual dollar amount of the dispensing fee established under the Act.

The proposed regulation at § 410.29(b) restricting coverage of or payment for home IV drugs to only those drugs dispensed either under arrangement or directly to the beneficiary by a qualified home IV provider may be perceived by some pharmacies as unnecessarily restricting entry of pharmacies into the Medicare home IV market. These pharmacies may argue that our interpretation of the law is too narrow, thus preventing many qualified pharmacies from competing for the sale of home IV drugs to Medicare beneficiaries.

As discussed in section V of this preamble, we believe that it is only prudent, on our part, to control the dispensing of home IV drugs to beneficiaries because of the high risk involved both in handling some of the drugs we would approve for home use and in the administration of all home IV drugs. Thus, to ensure that home IV drugs are prepared and administered safely and effectively, we believe it reasonable to restrict the source of IV drugs used in the home to those providers that meet the standards for home IV providers specified in the Act. Only by having a single provider organization responsible and accountable for all home IV services furnished at any one time to a beneficiary can we ensure that beneficiaries would receive safe and effective care.

With the assurance of adequate care, both the Medicare program and beneficiaries may realize certain economic benefits that might be lost if pharmacies and beneficiaries had access to the home IV drug market in the same manner as they would for the sale and purchase of other covered outpatient drugs. Without the proposed limitation on access to home IV drugs, patients might take it upon themselves to purchase home IV drugs without fully understanding the technical requirements of storing and handling these compounds. This could result in injuries to patients and higher costs to the program in the form of emergency care or hospitalization even if the drug were safely and effectively administered. Placing responsibility on a single entity for all home IV services, including pharmacy services should, we believe, greatly reduce the risk of an IV drug-related mishap and thus avoid the costs associated with treating these accidents.

As a final point, we note that the limitations we propose to impose on pharmacy access to the home IV drug market are no different, in practice, than the limitations hospitals and other types of providers place on pharmacy services. For example, in hospitals and nursing facilities, pharmacy access to beneficiaries is limited to the pharmacy services these providers either arrange for or furnish directly to patients. We believe that it is reasonable to maintain the same kind of relationship between the pharmacy and the home IV provider as exists between these other types of providers and their pharmacy services.

Therefore, for the reasons given in this section, we have determined, and the Secretary certifies, that this proposed rule would not have a significant effect on a substantial number of small entities.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

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

C. Voluntary Statement of Effects

As we have stated, we believe that we are not obligated to provide an analysis of the effects of this proposed rule. Nevertheless, we are voluntarily providing a summary of the effects (particularly on Medicare beneficiaries) that we believe may result from implementing sections 1861 (s)(2)(J) and (t) of the Act as amended by section 202 of Public Law 100–360. We are providing this statement because coverage of outpatient prescription drugs represents a significant expansion of Medicare benefits.

Readers may find the following discussion to be very similar to impact analyses appearing in other regulations or notices implementing provisions of the Medicare catastrophic drug benefit. We have purposefully provided complete analyses in each document (even though they may be repetitious) so as to provide readers with complete discussions of the possible effects of the provisions being implemented without having to refer to other **Federal Register** documents.

1. Benefits Beginning in 1990

Under section 1861(t)(3)(B) of the Act, as added by section 202(a)(2)(C) of Public Law 100–360, drugs used in immunosuppressive therapy and covered home IV drugs would be covered as a part of the Medicare

catastrophic benefit beginning January 1, 1990.

a. Coverage of drugs used in immunosuppressive therapy. As added, section 1861(t)(3)(B)(i) of the Act extends coverage for prescription drugs used in immunosuppressive therapy furnished beyond the first year following an organ transplant to an individual regardless of whether the beneficiary receives a transplant that is covered under the Medicare program. Under section 202(b)(4) of Public Law 100–360, payment for prescription drugs used in connection with immunosuppressive therapy would be included as part of the new catastrophic benefit (see section 1834(c)(2) of the Act). However, under section 1834(c)(1)(A)(iii) of the Act, a beneficiary requiring immunosuppressive drug therapy during the first year following a Medicare-covered organ transplant would not have to meet the covered outpatient drug deductible amount required under section 1834(c)(1)(C) of the Act (as added by section 202(b)(4) of Pub. L. 100–360). Also, under section 1834(c)(2)(C)(i) of the Act (as added by section 202(b)(4) of Pub. L. 100–360), the beneficiary coinsurance percentage for immunosuppressive drugs required in connection with a transplant covered under the Medicare program is limited to 20 percent during the first year following the organ transplant.

Under section 1861(t)(3)(B)(i) of the Act (as added by section 202(a)(2)(C) of Pub. L. 100–360), coverage would be provided under the catastrophic drug benefit beginning January 1, 1990 for drugs used in immunosuppressive therapy following a transplant that is not covered by the Medicare program (for example, a heart transplant performed in a hospital not approved by Medicare as a heart transplant facility). In these cases, however, the individual would be required to meet the deductible payment amount required by section 1834(c)(1)(C)(i) of the Act and the coinsurance percentages required under section 1834(c)(2)(C)(ii) of the Act (which were added by section 202(b)(4) of Pub. L. 100–360).

• In 1990, we estimate that about 9,500 beneficiaries will undergo an organ transplant that will be covered under the Medicare program. There may be an additional 7,600 beneficiaries who had undergone an organ transplant covered under the Medicare program sometime in 1989. Both groups would be covered under the catastrophic drug benefit for the drugs used in their immunosuppressive therapy beginning January 1, 1990, and would be exempt from the catastrophic drug deductible and subject only to a 20 percent catastrophic drug coinsurance rate for up to 1 year following their discharge from the hospital.

Also, beginning January 1, 1990, we expect that approximately 19,700 beneficiaries who had undergone a Medicare covered transplant before 1989 or had undergone or will undergo an organ transplant not covered under the Medicare program will be covered under the catastrophic drug benefit provisions. These beneficiaries, however, would be subject to the catastrophic drug deductible payment amount and to the 50 percent coinsurance rate that would be in effect for 1990.

b. Coverage of home IV drugs. Also, beginning January 1, 1990, home IV drugs would be covered under section 1861(t)(3)(B)(ii) of the Act (as added by section 202(a)(2)(C) of Pub. L 100–360). For covered home IV drugs furnished as part of a continuous course of therapy initiated while a beneficiary is a hospital inpatient, the deductible amount specified in section 1834(c)(1)(C) of the Act (as added by section 202(b)(4) of Pub. L. 100–360) does not apply in accordance with section 1834(c)(1)(A)(ii) of the Act (as added by section 202(b)(4) of Pub. L. 100–360). The beneficiary coinsurance percentage for all covered home IV drugs would be 20 percent under section 1834(c)(2)(C)(i) of the Act (which was added by section 202(b)(4) of Pub. L. 100–360). We estimate that as many as 65,000 Medicare beneficiaries would utilize home IV drugs in 1990. Of these, we estimate that 56,550 beneficiaries would begin their IV drug therapy while still in the hospital, thereby being exempted from the catastrophic drug benefit deductible and subject only to a 20 percent coinsurance payment rate that applies to all covered home IV drugs.

2. Prescription Drugs Covered Under This Proposed Rule Beginning in 1991

As of June 1988, there were 378 pharmaceutical firms licensed to manufacture prescription drug products in the United States. There are now about 9,700 different drugs meeting the statutory definition of a covered outpatient drug marketed in the United States. Of the total number of approved drug products, 1,975 products are each manufactured by a single firm, and almost 7,795 drugs are manufactured by more than one firm. Under this proposed rule, all the approved prescription drugs described above would be paid for beginning in 1991, in accordance with payment rules that we plan to publish in a separate document.

3. Benefits for Medicare Beneficiaries, 1991 Through 1993.

Our actuaries project that, without the catastrophic drug benefits provided under sections 1832 and 1861 (s) and (t) of the Act as amended by section 202 of Public Law 100–360, in 1991, total beneficiary expenditures for covered outpatient drugs would have totaled $12.4 billion. By 1993, this figure would have grown to $14.2 billion. By distributing total projected spending for covered outpatient drugs in 1991 over all Medicare beneficiaries, we expect the average incurred expense per beneficiary would have equalled about $405 for an average 18.7 prescriptions. Similarly, in 1993, we projected the average expenditure per beneficiary would have been an average of $450 per beneficiary for an average of 19.4 prescriptions.

While we made these projections in terms of all beneficiaries, we estimate that only about 85 percent of aged beneficiaries would actually purchase covered outpatient drugs in any given year. Thus, the amount for each beneficiary who would purchase prescription drugs in 1991 (the average expense for covered outpatient drugs per Medicare user) is expected to be about $475. By 1993, the average expense per Medicare user would increase to about $530. Although the level of the covered outpatient drug deductible in 1991 is set by statute at $600 (a level that would permit an estimated 24 percent of all beneficiaries to receive covered outpatient drug benefits), the percentage of beneficiaries meeting this deductible would equal nearly 28 percent of those beneficiaries who actually would purchase covered outpatient drugs. In 1993, the level of the covered outpatient drug deductible would be set at an amount that would permit 16.8 percent of all Medicare beneficiaries to qualify for the prescription drug benefit. Yet in terms of those who are expected to purchase covered outpatient drugs, the percent of users meeting the deductible amount would be about 20 percent.

Beginning in 1991, those who meet the deductible would receive an average benefit of about $345 for the year. As envisioned by the statute, and assuming adequate financing, in 1993, the average benefit payment made on behalf of a beneficiary who had met the deductible amount would increase to about $700. The projected growth in benefit payments per beneficiary would be largely the result of the increased portion of prescription drug costs the Medicare program would be required to

pay. In accordance with the statute, the proportion of drug costs covered by the program after the deductible amount is reached would increase from 50 percent in 1991 to 80 percent in 1993.

While the portion of drug costs covered by Medicare would increase from 1990 through 1993, the proportion of beneficiaries expected to meet the deductible amount would drop during this period. By law, the deductible amount, in 1991, would be set at $600, enabling about 24 percent of all beneficiaries to qualify for drug payment benefits (or about 28 percent of projected actual Medicare beneficiaries requiring covered outpatient drugs). In 1992, the deductible amount would increase to $652, which would enable 23 percent of Part B enrollees (or almost 27 percent of those beneficiaries projected to actually use covered outpatient drugs) to qualify for the drug benefit. In 1993, the law requires the deductible amount to be set at a level that would permit 16.8 percent of all beneficiaries to receive covered outpatient drug benefits. This would be the equivalent of about 20 percent of those beneficiaries who would purchase covered outpatient drugs during that period.

4. Benefits to Pharmaceutical Manufacturers and Others Involved in the Distribution and Sale of Covered Outpatient Drugs

In developing our estimates of benefit payments, we assumed that once a beneficiary reached the deductible amount, there would be an induced demand for prescription drugs that would increase the number of prescriptions written, and possibly, the cost of the prescriptions as well. That is, prescribing health professionals may feel freer to prescribe botn a larger quantity and more expensive drugs for a patient who has met the deductible amount than for one who has not met the deductible amount. Similarly, a patient who has met the deductible payment amount may feel less constrained to demand more medications or to have more prescriptions filled than a patient who has not met the deductible amount.

In attempting to predict the magnitude of the induced demand for covered outpatient drugs, we assumed that the effect would be directly related to the amount of program benefit payments. This amount, in turn, is a function of the deductible payment amount and the percentage of the beneficiary copayment. In 1991, we project that induced demand would account for about 23 percent of program benefit payments for covered outpatient drugs. In 1992, the percent of induced benefits for prescription drugs is expected to grow to 26.5 percent, and by 1993, the percentage is expected to reach 32.4 percent. Since these induced benefits would apply to purchases of additional covered outpatient drugs that would not otherwise have been purchased, in addition to possibly benefiting Medicare beneficiaries through enabling them to have greater access to medications, the induced demand for covered outpatient drugs could also financially benefit every entity involved in the manufacturing and marketing of prescription drugs.

It should be noted that the expected induced demand does not necessarily represent an abuse of the Medicare drug benefit. We believe that in many cases, the increased demand may represent a decision on the part of a health professional to treat a condition more aggressively than he or she might do if the catastrophic drug benefit were not available. Similarly, a beneficiary might forego having a prescription filled or avoid taking a drug at the prescribed frequency in order to conserve the available medication were it not for the coverage of outpatient drugs now afforded by the Act. Thus, the induced demand may represent, in part, a medically appropriate demand for prescription drugs that currently is not being met.

D. Conclusion

We have summarized the most significant effects of the covered outpatient drug provisions specified in section 1861 of the Act, as amended by section 202 of Pub. L. 100-360. We do not believe that we are required to furnish this information under either E.O. 12291 or the RFA. Nevertheless, in the interest of providing the public with information regarding a major revision to the Medicare program, we have voluntarily offered an analysis of the major effects of extending Medicare coverage to covered outpatient drugs as defined by the Act.

VII. Information Collection Requirements

These proposed regulations contain no information collection requirements and do not come under the provisions of the Paperwork Reduction Act of 1980.

VIII. Responses to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "Date" section of this preamble, and, if we proceed with a final rule, we will respond to the comments in the preamble of that rule.

IX. List of Subjects in 42 CFR Part 410

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

For the reasons set forth in the preamble, 42 CFR chapter IV, part 410, subpart B, would be amended as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

A. The table of contents for part 410, subpart B, is amended by revising the title of §§ 410.29 and 410.32 and adding new §§ 410.30, 410.31, and 410.33 to read as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

* * * * *

Subpart B—Medical and Other Health Services

Sec.

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410.29 Covered outpatient drugs.
410.30 Limitations on Part B coverage of drugs.
410.31 Prescription drugs used in immunosuppressive therapy.
410.32 Standards for assuring appropriate prescribing and dispensing practices of drugs.
410.33 Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

Authority: Secs. 1102, 1832, 1833, 1834, 1835, 1861 (r), (s), (t), and (cc), 1862, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395m, 1395n, 1395x (r), (s), (t), and (cc), 1395y, 1395hh, and 1395rr).

B. In § 410.10, the introductory paragraph is republished and paragraph (r) is added to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in § 410.12, "medical and other health services" includes the following services:

* * * * *

(r) Covered outpatient drugs, as described in § 410.29(a).

§§ 410.26 and 410.27 [Amended]

C. In §§ 410.26(b) and 410.27(b), the reference to "§ 410.29" is removed and "§ 410.30" is inserted in its place.

§ 410.28 [Amended]

D. In § 410.28(b), the reference to "§ 410.29 (b) and (c)" is removed and "§ 410.30" is inserted in its place.

E. Current §§ 410.29 and 410.32 are redesignated as §§ 410.30 and 410.33, respectively; new §§ 410.29, 410.31, and 410.32 are added, and the newly redesignated § 410.30 is revised to read as follows:

§ 410.29 Covered outpatient drugs.

(a) *"Covered outpatient drug"* includes the following:

(1) A drug that may be dispensed only upon prescription and that—

(i) FDA has approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the Federal Food, Drug, and Cosmetic Act (FFDCA), or has approved under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before October 10, 1962, or which is identical, similar or related to such a drug as defined in 21 CFR 310.6(b)(1), and which has not been the subject of a final determination by the FDA that it is a new drug or the subject of an action brought by the FDA under sections 301, 302(a), or 304(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331, 332(a), or 334(a)) to enforce sections 502(f) or 505(a) of that Act (21 U.S.C. 352(f) or 355(a)); or

(iii) Was approved by the FDA before October 10, 1962 solely on the basis of safety, and for which the FDA has—

(A) Determined there is compelling justification for its medical need, or which is identical, similar, or related to such a drug as defined in 21 CFR 310.6(b)(1); and

(B) Not issued a notice of opportunity for a hearing on a proposal to withdraw approval for marketing because the FDA has determined that the drug is less than effective for all conditions of use represented, recommended, or suggested on its labeling.

(2) A biological product that may be dispensed only upon prescription, is licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), and is produced at an establishment licensed under that Act to produce that product.

(3) Insulin certified under section 506 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 356), whether or not it is dispensed under a prescription.

(b) *"Covered home IV drug"* means a covered outpatient drug described in paragraph (a) of this section that is furnished directly or under arrangement by a qualified home IV drug therapy provider to an individual and is intravenously (IV) administered to that individual in a place of residence that is used as the individual's home and that—

(1) Is an antibiotic drug and HCFA has not determined, for the specific drug or for the indication for which it is applied, that the drug cannot generally be administered safely and effectively in a home setting, or

(2) Is not an antibiotic drug, and HCFA has determined for the specific drug and the indications for which the drug is being applied that it can generally be administered safely and effectively in a home setting.

A drug that would otherwise be a covered outpatient drug is excluded from coverage if the drug is intravenously administered in a home setting but does not meet the definition of a covered home IV drug set forth in this paragraph. (The drug must appear on the list that is published periodically under paragraph (c) of this section and be administered for one of the indications presented on that list.) Coverage does not require a prior inpatient hospital stay.

(c) *List of covered home IV drugs.*

(1) At least annually, HCFA will publish in the **Federal Register** a notice of additions or deletions to the list of covered home IV drugs and their indications with respect to which home IV drug therapy services under Medicare may be furnished.

(2) A covered home IV drug included on the list of covered home IV drugs may not be covered as part of durable medical equipment.

§ 410.30 Limitations on Part B coverage of drugs.

(a) Except for those drugs described as "covered outpatient drugs" in § 410.29(a), Medicare Part B does not pay for the following:

(1) Except as provided in § 410.28(a), any drug or biological that can be self-administered, whether furnished by a physician, a provider, or an entity other than a provider.

(2) Any drug product approved by the FDA before October 10, 1962 that is available only through prescription that does not meet all of the conditions identified in § 410.29(a)(1)(iii) (A) and (B).

(b) Beginning January 1, 1990 and until January 1, 1991, the term "covered outpatient drug" described in § 410.29 is limited to:

(1) Drugs that are used in immunosuppressive therapy.

(2) Covered home IV drugs as defined in § 410.29(b).

(c) The term "covered outpatient drug" does not include any drug, biological product, or insulin for which payment may be made under Medicare and that is furnished as, as part of, or as incident to, any of the following services or supplies:

(1) Inpatient hospital services (section 1861(b)(2) of the Act and § 409.10).

(2) Extended care services (section 1861(h)(5) of the Act and § 409.20).

(3) Physicians' services (section 1861(s)(2) (A) or (B) of the Act and § 410.10(c)).

(4) Dialysis supplies (section 1861(s)(2)(F) of the Act and § 410.10(k)).

(5) Antigens (section 1861(s)(2)(G) of the Act and § 410.10(q)).

(6) Blood clotting factors for hemophiliacs (section 1861(s)(2)(I) of the Act).

(7) Services of a physician assistant (section 1861(s)(2)(K)(ii) of the Act).

(8) Pneumococcal, hepatitis B, or influenza vaccines (section 1861(s)(10) of the Act and § 410.57).

(9) Rural health clinic services (section 1861(aa)(1) of the Act and § 491.9).

(10) Comprehensive outpatient rehabilitation facility services (section 1861(cc)(1)(F) of the Act and § 485.51).

(11) Hospice care (section 1861(dd)(1)(E) of the Act and § 418.202(f)).

(12) Certified nurse-midwife services (section 1861(gg)(1) of the Act).

(13) A covered surgical procedure in an ambulatory surgical center (section 1832(a)(2)(F)(i) of the Act and § 416.65).

(d) Payment may not be made under Part B for any expense incurred for a covered outpatient drug described in § 410.29(a) if one of the following conditions are met:

(1) HCFA finds that the specific use of the drug for a specific indication is not safe or not effective for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member, in a specific situation or for a particular beneficiary (for example, the drug is prescribed solely for cosmetic purposes, such as to correct or ameliorate conditions such as wrinkles and balding).

(2) After the drug deductible is met, the drug is dispensed in a quantity exceeding a 34-day supply (unless HCFA has specified an exception for a longer prescription as described in paragraph (e) of this section).

(e) An exception to the limitation described in paragraph (d)(2) of this section is allowed for drugs that are marketed only in an amount that exceeds a 34-day supply. For these drugs, payment may be made for the smallest supply in which the drug is marketed.

§ 410.31 Prescription drugs used in immunosuppressive therapy.

(a) *General rule.* Payment is made for prescription drugs used in immunosuppressive therapy only as described in paragraphs (b) and (c) of this section.

(b) *Drugs dispensed before January 1, 1990.* For drugs dispensed before January 1, 1990, payment may be made only for those drugs furnished after a Medicare covered organ transplant if the drugs—

(1) Have been approved for marketing by the FDA;

(2) Are either specifically labeled for the prevention or treatment of rejection of a transplanted organ or tissue, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy; and

(3) Are used for a period of up to 1 year beginning with the beneficiary's date of discharge from the inpatient hospital stay during which the transplant was performed.

(c) *Drugs dispensed beginning January 1, 1990.* Beginning January 1, 1990, payment may be made for drugs that meet the requirements for covered outpatient drugs described in § 410.29(a)(1) and that are used in immunosuppressive therapy after either a covered or noncovered organ transplant and without any prescribed time limitations.

§ 410.32 Standards for assuring appropriate prescribing and dispensing practices of drugs.

(a) *Selected compendia.* Drug standards that appear in the following medical compendia are used for certain aspects of drug utilization review, that is, to identify and educate physicians and pharmacists about inappropriate prescribing and dispensing practices and potential adverse drug reactions:

(1) The U.S. Pharmacopoeia Dispensing Information, volume 1 (Drug Information for the Health Care Professional).

(2) The American Medical Association's Drug Evaluations.

(3) The American Hospital Formulary Service Drug Information.

(b) *Changes in selected compendia or standards.* (1) If HCFA changes its selection of any of the compendia identified in paragraph (a) of this section, it will publish a proposed rule and subsequent final rule to announce the change(s).

(2) If HCFA modifies any of the standards used for purposes of the education program described in paragraph (a) of this section that are adopted from a selected compendium, it will do so using appropriate rulemaking procedures.

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

Dated: June 9, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

Approved: August 19, 1989.

Louis W. Sullivan,

Secretary.

[FR Doc. 89-20844 Filed 9-6-89; 8:45 am]

BILLING CODE 4120-01-M

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42 CFR Part 414

[BPD-614-P]

RIN 0938-AD99

Medicare Program; Payment for Covered Outpatient Drugs

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the methodology for determining payment for covered outpatient drugs under the new catastrophic drug benefit. This proposal would implement sections 1834(c) (2), (3), and (4) of the Social Security Act as added by section 202(b) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for these covered outpatient drugs under Part B of Medicare would be implemented on January 1, 1990 for drugs used in immunosuppressive therapy and covered home intravenous (IV) drugs and on January 1, 1991 for all other drugs.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on November 6, 1989.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-614-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, DC.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

If comments concern information collection or recordkeeping requirements, please address a copy of the comments to: Office of Management and Budget, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron.

In commenting, please refer to file code BPD-614-P. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave. SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Janice Flaherty, (301) 966-4574.

SUPPLEMENTARY INFORMATION:

I. Background

• Medicare consists essentially of two separate but complementary insurance programs, the Hospital Insurance (Part A) program and the Supplementary Medical Insurance (Part B) program. Under Part A, in addition to payment for inpatient hospital services, payment is made for medical services furnished in skilled nursing facilities (SNFs) and by home health agencies (HHAs), and by hospices as an alternative to hospitalization. Part A covered benefits also include many drugs furnished to beneficiaries in hospitals, SNFs, and hospices.

Current Medicare Part A rules concerning coverage of and payment for prescription drugs and biologicals (referred to collectively as drugs in this document) are as follows:

• Under section 1861(b)(2) of the Social Security Act (the Act), we cover drugs used in the hospital that are ordinarily furnished by the hospital for the care and treatment of patients. For hospitals under the prospective payment system, payment is included in the prospective payment rates. For hospitals excluded from the prospective payment system, payment is made on a reasonable cost basis.

• Under section 1861(h)(5) of the Act, we cover drugs furnished for use in a SNF that ordinarily are furnished by the facility for the care and treatment of inpatients. Payment is determined on a reasonable cost basis.

• Under section 1861(dd)(1)(E) of the Act, we cover drugs furnished to terminally ill individuals under a written

plan as part of a hospice program. Payment is made as a component of the prospective payment rate for hospices.

Currently, under the provisions of sections 1832, 1833, and 1842 of the Act, payment is made under Part B for a wide range of medical services and supplies including those furnished by physicians or others in connection with physicians' services, outpatient hospital services, outpatient physical and occupational therapy services, and home health services. Payment under Part B is also made for drugs provided as part of certain Part B services. Generally, these are drugs that cannot be self-administered. Payment is also made for a few specified drugs as separate services.

All Medicare Part B coverage of drugs is derived from the scope of benefits provisions in section 1832 of the Act. Certain paragraphs in section 1861 of the Act define the terms in the scope of benefits provisions as including outpatient drugs. Thus, section 1832 of the Act provides for Part B coverage of outpatient drugs. Current Medicare Part B rules generally provide coverage and payment for outpatient drugs as follows:

- Under section 1861(s)(2)(A) of the Act, we cover drugs that cannot be self-administered and that are furnished incident to a physician's professional services. Payment is determined on the basis of the approximate cost for ingredients and supplies plus an injection fee.
- Under section 1861(s)(2)(C) of the Act, we cover diagnostic services furnished by a hospital to outpatients, including drugs required in the performance of these services. Payment is determined on a reasonable cost basis.
- Under section 1861(s)(2)(F) of the Act, we cover dialysis supplies, including drugs, under the end-stage renal disease (ESRD) prospective payment rate. Under 42 CFR 413.170, payment to an ESRD facility is based on cost.
- Under section 1861(s)(2)(G) of the Act, we cover antigens that are prepared by a physician for a particular patient and that are administered by or under the supervision of a physician. Payment is determined based on the cost of the antigens plus an injection fee.
- Under section 1861(s)(2)(I) of the Act, we cover blood clotting factors for hemophilia patients competent to use those factors to control bleeding without medical or other supervision. Payment is determined on a reasonable charge basis.
- Under the former section 1861(s)(2)(J) of the Act, we covered immunosuppressive drugs and drugs that are needed for effective immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under Medicare and that are furnished within 1 year after the date of the transplant procedure. Payment is determined on the basis of approximate cost for ingredients and supplies. Because drugs used in immunosuppressive therapy are self-administered, no additional payment is made for administration.
- Under section 1861(s)(2)(K)(ii) of the Act, we cover drugs that cannot be self-administered that are incident to a physician assistant's services furnished under the supervision of a physician. Payment is determined based on the approximate cost for ingredients and supplies of the drug plus an injection fee.
- Under section 1861(s)(10) of the Act, we cover pneumococcal and hepatitis B vaccines, as well as influenza vaccines for some beneficiaries under a demonstration project. Payment is determined based on the approximate cost for ingredients and supplies plus an injection fee.
- Under section 1861(cc)(1)(F) of the Act, we cover drugs that cannot be self-administered and that are furnished to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility. Payment is determined on a reasonable cost basis.
- We cover drugs that cannot be self-administered and that are furnished as part of or incident to the provision of the following covered services:

—Covered rural health clinic services (section 1861(aa)(1) of the Act). Payment is made on a cost-related rate per visit, subject to an upper limit.

—Partial hospitalization services (section 1861(ff)(2)(D) of the Act). Payment is determined on a reasonable cost basis.

—Certified nurse-midwife services (section 1861(gg)(1) of the Act). Payment is determined based on the approximate cost for ingredients and supplies plus an injection fee. Some carriers provide an amount for additional related supplies.

—Ambulatory surgical center (ASC) services (section 1832(a)(2)(F)(i) of the Act). Under §§ 416.61(c) and 416.120, payment is made as a component of the prospective payment rate for ASCs.

Medicare generally pays 80 percent of each payment amount determined above for covered drugs and services after the beneficiary has met a $75 deductible. The beneficiary is then liable for the remaining amount of the charge (coinsurance), which is usually 20 percent of the payment amount. The only exception to this rule is payment for pneumococcal and influenza vaccines and for the services connected with the furnishing of these two vaccines, which, under the authority of section 1833(a)(1)(B) of the Act, are not subject to the 20 percent coinsurance (that is, Medicare pays 100 percent of the payment amount). In addition to the deductible and coinsurance amounts, if a physician or other supplier does not accept assignment (that is, does not agree to accept Medicare's determination of the reasonable charge amount as payment in full for covered drugs), the beneficiary is liable for the difference between Medicare's reasonable charge and the supplier's actual charge, subject to certain limits on that charge.

II. The Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360, enacted on July 1, 1988) established a new catastrophic outpatient drug benefit under Medicare Part B. For purposes of coverage, payment, deductibles, and coinsurance, the new Part B catastrophic outpatient drug benefit is distinct and separate from the pre-existing Medicare drug benefits. The current Medicare drug benefit includes both Part A and Part B coverge as described above. Except for drugs used in immunosuppressive therapy, the current drug benefit (including both coverage and payment provisions) has not been changed by Public Law 100–360.

In general, section 202 of Public Law 100–360 provides for coverage of and payment for drugs used in immunosuppressive therapy following an organ transplant without regard to the duration of that therapy or whether the organ transplant procedure was covered by Medicare, and for covered home intravenous (IV) drugs. Payment for these two categories of benefits begins January 1, 1990 and for all other covered outpatient drugs (including insulin) payment begins on January 1, 1991.

Specifically, section 202(a) of Public Law 100–360 amended sections 1861 (s)(2)(J) and (t) of the Act to include "covered outpatient drugs" as part of the "medical and other health services" benefit under sections 1832 (a)(1) and (a)(2)(B) of the Act. As discussed below, current coverage for drugs used in immunosuppressive therapy would be expanded under the provisions of Public Law 100–360, and these drugs would be

included as part of the new catastrophic drug benefit.

As revised, section 1861(s)(2)(J) of the Act provides coverage of "covered outpatient drugs", as defined in section 1861(t)(2) of the Act. Section 1861(t)(2) of the Act defines that term to include a broad range of drugs, biological products, and insulin. In this proposed rule, we use the term "drugs" to include biologicals and insulin because payment would be determined in the same manner for these items as for drugs. Sections 1861(t)(4) (A) and (B) of the Act specify that, in general, covered home IV drugs are defined as covered outpatient drugs that are safe and effective for intravenous administration to an individual in a place of residence used as the individual's home.

The payment methodology for covered outpatient drugs is set forth in sections 1834(c) (2), (3), and (4) of the Act as added by section 202(b) of Pub. L. 100–360. Briefly, the payment methodology is as follows:

- Subject to the catastrophic drug deductible, the payment amount for covered outpatient drugs is equal to the payment percent of the lesser of—

—The actual charge for the drug; or

—The applicable payment limit for the drug.

- The payment percent is equal to 100 percent minus the applicable coinsurance amount.

- A separate payment limit is calculated for—

—Nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions; and

—Multiple-source drugs without restrictive prescriptions.

These provisions are discussed in detail below as a part of our discussion of the provisions of this proposed rule, which set forth the methodology for determining payment for covered outpatient drugs. Coverage of outpatient drugs, including definitions, is discussed in a separate notice of proposed rulemaking. In addition, we are publishing other proposed rules to implement the new catastrophic drug benefit. These proposed rules include separate documents detailing coverage requirements for home IV drug therapy services, conditions of participation for qualified home IV drug therapy providers, catastrophic drug deductibles and coinsurance amounts, the fee schedule for home IV drug therapy services, requirements for participating pharmacies, and the list of covered home IV drugs.

III. Provisions of This Proposed Rule

A. General

This proposed rule sets forth the payment methodology for outpatient drugs that are covered under the new catastrophic drug benefit, including covered prescription drugs used in immunosuppressive therapy following an organ transplant and covered home IV drugs, effective January 1, 1990. Coverage and payment for all other covered outpatient drugs would begin January 1, 1991.

Immunosuppressive drugs were covered effective January 1, 1987 if furnished within 1 year after the beneficiary's date of discharge from an inpatient hospital stay during which a covered organ transplant was performed. Coverage was extended to all prescription drugs used in immunosuppressive therapy furnished after a covered transplant within 1 year after the beneficiary's date of hospital discharge beginning December 22, 1987. The provisions of section 1861(t) of the Act, as amended by section 202(a) of Public Law 100–360, effectively extend the coverage of drugs used in immunosuppressive therapy to include those drugs furnished in subsequent years after the first year following a covered transplant and those drugs furnished after a noncovered transplant irrespective of any time limitations. Thus, beginning in 1990, prescription drugs used in immunosuppressive therapy are considered part of the catastrophic drug benefit, rather than the original Medicare drug benefit. Therefore, drugs used in immunosuppressive therapy would no longer be subject to the provisions of the law pertaining to the current Medicare benefit for drugs, but, effective January 1, 1990, will be subject to the coverage and payment rules applicable to the catastrophic drug benefit.

The payment methodology described herein pertains to Medicare payments for all covered outpatient drugs after Medicare beneficiaries meet the drug deductible. The amount payable for a covered outpatient drug would be the applicable payment percent for the drug multiplied by the lesser of the actual charge for the drug or the applicable payment limit for the drug. The payment limit for multiple-source drugs without restrictive prescriptions and the payment limit to be used for both multiple-source drugs with restrictive prescriptions and nonmultiple-source drugs are determined under two separate calculations.

B. Payment Percent

Under section 1834(c)(2)(B) of the Act, the payment percent equals 100 percent minus the applicable percent. Under section 1834(c)(2)(C) of the Act, the coinsurance percents are as follows:

- For covered home IV drugs and drugs used in immunosuppressive drug therapy that are furnished during the first year after a covered organ transplant, 20 percent.

- For all other covered outpatient drugs—

—50 percent for drugs dispensed in 1990 or 1991;

—40 percent for drugs dispensed in 1992; and

—20 percent for drugs dispensed in 1993 or a subsequent year.

Because the payment percent equals 100 percent minus the applicable coinsurance percent, the payment percent is as follows:

- For covered home IV drugs and drugs used in immunosuppressive drug therapy that are furnished during the first year after a covered organ transplant, 80 percent.

- For all other covered outpatient drugs—

—50 percent for drugs dispensed in 1990 or 1991;

—60 percent for drugs dispensed in 1992; and

—80 percent for drugs dispensed in 1993 or a subsequent year.

C. Determination of Payment Limit

As stated above, the payment limit for multiple-source drugs without restrictive prescriptions would be determined under a different methodology than the methodology used for both multiple-source drugs with restrictive prescriptions and nonmultiple-source drugs. These payment limits would be determined for specific payment calculation periods. In addition, under section 1834(c)(3)(C)(iv) of the Act, the average price component of the payment limits is to be determined on a national basis except that the Secretary may make these determinations on a regional basis if it can be demonstrated that there are limitations on the availability of drug products and variations among different areas in the average wholesale or comparable direct price (referred to in this document as average price) for a drug product. We intend to determine the average price component of the payment limits on a national basis. We would consider exceptions to the national price if presented with documented information regarding limited availability and price variations. Such determinations would be made on

a case-by-case basis. Explanations of these terms and the two methodologies that would be used in determining the payment limits are set forth below.

1. Definitions

a. Payment Calculation Period. As provided in section 1834(c)(9)(C) of the Act, the term "payment calculation period" means either the 6-month period beginning January 1st of each year or the 6-month period beginning July 1st of each year. Thus, a new payment limit would be calculated for all covered drugs every 6 months.

b. Multiple-Source Drug. In accordance with the provisions of section 1834(c)(9) of the Act, we would define a multiple-source drug as a covered outpatient drug for which, during a payment calculation period, there are two or more drug products that meet all of the following conditions:

- The drug products are rated as therapeutically equivalent by the Food and Drug Administration (FDA) in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."
- The drug products have been determined by the FDA to be pharmaceutically equivalent and bioequivalent as follows:

—As set forth in section 1834(c)(9)(A)(iii)(I) of the Act, pharmaceutically equivalent drug products are those drug products that contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity.

—As defined in section 1834(c)(9)(A)(iii)(II) of the Act, drug products are bioequivalent if they do not present a known or potential bioequivalence problem or, if they do present such a problem, are shown to meet an appropriate standard of bioequivalence.

However, as provided in section 1834(c)(9)(A)(ii) of the Act, this requirement that drug products be pharmaceutically equivalent and bioequivalent does not apply if the FDA changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the FDA's most recent publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent. In this case, the drug product would have to meet the revised FDA definition of therapeutic equivalence.

- The drug products are sold or marketed during the period. Under the provisions of section 1834(c)(9)(A)(iii)(III) of the Act, a drug is considered to be sold or marketed if it is listed in FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (other than in the Discontinued Drug Product List in that publication) and we do not determine that the sale or marketing is not actually occurring.

c. Nonmultiple-Source Drug. Section 1834(c)(3)(A) of the Act refers to the case of a drug that "is not a multiple-source drug (as defined in paragraph (9)(A) (of section 1834(c) of the Act))." We would define a nonmultiple-source drug as any drug that does not meet the definition of a multiple-source drug. In general, this would mean a drug that is available for purchase under only one "brand name" or a drug that has several drug products that are not rated therapeutically equivalent.

d. Drug with a Restrictive Prescription. As provided in section 1834(c)(9)(B) of the Act, we would define a drug as having a restrictive prescription if either of the following conditions apply:

- In the case of a written prescription for a drug, the prescribing physician (or other legally authorized person who is prescribing the drug) includes on each prescription form in his or her own handwriting, the specific phrase "brand medically necessary," meaning that the particular drug must be dispensed.
- In the case of a prescription for a drug that is issued by telephone, the prescribing physician (or other legally authorized person who is prescribing the drug) states "brand medically necessary," meaning that the particular drug must be dispensed and, within 30 days of the date of the telephone call, sends a written confirmation (for example, a completed prescription form) to the pharmacy indicating that the particular drug was required. Each confirmation must also include the phrase "brand medically necessary" in the handwriting of the prescriber and the prescriber's signature.

In these cases where the pharmacist fills a prescription for a multiple-source drug with a brand-name product even though the prescriber has not restricted the prescription by indicating "brand medically necessary," the Medicare payment amount would be that for a multiple-source drug without a restrictive prescription.

We propose to limit acceptable phrases to those that include the phrase "brand medically necessary" although section 1834(c)(9)(B) of the Act permits the Secretary to accept other phrases if he determines that they are appropriate. We believe that any prescription for a brand name drug should be the result of a conscious decision concerning the medical necessity of the particular drug. Thus, alternatives such as dual-line prescription forms (in which the prescribing physician furnishes his or her signature above a statement that reads "dispense as written" or "product selection permitted"), notations and phrases such as "d.a.w. (dispense as written)" or "N/S (no substitution)," or check boxes, all of which may be acceptable for some State generic drug laws, would not be acceptable because they do not establish satisfactorily a conscious determination of the medical necessity to override generic substitution in order to obtain the more costly brand name drug for a particular patient.

We also believe that limiting acceptable phrases to "brand medically necessary" would be simpler for prescribers because they would have only one phrase to remember. We are interested in receiving public comment concerning whether there are any additional phrases that we could include as allowable that convey the concept of medical necessity.

Under section 1834(c)(9)(B)(ii) of the Act, if a prescription is issued by telephone, the written confirmation must be received within 30 days of the telephone call and must be "in the handwriting of the physician or other person prescribing the drug" and must indicate "with such appropriate phrase (as "brand medically necessary") that the particular drug was required to have been dispensed" in order to be considered a restrictive prescription. A prescription form prepared by the prescriber with "brand medically necessary" in the handwriting of the prescriber with his or her signature and forwarded by the prescriber to the pharmacy would meet the requirement for a written confirmation.

As noted above, under the requirements of section 1834(c)(9)(B)(ii)(II) of the Act, a prescriber is responsible for providing a written confirmation to a pharmacy within 30 days of a telephone prescription. However, if a written confirmation is not provided to the pharmacy by the prescriber, it is the pharmacy that could suffer any resulting payment reduction. That is, in the absence of a written confirmation that a brand name drug was medically necessary, the prescription would not meet the definition of a restrictive prescription as set forth in section 1834(c)(9)(B)(ii) of the Act. Thus,

payment for the drug prescribed would be made using the payment methodology set forth in section 1834(c)(3)(B) of the Act for multiple-source drugs without a restrictive prescription, which is expected to result in a lower payment amount than the payment methodology set forth in section 1834(c)(3)(A) of the Act for multiple-source drugs with a restrictive prescription.

Since the statute places the obligation to confirm a telephone prescription for a brand name drug on the prescriber and at the same time imposes any penalty for not having that confirmation on the pharmacy, we would allow pharmacies to assist the prescribers in meeting their obligation. If a pharmacy chooses to, it would be permitted to complete a form for each restrictive prescription and send the form to the prescriber so that the prescriber could write in his or her own handwriting the phrase "brand medically necessary" on the form, sign it, and return it to the pharmacy. We believe that this approach would both satisfy the requirements of section 1834(c)(9)(B)(ii)(II) of the Act and assist the pharmacy in obtaining written confirmations from prescribers who do not fulfill their obligation to provide them. We are interested in receiving suggestions regarding other methods that could be used to assist pharmacies in obtaining written confirmations. We note that we would consider only methods that comply with the statute; that is, each restrictive telephone prescription must have a written confirmation with the phrase "brand medically necessary" in the prescriber's own handwriting.

We are also seeking comments on the appropriate designation of restrictive prescriptions transmitted to pharmacies by facsimile (FAX) machines. We are proposing that such prescriptions be considered telephone prescriptions because it is not always possible for the pharmacist to determine from a "faxed" prescription that the prescriber wrote "brand medically necessary" in his or her own handwriting on each prescription. Thus, the same requirements for a written confirmation that apply to telephone prescriptions would apply to prescriptions transmitted by a FAX machine.

2. General Methodology for Payment Limits

This section sets forth the methodologies that would be used in determining the two different payment limits. Explanations of the provisions that apply to both payment limits (that is, the administrative allowance and determination of dosage unit average price) are set forth in sections III.C.3 and III.C.4 of this preamble, below. Section III.C.5. of this preamble discusses the determination of the 90th percentile of actual charges, which would be used for determining the payment limit for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions only.

a. Payment Limit Methodology for Multiple-Source Drugs Without Restrictive Prescriptions. As provided in section 1834(c)(3)(B) of the Act, the payment limit for a multiple-source drug without a restrictive prescription is equal to the sum of—

- The amount of the administrative allowance (as set forth in section 1834(c)(4) of the Act); and
- The product of the number of tablets (or other dosage units) dispensed and the per dosage unit average price for the drug during the payment calculation period in which the drug is dispensed.

b. Payment Limit Methodology for Nonmultiple-Source Drugs and Multiple-Source Drugs With Restrictive Prescriptions. As provided in section 1834(c)(3)(A) of the Act, the payment limit for a nonmultiple-source drug and a multiple-source drug with a restrictive prescription is determined as follows:

- For drugs dispensed on or after January 1, 1990 and before January 1, 1992, the payment limit equals the sum of—

—The amount of the administrative allowance; and
—The product of the number of tablets or other dosage units dispensed and the per dosage unit average price for the drug during the payment calculation period in which the drug is dispensed

- For drugs dispensed on or after January 1, 1992, the payment limit is equal to the lesser of the following:

—The amount of the administrative allowance plus the product of the number of tablets or other dosage units dispensed and the per dosage unit average price for the drug during the payment calculation period in which the drug is dispensed.
—The 90th percentile of the actual charges for the drug for the second previous payment calculation period. (For example, if the current payment calculation period is January 1, 1992 through June 30, 1992, then the second previous payment calculation period would be January 1, 1991 through June 30, 1991.) The charge screens for actual charges would be computed on a per dosage unit basis, taking into consideration dosage form and strength.

3. Administrative Allowance

In this proposed rule, as provided in section 1834(c)(4)(A) of the Act, the amount of the administrative allowance, which is paid to a pharmacy for dispensing a covered outpatient drug, is determined as follows:

- For drugs dispensed in 1990 and 1991, the administrative allowance is equal to—

—$4.50 for a drug dispensed by a participating pharmacy; and
—$2.50 for a drug dispensed by a pharmacy that is not a participating pharmacy.

- In each year subsequent to 1991, the administrative allowance is equal to the allowance for the preceding year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as pubished by the Department of Commerce in its "Survey of Current Business") over the 12-month period ending with August of that preceding year. In making this calculation, the amount of the new allowance is rounded to the nearest penny.

We are proposing that separate administrative allowance for pharmacy services would not be made for dispensing a drug to be used in home IV drug therapy because payment for pharmacy services, including the administrative cost connected with dispensing drugs for home IV drug therapy, would be made as part of a home IV drug therapy services per diem fee schedule for pharmacy services and supplies, nursing services and supplies, and other equipment necessary for home IV drug therapy. (As noted above, our proposed methodology for determining this per diem fee schedule will be published as a separate notice of proposed rulemaking.) Consequently, the charge reflected by the home IV drug therapy provider for the drug ingredient should not include any items that are paid for under the per diem fee schedule, that is, pharmacy services and supplies, nursing services and supplies, or other equipment.

We are also proposing to limit the payment of the administrative allowance for drugs dispensed on an "as needed" basis to residents of long-term care facilities. We are proposing to pay the administrative allowance each time a drug product is prescribed on an as-needed basis, that is, each time the prescriber makes a notation in the patient's chart. It should be noted that these prescriptions must meet the

requirements concerning the length of time or number of doses of a prescription set forth in our proposed rule on coverage of drugs under Public Law 100–360. A second administrative allowance would be paid for the same drug product only when it is prescribed a second time.

The purpose of this limitation is to preclude situations where an administrative allowance would be charged each time a dose of the "as needed" drug is dispensed. We invite comments regarding other approaches for the payment of an administrative allowance for drugs dispensed on an "as needed" basis to residents of a long-term care facility that would avoid excessive changes for dispensing these drugs.

In the case of insulin that is injected by the beneficiary subcutaneously and is available without a prescription, we would pay an administrative allowance each time a reasonable quantity of insulin is purchased. We consider a reasonable quantity of insulin to be a 30-day supply. If a beneficiary purchases two or more bottles of insulin at one time, we would pay one administrative allowance for the purchase.

We fully expect that most beneficiaries who purchase nonprescription insulin will purchase it in 30-day supplies. However, we also recognize that there are exceptional circumstances where purchases would need to be made more often and an administrative allowance would be paid in these circumstances; for example, there is a change in the type of insulin the beneficiary uses or the beneficiary's insulin regimen is otherwise modified, or if because of travel plans, the beneficiary needs to make smaller purchases or forgets to bring along enough insulin for duration of the trip.

We believe that paying an administrative allowance each time a 30-day supply of insulin is purchased would be reasonable because many diabetics purchase insulin in approximately a 30-day supply and because, if the Medicare program routinely pays for more frequent purchases, program costs and premiums may be higher than necessary with no corresponding benefit to the beneficiaries.

Under section 1842(o)(1) of the Act as added by section 202(c)(1)(C) of Public Law 100–360, a participating pharmacy means, with respect to covered outpatient drugs dispensed on or after January 1, 1991, an entity that is authorized under a State law to dispense covered outpatient drugs and that has entered into an agreement with the Secretary under which the pharmacy agrees to accept payment on an assignment-related basis for all covered outpatient drugs dispensed to a Medicare beneficiary after the pharmacy has been notified that the beneficiary has met the catastrophic drug deductible. (As noted above, we are preparing a separate notice of proposed rulemaking concerning the requirements for participating pharmacies.)

Although section 1834(c)(4)(A) of the Act provides for an administrative allowance in 1990 for participating pharmacies, section 1842(o)(1) of the Act, as noted above, defines participating pharmacies only in the context of dispensing covered drugs on or after January 1, 1991. Because under 1842(o)(1) of the Act an entity cannot be a participating pharmacy until January 1, 1991, the administrative allowance for drugs dispensed in 1990 (other than drugs to be used in home IV therapy, for which payment for pharmacy services would be made under a fee schedule) would have to be made at the nonparticipating pharmacy rate of $2.50. Because section 1861(t)(3)(B) of the Act limits covered outpatient drugs to be dispensed in 1990 to drugs used in immunosuppresive therapy and covered home IV drugs, an administrative allowance would be made in 1990 only for dispensing drugs used in immunosuppressive therapy.

Under section 1834(c)(4)(B) of the Act, after consultation with pharmacists, groups representing the elderly, and private insurers, the Secretary may, by regulation, reduce the administrative allowance for any drug dispensed by a mail-service pharmacy (as defined by the Secretary). Any reduction must be based on differences between mail service pharmacies and other pharmacies with respect to operating costs and other economies.

We are not proposing to make any reduction to the statutory administrative allowance for a drug dispensed by a mail-service pharmacy at this time. However, we will continue to pursue setting a reduced administrative allowance for drugs dispensed by a mail-service pharmacy based on a variety of factors, including operating costs, overall charge levels, and the extent of use of mail-service pharmacies by Medicare beneficiaries. In addition, we are specifically seeking public comment from pharmacists, groups representing the elderly, and private insurers concerning whether it would be appropriate to make a reduction in the administrative allowance for drugs dispensed by a mail-service pharmacy. If a commenter believes that some reductions are appropriate, we are interested in receiving data and suggestions concerning these adjustments.

4. Determination of Dosage Unit Average Price

Dosage unit average price would be based on dosage form and strength for each drug product. Dosage unit average price would be determined in one of two ways: Using published average wholesale or comparable direct prices for the drug or using survey prices. We intend to conduct a biannual survey of nonmultiple-source drugs that are most commonly used by beneficiaries. We are considering conducting a survey of the most commonly used multiple-source drugs. We would use commonly recognized comprehensive listings, discussed below, to determine the published average prices. If there is both a survey average price and a published average price, we would use the lower of the two prices. If a specific drug is not included in the survey, the determination of average price would be based on published average wholesale or comparable direct prices for the drug.

For both a survey and a published average price, the prices used would be those in effect on the first day of the previous payment calculation period as required by section 1834(c)(3)(C)(iii) of the Act. For example, for determining payment for a drug to be dispensed on or after January 1, 1992 and before July 1, 1992, the prices that would be used are those in effect on July 1, 1991.

Under section 1834(c)(3)(C)(iii) of the Act, we are required to use reasonable quantities, which we define as the most frequently purchased package size, as appropriate. In addition, under section 1834(c)(3)(C)(iv) of the Act, the determination is made on a national basis, except that we may make this determination on a regional basis if it can be demonstrated that there are limitations on the availability of drug products and variations among regions in the average prices for a drug product. As we stated above, we intend to make the determination of the average price component on a national basis.

a. Biannual Survey. Under section 1834(c)(3)(C)(ii)(I) of the Act, the Secretary must conduct a biannual survey of nonmultiple-source drugs to determine the per dosage unit average price for the drug. However, the Secretary need not conduct a survey if—

- During 1990, the Secretary determines that a survey is not appropriate for a specific covered outpatient drug; or
- After 1990, there is a low volume of sales for the drug or there are other

appropriate reasons not to conduct a survey.

Under section 1834(c)(3)(C)(ii)(II) of the Act, for multiple-source drugs, the Secretary may base the per dosage unit average price for the drug on either the published average price for the drug or on a biannual survey.

The biannual surveys must be based on prices in effect the first day of the previous payment calculation period. For example, for drugs dispensed on or after January 1, 1991 and before July 1, 1991, the survey must be based on prices in effect on July 1, 1990. In addition, the biannual surveys must be based on a representative sample of direct sellers, wholesalers, or pharmacies (as appropriate) of wholesale or comparable direct prices excluding discounts to pharmacies. That is, in determining the average price, the Secretary cannot take into account any discount provided to a pharmacy.

We are considering use of a survey for multiple-source drugs that are commonly prescribed to Medicare beneficiaries. We intend to conduct the survey on a selected basis because we believe that the survey results may give a more accurate reflection of prices (exclusive of discounts) of prescription drugs compared to the published average prices in the comprehensive listings. The extent of the survey would be determined on an on-going basis. As required by section 1834(c)(3)(B)(ii) of the Act, we would use the unweighted median of the surveyed prices. We also intend to limit the survey of nonmultiple-source drugs to those drugs that are more commonly prescribed to Medicare beneficiaries. In this case, we would use the median of the surveyed prices.

Any survey that we conduct would use statistically valid methods of sampling, estimation, and imputation in order to establish the drug prices in effect for the payment calculation period.

Section 1834(c)(3)(C)(ii) of the Act specifies that discounts to pharmacies should not be considered in determining the average price. There is a common billing practice of showing both suggested list price and the wholesaler's or manufacturer's actual selling price on invoices. For example, an invoice has one column marked "suggested list price," "list AWP," or a similar phrase. A second column is marked "actual cost" or "price." We would use the actual selling prices (before discounts) for purposes of the survey because the suggested list prices (or list AWP) are essentially comparative prices to demonstrate that when the purchaser pays the actual selling price, the purchaser pays less than the suggested list prices. The actual selling price is the price at which the drug product is generally available to pharmacies, either from a wholesaler or a manufacturer.

For determining survey prices, we would use the generally available selling price instead of the "list average wholesale price (AWP)" because we believe this is consistent with Congressional intent. The Conference Report states that the survey "is vital to ensuring the integrity of reimbursement limits" and, to that end, Congress gave the Secretary the authority to impose civil monetary penalties if a wholesaler or direct seller refuses to provide information to the Secretary or provide false information. (H.R. Rep. No. 661, 100th Cong., 2d Sess. 189 (1988).) Implicit in the statement that the survey is vital to the integrity of payment limits and in the provisions for civil monetary penalties is the assumption that the prices to be derived from the survey will be more accurate and, in all likelihood, lower than the prices in the nationally recognized comprehensive published price listings.

The "list AWP" on invoices sampled for the survey activity is the same as or similar to the average wholesale price in the published price listings. There would be no value in conducting a survey of this nature if it would be merely an exercise in gathering data already available in the published price listings. In addition, there would be no purpose in expending public funds to carry out the survey if it duplicates price information that is already publicly available. There would also seem to be no purpose in Congress giving the Secretary authority to impose civil monetary penalties for refusal to provide information or provision of false information if we would only be gathering price information that is already available. We are, however, specifically requesting comments on using the generally available selling price in determining survey prices.

b. Published Average Price. We intend to use the Red Book published by Medical Economics, the American Druggist Blue Book (Blue Book) published by the Hearst Corporation, and prices published by Medi-Span, Inc. (Medi-Span) for determinations of published average price. In developing the unweighted median of the published average prices for a multiple-source drug without a restrictive prescription, we would array the average prices from these three publications. If there is a difference in the published listings of a distributor's price, we would use the lowest price.

For nonmultiple-source drugs and multiple-source drugs with a restrictive prescription, we would use the lowest published price from the sources listed above, as stated in the Conference Report (H.R. Rep. No. 661, 100th Cong. 2nd Sess. 189 (1988)).

c. New Therapeutically Equivalent Drugs. If drugs are added to the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," during a 6-month payment calculation period, the following would apply:

- If addition of a drug changes the status of the drug from a nonmultiple-source drug to a multiple-source drug, we would recompute the dosage unit average price. The new dosage unit average price would be reflected in payments within 1 month of when the FDA published the addition of a therapeutically equivalent product in "Approval Drug Products with Therapeutic Equivalence Evaluations."
- If a drug was already a multiple-source drug at the beginning of the payment calculation period, we do not anticipate making any adjustment to the dosage unit average price. Of course, after the 6-month payment calculation period in which a drug is added to "Approved Drug Products with Therapeutic Equivalence Evaluations," we would consider the pricing information for the drug just as we consider pricing information for other drugs.

We believe that these decisions on how to handle additions to "Approved Drug Products with Therapeutic Equivalence Evaluations" would be reasonable. In the case of a drug that becomes a multiple-source drug during the payment calculation period, the price at which a therapeutically equivalent product is available is likely to be less. We believe that these potential price reductions should be incorporated into Medicare payments. For a drug that was already a multiple-source drug, we believe the addition of another drug product is less likely to modify the Medicare payment limits in a significant way.

5. Determining the 90th Percentile of Actual Charges

Under section 1834(c)(3)(A)(i) of the Act, the Secretary computes the 90th percentile of actual charges on any geographic basis that he determines to be appropriate, for example, carrierwide or statewide. The most administratively feasible bases for these computations would be carrierwide or national. We considered using a carrierwide basis, that is, calculating the 90th percentile in

each of the drug bill processor regions. However, we are proposing to use a national basis for determining the 90th percentile of actual charges because the other payment limit component (the administrative allowance plus the product of the number of tablets or other dosage units dispensed and the per dosage unit average price for the drug) would also be computed on a national basis. We believe that using two nationally based amounts would yield the most equitable comparison. We are, however, interested in receiving comments on the advisability of using a carrierwide basis instead of a national basis for these computations.

The determination of the 90th percentile of actual charges would be made on a per dosage unit basis taking into consideration the dosage form and strength.

D. Nontherapeutically Equivalent Drugs

In classifying generic drugs, the FDA uses two categories. The A category includes drug products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products. The B category includes drug products that the FDA does not at this time consider to be therapeutically equivalent to other pharmaceutically equivalent products. Drugs in category B do not meet the definition of multiple-source drugs as set forth in section 1834(c)(9)(A) of the Act because category B drugs are not therapeutically equivalent. Thus, B category drugs may not be substituted for category A drugs or for "brand name" drugs.

We are proposing to pay for category B drugs but only as nonmultiple-source drugs and only if the prescription specifically identifies the category B drug. We are specifically seeking public comments about category B drugs and our proposal to pay for them only as nonmultiple-source drugs.

E. Changes to the Regulations

The regulations implementing the provisions of sections 1834(c) (2), (3), and (4) of the Act that provide for payment for drugs under the catastrophic drug benefit provisions would be located in Subpart I (Payment for Drugs Under the Catastrophic Drug Benefit) of a new Part 414 (Payment for Part B Medical and Other Health Services). We intend to issue a separate final rule to move the current sections on reasonable charges for Part B services from Part 405, Subpart E to Part 414. Other subparts will be added in separate documents as new provisions of the law are implemented through the usual rulemaking process.

IV. Regulatory Impact Statement

A. Executive Order 12291 and Regulatory Flexibility Analyses

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

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

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all pharmacists, most pharmacies, and some pharmaceutical manufacturers qualify as small entities.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

Readers may find the following discussion to be very similar to impact analyses in other regulations or notices implementing provisions of the Medicare catastrophic drug benefit. We have purposefully provided complete analyses in each document (even though they may be duplicative) to provide readers with complete discussions of the possible effects of the provisions being implemented without having to refer to other Federal Register documents.

This proposed rule would implement section 202(b) of Public Law 100-360, which provides Part B payment for covered drugs used in immunosuppressive therapy and covered home IV drugs effective January 1, 1990 and for all other covered drugs effective January 1, 1991. As envisioned by the statute and assuming adequate financing, we anticipate that Medicare payment for these drugs would result in the following costs:

TABLE I—PROJECTED COSTS AS A RESULT OF MEDICARE PAYMENT FOR OUTPATIENT PRESCRIPTION DRUGS

[In millions]*

Fiscal year—			
1990	1991	1992	1993
$130	$1,210	$3,600	$3,830

*Rounded to the nearest $10 million.

We believe that any effects of these provisions on the economy and public would primarily be the result of the statute and not this proposed rule. This is because we have proposed to implement the statute exercising administrative discretion in the following four areas only:

- Determining the 90th percentile of actual charges for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions on a national basis.
- For all covered drugs, the Secretary must calculate the average price component on a national basis. However, to take account of limitations on the availability of drug products and variations among different areas in the average price for a drug product, the Secretary may determine the average price component of the payment limits on a regional basis.
- For multiple-source drugs without restrictive prescriptions, the Secretary may base the per dosage unit average price for the drug on either the published average price for the drug or on a biannual survey. We are considering use of a survey for multiple-source drugs that are commonly prescribed to Medicare beneficiaries. The statute makes no mention of a survey for multiple-source drugs with restrictive prescriptions. Therefore, their price would be determined by the lowest published price.
- For nonmultiple-source drugs, the Secretary must base the per dosage unit average price for the drug on a biannual survey. However, the Secretary need not conduct a survey if, during 1990, the Secretary determines that a survey is not appropriate for a specific covered outpatient drug, or, after 1990, there is a low volume of sales for the drug or there are other appropriate reasons not to conduct a survey. In such cases, the per dosage unit average price is based on the published average price.

In section III of this preamble, we discuss our rationale for choosing specific provisions. As discussed below in the analyses in section IV.B. of this preamble, we do not believe these provisions would result in significant

effects under E.O. 12291, RFA, or rural hospital criteria.

The major provisions of this proposed rule are prescribed by the Act as amended by Pub. L. 100-360. This rule would conform the provisions of the Code of Federal Regulations to the changes made by the statute. However, we have prepared voluntary E.O. 12291 and regulatory flexibility analyses (at section IV.C. below) for this proposed rule because coverage of outpatient prescription drugs would represent a significant expansion of Medicare benefits and because of the large number of pharmacists, pharmacies, and pharmaceutical manufacturers who would be affected by the statute.

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

B. Use of Administrative Discretion

Below is a discussion of those areas in which we have exercised administrative discretion and a discussion of why we believe the effects of our choices would be negligible.

Section 1834(c)(3)(A) of the Act sets forth the payment limit for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions. The payment limit for these drugs for a payment calculation period is equal to the lesser of the 90th percentile of the actual charges (computed on a statewide basis, carrierwide basis, or other appropriate geographic area basis, as specified by the Secretary) or the amount of the administrative allowance plus the product of the number of tablets and the per tablet or unit average price for such drug. We are given discretion in determining the appropriate geographic basis for calculating the 90th percentile of actual charges. As stated in section III. of this preamble, we propose to do this on a national basis.

We believe that the most administratively feasible basis for determining the 90th percentile of charges is either carrierwide or national. We propose to use a national basis because the other payment limit component (the administrative allowance plus the product of the number of tablets or other dosage units dispensed and the per dosage unit average price for the drug) is computed on a national basis. We believe using two nationally-based amounts would yield the most equitable comparison. We believe that use of a national basis could benefit those pharmacies that have overhead and operating costs lower than the median. However, we do not believe that this would have any significant effect on pharmacies.

Under section 1834(c)(3)(C)(iv) of the Act, the average price component of the payment limits for all covered drugs is to be determined on a national basis. However, the Secretary may make these determinations on a regional basis if it can be demonstrated that there are limitations on the availability of drug products and variations among different areas in the average price for a drug product.

We expect that the instances when we would use this authority would be unusual. That is, we believe it is unlikely that the availability or price of a drug would vary significantly in one area relative to others. The purpose of the authority to make these adjustments is to take account of such unusual situations regarding the availability and price of drugs. Since these adjustments should more accurately reflect pharmacy costs in unusual circumstances, we anticipate that their effect, while minimal, would not be adverse.

In accordance with section 1834(c)(3)(C)(ii)(I) of the Act, the Secretary is required to survey wholesalers, manufacturers, and other direct sellers of covered outpatient drugs to determine the average wholesale price of nonmultiple-source drugs. In 1990, the Secretary may exclude a drug from the survey if he determines there is good reason to do so. For surveys conducted after 1990, a drug may be excluded from the price survey either because of a low volume of sales for that drug or for some other appropriate reason.

As explained in section III.C.4. of this preamble, we intend to survey all commonly prescribed nonmultiple-source drugs to determine their average wholesale price. In order to determine which nonmultiple-source drugs are commonly prescribed for Medicare beneficiaries, we will collect data on the volume of Medicare sales of these drugs in addition to obtaining wholesale price information.

Under section 1834(c)(3)(C)(ii)(II) of the Act, for all multiple-source drugs without restrictive prescriptions, the Secretary may base the per dosage unit average price for the drug on either the published average price for the drug or on a biannual survey.

We are considering use of a survey for multiple-source drugs that are commonly prescribed to Medicare beneficiaries. We intend to conduct the survey on a selected basis because we believe that it may give a more accurate reflection of prices (exclusive of discounts) of prescription drugs than by using the published prices. We will also be collecting sales data so that we can determine which multiple-source drugs to include in constructing the payment limit. In this case, we would use the unweighted median of the surveyed prices.

After conducting a survey, we would pay the lesser of the survey price and the published price for all covered drugs because this would best reflect the true acquisition cost of the drug. By paying the lower price, we better serve the beneficiaries, who together pay premiums for 100 percent of this benefit, and we serve as prudent stewards of the Part B trust funds.

C. Voluntary Regulatory Flexibility Analysis

1. Effects on Beneficiaries

a. Benefits for Medicare Beneficiaries Beginning in 1990. In 1990, we estimate that about 9,500 beneficiaries will undergo an organ transplant that will be covered under the Medicare program. There may be an additional 7,600 beneficiaries who had undergone an organ transplant covered under the Medicare program sometime in 1989. Both groups would be covered under the catastrophic drug benefit for the drugs used in their immunosuppressive therapy beginning January 1, 1990, and would be exempt from the catastrophic drug deductible and subject only to a 20 percent catastrophic drug coinsurance rate for up to 1 year following their discharge from the hospital.

Also, beginning January 1, 1990, we expect that approximately 19,700 beneficiaries who had undergone a Medicare covered transplant before 1989 or had undergone or will undergo an organ transplant not covered under the Medicare program will be covered under the catastrophic drug benefit provisions. These beneficiaries, however, would be subject to the catastrophic drug deductible payment amount and to the 50 percent coinsurance rate that would be in effect for 1990.

We estimate that as many as 65,000 Medicare beneficiaries would use covered home IV drugs in 1990. Of these, we estimate that about 56,550 beneficiaries would begin their IV drug therapy while still in the hospital and thus be exempt from the catastrophic drug benefit deductible and subject only to a 20 percent coinsurance payment rate for home IV drugs furnished as part of home IV drug therapy.

b. Benefits for Medicare Beneficiaries, 1991 through 1993. Our actuaries project that, without the

catastrophic drug benefits provided under sections 1832 and 1861 (s) and (t) of the Act as amended by section 202 of Public Law 100–360, in 1991, total beneficiary expenditures for prescription drugs would have been $12.6 billion. By 1993, our actuaries project that this figure would have grown to $14.2 billion. By distributing total projected spending for outpatient drugs in 1991 over all Medicare beneficiaries, we expect the average expenditure per beneficiary would have been about $405 for an average 18.7 prescriptions. Similarly, in 1993, we expect that the average expenditure per beneficiary would have been $450 per beneficiary for an average of 19.4 prescriptions.

While we make these projections in terms of all beneficiaries, we estimate that only about 85 percent of all beneficiaries would purchase covered prescription drugs in any given year. Thus, the amount for each beneficiary who would actually purchase prescription drugs in 1991 (that is, the average expense for outpatient prescription drugs per Medicare user) is expected to be about $475. By 1993, the average expense per Medicare user would increase to about $540.

Although the level of the prescription drug deductible in 1991 is set by statute at $600 (a level that would permit an estimated 24 percent of all beneficiaries to receive covered outpatient drug benefits), the percentage of beneficiaries meeting this deductible would equal nearly 28 percent of those beneficiaries who actually would purchase covered outpatient drugs. In 1993, the level of the covered outpatient drug deductible would be set at a level that would permit 16.8 percent of all Medicare beneficiaries to qualify for the covered outpatient drug benefit. Yet in terms of those who are expected to actually purchase covered outpatient drugs, the percent of users meeting the deductible amount would be about 20 percent.

Beginning in 1991, those who meet the deductible would receive an average benefit of about $345 for the year. As envisioned by the statute, and assuming adequate financing, in 1993, the average benefit payment made on behalf of a beneficiary who had met the deductible amount would increase to about $700. The projected growth in benefit payments per beneficiary would be largely the result of the increased portion of prescription drug costs the Medicare program would be required to pay. In accordance with the statute, the proportion of drug costs covered by the program after the deductible amount is reached would increase from 50 percent in 1991 to 80 percent in 1993.

While the portion of drug costs covered by Medicare would increase from 1990 through 1993, the proportion of beneficiaries expected to meet the deductible amount would drop during this period. Section 1834(c)(1)(C) of the Act sets forth the catastrophic drug deductible amount for 1990, 1991, and 1992 and requires that the Secretary determine for 1993 a deductible amount that will result in 16.8 percent of beneficiaries incurring expenses for covered outpatient drugs sufficient to meet the catastrophic drug deductible. The deductible amount in 1991 would be set at $600, enabling about 24 percent of all beneficiaries to qualify for drug payment benefits (or about 28 percent of projected actual Medicare beneficiaries requiring covered outpatient drugs). In 1992, the deductible amount would increase to $652, which would enable 23 percent of all beneficiaries (almost 27 percent of those beneficiaries projected to actually use covered outpatient drugs) to qualify for the drug benefit. In 1993, as required by the statute, the deductible amount would be set at a level that would permit 16.8 percent of all beneficiaries to receive covered outpatient drug benefits. This would be the equivalent of about 20 percent of those beneficiaries who would require covered outpatient drugs during that period.

2. Effects on Pharmacists, Pharmacies, and Pharmaceutical Manufacturers

As of June 1988, there were 378 pharmaceutical firms licensed to manufacture prescription drug products in the United States. There are now about 9,700 different drug products meeting the statutory definition of a covered outpatient drug marketed in the United States. Of the total number of approved drug products, 1,975 products are manufactured by a single firm, and almost 7,795 products are manufactured by more than one firm. We estimate that we will process data from more than 55,000 pharmacies for outpatient prescription drug bills.

Sections 1834(c)(9)(B) (i) and (ii) of the Act requires that the prescribing physician or other legally authorized person who is prescribing the drug indicate with an appropriate phrase such as "brand medically necessary" in his or her handwriting if the prescriber wants to prohibit generic substitution by the pharmacist.

We believe that the provision cited above, along with section 1834(c)(3)(B) of the Act, which sets forth the payment limit methodology for multiple-source drugs without restrictive prescriptions, would result in an increase in the generic dispensing rate for all pharmacies. This is because it would be in a pharmacy's best economic interest in those instances when the phrase "brand medically necessary" was not used in the prescribing process to substitute a lower-cost generic equivalent for the original brand since to do otherwise would result in a lower profit on each prescription dispensed. We also believe that these provisions of the statute might adversely affect those pharmaceutical manufacturers who do not manufacture generic equivalents since we believe their market share might decrease.

Furthermore, we believe that pharmacies may see a decrease in their profit per dispensed prescription for Medicare beneficiaries to the extent that those prescription drugs would have been dispensed as a higher-priced brand name drug if Public Law 100–360 had not been enacted. This is because we believe there is currently more profit in dispensing higher-priced brand name prescriptions than there is in dispensing their generic equivalents. However, we believe the decrease in profit per dispensed prescription would be offset by an increase in the number of prescriptions dispensed. We address this issue as "induced" demand later in this section.

The administrative allowance for all drugs dispensed in 1990 would be at the nonparticipating pharmacy rate of $2.50 because there is no statutory provision for participating pharmacies in 1990. In 1990, this administrative allowance is only relevant to immunosuppressive drugs because the administrative allowance would not be applied in computing the payment for dispensing home IV drugs. Instead, as explained in section III.C.3. above, payment for dispensing drugs used in home IV drug therapy would be made as part of a home IV drug therapy services per diem fee schedule.

Each time a prescription is filled in 1991, the Medicare program would pay an administrative allowance of $4.50 for drugs dispensed by a participating pharmacy and $2.50 for drugs dispensed by a nonparticipating pharmacy, as required by section 1834(c)(4)(A)(i) of the Act. Section 1834(c)(4)(A)(ii) of the Act requires that after 1991 the allowances be adjusted annually based on changes in the implicit price deflator for the GNP. The implicit price deflator measures the rate of inflation for the entire U.S. economy and is the means by which the GNP is adjusted for inflation. We have no administrative discretion in setting either the amount of the

administrative allowances or the rate of increase since both are set by statute.

The dosage unit average price would be updated every 6 months. For example, if a survey of drug prices were made on January 1, 1991, those prices would be used for prescription reimbursement from July 1 through December 31, 1991. Thus, the dosage unit average prices would be 6 months out of date at the beginning of each 6-month period and 12 months out of date before they would be updated.

In developing our estimates of benefit payments, we assumed that once a beneficiary reached the deductible amount, there would be an "induced" demand for prescription drugs that would increase the number of prescriptions written and, possibly, the cost of prescriptions as well. That is, prescribing health professionals may feel freer to prescribe both a larger quantity and more expensive drugs for a patient who has met the deductible amount than for one who has not met the deductible amount. Similarly, a patient who has met the deductible payment amount may feel less constrained to demand more medications or to have more prescriptions filled than a patient who has not met the deductible amount.

In attempting to predict the magnitude of the "induced" demand for covered outpatient drugs, we assumed that the effect would be directly related to the amount of program benefit payments. This amount, in turn, is a function of the deductible payment amount and the percentage of the beneficiary copayment. In 1991, we project that "induced" demand would account for about 23 percent of program benefit payments for covered outpatient prescription drugs. In 1992, the percent of "induced" benefits for prescription drugs is expected to grow to 26.5 percent, and by 1993, the percentage is expected to reach 32.4 percent. Since these "induced" benefits would apply to purchases of additional covered outpatient drugs that would not otherwise have been purchased, in addition to possibly benefiting Medicare beneficiaries through enabling them to have greater access to medications, the "induced" demand for covered outpatient drugs could also financially benefit every entity involved in the manufacturing and dispensing of prescription drugs.

It should be noted that the expected "induced" demand does not necessarily represent an abuse of the Medicare drug benefit. We believe that in many cases, the increased demand may represent a decision on the part of a health professional to treat a condition more aggressively than he or she might do if the catastrophic drug benefit were not available. Similarly, a beneficiary might forego having a prescription filled or avoid taking a drug at the prescribed time interval in order to conserve the available medication (and thus save money) were it not for the coverage of outpatient drugs now afforded by the Act. Thus, the "induced" demand may represent, in part, a medically appropriate demand for prescription drugs that currently is not being met.

Pharmaceutical manufacturers' benefits from the payment provisions of section 202(b) of Public Law 100-360 would be based on the benefits that would accrue to pharmacies. Assuming that pharmacies experience an increase in prescriptions written and prescription drugs sold, the pharmaceutical manufacturing industry would likewise experience a concomitant increase in the amount of pharmaceutical drugs sold for distribution to pharmacies and final distribution to Medicare beneficiaries.

D. Conclusion

We have summarized the most significant effects of the outpatient prescription drug payment provisions specified in section 1834 of the Act as amended by section 202(b) of Public Law 100-360. We do not believe that we are required to furnish this information under either E.O. 12291 or the RFA. Nevertheless, in the interest of providing the public with information regarding a major revision to the Medicare program, we have voluntarily offered an analysis of the major effects of the payment methodology for covered outpatient drugs.

V. Other Required Information

A. Paperwork Burden

Sections 414.508 (b) and (c) of this proposed rule contain information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3511). Section 414.508(b) requires, for a handwritten restrictive prescription, that the physician or the person prescribing the drug use specific language on the prescription and that this language must be in the prescribing person's handwriting. Section 414.508(c) requires, for a telephone restrictive prescription, that the prescriber provide a written and signed confirmation, in his or her own handwriting, to the pharmacy. We estimate that complying with the requirement in 414.508(b) to write "brand medically necessary" on handwritten prescriptions will require an additional 5 to 10 seconds per prescription. We estimate that completing a prescription form for a telephone prescription, as required in §414.508(c), would routinely require no more than 1 to 2 minutes per prescription.

A notice will be published in the Federal Register after OMB approval of these requirements is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the "ADDRESS" section of this preamble.

B. Public Comment

Because of the large number of pieces of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date specified in the "Dates" section of this preamble, and we will respond to the comments in the preamble of the final rule.

List of Subjects in 42 CFR Part 414

Drugs, Medicare, Reporting and recordkeeping.

A new 42 CFR Part 414 would be added as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

Subpart A-H—[Reserved]

Subpart I—Payment for Outpatient Drugs Under the Catastrophic Drug Benefit

Sec.

Authority: Secs. 1102, 1834(c), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395m(c), and 1395hh).

Subpart A-H—[Reserved]

Subpart I—Payment for Outpatient Drugs Under the Catastrophic Drug Benefit

§ 414.500 Purpose.

This subpart implements section 1834(c) of the Act in part by specifying how payments are made for covered outpatient drugs under the catastrophic drug benefit.

§ 414.502 Definitions.

For purposes of this subpart, the following definitions apply:

Average price means the price that is determined through the use of either published or survey data concerning amounts pharmacies pay for drug products.

Multiple source drug means a covered outpatient drug for which there are two or more drug products that meet all of the following conditions during a payment calculation period:

(a) *Therapeutically equivalent.* The drug products are rated as therapeutically equivalent by the Food and Drug Administration (FDA) in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

(b) Pharmaceutically equivalent and bioequivalent. (1) Except as provided in paragraph (b)(2) of this section, the drug products have been determined by FDA to be pharmaceutically equivalent and bioequivalent.

(2) The drug products are not required to meet the condition concerning pharmaceutically equivalency and bioequivalency as set forth in paragraph (b)(1) of this section if FDA changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the "Approved Drug Products with Therapeutic Equivalence Evaluations," in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.

(c) *Available for sale or marketing.* The drug products are considered to be available for sale or marketing. Drug products meet this condition if they are listed by FDA in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (other than in the Discontinued Drug Product List in that publication) unless HCFA determines that sale or marketing is not actually occurring.

Nonmultiple-source drug means a covered outpatient drug that does not meet the definition of a "multiple-source drug."

Payment calculation period means the 6-month period beginning January 1st of each year or the 6-month period beginning July 1st of each year.

§ 414.504 Determination of amount payable.

(a) *General.* The amount payable for a covered outpatient drug under the catastrophic drug benefit as described in § 410.29 of this chapter is the applicable payment percent for the drug as determined under § 414.514 multiplied by the lesser of—

(1) The actual charge; or

(2) The payment limit determined under § 414.506.

(b) *Effective date.* Payment is determined under the criteria described in paragraph (a) of this section for—

(1) Drugs dispensed for immunosuppressive therapy after a transplant or covered home IV drugs on or after January 1, 1990; and

(2) All other covered outpatient drugs dispensed on or after January 1, 1991.

§ 414.506 Determination of the payment limit.

(a) *General.* To determine the payment limit for a drug, HCFA uses the procedures set forth in paragraph (b) or (c) of this section.

(b) *Nonmultiple-source drug and multiple-source drug with a restrictive prescription.* For a nonmultiple-source drug and multiple-source drug with a restrictive prescription as described in § 414.508, the payment limit is determined as follows:

(1) For drugs dispensed on or after January 1, 1990 and before January 1, 1992, the payment limit is equal to the sum of—

(i) The amount of the administrative allowance as set forth in § 414.512; and

(ii) The product of the number of tablets or other dosage units dispensed and the dosage unit average price as determined in § 414.510 for the payment calculation period in which the drug is dispensed.

(2) For drugs dispensed on or after January 1, 1992, the payment limit is equal to the lesser of—

(i) The amount of the administrative allowance plus the product of the number of tablets or other dosage units dispensed and the average price per dosage unit determined under § 414.510 for the payment calculation period in which the drug is dispensed; or

(ii) The 90th percentile of actual charges for a drug for the second previous payment calculation period adjusted to reflect the number of tablets or other dosage units dispensed.

(c) *Multiple-source drug without a restrictive prescription.* For a multiple-source drug without a restrictive prescription, the payment limit is equal to the sum of—

(1) The administrative allowance; and

(2) The product of the number of tablets or other dosage units dispensed and the dosage unit average price based on the unweighted median determined under § 414.510 for the payment calculation period in which the drug is dispensed.

§ 414.508 Determining whether a prescription is restrictive.

(a) *General.* A drug has a restrictive prescription if it meets the conditions set forth in either paragraph (b) or paragraph (c) of this section.

(b) *Handwritten prescription.* In the case of a written prescription for a drug, only if the prescribing physician (or other person prescribing the drug) includes in his or her handwriting the phrase "brand medically necessary."

(c) *Telephoned prescription.* In the case of a prescription for a drug that is telephoned to the pharmacy, the prescribing physician (or other legally authorized person who is prescribing the drug) indicates that the particular drug must be dispensed by stating the phrase "brand medically necessary" both—

(1) During the telephone call; and

(2) Within 30 days after the telephone call, in a written and signed confirmation, in his or her handwriting, to the pharmacy.

§ 414.510 Determination of dosage unit average price.

(a) *General.* HCFA determines the average price on a per dosage unit basis for purchases in reasonable quantities, as appropriate, based on prices in effect on the first day of the previous payment calculation period. The average price is based on dosage form and strength for each drug product.

(b) *Sources for dosage unit average price.* HCFA obtains the information described in paragraph (a) of this section from the lower of—

(1) When available, a biannual survey of a representative sample of direct sellers, wholesalers, or pharmacies as appropriate; or

(2) Prices published in commonly recognized, comprehensive listings of drug prices.

(c) *Performance of surveys*—(1) *Nonmultiple-source drugs.* (i) HCFA performs the biannual survey described in paragraph (b)(1) of this section for those nonmultiple-source drugs that are commonly prescribed to Medicare beneficiaries except that this survey does not have to be performed in—

(A) Any year in which HCFA determines that a survey is not appropriate for a specific covered outpatient drug; or

(B) In years subsequent to 1990, any year in which HCFA determines that there is a low volume of sales for a drug.

(ii) The dosage unit average price is based on the median of the surveyed prices.

(2) *Multiple-source drugs.* HCFA performs the biannual survey described in paragraph (b)(1) of this section for

multiple-source drugs, but only if HCFA determines a survey to be appropriate. The dosage unit average price is based on the unweighted median of the surveyed prices.

(d) *Use of published prices—(1) Nonmultiple source drugs and multiple-source drugs with restrictive prescriptions.* The dosage unit average price for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions is based on the lowest published price.

(2) *Multiple-source drugs without restrictive prescriptions.* The dosage unit average price for multiple-source drugs without restrictive prescriptions is based on the unweighted median of published prices.

(e) *National determination.* The determination of the dosage unit average price is made on a national basis unless HCFA makes the determination on a regional basis to take into account limitations on the availability of drugs and variations on the prices among different areas.

(f) *Discounts.* In determining the dosage unit average price, HCFA does not consider discounts.

§ 414.512 Administrative allowance.

(a) *For 1990 and 1991.* For a drug dispensed on or after January 1, 1990 and before January 1, 1992, the administrative allowance for dispensing the drug is—

(1) $4.50 per prescription for a pharmacy that meets the requirements under subpart B of part 490 of this chapter for a participating pharmacy; or

(2) $2.50 per prescription for a pharmacy that is not a participating pharmacy.

(b) *For years subsequent to 1991.* For each year subsequent to 1991, the administrative allowance is the allowance applicable to the previous year increased by the percentage increase in the implicit price deflator for gross national product over the 12-month period ending with August of the preceding year as published by the Department of Commerce rounded to the nearest penny.

(c) *Limitation on administrative allowance for dispensing insulin—(1) Purchase of a 30-day supply.* For insulin that is available without a prescription, the administrative allowance is made for each purchase of a reasonable quantity, that is, a 30-day supply.

(2) *Exceptions.* An administrative allowance is made for a purchase of a supply of insulin for fewer than 30 days in the following circumstances (or if other extenuating conditions exist):

(i) There is a change in the type of insulin the beneficiary uses or the insulin regimen is otherwise modified; or

(ii) If, because of travel plans, the beneficiary needs to make smaller purchases or forgets to bring along enough insulin for duration of the trip.

(d) *Exception for drugs dispensed for home IV drug therapy.* No administrative allowance is paid for dispensing a drug that is to be used in home IV drug therapy. An allowance for dispensing IV drugs is made under the fee schedule for payment for services related to home IV drug therapy under subpart J of part 414.

§ 414.514 Amount of the payment percent.

(a) *Immunosuppressive and Home IV drugs.* For drugs related to immunosuppressive drug therapy dispensed during the first year after a covered organ transplant and for home IV drugs, the payment percent equals 80 percent.

(b) *Other drugs.*

The payment percent for covered outpatient drugs other than the drugs described in paragraph (a) of this section equals the following:

(1) In 1990 and 1991, 50 percent.

(2) In 1992, 60 percent.

(3) In 1993 and subsequent years, 80 percent.

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

Dated: July 12, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

Approved: August 19, 1989.

Louis W. Sullivan,

Secretary.

[FR Doc. 89-20846 Filed 9-6-89; 8:45 am]

BILLING CODE 4120-01-M

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42 CFR Parts 400, 417, 485, and 489

[BPD-617-P]

RIN 0938-AE09

Medicare Program; Conditions of Participation for Home Intravenous Drug Therapy Providers

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

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth the conditions of participation that an entity would be required to meet in order to qualify as a home intravenous drug therapy provider. This proposal would implement the provisions of section 1861(jj)(3) of the Social Security Act, which was added by section 203(b) of the Medicare Catastrophic Coverage Act of 1988. An entity that meets these conditions of participation would be eligible for payment from Medicare for covered home IV drug therapy services furnished to Medicare beneficiaries.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on November 6, 1989.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-617-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309 G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

If comments concern information collection or recordkeeping requirements, please address a copy of the comments to:

Office of Management and Budget, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron.

In commenting, please refer to file code BPD-617-P. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION, CONTACT: Betty Burrier, (301) 966-4649.

SUPPLEMENTAL INFORMATION:

I. Background

Many individuals require intravenous (IV) drug therapy on an ongoing basis because the medication is not available in oral dosage form, the patient is unable to take the medication orally or by other less invasive means, or the medication is more effective if administered intravenously. Most of these individuals require hospitalization for the initiation of IV drug therapy and must remain hospitalized for the duration of the therapy. There is,

however, an increasing number of individuals whose IV drug therapy care, in whole or in part, can be managed at home. Allowing these patients to receive drug therapy at home rather than in the hospital can improve the quality of their lives and potentially allow their return to normal activities.

Currently, under the Medicare Part A (Hospital Insurance) program coverage of drugs and biologicals is provided as follows:

- Under section 1861(b)(2) of the Social Security Act (the Act), we cover drugs and biologicals used in the hospital that are ordinarily furnished by the hospital for the care and treatment of patients.
- Under section 1861(h)(5) of the Act, we cover drugs and biologicals furnished for use in a skilled nursing facility that are ordinarily furnished by the facility for the care and treatment of inpatients.
- Under section 1861(dd)(1)(E) of the Act, we cover drugs and biologicals furnished to terminally ill individuals under a written plan as part of a hospice program.

The Medicare Part B (Supplementary Medical Insurance) program covers drugs as defined in the scope of benefits set forth in section 1832 of the Act. Certain sections of section 1861 of the Act define the coverage provisions specified in section 1832 of the Act.

Current Medicare Part B coverage of outpatient drugs and biologicals is, in part, provided for under section 1861 of the Act as follows:

- Under section 1861(s)(2) (A) and (B) of the Act, we cover drugs and biologicals that cannot be self-administered and that are furnished as incident to a physician's service.
- Under section 1861(s)(2)(C) of the Act, we cover diagnostic services furnished by a hospital to outpatients, including drugs and biologicals required in the performance of these services.
- Under section 1861(s)(2)(F) of the Act, we cover dialysis supplies, including drugs and biologicals.
- Under section 1861(s)(2)(G) of the Act, we cover antigens that are prepared by a physician for a particular patient and that are administered by or under the supervision of a physician.
- Under section 1861(s)(2)(I) of the Act, we cover blood clotting factors for hemophilia patients competent to use those factors to control bleeding, without medical or other supervision.
- Under section 1861(s)(2)(J) of the Act, we cover immunosuppressive drugs and drugs that are needed for effective immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under Medicare and that are furnished within 1 year after the date of the transplant procedure.
- Under section 1861(s)(2)(K)(ii) of the Act, we cover supplies that are incident to a physician assistant's services furnished under the supervision of a physician, including drugs and biologicals.
- Under section 1861(s)(10) of the Act, we cover pneumococcal, influenza, and hepatitis B vaccines.
- Under section 1861(cc)(T)(F) of the Act, we cover drugs and biologicals that cannot be self-administered and that are furnished to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility.
- We cover drugs and biologicals furnished as part of or incident to the provision of the following covered services:

—Rural health clinic services (section 1861(aa)(1) of the Act).
—Partial hospitalization services (section 1861(ff)(2)(D) of the Act).
—Certified nurse-midwife services (section 1861(gg)(1) of the Act).
—Qualified psychologist services (section 1861(ii) of the Act).

- Payment has also been made for certain drugs and biologicals as part of the durable medical equipment (DME) benefit (section 1861(n) of the Act) and the prosthetic device benefit (section 1861(s)(8) of the Act).

Drugs and biologicals are also covered as part of or incident to services furnished in qualified ambulatory surgical centers as stated in section 1832(a)(2)(F)(i) of the Act.

Section 203(a) of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360), enacted on July 1, 1988, amended section 1832(a)(2)(A) of the Act to establish coverage under Part B for home IV drug therapy services furnished on or after January 1, 1990. Section 203(b) of Public Law 100-360 added section 1861(jj) to the Act to define home IV drug therapy services. Under new 1861(jj)(2) of the Act, home IV drug therapy services means "nursing, pharmacy, and related items and services (including medical supplies, intravenous fluids, delivery, and equipment) as are necessary to conduct safely and effectively an intravenously administered drug regimen * * *." As stated in section 1861(jj)(1) of the Act, home IV drug therapy services are to be "furnished to an individual who is under the care of a physician—(A) in a place of residence used as such individual's home; (B) by a qualified home intravenous drug therapy provider or by others under arrangements with them made by such provider and (C) under a plan established and periodically reviewed by a physician."

A qualified home IV drug therapy provider (referred to below as home IV providers) is defined in section 1861(jj)(3) of the Act as an entity that the Secretary determines meets the following requirements:

- The entity is capable of providing or arranging for the items and services described in section 1861(jj)(2) of the Act (that is, the provision of nursing, pharmacy, and related services) as are necessary to conduct safely and effectively an intravenously administered drug regimen through use of a covered home IV drug, as defined in section 1861(t)(4) of the Act. Under the provision of the law, the entity must also be capable of providing covered home IV drug directly or under arrangements.
- The entity maintains clinical records on all patients.
- The entity adheres to written protocols and policies with respect to the provision of the covered items and services.
- The entity makes services available (as needed) seven days a week on a 24-hour basis.
- The entity coordinates all services with the patient's physician.
- The entity conducts a quality assessment and assurance program, including drug regimen review and coordination of patient care.
- The entity assures that only trained personnel furnish covered home IV drugs (and any other service for which training is required to furnish the service safely).
- The entity assumes responsibility for the quality of services furnished by others under arrangements with the agency or entity.
- In the case of an entity in any State in which State or applicable local law provides for the licensing of entities of this nature, the entity—

—Is licensed under that law; or
—Is approved by the agency of the State or locality responsible for licensing entities of this nature as meeting the standards established for that licensing.

- The entity meets such other requirements as the Secretary may determine are necessary to assure the safe and effective provision of home IV drug therapy services and the efficient administration of the home IV drug therapy benefit.

This proposed rule sets forth the conditions that a home IV drug therapy provider would have to meet to participate in the Medicare program.

That is, we would consider any entity that complies with the requirements of the Act and this proposed rule to meet the definition of home IV provider under the provisions of new section 1861(jj)(3) of the Act. (Our proposals concerning coverage of specific drugs for use in home IV drug therapy, coverage of the services connected with home IV drug therapy, payment rules for the drugs, and the fee schedule under which the services will be paid will be addressed in separate rulemaking documents.)

Under section 1861(jj)(3) of the Act, the Secretary is required to establish the conditions of participation under which entities may qualify as home IV providers. In addition, as mentioned above, under section 1861(jj)(3)(x) of the Act, the Secretary may determine the conditions necessary for the assurance of safe and effective provision of home IV drug therapy services and the efficient administration of the home IV drug therapy benefit.

In order to become familiar with the wide range of current practices and arrangements for furnishing home IV drug therapy, we received information from companies that currently furnish home IV drug therapy services, home health agencies (HHAs), pharmaceutical manufacturers, physicians, pharmacists, and various professional associations. In addition, we contacted two major professional organizations that currently have standards for the provision of home IV drug therapy services; that is, the Joint Commission for the Accreditation of Health Care Organizations (JCAHO), which has developed the "Standards for the Accreditation of Home Care," and the Intravenous Nursing Society (INS), which developed the "Intravenous Nursing Standards of Practice." We reviewed both the JCAHO and INS standards in detail along with existing HCFA standards for different types of providers of services.

The delivery of home IV drug therapy services under Medicare will involve the administration of potentially dangerous drugs, using sophisticated medical equipment and techniques, to a predominantly elderly population in their homes. Accordingly, we intend that the conditions of participation for home IV providers, once adopted, will assure the safe and effective delivery of home IV drug therapy services to these patients.

Thus, our main objective in establishing these conditions of participation is to minimize the risks for the Medicare beneficiaries while maximizing the benefits. Therefore, after reviewing both the materials furnished by the organizations and individuals we contacted and various medical journal articles about home IV drug therapy, we extracted the provisions that we believe would be most important to meet the requirements of the statute and our responsibilities in assuring that this new benefit will be furnished in the most safe and effective manner possible.

In general, we also want to state that, in setting forth the provisions of section 203 of Pub. L. 100-360, Congress established strong standards for the establishment of conditions of participation for home IV providers and made it clear that entities wishing to qualify as home IV providers must do so under these conditions of participation. For example, in the case of HHAs or DME suppliers, such entities may qualify as a home IV provider for purposes of furnishing home IV therapy services if they meet the requirements of these conditions of participation. (See H.R. Rep. No. 661, 100th Cong., 2nd Sess. 201 (1988).)

II. Provisions of the Proposed Regulations

Most of the conditions for home IV providers would be based on the specific requirements set forth in sections 1861(jj)(3) (i) through (ix) of the Act. The remaining conditions would be established under the general authority of section 1861(jj)(3)(x) of the Act concerning safety and effectiveness and the efficient administration of home IV therapy services.

We are proposing to add a new Subpart C to 42 CFR Part 485 (Conditions of Participation and Conditions for Coverage: Specialized Providers) in which we would set forth the proposed conditions that entities must meet to satisfy the definition of a home IV provider under section 1861(jj) of the Act and to be accepted for participation in Medicare in accordance with the provisions of Part 489 (Provider Agreements under Medicare). These conditions of participation would serve as the basis for survey activities on the part of the Medicare State survey agencies. (We note that once the conditions of participation are in place under a final rule, noncompliance with them could result in the application of sanctions including intermediate sanctions set forth in section 1846 of the Act, as amended by section 203(e) of Public Law 100-360. A separate rulemaking document that deals with intermediate sanctions and appeal rights for home IV drug therapy providers is being developed.)

We would make a conforming change to § 489.2 to include a home IV provider as one of the entities that must have a provider agreement in order to furnish and receive payment for services under Medicare.

In addition, we would amend § 400.202 to include a home IV provider in the definition of "provider" under Medicare. (We would also make a technical correction in that definition to delete the end of the effective date for hospice care. Although section 122(h)(1)(A) of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-35) specified that hospice care would not be covered under Medicare after September 30, 1986, this sunset provision was repealed by section 9123 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272). We would also amend § 417.416 to add hospices and home IV providers to the list of providers that must meet the applicable conditions of participation in Medicare in order to furnish services to an HMO enrollee.)

A. Definition

In accordance with section 1861(jj)(3) of the Act, in § 485.101, we would define a "home IV drug therapy provider" as an entity that—

- Is capable of furnishing covered home IV drugs, nursing and pharmacy services, and other services necessary for the administration of home IV drug therapy; and
- Meets the conditions specified under proposed new §§ 485.105 through 485.165 and other applicable requirements of the statute and regulations.

B. Compliance With Federal, State, and Local Laws

In § 485.105, we would require that a home IV provider be in compliance with applicable Federal and State laws. Also, we would require that a home IV provider ensure that personnel who furnish services, including those who do so under arrangements with the provider, meet all applicable standards that are required by State and local laws. This condition would implement the provisions of section 1861(jj)(3)(ix) of the Act, which specify that an entity meet State and local licensing requirements. Our proposed language in § 485.105 is similar to that which we use in regulations governing conditions of participation for other providers, such as hospitals (§ 482.11) and comprehensive outpatient rehabilitation facilities (§ 485.54).

C. Governing Body and Administration

In accordance with sections 1833(jj)(3) (i) thru (vii) of the Act, which set forth the specific responsibilities of a home IV provider, we would require in § 485.110

that a home IV provider have either a governing body or designated individuals who are legally responsible for the conduct of the home IV provider in furnishing the required services. We believe that this condition is necessary for the purpose of centralization of authority and responsibility for overall operation of the provider.

1. Standard: Disclosure of ownership

We would require a home IV provider to disclose certain information about ownership and control. We would include this requirement because section 1124 of the Act requires a provider of services to disclose ownership information and because section 1834(d)(3) of the Act prohibits a home IV provider from furnishing services to a Medicare beneficiary based on a referral from a physician (or an immediate family member of the physician) who has an ownership interest in, or receives compensation from, the provider. The referring physician is the physician who prescribes the home IV drug or establishes the plan of care for this therapy, or both. Congress established several exceptions to this prohibition that are addressed in a separate proposed rulemaking document concerning coverage of home IV drug therapy services

2. Standard: Participation in reports and studies

New section 1861(jj)(3)(x) of the Act states that an entity wishing to qualify as a home IV provider must meet such "* * * requirements as the Secretary may determine are necessary to assure * * * the efficient administration of the home intravenous drug therapy benefit." Under this provision, we propose to require that home IV providers furnish information as requested by the Secretary concerning cost matters or other issues that may relate to the efficient administration of the home IV drug therapy benefit. We would expect providers to cooperate as needed in this regard and participate in any reports or studies that are conducted.

3. Standard: Chief executive officer

We would require that a home IV provider have a chief executive officer who is responsible for the day-to-day operations of the provider because we believe that it is necessary that there be one person who is accountable for the operation of the provider. The language we are proposing to use is similar to the language in § 482.12, which specifies that a participating hospital must have a chief executive officer who is responsible for managing the hospital.

4. Standard: Patient care policies

Under this proposed rule, a patient's referring physician would determine whether a particular patient would be a good candidate for home IV drug therapy and would determine the drug regimen for each patient. Section 1833(jj)(3)(iii) of the Act requires that a home IV provider adhere to the physician's directions for the provision of items and services. In implementing section 1833(jj)(3)(iii) of the Act, we would require that a home IV provider have written patient care policies to govern the services it furnishes. The patient care policies must include the following:

- A description of the services furnished by the home IV provider's employees and those furnished under arrangements.
- The criteria specifying by diagnoses the patient population for whom the services are designed. That is, the home IV provider would be required to design criteria under which it would admit only a patient whose needs can be met by the services it provides.
- Procedures for the acceptance of a referral, including the assignment of appropriate staff to conduct a timely assessment of the patient's medical and psychological readiness for home IV drug therapy services.
- Procedures for quickly notifying the referring physician if the patient does not meet the home IV provider's admission criteria.
- Procedures for notifying the referring physician of incidences of phelebitis, IV infiltration, or site infection once a course of home IV drug therapy has began.

5. Standard: Contracted services and professional management responsibility

Section 1861(jj)(3)(viii) of the Act provides that a qualified home IV provider must assume "responsibility for the quality of services provided by others under arrangements with the agency or entity." Thus, we believe that Congress did not intend that the home IV provider merely serve as a billing agency for the entity or individual who actually furnishes the services. Therefore, we are proposing that the home IV provider must retain professional and administrative responsibility for, and control and supervision of, contracted services and must ensure that they are furnished in a safe and effective manner by nurses and pharmacists in accordance with the patient's plan of care and other applicable requirements.

Under proposed § 485.110(e), the home IV provider must maintain a legally binding written agreement with each contractor who provides arranged services that includes at least the following provisions:

- Identification of the services to be provided.
- A requirement that contracted services are provided only if directly authorized by the home IV provider.
- A description of the manner in which the contracted services are coordinated, supervised, and evaluated by the home IV provider.
- Delineation of the roles of the home IV provider and the contractor in the patient care process.
- A requirement for the preparation of patient records including the prompt incorporation of progress notes and other observations by the physician, nurse, and pharmacist.
- A requirement that both the personnel and services provided under arrangements meet the same requirements that would be applicable if the personnel and services were furnished directly by the home IV provider.
- Specification of the financial arrangements with a contractor who furnishes home IV therapy services under arrangements. We would require that the financial arrangements provide that the contractor may not bill the patient or Medicare for covered services. This is because, under section 1861(w)(1) of the Act, covered services furnished under arrangements must be billed through the home IV provider exclusively and receipt of payment by the home IV provider for these services on behalf of an entitled individual discharges the individual's liability to pay for services. (Under Medicare, participating providers accept Medicare payment as payment in full except for any applicable deductible and coinsurance amounts, which are the responsibility of the beneficiary. There are no deductible or coinsurance amounts applicable to home IV drug therapy services.)

We are including these requirements because we believe that the professional supervision of the contracted services must include application of many of the same controls as would be applied to services furnished by employees of the home IV provider. This proposed delineation of the roles for the employees of the home IV provider and employees of a contractor is generally similar to the same standard concerning the provision of contracted services by individuals who are not employees of a hospice (§ 418.56).

D. Patient Selection

We propose in § 485.115 that the home IV provider must make a comprehensive assessment of each patient and the patient's needs at the time of patient selection. In order to assess patients, the home IV provider would need to assemble a multidisciplinary team of experts who are aware of both the problems that can occur at home with IV therapy and the criteria that must be met before a patient is accepted. In the case of a hospital inpatient, we would require that this assessment occur before the patient is discharged from the hospital.

The home IV provider would furnish services only to a patient whose needs can be met by these services. In the case of a hospital inpatient, the home IV provider must determine that the patient is medically suitable for their program of home IV therapy and services. We believe and emphasize that proper patient selection is necessary for a safe, effective program of home IV therapy. In considering the home care alternative, it is important for the home IV provider to assess the degree of self-care that is feasible, that is, whether the patient will actually be able to administer the medication, and if not, whether the patient would have available the aid that would be necessary from a caregiver. We believe that patient compliance with the necessary elements of successful home IV therapy is an important factor in allowing the patient to remain at home and not be readmitted to a hospital.

1. Standard: Medical Criteria

We are proposing that in order to be selected for home IV drug therapy, a patient must meet certain medical criteria. We would require that the patient—

- Be under the care of the referring physician who either prescribes the home IV drug or establishes the plan of care for the services, or both, and, therefore, monitors the progress of the home IV drug therapy;
- Have a clinical status that allows IV drugs to be safely administered at home;
- Have body sites available for peripheral IV catheter or needle placement or have a central venous catheter or other central venous access device; and
- For medical or therapeutic reasons, be unable to take the prescribed IV medication orally.

2. Standard: Nonmedical criteria

In addition to the medical criteria, we are proposing that the patient must meet certain nonmedical criteria. It is necessary to assess the patient's nonmedical condition because we believe that an uncooperative patient or one who lacks certain skills would not be able to comply with a home IV regimen successfully. Thus, we would require that the patient—

- Be capable of performing self-administration of drugs and self-care after adequate patient education (for example, be able to learn aseptic technique and heparin lock maintenance and be able to read the drug labeling) or have a primary caregiver who can perform these tasks;
- Be motivated to use home IV drug therapy services;
- Be psychologically stable (that is, the prospect for adherence to a disciplined medical regimen is realistic); and
- Have a home environment that is conducive to the provision of home IV drug therapy services (that is, a clean home with electricity, water, a telephone, refrigeration, and enough space to support home IV drug therapy services).

We are proposing these requirements under the authority of section 1861(jj)(3)(x) of the Act, which states that the Secretary may determine requirements for home IV providers that are necessary to assure the safe and effective provision of home IV drug therapy. We believe that home IV drug therapy could not safely and effectively be furnished to patients who do not meet the above nonmedical criteria.

E. Plan of Care and Physician Review

Section 1861(jj)(1)(C) of the Act requires that home IV drug therapy services be furnished under a plan established and periodically reviewed by a physician. Therefore, we propose that an individual plan of care be developed by the patient's referring physician for a patient to receive home IV drug therapy services. The patient's individual plan of care would be based on initial and ongoing individualized patient assessments by the patient's physician. The plan of care would be reassessed and updated when the patient's physician determines an update is necessary but, as stated below, at least once every 30 days. (We expect that generally the referring physician would also be the patient's physician while receiving home IV drug therapy. However, there may be situations in which this is not the case. For example, a patient may have been an inpatient in a specialty hospital in one city and then referred for home IV drug therapy in the patient's home that is in another city.)

1. Standard: Development of a plan of care

A requirement would be imposed that a plan of care be developed for each patient in accordance with the following provisions:

- The patient's referring physician develops the individual's plan of care.
- The home IV provider assesses the patient and, if the patient is accepted, implements the plan of care as written by the referring physician.
- The plan of care is based on the referring physician's initial and continued patient assessments.
- The plan of care is reassessed by the referring physician as needed but at least once every 30 days.
- The plan of care includes at least the following current information about the patient and the home IV drug therapy services to be provided:

—Name, gender, age, and lean body weight.
—A narrative description of the appropriate diagnoses.
—Drug allergies or sensitivities.
—Current drug therapy, including nonprescription drugs and home remedies.
—The goal of home IV drug therapy services for the patient including duration of IV drug therapy services.
—The drugs to be furnished and the method used to furnish the drugs by the home IV provider including the following:
  + Amount of dosage and timing of administration.
  + Route of administration, that is, either peripheral or central venous line. (A peripheral line is the usual form of administering IV drugs through a surface vein. The needle must be changed every few days. A central line is inserted semipermanently only by a physician in a vein feeding the heart.)
  + Frequency of IV site monitoring.
  + Type of IV equipment, related supplies, and other equipment, and fluids to be administered.
—Physician identifier, date, and signature.

2. Standard: Physician review of plan of care

Various Medicare benefits require a physician to develop and review a plan of care. Generally, how often a plan of care is reviewed varies depending on the type of provider. Under current regulations, the plan of care of a patient receiving services furnished by an HHA must be reviewed at least once every 60 days (§ 405.1223(b)); however, we

require that the plan of care for a hospice patient be reviewed at intervals specified by the physician (§ 418.58(b)). The difference in these requirements is specifically related to the medical condition and medical problems of the type of patient served by those providers and the needs of those patients; that is, hospice care is continuous whereas we do not expect that services provided by an HHA would ordinarily be continuous.

In keeping with this concept, we believe that a review of the plan of care for home IV drug therapy patients every 30 days would not be unreasonable. In addition, in a separate proposed rulemaking document, we would require that prescriptions for covered home IV drugs be written for an amount that ordinarily does not exceed a 34-day supply. Thus, the referring physician would review the prescription on a monthly basis. We believe that the referring physician should review the plan of care at the same time that he or she reviews the need for continued drug therapy.

We are proposing that the review of the plan of care by the referring physician meet the following requirements:

—At least once every 30 days, the physician reviews the patient's progress in attaining the objectives of the plan of care.
—This review is based upon appropriate information provided by health professionals, including information furnished by the home IV provider's registered nurse and pharmacist.

F. Central Clinical Records

This condition would implement the provisions of section 1861(jj)(3)(ii) of the Act, which require that home IV providers maintain clinical records on all patients including those who are not entitled to Medicare. In accordance with accepted principles of medical record practice, we propose to require that the home IV provider establish and maintain a clinical record for every individual receiving care and services. We would require that each clinical record be completely, promptly, and accurately documented, readily accessible, and systematically organized to ease retrieval and compilation of information.

1. Standard: Content

We propose the following:

• Each clinical record be a comprehensive compilation of medical and other data that contains sufficient information to identify the patient clearly and to justify the diagnoses and treatment.

• Entries in the clinical record be made for all services provided directly or under arrangements.

• Entries be made for each treatment performed and signed by the individual who provides the services.

• Documentation on each patient be consolidated into one clinical record that is required to contain the following information:

—Patient identification data.
—The initial patient assessment and subsequent reassessments.
—Current plan of treatment.
—Consent and authorization forms.
—Past and present pertinent medical history.
—Complete documentation of all services provided.
—Upon completion of treatment, a summary that includes patient status relative to goal achievement, prognosis, and future treatment considerations.

2. Standard: Retention and preservation.

Generally, the home IV provider would be required to retain clinical records for the appropriate time period provided below beginning with the date of the patient's last treatment. If the requirements of State law concerning retention of records are used, they must be requirements of the law of the State in which the services were provided to the patient. More specifically, we would require the following:

• The home IV provider must maintain clinical records for the time period provided under the appropriate State law.

• In the absence of an appropriate State law, the home IV provider must maintain clinical records for the time period provided under the appropriate statute of limitations concerning medical malpractice in the State.

• If there is no appropriate State law or State statute of limitations concerning medical malpractice, the home IV provider must maintain clinical records for at least 5 years.

• In addition to all other requirements for maintaining clinical records, in the case of home IV drug therapy services furnished to a minor, the home IV provider must maintain clinical records for at least 3 years after the individual attains the age of majority under State law.

3. Standard: Protection of information

We are proposing that the home IV provider be required to safeguard the clinical record against loss, destruction, or unauthorized use. The home IV provider would be required to have procedures that govern the use and removal of records and the conditions for release of information to authorized individuals. The home IV provider would also have to ensure that unauthorized individuals cannot gain access to or alter patient records. The patient's written consent would have to be obtained before release of any information not required to be released by law. Original records would be released by the home IV provider only in accordance with Federal or State laws, court orders, or subpoenas.

4. Standard: Patient access

In § 485.125(d), we would specify that the home IV provider permit each patient (or his or her legal representative) to inspect or obtain copies of his or her clinical records within 48 working hours after the provider receives a written request.

G. Core Staff and Services

In complying with the authority of section 1861(jj)(3)(x) of the Act under which the Secretary may require such other requirements as are necessary to assure the safe and effective provision of home IV drug therapy services and the effective administration of the home IV drug therapy benefit, we carefully reviewed the available information on current home IV drug therapy practices. It is clear that home IV drug therapy services have become increasingly sophisticated during the approximately 10 years that home IV therapy has been available. However, because Medicare beneficiaries often have several concurrent medical problems, they are often in need of long term, interrelated therapies. In addition, beneficiaries frequently have suffered a loss of visual acuity and manual dexterity, making them less clinically eligible for a course of home IV therapy that involves self-administration of drugs and the use of sophisticated equipment. Also, in many cases, the available caregiver would also be an elderly person for whom the complexities of home IV drug therapy could be very difficult to confront.

It is also true that, although many home IV providers have established safeguards for home IV therapy administration, their experience with Medicare beneficiaries may have been limited because home IV drug therapy has not been a covered service. Accordingly, we believe that we have ample justification for establishing conditions of participation that will help to assure the safe and effective provision of home IV drug therapy services.

Existing entities that furnish home IV drug therapy currently provide different types of IV drug therapies such as

antibiotics, analgesics, and hydration and electrolyte replacement. In addition, some entities offer heparin infusion (blood clotting care) and aminophylline therapy (asthma therapy). All of these IV drug therapies may cause one or more side effects such as rash, diarrhea, fever, kidney toxicity, blood coagulation problems, and phlebitis (inflammation of the vein). In addition, the provision of IV drug therapies may cause the possibly life threatening conditions of anaphylaxis (allergy reaction), IV infiltration (leaking of fluid into surrounding tissues), and site infection.

All home IV drug therapies involve the separate functions of mixing and administering potentially dangerous drugs. Each of these functions plays a critical role in the safe administration of home IV drug therapy. Thus, we do not consider the home IV drug therapy benefit as being either a nursing benefit or a pharmacy benefit but rather a benefit that requires a team effort involving safe and effective patient care. We believe that such an effort is necessary to maintain patient safety and is the key to successful home IV drug therapy.

To take into account patient safety, we had to consider both existing and potential complications for the beneficiary. Complications may be related to disease progression, combinations of disease processes and their therapies, and the aging process in general. Psychoses or neuroses of a patient can present an additional challenge in gaining appropriate patient involvement. In addition, patient safety might be barred by noncompliance with the drug therapy regimen, poor living conditions, or high stress levels of both a patient and the spouse or other caregiver, or a combination of these factors.

In reviewing the available literature, we had to identify potential side effects, complications, and risks of the therapy and determine the probability and severity of each of these harmful effects. For example, for each possible complication, we had to consider whether the complication could cause reversible damage, permanent damage, or threaten the life of the patient. In addition, we considered whether the onset of side effects or complications might be sudden or gradual. We also had to consider how the beneficiary or caregiver could obtain immediate help from the home IV provider if he or she has a problem with the infusion.

In reviewing various options under the provisions of the law, we had to consider whether it would be safe for one organization to deliver the drugs, another to provide nurses, and a third to provide equipment. We considered the difficulties that might arise if the beneficiary or the caregiver is required to call all three organizations to resolve a problem. We considered how long it might take to get a problem resolved if the beneficiary had an infusion problem at midnight and how the beneficiary would know whom to call in an emergency or for a routine question.

Once we collected factual information about home IV drug therapy, we examined factors that could either increase or decrease the level of safety. It appears to us that home IV drug therapy is potentially as dangerous as it is helpful. The potential side effects of the therapy are so great that we are sure, as we noted earlier, that Congress did not intend for a "store front operation" or a "billing operation" to qualify as a home IV provider. That is, we do not believe Congress intended that a business that acts strictly as an answering service and a billing agent while contracting out all the home IV drug therapy services should be a Medicare home IV provider.

Although some existing entities that furnish home IV drug therapy contract out one or more of the different services they provide, other entities furnish all of the services themselves. While we believe that having one entity furnishing all the drug therapy services would be the most safe and effective method and the easiest configuration with which our beneficiary population could work, we are precluded by sections 1861(jj) (1)(B) and (3)(i) of the Act from requiring that all services to beneficiaries be provided by individuals directly employed by the home IV provider.

As discussed earlier, in providing that an entity wishing to qualify as a home IV provider must be capable of providing or arranging for the provision of the nursing, pharmacy, and related services necessary to conduct an intravenously administered drug regimen in the home safely and effectively, section 1861(jj) (3)(i) of the Act specifically cross-refers to section 1861(jj)(2) of the Act. Section 1861(jj)(3) of the Act then goes on to list several functions that the entity itself must be able to perform or to assure their performance. Thus, we believe these provisions of the Act draw a distinction between the home IV drug therapy services that involve direct patient care and those that relate to oversight of patient care and supervision of the persons directly furnishing the patient care. Section 1861(jj)(2) of the Act defines home IV drug therapy services that are to be "furnished to an individual" in his or her home as "such nursing, pharmacy, and related services * * * as are necessary to conduct safely and effectively an intravenously administered drug regimen * * * ." It is these direct patient care services (for example, nursing visits and mixing and delivery of the IV drugs) that sections 1861(jj) (1)(B) and (3)(i) of the Act state may be furnished under arrangements. (We note that when covered services are furnished "under arrangements", Medicare payment to the provider discharges the beneficiary's obligation to pay for those services furnished by the outside source under contract with the provider. See section 1861(w)(1) of the Act.)

On the other hand, certain functions, some of which have already been discussed above, are not subject to the "under arrangements" language of the statute. These functions are set forth in section 1861(jj)(3) of the Act and pertain not to direct care services to beneficiaries but to administration, management, and quality control issues. We believe that the responsibility for these functions must rest with the home IV provider itself. That is, the provider must perform these functions rather than make arrangements with an outside source to perform them. These functions are the following:

- Maintenance of clinical records on all patients (section 1861(jj)(3)(ii) of the Act).
- Adherence to written protocols and policies concerning provision of items and services (section 1861(jj)(3)(iii) of the Act).
- Assurance of the availability of services, as needed, 7 days a week on a 24-hour basis (section 1861(jj)(3)(iv) of the Act).
- Coordination of all services (that is, nursing, pharmacy, and related services) with the patient's physician (section 1861(jj)(3)(v) of the Act).
- Performance of a quality assessment and assurance program, including drug regimen review and coordination of patient care (section 1861(jj)(3)(vi) of the Act).
- Assurance that only trained personnel provide covered home IV drugs, and any other service that necessarily entails training, to ensure safety (section 1861(jj)(3)(vii) of the Act).
- Assumption of responsibility for the quality of those services furnished to patients under arrangements (section 1861(jj)(3)(viii) of the Act).
- Licensure of the home IV provider to the extent required by States in local law (section 1861(jj)(3)(ix) of the Act).
- Compliance with other safety and effectiveness requirements as set forth

by the Secretary (section 1861(jj)(3)(x) of the Act).

We note that by stating that coordination of services with the patient's physician is the function of the home IV provider, we do not intend to diminish the responsibility in this respect of an organization under contract with the home IV provider. For example, nurses employed by an organization that is furnishing nursing services under contract with a home IV provider would still be obligated, as they would under routine circumstances and prevailing standards of patient care, to coordinate the particulars of patient care with the attending physician. In this context, it is the oversight function of ensuring that such coordination is routinely and effectively conducted that would be the responsibility of the home IV provider.

In addition, the home IV provider would itself have a role in coordination of patient care with the physician in terms of consultation about the plan of care and its periodic review and updating. Similarly, an organization under contract with a home IV provider would normally be responsible for the training of its own personnel who, for example, deal with the drugs to be furnished to beneficiaries or conduct nursing visits, but it is the obligation of the home IV provider to verify and ensure that these personnel are adequately trained. In other words, the requirement that the home IV provider assure that only trained personnel furnish covered home IV drugs (section 1861(jj)(3)(vii) of the Act) applies to both its own employees and those of an organization under contract. The provider would also be required to maintain professional, financial, and administrative responsibility for services furnished under arrangements.

Accordingly, as we discuss in greater detail below, we believe that a home IV provider must directly employ core staff to perform administrative, quality assurance, and other oversight and supervisory functions necessary for the safe and effective provision of the home IV drug therapy benefit. In addition, the home IV provider must also either furnish directly (through its own facilities and employees) or through others under arrangements the patient care services and home IV drugs necessary for a safely and effectively administered home IV drug regimen.

We concluded that we should propose, under the authority of section 1861(jj)(3)(x) of the Act, which gives the Secretary broad discretion to add conditions necessary for safe and effective administration of the home IV benefit, that a home IV provider must, at a minimum, employ directly on a full-time basis core staff of either a nurse or a pharmacist.

In making this proposal, we draw a distinction between what we have identified as the core staff requirement and the core services requirements reflected in the law (that is, those functions that must be performed by the home IV provider). The key point is that the home IV provider would be responsible, through its directly employed nurse or pharmacist, for the oversight and supervisory functions discussed above. In addition, the home IV provider would be required to assure that the needs of patients, both routine and urgent, ranging from routine or emergency inquiries to the actual furnishing of patient care services, are met on a 24-hour-a-day, 7-day-a-week basis either through its own employees or those furnishing services under arrangements, or through a combination of professionals directly employed and under contract either on duty or on call.

For example, we view this approach working as follows. A home IV provider directly employs a pharmacist who participates, along with other provider employees, in the oversight functions of coordination of patient care, conducting a quality assurance program and drug regimen review for all patients, and other required core service tasks. The pharmacist also helps in addressing patient inquiries during the normal work day and is periodically on call for this purpose after the work day ends. The home IV provider also has arrangements with outside sources to furnish some or all of the necessary patient care related pharmacy and nursing services. In this case, the home IV provider would be responsible for ensuring the quality of the services furnished, making certain that the pharmacy under contract and the organization furnishing the nursing services comply with the requirements set forth in the condition of participation, and verifying that all pharmacists and nurses employed by the organizations working under arrangements meet the professional standards and qualifications established in the conditions of participation.

The home IV provider would also be responsible for ensuring that staff are available to furnish phone coverage to handle patient inquiries 24 hours a day, 7 days a week. Furthermore, as necessary, a nurse furnishing services under arrangements might contact the patient's physician for coordination of care, but the home IV provider would be responsible for keeping abreast of these contacts for overall coordination of patient care among the physician and the nurses and pharmacy working under arrangements, as well as for overall coordination of the patient's plan of care and its timely updating and review by the physician.

There are several alternatives to the core staff requirement of a nurse or pharmacist that we considered:

- One such alternative would be to specify that the home IV provider directly employ the number of full-time equivalent (FTE) nurses *and* pharmacists necessary to perform around the clock core service supervisory and consultative nursing *and* pharmacy functions. Our initial supposition was that this requirement could be met with as few as 2.5 FTE nurses and 2.5 FTE pharmacists.
- Second, we considered requiring that a home IV provider must directly employ at least one full-time nurse *and* one full-time pharmacist whose services could be supplemented as necessary by other directly employed nurses or pharmacists to ensure around the clock coverage.
- Third, we considered stating that each provider could determine the number of core staff it needs; that is, that the home IV provider would only be required to employ directly, as core staff, a sufficient number of nurses and pharmacists to be able to respond to patients at all times.

We are specifically interested in receiving suggestions and comments from the public about these or other alternatives to the single directly-employed nurse or pharmacist requirement. We emphasize that our interest in this regard is protecting the health of beneficiaries and providing for their safety to the greatest extent that is reasonably possible without putting undue staffing burdens on potential home IV providers.

1. Standard: Core Staffing Requirements

To reiterate, we propose that a home IV provider be required to employ directly, at a minimum, either a full-time nurse or a full-time pharmacist. The provider may also employ additional pharmacists and nursing staff as it chooses, either part-time or full-time.

As we have stated, we believe that Congress did not intend for a billing operation to qualify as a home IV provider, that is, an answering service or business office that contracts out all the work. Thus, we believe this core staff requirement is necessary.

2. Standard: Core Services Requirements

The home IV provider would be required to ensure that its employees perform the following functions:

• Developing, supervising, and coordinating all activities of nursing and pharmacy services including assuming responsibility for assuring that only qualified individuals administer home IV drugs.

• Consulting with pharmacists involved in patient care to coordinate the patient's plan of care with the patient's physician.

• Performing a quality assessment and assurance program including drug regimen review.

3. Standard: Twenty-Four-Hour Availability of Services

This standard would implement the provision of section 1861(jj)(3)(iv) of the Act that requires that home IV providers make needed services available, as needed, on a 24-hour-a-day, 7-day-a-week basis.

A home IV provider would be required to meet the following time requirements related to care of the patient:

• The home IV provider must make available routinely or urgently needed nursing, pharmacy, and related services and home IV drugs and supplies 24 hours every day.

• The home IV provider must be accessible to the patients at all times. If a patient or caregiver telephones the home IV provider with a problem relating to either the administration of a drug or the malfunctioning of equipment, the home IV provider must be able to make telephone contact with the patient or caregiver within 10 minutes, and the provider must be able to resolve the patient's problem expeditiously within periods of time contingent upon the nature of the problem (that is, mechanical or medical). For example, we believe that a period of 90 minutes should be adequate to resolve a problem and provide for the needs of a patient, but we specifically request comments about appropriate limits and preferred methods for establishing limits.

We believe that the relatively short time frames we are proposing to require for dealing with patient problems are reasonable given the medical necessity of administering completely an IV drug on a timely basis. Because of the burden that these requirements could place on a home IV provider, we are specifically interested in public comments concerning any reasonable alternatives that would ease the burden on the providers but at the same time, meet the needs of the patient.

• In an emergency, the home IV provider must be able to deliver IV drugs to the patient at least 30 minutes before the drugs are scheduled for use. We are proposing this requirement for several reasons. Elderly people (that is, individuals 65 years of age and older), when compared to other individuals, have decreased lean body mass, decreased total body water, decreased serum albumin and, in proportion, increased body fat. Because of these factors, the percentage of "free drug" circulating in their bodies is increased. Thus, the dose and the appropriate dose interval prescribed by the physician must be carefully followed to ensure effective use of a drug, as well as to decrease morbidity and additional cost from adverse reactions. Therefore, if a patient needs a drug on an emergency basis, we believe the provider must be capable of responding timely. Since it is common practice to keep IV medications either refrigerated or frozen, the drug would have to be kept at room temperature for a certain amount of time before infusion. We believe that 30 minutes is an appropriate amount of time, and that is why we are proposing that time requirement.

• The home IV provider must furnish services in a manner consistent with acceptable standards of practice.

H. Nursing Services

Under this proposed rule, the home IV provider would be responsible for furnishing nursing services using only registered nurses (except, as discussed below, with respect to those States in which physicians or physician assistants may furnish IV therapy related nursing services). In addition, the provider would also have to ensure the following:

• Nursing services are directly supervised by the home IV provider and are made available to ensure that the needs of the patients are met.

• Patient care responsibilities of the nurses are specified.

• All nurses employed directly by the home IV provider or whose services are obtained under arrangements with a contractor meet the following requirements concerning education, experience, and proficiency:

—Each nurse must have been educated in the principles and practices of infusion therapy and cardiopulmonary resuscitation.

—Each nurse must have at least 2 years experience in patient assessment and infusion therapy.

—Each nurse must be proficient in all clinical aspects of IV therapy with validated competency in clinical judgment and practice demonstrated by education credentials or job experience. For example, each nurse must be able to access peripheral veins and recognize medication and solution incompatibilities.

—Each nurse must be able to perform the following procedures:

+Interpret the physician's order for IV therapy and administer IV medications as ordered.

+Perform venipuncture and insertion of all types of needles and catheters commercially available (excluding the insertion of subclavian, jugular, and cut-down catheters).

+Prepare IV solutions with the addition of medications in the absence of admixture services.

+Initiate, monitor, and terminate IV solutions and additives.

+Set the flow rates, as established by the physician, for all IV solutions and medications.

+Maintain and replace sites, tubing, and dressings in accordance with established policy.

+Draw blood.

—Each nurse must have a thorough knowledge of and proficient technical ability in the use of the specific type of IV equipment to be used so that the nurse is able to evaluate the equipment and identify when maintenance would be necessary.

—Each nurse must be able to observe and assess all significant reactions related to IV therapy and initiate appropriate nursing interventions. All significant findings must be reported to the physician.

—Each nurse must follow established infection control and aseptic practices.

—Each nurse must document his or her actions associated with the preparation, administration, and termination of all aspects of IV therapy.

We are proposing this condition under section 1861(jj)(1)(B) of the Act under which the home IV provider furnishes directly, or arranges for the furnishing of, nursing, pharmacy, and related services as described in section 1861(jj)(2) of the Act and under section 1861(jj)(3)(x) of the Act under which the Secretary is authorized to make additional requirements as necessary to assure the safe and effective provision of home IV drug therapy services.

We would allow a registered nurse, a physician, or, in States in which State medical practice acts permit physicians and physician assistants to do so, a physician assistant under the supervision of a physician to furnish nursing services in connection with home IV drug therapy services. (In such States, the references found in this proposed rule to "registered nurse" or

"nurse" are read to include physician assistants.) Services performed by a physician or physician assistant could not be billed for separately. (That is, as discussed below, the nursing services furnished in connection with home IV drug therapy by these individuals would be paid for under the fee schedule.)

We contacted the National Council of State Boards of Nursing to determine whether States allow licensed practical nurses or other allied health professionals (other than physician's assistants) to administer IV drug therapy. Based on information obtained from this organization, we learned that, except for some limited exceptions, State laws allow only registered nurses to administer IV drug therapy. There are currently approximately three States that allow a licensed practical nurse to disconnect an established IV line. Several States permit a licensed practical nurse to hang a clear IV bottle. However, even these States require the direct supervision of a registered nurse when these services are performed by a licensed practical nurse. In addition, none of the entities that we contacted that currently furnish home IV drug therapy allow anyone but a registered nurse to furnish nursing services connected with IV drug therapy. Therefore, our proposal not to allow licensed practical nurses or other allied health professionals other than physician's assistants to furnish the nursing services associated with home IV drug therapy is, in general, consistent with established State laws on the provision of IV drug therapy.

As mentioned above, as part of a separate rulemaking document, we are proposing that payment for nursing services under the home IV drug therapy benefit would be made as part of a fee schedule that would cover the provisions of all home IV drug therapy services. We reiterate that, if a physician or a physician's assistant does perform services, these services could not be billed for separately because they would be taken into account in the home IV drug therapy fee schedule.

I. Pharmacy Services

As with our proposals concerning nursing services, we are proposing the following condition concerning the provision of pharmacy services under section 1861(jj)(1)(B) of the Act, which states that the home IV provider directly provides or arranges for nursing, pharmacy, and related services, and section 1861(jj)(3)(x) of the Act, which gives the Secretary the authority to make additional requirements he or she deems necessary to assure the safe and effective provision of home IV drug therapy services. Under this condition, we would specify that the home IV provider must ensure that a registered pharmacist is responsible for the purchasing, preparation, safe administration, and clinical monitoring of drugs.

1. Standard: Pharmancy Services Management

The home IV provider would be required to manage its pharmacy services, or ensure that pharmacy services obtained under arrangements are furnished, in accordance with the following provisions:

- The policies and procedures of the home IV provider include provisions designed to ensure that pharmacy practice at all times is consistent with applicable law and regulations governing professional licensure and operation of pharmacies.
- The home IV provider maintains and makes available up-to-date pharmaceutical references that include a copy of HCFA's current list of covered home IV drugs (that is, HCFA's list of covered home IV drugs as published in the **Federal Register**) and official pharmaceutical compendia, periodicals, and current editions of texts and reference books covering pharmaceutical practice as it relates to patient care.
- The home IV provider maintains patient profiles that includes—

—The patient name, age, and lean body weight;
—The patient's diagnosis or diagnoses;
—Clinical information relating to the patient's initial and ongoing home IV drug therapy;
—Current drug therapy provided to the patient including nonprescription and home remedy products; and
—A description of the patient's drug allergies or sensitivities.

- A pharmacist reviews each prescription order before a drug is dispensed to ensure that the drug is a covered home IV drug and to ensure that the correct drug is dispensed to the patient.
- A pharmacist and the patient's physician determine the appropriate lab monitoring schedule for monitoring the patient through laboratory testing. This schedule must include a list of the laboratory tests that are to be performed, identification of the Medicare-approved laboratory that will perform the tests, the frequency of the tests, and the schedule to be followed for obtaining the results.
- A pharmacist supervises support personnel to ensure adequate quality of the drugs and pharmaceutical supplies.

2. Standard: Storage, Equipment, and Preparation Area

- The home IV provider would be required to ensure that drugs, supplies, and equipment are maintained either in its own pharmacy or in a pharmacy furnishing services under arrangements in accordance with the following procedures:

—Drugs must be stored separately from other materials under proper conditions of sanitation, temperature, light, moisture, ventilation, and security.
—Areas used in the preparation of sterile products must be constructed to minimize opportunities for particulate and microbial contaminations and must be separate from areas used in the preparation of nonsterile products.
—Work surfaces are kept free of equipment, supplies, records, and labels unrelated to the preparation of a given prescription.
—Work surfaces and equipment must be disinfected after preparation of each prescription.
—Clean benches or laminar flow hoods must be used in the preparation of IV drugs and must be inspected at least annually in accordance with standard inspection practice.
—Both ingredients and final products must be inspected for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination. The equipment necessary for such an inspection must be maintained by the pharmacy.
—Drugs must be kept in a locked storage area.
—Each dosage unit of both a cytotoxic drug and a Schedule II controlled drug must be accounted for in a distribution log.

- Unless contraindicated, an appropriate air-eliminating filter is employed in the home for delivery of IV fluids. We are proposing that an appropriate air-eliminating filter be used to protect the patient from particulates, possible air emboli, pathogenic bacteria (micro-organisms), and the risks of IV-related complications and sepsis.
- Mislabeled or otherwise unusable drugs are not made available for patient use.
- Outdated drugs are destroyed using accepted methods of disposal.

We welcome public comment on the above standards. In particular, we are interested in receiving comments regarding the marginal effectiveness in preventing IV drug contamination of requiring laminar flow hoods over clean

work benches. We would be interested in any data reflecting differences in: (a) Expected levels of drug contamination; and (b) Equipment acquisition costs.

3. Standard: Drug Labeling

We would specify that the label on any IV drug or solution that has been dispensed to a patient by the provider or by a pharmacy furnishing services under arrangements contain at least the following information:

- The name, address, and telephone number of the dispensing pharmacy and the telephone number of the home IV provider if the pharmacy services are furnished under arrangements.
- The dates of both preparation and expiration of the drug.
- The pharmacy's identifying serial number for the drug order or prescription.
- The full name of both the patient and prescribing physician.
- The name of the drug, its strength, and the amount dispensed.
- The directions for use including the scheduled date, time, and rate of administration and appropriate space for the patient or caregiver to add the date and time the IV is started. The directions must include information that the patient is to completely use or discard IV fluids within 24 hours of mixing or unfreezing a mixture.
- The directions for storage.
- Cautionary or accessory labels if appropriate.
- The lot number or control number of the batch from which the drug was obtained.

J. Patient and Caregiver Evaluations and Instructions

In general, home IV drug therapy programs are designed for patients whose referring physicians recommend home IV drug therapy. These patients may have started IV drug therapy in a hospital and are now ready to leave the hospital except for needing to continue a course of IV drug therapy. Although the referring physician may have recommended a patient for a course of home IV drug therapy, under proposed § 485.145 the home IV provider is responsible for accepting only those patients whose needs it can meet. Once it is determined that the patient meets all criteria for acceptance, the provider is responsible for assessing the adequacy of any training previously received and for furnishing any new or supplemental training the patient or caregiver may need. We believe that having a registered nurse teach the patient or caregiver or both individuals, IV therapy care helps to ensure safe provision of IV drug therapy for the patient at home. We are proposing these standards under the authority provided in section 1861(jj)(3)(x) of the Act under which the Secretary is authorized to make additional requirements to assure the safe and effective provision of home IV drug therapy services.

As discussed above, we believe the patient selection is critical in ensuring a successful outcome in home IV drug therapy. However, once the patient is selected, it is just as critical that the home IV provider's program for patient and caregiver education be comprehensive. A selected patient or caregiver must undergo a training program for the purpose of learning to administer potent drugs, generally antibiotics, intravenously. We believe that a patient or caregiver must be able to demonstrate proficiency in home IV drug therapy care before discharge from the hospital. Hospitals are currently doing this training and we expect them to continue. We are assuming continuity of this responsibility and are using it as a basis for our general approach to coverage and payment policies. This responsibility for patient training while in the hospital is required under § 482.21(b) of the hospital conditions of participation under which a "hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients."

We would require that the patient or caregiver be supervised at home for the first infusion of the IV drug to verify the ability of the patient or caregiver to transfer learning from the hospital setting to the home setting. Supervision of the first infusion at home would also allow the home IV provider staff to provide additional training in the home, as necessary. The IV therapy nurse would be required to provide instructions in heparin lock care and administration of the IV medication. A patient who requires a Hickman or Broviac catheter (that is, a central line) must be provided with instructions in catheter care and infusion care. If necessary, a second training session for a patient who started IV drug therapy in a hospital would be appropriate. We expect that a patient who starts IV drug therapy at home would need three or four training sessions.

We would specify that each patient receive a set of written and illustrated instructions along with a telephone number of the home IV provider, which must be staffed 24 hours each day, because, as provided in proposed § 485.130(a)(3), the patient or caregiver must be able to make contact with either a nurse or a pharmacist within 10 minutes of his or her initial telephone call.

K. Protocols and Policies

Section 1861(jj)(3)(iii) of the Act provides that a home IV provider must adhere to written protocols and policies concerning the provisions of home IV drug therapy services. We are proposing that the IV provider adhere to the following procedures and have written protocols and policies with respect to the provision of home IV drug therapy items and services.

1. Standard: First Dose

Based on our research, we believe that the first dose of any intravenous medication to be provided outside of an institutional setting should be given under direct physician or home IV provider's nurse supervision. For example, if a patient was receiving tetracycline intravenously and then the physician ordered the IV medication to be changed to ampicillin, we believe that the first dose of the ampicillin needs to be given under the direct supervision of a physician or nurse.

We are proposing that if this supervision is provided by a physician it could be furnished as a physician service in the physician's office, in the outpatient department of a hospital, or even in the patient's home. If the first dose is administered at home under the direct supervision of the home IV provider's nurse, the first dose would be considered a home IV drug therapy service. After the first dose is administered, we are proposing that the supervising nurse or physician remain in attendance with the patient for a length of time sufficient to make sure that the patient is stable. Under this proposed rule, resuscitation medication and equipment to treat anaphylaxis must be readily available.

Since we are concerned about creating a possibly unnecessary delay between the time a physician decides that an IV medication should be changed and the time at which the new IV medication can be administered, we are proposing that a first dose of a different IV medication could be administered by registered nurse. However, we are specifically seeking public comment about the safety of this proposal, that is, whether it is medically acceptable to allow the first dose of a different IV medication to be given without a physician in attendance. If a commenter believes that it is necessary for a physician to be present during the first dose of an IV medication furnished outside of an institution, we are

interested in receiving information about the specific IV medications that the commenter believes could not be started safely without a physician present.

2. Standard: Venipuncture and Catheter Care

We are proposing that a registered nurse rotate the peripheral injection site at least every 3 days to reduce the possibility of phlebitis. If applicable, the nurse must inspect the central line catheter site at least once each week. Aseptic techniques would be practiced during all venipuncture, dressing changes, catheter care, and assembly of IV infusion systems for both peripheral and central line patients.

For infection control purposes, we would require that the home IV drug provider make sure that the patient or the caregiver changes the IV administration set at least every 24 hours and the IV dressings at least every 48 hours or immediately if soiled or wet. (An administration set usually consists of a length of tubing that connects the source of the IV drug to the needle.) The air elimination filter would be routinely changed by the nurse.

3. Standard: Quality of the Air Elimination Filter and Sterility of the Catheter

For a sample of patients, the nurse would be required to package air elimination filters that have been removed from IV tubing and immediately send them to an independent laboratory for analysis of particulate matter and bacterial and fungal contamination. Also, on a sample basis, the nurse would package and send IV catheters that have been removed from patients to a laboratory for analysis of sterility.

In addition, we would specify that the home IV provider must keep copies of laboratory results on the testing of both the air elimination filter and the catheter that must be made available for review on request.

4. Standard: Drug Therapy Review

We are proposing that the pharmacist and nurse review the combination of drugs and equipment for appropriateness before drug therapy is initiated. In addition, the pharmacist would be required to conduct ongoing review (at least once every 3 days) to evaluate the effectiveness of the drug therapy. We would require that he or she then inform the physician of his or her findings as necessary. At a minimum, we would require that this review evaluate the following:

- The therapeutic appropriateness of the choice of drugs for the patient and the drug regimen (including therapeutic duplication of drugs).
- The effectiveness of the dosage, frequency, and route of administration.
- The patient's adherence to the drug regimen.

5. Standard: Patient Rights and Responsibilities

Because the patient's care is usually continuous in nature, we propose to require that the home IV provider ensure that the following conditions concerning the rights and responsibilities of patients are met.

- The home IV provider begins treatment of a patient only if the home IV provider is capable of furnishing needed care at the level of intensity required by the condition of the patient.
- Each patient receives care appropriate to his or her needs in a timely manner.
- The home IV provider informs the patient in a timely manner of the need for transfer to another medical entity or level of care and of any appropriate alternatives.
- If the home IV drug therapy is to end without transfer to another medical entity, the home IV provider informs the patient in a timely manner of the impending discharge, continuing care requirements, and other available services, if needed.
- The home IV provider honors a patient's rights and informs a patient of his or her responsibilities, if any, in the care process. The rights and responsibilities are clearly stated in materials or brochures distributed to a patient upon admission into the home IV drug therapy program.
- The home IV provider sets up procedures to deal with patient grievances and patient-recommended changes in policies and services without coercion, discrimination, reprisal, or interruption of services. The home IV provider informs the patient at the beginning of IV drug therapy about these procedures for making, reviewing, and resolving complaints.

L. Quality Assurance

Section 1861(jj)(3)(vi) of the Act provides that a home IV provider is required to conduct "* * * a quality assessment and assurance program, including drug regimen review and coordination of patient care." We are proposing that a home IV provider maintain an ongoing quality assurance program designed for monitoring patient care objectively and systematically, evaluating the quality and appropriateness of patient care, resolving identified problems, and pursuing other opportunities to improve patient care.

1. Standard: Program Objectives

We would require that, through an ongoing, planned, and systematic process, the home IV provider monitors and evaluates the quality and appropriateness of patient care, including the performance of employees and other personnel who furnish services under arrangements with the home IV provider.

We propose that the home IV provider include at least the following in a written plan:

- Scope and objectives of the quality assurance activities.
- Activities identified for monitoring and evaluation.
- Methods for implementing the monitoring and evaluation activities and for reporting the results.
- Mechanisms for taking follow-up action.
- The responsibility of staff for each activity in the quality assurance program.

2. Standard: Patient Care

We would require that the home IV provider monitor and evaluate the quality and appropriateness of patient care, including identification of important aspects of care or service that focus on high-risk, high-volume, or problem-prone activities. Thus, the home IV provider would be required to collect data on the following:

- Length of home IV drug therapy by diagnosis and treatment.
- Incidences of rehospitalization and the cause of rehospitalization.
- Incidences of—

—Phelebitis;
—Infiltration;
—Site infection; and
—Other infection.

- Hydration and nutritional status (including sudden or large weight loss, loss of appetite, or reduction in serum albumin level to a subnormal level).

We propose that the data collected by the home IV provider be reviewed and analyzed at least once annually to determine the frequency of negative outcomes, to ascertain whether corrective action was taken immediately in cases of negative outcomes, and whether negative outcomes were analyzed as soon as possible to evaluate the effectiveness of the chosen corrective action. We would expect that such analyses would result in necessary changes to recommended courses of action so that recurrences of negative outcomes would be reduced.

3. Standard: Patient Satisfaction

We would use patient satisfaction as an indicator of quality. The provider would be required to determine from the patient that—

- Drugs and IV equipment were delivered timely to the patient.
- The patient could read the preparation and expiration dates on the drug labels.
- A nurse visited any patient with a peripheral IV catheter placement every 3 days and rotated the peripheral IV injection site.
- A nurse visited any patient with a central line at appropriate intervals for monitoring.
- Procedures have been established to enable patients to make complaints for which the home IV provider finds acceptable solutions and keep a record of the complaints and solutions.

M. Infection Control

Under this proposed rule, we would require that a home IV provider develop infection control procedures to be used in connection with the provision of services. These procedures must concern at least personal hygiene, isolation precautions, aseptic procedures, staff health, including transmitted infections, and cleaning and sterilization of equipment.

Furthermore, we would specify that the home IV provider advise staff, patients, and caregivers of any necessary precautions, including infection control and personal hygiene and their responsibilities in the infection control program. Also required would be a system for evaluating, reporting, and maintaining records of infection related to the care or service provided among patients and, as appropriate, among staff.

III. Regulatory Impact Statement

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

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

In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we would treat all home IV therapy providers as small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any proposed rule that 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside a metropolitan statistical area.

This proposed rule would implement the provisions of section 1861(jj) of the Act as enacted by section 203(b) of Public Law 100-360. Although we have made a concerted effort to estimate the effects of our proposal, we have found that we cannot estimate, with any degree of confidence, the incremental cost of this rule to entities that provide home IV drug therapy services. In light of the fact that many of the proposed requirements are both currently practiced and recommended by companies that currently provide home IV drug therapy services, we believe that this proposed rule would not have a significant economic impact on these companies. In addition, we believe that any effects that this proposed rule may have on small individual entities that furnish home IV drug therapy services, particularly those in rural areas would be minor.

For these reasons, we have determined that a regulatory impact analysis is not required. Further, we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis.

IV. Other Required Information

A. Paperwork Reduction Act

Proposed regulations at §§ 485.110, 485.120, 485.125, 485.135, 485.140, 485.145, 485.150, 485.155, and 485.160 contain information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501-3511). Home IV drug therapy providers must provide documentation to assure compliance with the conditions of participation in order to receive Federal funds on behalf of Medicare beneficiaries. The total reporting burden for each home IV provider for this collection of information is estimated to be 3 hours per beneficiary treated during the first 12-month period that the rule would be in effect. A notice will be published in the **Federal Register** after OMB approval of these requirements is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the **"ADDRESS"** section of this preamble.

B. Public Comment

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the **"DATE"** section of this preamble, and we will respond to the comments in the preamble of that rule.

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 417

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

42 CFR Part 485

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Chapter IV would be amended as set forth below:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Part 400 is amended as follows:

PART 400—INTRODUCTION; DEFINITIONS

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

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

Subpart B—Definitions

B. In § 400.202, the introductory text is republished and the definition of "Provider" is revised to read as follows:

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

* * * * *

"Provider" means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, a home IV drug therapy provider, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

* * * * *

II. Part 417 is amended as follows:

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

A. The authority citation for Part 417 continues to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97–248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215 and 1301 through 1318 of the Public Health Service Act, as amended (42 U.S.C. 216 and 300e through 300e–17), unless otherwise noted.

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

B. Section 417.416 is amended by revising paragraph (b)(1) to read as follows:

§ 417.416 Qualifying condition: Furnishing of services.

* * * * *

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1) Hospitals, SNFs, HHAs, comprehensive outpatient rehabilitation facilities, hospices, home IV drug therapy providers, and providers of outpatient physical therapy or speech pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

* * * * *

III. Part 485 is amended as follows:

PART 485—CONDITIONS OF PARTICIPATION AND CONDITIONS FOR COVERAGE: SPECIALIZED PROVIDERS

A. The authority citation for Part 485 is revised to read as follows:

Authority: Secs. 1102, 1124, 1138, 1154, 1861 (aa), (cc), and (jj), and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–3, 1320b–8, 1320c–3, 1395x (aa), (cc), and (jj), and 1395(hh).

B. A new Supart C is added to read as follows:

Subpart C—Conditions of Participation: Home IV Drug Therapy Providers

Sec.

Subpart C—Conditions of Participation: Home IV Drug Therapy Providers

§ 485.100 Basis and scope.

This subpart sets forth the conditions that entities must meet to be approved for participation in Medicare as home IV drug therapy providers under section 1861(jj) of the Act and Part 489 of this chapter.

§ 485.101 Definition.

As used in this subpart, unless the context indicates otherwise, *"home intravenous (IV) drug therapy provider"*, *"home IV provider"*, or *"provider"* means an entity that—

(a) Is capable of providing covered home IV drugs, nursing and pharmacy services, and other services as are necessary for the administration of home IV drug therapy; and

(b) Meets all the requirements of this subpart.

§ 485.105 Condition of participation: Compliance with Federal, State, and local laws.

The home IV provider and all personnel who furnish services must be in compliance with applicable Federal, State, and local laws and regulations.

(a) *Standard: Compliance with Federal laws.* The home IV provider must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) *Standard: Licensure of home IV provider.* If State or local law requires licensing, the home IV provider must be currently licensed or approved as meeting the standards established for licensure.

(c) *Standard: Licensure of personnel.* Personnel who provide services, including individuals who provide services under arrangements with the home IV provider, must be licensed, registered, certified, or meet other applicable standards in accordance with applicable State and local laws.

§ 485.110 Condition of participation: Governing body and administration.

(a) *Standard: Governing body.*

A home IV provider must have either—

(1) A governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing all operations of the home IV provider; or

(2) Individuals who are legally responsible for the conduct of the home IV provider and who carry out the governing body functions that are specified in this section.

(b) *Standard: Disclosure of ownership.* The home IV provider must comply with the provisions of Subpart C of Part 420 of this chapter, which require health care providers and fiscal agents to disclose certain information about ownership and control.

(c) *Miscellaneous reporting.* The home IV provider must furnish information relevant to, and participate in, surveys and studies concerning cost-finding or other issues relating to the efficient administration of the home IV therapy benefit as requested by the Secretary under section 1861(jj)(3)(x) of the Act.

(d) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who meets the following conditions:

(1) Assumes responsibility for the overall management of the facility under the authority delegated by the governing body.

(2) Assumes responsibility for the day-to-day operation of the home IV provider.

(e) *Standard: Patient care policies.* The home IV provider must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services furnished by the home IV provider's employees and those furnished under arrangements.

(2) The diagnostic criteria that identify the patients for whom the services are designed.

(3) Provisions for accepting only those patients whose needs can be met by the services it furnishes.

(4) Procedures for the acceptance of a referral, including the assignment of appropriate staff to conduct a timely assessment of the patient's medical and psychological readiness for home IV drug therapy services.

(5) Procedures for quickly notifying the referring physician if the patient does not meet the home IV provider's admission criteria.

(6) Procedures for notifying the referring physician of incidences of phlebitis, IV infiltration, or site infection that occurs after the provider begins furnishing home IV drug therapy services.

(f) *Standard: Contracted services and professional management responsibility.*

(1) The home IV provider must—

(i) Retain professional and administrative responsibility for and control and supervision of contracted services; and

(ii) Ensure that the services are furnished—

(A) In a safe and effective manner by nurses or pharmacists meeting the qualifications of this subpart; and

(B) In accordance with the patient's plan of care and other applicable requirements of this subpart.

(2) With each contractor that provides arranged services, the home IV provider must have a legally binding written agreement that meets at least the following requirements:

(i) Identifies the services to be provided.

(ii) Specifies that contracted services are provided only if directly authorized by the home IV provider.

(iii) Describes the manner in which the contracted services are coordinated, supervised, and evaluated by the home IV provider.

(iv) Delineates the roles of the home IV provider and the contractor in the patient care process.

(v) Provides for the preparation of patient records with progress notes and observations and for the prompt incorporation of the patient records into the clinical record of the home IV provider.

(vi) Provides that the requirements for the services furnished under arrangements and personnel who furnish them are the same as for the services furnished directly by the home IV provider and the personnel who furnish them.

(vii) Specifies the financial arrangements that provide for payment to the contractor by the home IV provider for the provision of covered services.

(viii) Specifies that a contractor that furnishes services under arrangements may not bill the patient or Medicare for covered services.

§ 485.115 Condition of participation: Patient selection.

After a patient's referring physician requests home IV drug therapy, the home provider makes an assessment of each patient and his or her needs. For hospital inpatients, the home IV provider must make this assessment prior to discharge. The home IV provider furnishes services only to patients whose needs can be met by its services.

(a) *Standard: Medical critieria.*

A patient must—

(1) Be under the care of a licensed referring physician who either prescribed the home IV drug or established the plan of care, or both, and who continually monitors the home IV drug therapy;

(2) Have a clinical status that allows IV drugs to be safely administered in the home;

(3) Have venous sites available for peripheral IV catheter or needle placement or have a central venous catheter or other central venous access device; and

(4) Be unable, for medical or therapeutic reasons, to take the provided medication orally or by other means less intrusive than IV.

(b) *Standard: Nonmedical criteria.*

A patient must—

(1) Be capable of performing safely self-administration of drugs and self-care after adequate patient education (for example, be able to learn aseptic technique and heparin lock maintenance and read and understand the labeling of the home IV drugs) or have a primary caregiver who can perform these tasks;

(2) Be motivated to use home IV drug therapy services;

(3) Be psychologically stable (that is, the prospect for adherence to a disciplined medical regimen is realistic); and

(4) Have a home environment that is conducive to the provision of home IV drug therapy services (that is, a clean home with electricity, a telephone, running water, refrigeration, and enough space to support home IV drug therapy services).

§ 485.120 Condition of participation: Plan of care.

For each patient, the referring physician must establish and periodically review a plan of care.

(a) *Standard: Development of the plan of care.* A plan of care must meet the following requirements:

(1) The plan of care is developed by the patient's referring physician.

(2) The plan of care is implemented by the home IV provider.

(3) The plan of care is based on the referring physician's initial and ongoing individual patient assessments.

(4) The plan of care is reviewed by the referring physician as necessary, but at least once every 30 days.

(5) The plan of care includes at least the following current information about the patient and the home IV drug therapy services to be provided:

(i) The patient's name, gender, age, and lean body weight.

(ii) A narrative description of the appropriate diagnoses.

(iii) The patient's drug allergies or sensitivities.

(iv) The patient's current drug therapy, including nonprescription drugs, and home remedies.

(v) The goal of the provision of home IV drug therapy services for the patient.

(vi) The drugs and method of drug therapy administration to be furnished by the home IV provider including—

(A) Amount of dosage and timing of administration;

(B) Route of administration, either peripheral or central venous line.

(C) Frequency of IV site monitoring; and

(D) Type of IV equipment, related supplies and other equipment, and fluids to be administered.

(vii) Identifying physician information, the physician's signature, and the date.

(b) *Standard: Referring physician review of plan of care.* The referring physician review of the plan of care must meet the following requirements:

(1) The referring physician reviews the patient's process in attaining the objectives of the plan of care at least every 30 days.

(2) The review is based upon appropriate information provided by health professionals, including information furnished by the registered nurse and pharmacist employed by the home IV provider.

§ 485.125 Condition of participation: Central clinical records.

In accordance with accepted principles of medical record practice, the home IV provider must establish and maintain a clinical record for all individuals receiving care and services including those who are not entitled to Medicare. Each clinical record must be completely, promptly, and accurately documented, readily accessible, and systematically organized to ease retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record is a comprehensive compilation of information of medical and other data that must contain sufficient information to identify the patient clearly and to justify the diagnoses and treatment. Entries in the clinical record must be made for all services provided directly or under arrangements. Entries must be made for each treatment performed and must be signed by the individual who performs the services. Documentation on each patient must be consolidated into one clinical record that must contain the following information:

(1) Patient identification data.

(2) The initial patient assessment and subsequent reassessments.

(3) Current plan of treatment.

(4) Consent and authorization forms.

(5) Past and present pertinent medical history.

(6) Complete documentation of all services provided.

(7) Upon completion of treatment, a summary that includes a description of patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Retention and preservation.* The home IV provider must retain clinical records for the appropriate time period as specified in this paragraph. If the requirements of State law are used to define the time period for maintaining clinical records, it must be the law of the State in which the services were provided to the patient.

(1) If the State where the services are furnished has a law that applies to the provider governing the maintenance of clinical records, the home IV provider must maintain its clinical records for the time required by that law.

(2) In the absence of an applicable State law, the home IV provider must maintain clinical records for the time periods provided under the appropriate statute of limitations concerning medical malpractice in the State.

(3) If there is no applicable State law or State statute of limitations concerning medical malpractice, the home IV provider must maintain clinical records for at least 5 years.

(4) In addition, for services furnished to a minor, the home IV provider must maintain clinical records for at least 3 years after the individual attains the age of majority under State law.

(c) *Standard: Protection of information.* The home IV provider must—

(1) Safeguard the clinical record against loss, destruction, or unauthorized use;

(2) Have procedures to govern the use and removal of records, to ensure release of information only to authorized individuals, and to ensure that unauthorized individuals cannot gain access to, or alter, patient records;

(3) Obtain the patient's written consent before releasing information not required to be released by law; and

(4) Release original records only in accordance with Federal or State laws, court orders, or subpoenas.

(d) *Standard: Patient access.* The home IV provider must permit each patient or his or her legal representative to inspect or obtain copies of his or her clinical records within 48 working hours after the provider receives a written request.

§ 485.130 Condition of participation: Core staff, core services, and full-time availability of patient care services.

A home IV provider must make all necessary nursing and pharmaceutical services available 24 hours a day, 7 days a week to meet the reasonable needs of its patients with respect to home IV drug therapy services.

(a) *Standard: Core staffing requirements.* A home IV provider must employ directly either a full-time registered nurse or a full-time registered pharmacist.

(b) *Core services.* A home IV provider must perform the following oversight and supervisory functions itself (that is, these functions may not be furnished under arrangements):

(1) Assurance that all patient care related nursing and pharmacy services, whether furnished directly or under arrangements, are available on a 24-hour-a-day, 7-day-a-week basis.

(2) Development and coordination of all activities of nurses and pharmacists including assuring that only qualified, properly trained individuals furnish these services.

(3) Necessary consultations and coordination concerning a patient's plan of care with the patient's physician and provision of all patient laboratory test results.

(4) Conducting a quality assessment and assurance program including drug regimen review.

(c) *Standard: Twenty-four-hour availability of patient care services.* (1) To meet the needs of patients, a home IV provider may contract for additional nursing or pharmacy services to supplement the services directly furnished by the home IV provider. If services directly furnished under arrangements, the provider must maintain professional, financial, and administrative responsibility for the services.

(2) A home IV provider must be able to meet the following time requirements related to care of a patient:

(i) The home IV provider must make routine or urgently needed nursing, pharmacy, and related services and home IV drugs and supplies available 24 hours a day, 7 days a week.

(ii) The home IV provider must be accessible to patients at all times. If a patient or caregiver telephones the home IV provider with a problem concerning the administration of a drug or malfunctioning equipment, the provider must be able to make telephone contact with the patient or caregiver within 10 minutes, and the provider must be able to resolve the problem as expeditiously as possible given the nature of the problem.

(iii) In an emergency, the provider must be able to deliver drugs to the patient at least 30 minutes before the drugs are scheduled for use.

(iv) The home IV provider must furnish services in a manner consistent with accepted standards of medical practice.

§ 485.135 Condition of participation: Nursing services.

(a) *General requirements.* The home IV provider is responsible for furnishing nursing services, directly or under arrangements, that are necessary for the provision of IV drug therapy services. Persons furnishing the nursing services either as employees of the home IV provider or of the organization under contract with the home provider must be either registered nurses, or in States that permit such practice, physicians or physician assistants under the supervision of a physician. (In such States, the references in this subpart to a "registered nurse" or "nurse" are read to include physician assistants.) In addition, the home IV provider must—

(1) Direct and staff nursing services to ensure that the needs of its patients are met;

(2) Specify the patient care responsibilities of the nurses; and

(3) Ensure that the requirements of paragraphs (b) through (d) of this section are met.

(b) *Education and experience.* (1) The home IV provider must ensure that each nurse who furnishes home IV drug therapy services meets the following requirements for education, experience, and proficiency:

(i) Education in the principles and practices of infusion therapy and cardiopulmonary resuscitation.

(ii) Experience in patient assessment and infusion therapy.

(iii) Proficiency in all clinical aspects of IV therapy with validated competency in clinical judgment and practice demonstrated by work experiences. For example, each nurse must be able to access peripheral veins and must be able to recognize medication and solution incompatibilities.

(iv) Ability to perform the following procedures:

(A) Interpret the physician's order for IV therapy and administer IV medications as ordered.

(B) Perform venipuncture and insertion of all types of needles and catheters commercially available (excluding the insertion of subclavian, jugular, and cut-down catheters).

(C) Prepare IV solutions with the addition of medications in the absence of admixture services.

(D) Initiate, monitor, and terminate IV solutions and additives.

(E) Evaluate the effectiveness of the dosage, frequency and route of administration of IV drugs and the patient's adherence to the drug regimen.

(F) Set the flow rates established by the physician for all IV solutions and medications.

(G) Maintain and replace sites, tubing, and dressings in accordance with established policy.

(H) Draw blood.

(v) Thorough knowledge of and proficient technical ability in the use of the specific type of IV equipment to be used by a particular patient so that the nurse is able to evaluate IV equipment and identify when maintenance would be necessary.

(vi) Ability to observe and assess all significant reactions related to IV therapy and initiate appropriate nursing interventions.

(c) *Aseptic practices.* Each nurse must follow established infection control and aseptic practices.

(d) *Physician notification.* All significant findings of the nurse in the course of delivering home IV services must be communicated to the physician.

(e) *Documentation.* Each nurse must document in the patient's clinical record his or her actions associated with the preparation, administration, and termination of all aspects of IV therapy.

§ 485.140 Condition of participation: Pharmacy services.

The home IV provider must ensure that a registered pharmacist is responsible for purchasing, preparation, safe administration, and clinical monitoring of drugs. The home IV provider may directly furnish necessary pharmacy services or it may enter into arrangements for the services.

(a) *Standard: Pharmacy services management.* The home IV provider must ensure that necessary pharmacy services, furnished directly or under arrangements, are furnished in accordance with the following requirements:

(1) The policies and procedures of the home IV provider must ensure that pharmacy practice at all times is consistent with applicable law and regulations governing professional licensure and operation of pharmacies.

(2) The home IV provider must maintain and make available an up-to-date copy of HCFA's list of covered home IV drugs and pharmaceutical references that include official pharmaceutical compendia, periodicals and current editions of texts and reference books covering pharmaceutical practice as it relates to patient care.

(3) The home IV provider must maintain patient profiles that include—

(i) The patient's name, age, and lean body weight;

(ii) The patient's diagnosis or diagnoses;

(iii) Clinical information relating to the patient's initial and ongoing home IV drug therapy;

(iv) Current drug therapy provided to the patient including nonprescription and home remedy products; and

(v) A description of the patient's drug allergies or sensitivities.

(4) A pharmacist reviews each prescription order before dispensing a drug to ensure that the drug is a covered home IV drug and that the correct drug is dispensed to the patient.

(5) A pharmacist assists the physician in determining the appropriate schedule for monitoring the patient through laboratory testing. This schedule must include identification of tests to be performed and the Medicare-approved laboratory that will perform the tests and the frequency of testing and obtaining the results.

(6) A pharmacist supervises support personnel to ensure adequate quality of the drugs and pharmaceutical supplies.

(b) *Standard: Storage, equipment, and preparation area.* (1) The IV provider must ensure that drugs, supplies, and equipment are maintained in the pharmacy in accordance with the following procedures:

(i) Drugs must be stored separately under proper conditions of sanitation, temperature, light, moisture, ventilation, and security.

(ii) Areas used in the preparation of sterile products must be constructed to minimize opportunities for particulate and microbial contaminations and must be separate from areas used in the preparation of nonsterile products.

(iii) Work surfaces are kept free of equipment, supplies, records, and labels unrelated to the preparation of a given prescription.

(iv) Work surfaces and equipment must be disinfected after the preparation of each prescription.

(v) Clean work benches or laminar flow hoods must be used in the preparation of IV drugs and must be inspected at least annually in accordance with standard inspection practice.

(vi) Both ingredients and final products must be inspected for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination. The equipment necessary for such an inspection must be maintained by the pharmacy.

(vii) Drugs must be kept in a locked storage area.

(viii) Each dosage unit of both a cytotoxic drug and a Schedule II controlled drug must be accounted for in a distribution log.

(2) Unless contraindicated, an appropriate air-eliminating filter must be employed in the home for delivery of IV fluids.

(3) Mislabeled or otherwise unusable drugs must not be made available for patient use.

(4) Outdated drugs must be destroyed.

(c) *Standard: Drug labeling.* The label on any IV drug or solution that has been dispensed to a patient must contain at least the following information:

(1) The name, address, and telephone number of the pharmacy and the telephone number of the home IV provider if the pharmacy services are furnished under arrangements.

(2) The dates of both preparation and expiration of the drug.

(3) The pharmacy's identifying serial number for the drug order or prescription.

(4) The full name of both the patient and prescribing physician.

(5) The name of the drug, its strength, and the amount dispensed.

(6) The directions for use including the scheduled date, time, and rate of administration, and appropriate space for the patient or caregiver to add the

date and time the solution is started. These directions must indicate that the IV fluids must be completely used or discarded within 24 hours of mixing or unfreezing a mixture.

(7) The directions for storage.

(8) Cautionary or accessory labels if appropriate.

(9) The lot number or control number of the batch from which the drug was obtained.

§ 485.145 Condition of participation: Patient and caregiver evaluations and instructions.

To ensure safe home IV therapy for the patient, a registered nurse who is proficient in the delivery of home IV drug therapy services evaluates the patient to determine suitability for the provision of home IV drug therapy services. If the nurse determines that the patient is suitable for this therapy and the home IV provider can furnish the necessary therapy, the nurse trains the patient or caregiver or both, as appropriate, in providing the therapy and in proper maintenance of the equipment.

(a) *Standard: Patient evaluation.* The registered nurse performs the following activities:

(1) Reviews the referring physician's medical orders before evaluating a patient for home IV drug therapy.

(2) Before accepting the patient for care, evaluates the patient or caregiver for general competency and specific comprehension of the particualr IV drug therapeutic procedures to be used. In making this evaluation, the nurse—

(i) Discusses possible complications of the treatment with the patient or caregiver or both, as appropriate;

(ii) Explains and demonstrates home IV drug therapy procedures to the patient or caregiver;

(iii) After the patient or caregiver demonstrates IV drug therapy procedures, including aseptic techniques, evaluates and documents the competency and proficiency of the patient or caregiver.

(3) May inspect the patient's home prior to hospital discharge to ascertain that there is an area in the home available for storage of drugs and supplies and an area available for use of sterile supplies.

(4) Supervises the patient or caregiver when either starts the first infusion therapy at home to verify his or her ability to transfer learning from the provider setting to the home setting.

(b) *Standard: Patient and caregiver education and instructions.* The nurse instructs the patient or caregiver, as appropriate, in home IV drug therapy procedures, including aseptic techniques and provides written and illustrated instructions.

(1) The written instructions that are prepared for each different drug class and administration route must include the following information:

(i) A step-by-step description of the procedures that the patient or caregiver must follow in administering an IV drug, including procedures for any probable emergency that might arise.

(ii) Storage procedures.

(iii) Procedures for disposal of drugs and IV equipment.

(iv) A telephone number that would enable a patient to receive assistance at any time.

(2) The nure must instruct the patient or caregiver about the following:

(i) Methods of detecting early signs and symptoms of IV-related sepsis and complications so that they may be reported immediately to the home IV provider's medical personnel.

(ii) When appropriate use of electronic controlling devices (for example, an infusion pump) in delivery of home IV drug therapy so that the patient or caregiver can recognize any malfunction that should be reported to the home IV provider.

(iii) Emergency interventions for possible IV complications that can be performed by the patient or caregiver.

(iv) Discarding IV needles in an appropriate receptacle (such as a Sharp's container) that is properly labeled and that is removed by the home IV provider staff or personnel at least every 3 days.

(v) Procedures for recording the administration of IV solutions and drugs so the information can be given to the home IV provider and attached to the patient's clinical record.

(3) The nurse must discuss the range of physical activity that is appropriate for the patient.

§ 485.150 Condition of participation: Protocols and policies.

The home IV provider adheres to the following procedures and has written protocols and policies consistent with respect to the provision of home IV drug therapy items and services.

(a) *Standard: First dose.* The first dose of any drug not previously administered intravenously is administered under the direct supervision of a physician or nurse who must—

(1) remain in attendance for a time period sufficient to make sure that the patient is stable; and

(2) Have resuscitation medication and equipment to treat anaphylaxis readily available.

(b) *Standard: Venipuncture and catheter care.* (1) The site of a peripheral catheter is rotated by the nurse at least every 3 days. A catheter whose tip lies in a central vessel must be rotated by a physician when appropriate.

(2) IV administration sets are changed at least every 24 hours by the patient or caregiver.

(3) IV dressings should be changed at least every 48 hours or immediately upon becoming soiled or wet.

(4) The air elimination filter is routinely changed.

(5) The central line catheter site is inspected by a nurse at least once each week.

(6) Aseptic techniques are practiced during all venipuncture, dressing changes, catheter care, and assembly of IV infusion systems.

(c) *Standard: Quality of the air elimination filter and sterility of the catheter.* (1) On a sample of patients, the nurse packages air elimination filters that have been removed by the nurse from the IV tubing and immediately sends them to an independent laboratory for analysis of particulate matter and bacterial and fungal contamination.

(2) On a sample basis, the home IV provider packages catheters that have been removed from patients and immediately sends them to an independent laboratory for analysis of sterility.

(3) The home IV provider keeps copies of laboratory results on the testing of both air elimination filters and catheters that are made available for review upon request.

(d) *Standard: Drug therapy review.* (1) The pharmacist and nurse must review the combination of IV drugs and equipment for appropriateness before drug therapy is initiated.

(2) The pharmacist must conduct ongoing review (at least once every 3 days) of the drug therapy and inform the physician of significant findings. At a minimum, this review must include the appropriateness of the drug regimen and any instances of therapeutic duplication of drugs.

(e) *Standard: Patient rights and responsibilities.* The home IV provider must ensure that the following requirements are met:

(1) Treatment of a patient begins only if the home IV provider is capable of furnishing needed care at the level of intensity required by the condition of the patient.

(2) Each patient receives care appropriate to his or her needs in a timely manner.

(3) The patient is informed in a timely manner of the need for transfer to

another medical entity or level of care and of any appropriate alternatives.

(4) If the home IV drug therapy is to end without transfer to another medical entity, the patient is informed in a timely manner of the impending discharge, continuing care requirements and other available services, if needed.

(5) Patients' rights as set forth in this paragraph are honored and patients are informed of their responsibilities, if any, in the care process. The rights and responsibilities are clearly stated in documents distributed to patients upon admission to the home IV drug therapy program.

(6) Procedures are established to deal with patient grievances and patient-recommended changes without coercion, discrimination, reprisal, or interruption of services. A patient is informed at the beginning of home IV drug therapy about these procedures for making, reviewing, and resolving complaints.

(f) *Standard: Written protocols and policies.* The home IV provider has written protocols and policies that are consistent with these procedures.

§ 485.155 Condition of participation: Quality assurance.

The home IV provider maintains an ongoing quality assurance program designed to monitor patient care objectively and systematically, evaluate the quality and appropriateness of patient care, resolve identified problems, and pursue other opportunities to improve patient care.

(a) *Standard: Program objectives.* Through an ongoing, planned, and systematic process, the home IV provider monitors and evaluates the quality and appropriateness of patient care, including the performance of employees and other personnel who furnish services under arrangements with the home IV provider.

The home IV provider includes at least the following in a written evaluation plan:

(1) Scope and objectives of the quality assurance activities.

(2) Activities identified for monitoring and evaluation.

(3) Methods for implementing the monitoring and evaluation activities and for reporting the results.

(4) Mechanisms for taking follow-up action.

(5) Staff responsibilities for each activity in the quality assurance program.

(b) *Standard: Patient care.* (1) The monitoring and evaluation of the quality and appropriateness of patient care by the home IV provider must include identification of important aspects of care or service and focus on high-risk, high-volume, or problem-prone activities.

(2) The home IV provider collects data about the following matters:

(i) Length of home IV drug therapy by diagnosis and treatment.

(ii) Incidences and causes of patient rehospitalization.

(iii) Incidences of—

(A) Phlebitis;

(B) Infiltration;

(C) Site infection; and

(D) Other infection.

(iv) Hydration and nutritional status.

(3) The home IV provider analyzes the data it collects at least annually to determine the frequency of negative outcomes and prescribes corrective action for negative outcomes.

(c) *Standard: Service delivery.* The provider determines the following:

(1) Drugs and IV equipment were delivered timely to the patient.

(2) The patient could read the preparation and expiration dates on the drug labels.

(3) A nurse visited any patient with a peripheral IV catheter placement every 3 days and rotated the peripheral IV injection site.

(4) A nurse visited any patient with a central line at appropriate intervals for monitoring.

(5) Procedures have been established to enable patients to make complaints.

(6) The provider found acceptable solutions for complaints and kept a record of both.

§ 485.160 Condition of participation: Infection control.

The home IV provider must develop infection control procedures. These procedures must address at least staff personal hygiene and health status, isolation precautions, aseptic procedures, cleaning and sterilization of equipment, and methods to avoid transmitting infections. The home IV provider—

(a) Advises staff, patients, and caregivers of any necessary precautions, including infection control and personal hygiene and their responsibilities in the infection control program; and

(b) Develops a system for evaluating, reporting, and maintaining records of infection related to the care or service provided among patients and as appropriate, among staff.

IV. Part 489 is amended as follows:

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

A. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

Subpart A—General Provisions

B. In § 489.2, the introductory text of paragraph (b) is republished and a new paragraph (b)(7) is added to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) The following providers are subject to the provisions of this part:

* * *

(7) Home IV drug therapy providers.

* * * * *

(Catalog of Federal Domestic Assistance Programs No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: June 23, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

Approved: August 19, 1989.

Louis W. Sullivan.

Secretary.

[FR Doc. 89-20958 Filed 9-6-89; 8:45 am]

BILLING CODE 4120-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPD-621-PN]

RIN: 0938-AE10

Medicare Program; Outpatient Prescription Drugs: List of Covered Home IV Drugs

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

ACTION: Proposed notice.

SUMMARY: This notice sets forth a list of intravenous drugs that we propose to cover on the basis that they can be safely and effectively administered in the home. The notice would implement section 1861(t)(4) of the Social Security Act as added by section 202(a) of the Medicare Catastrophic Coverage Act of 1988.

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on November 6, 1989.

ADDRESS: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-621-PN, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC., or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

In commenting, please refer to file code BPD-621-PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (Phone 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Holly McBryde, (301) 966-6731.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Program

Medicare (title XVIII of the Social Security Act (the Act)) consists of two separate but complementary insurance programs, the Hospital Insurance program (known as Part A) and the Supplementary Medical Insurance program (known as Part B). Under Part A, covered benefits generally include services furnished in hospitals, skilled nursing facilities (SNFs) or by home health agencies (HHAs) and hospices.

Part B covers a wide range of medical services and supplies such as those furnished by physicians or others in connection with physicians' services, outpatient hospital services, and outpatient physical and occupational therapy services. Part B also currently covers certain drugs and biologicals that cannot be self-administered.

More specifically, under Part B, outpatient drugs have been covered only for specific purposes and only under certain conditions. For example, we currently cover hepatitis B vaccine but not flu shots or other immunizations; injections by physicians but not drugs that can be self-administered; and injectable drugs administered in comprehensive outpatient rehabilitation facilities but not injectable drugs administered in the home by HHAs.

B. Current Coverage of IV Drugs

Generally, drugs administered by an intravenous (IV) route, if furnished in an inpatient setting, are covered under Part A. As noted above, drugs administered in certain outpatient settings, including IV drugs, also can be covered.

C. FDA Approval of Drugs as Safe and Effective for Marketing

With the exception of "grandfathered" or certain experimental cancer drugs described below, the Food and Drug Administration (FDA) must approve a drug or license a biological for marketing before Medicare will cover the product. Following is a brief summary of the FDA approval processes.

The FDA's current role as it relates to approval of drugs is controlled by the Federal Food, Drug and Cosmetic Act of 1938 (FFDCA) (Pub. L. 75-717, 21 U.S.C. 301, et seq.). Before enactment of FFDCA, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The FFDCA first established the requirement that a manufacturer had to prove the safety of a drug before it could market it in the United States. In accordance with the FFDCA, drugs marketed before passage of the 1938 Act were "grandfathered" so that manufacturers, if they did not change the representations on the drugs' labels, were allowed to continue to market them unless evidence was developed to indicate that they were not safe. However, once a manufacturer changed the representation on a drug's label, that drug was considered a "new drug" and the manufacturer was required to prove that the drug was safe for its intended use.

In 1962, the FFDCA was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the Drug Amendments of 1962 (Pub. L. 87-781, enacted on October 10, 1962), all new drugs must be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962. These drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established to review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program. The pre-1962 drugs that are subject to review under this program are referred to as the "DESI" drugs. If the FDA decides that a DESI drug lacks substantial evidence of effectiveness for the condition(s) it is intended to treat, it publishes a notice of opportunity for a hearing in the Federal Register concerning its proposal to withdraw approval for marketing. This process affords the manufacturer an opportunity for a hearing before a final determination is made. Drugs for which a notice of opportunity for hearing has been issued are considered by the FDA to be less than effective until the hearing has been completed.

Biologicals were first required to be licensed under the Biologics Control Act of 1902, which was recodified in 1944 as section 351 of the Public Health Service Act (PHS Act, 42 U.S.C. 262). To be licensed under section 351 of the PHS Act, a biological must be shown to be safe, pure, and potent. The majority of biological products also meet the drug definition in the FFDCA subject to the drug adulteration, misbranding, and registration provisions of the FFDCA.

When the Bureau of Biologics (currently the Center for Biologics Evaluation and Research) became a part of FDA in 1972, biologicals licensed before July 1972 were reviewed for efficacy by expert advisory review panels. Similar to the DESI program described above, manufacturers of biologicals with inadequate evidence of effectiveness are offered an opportunity for a hearing on proposals to revoke product licenses.

When a manufacturer submits an application for the approval of a new drug, it indicates on the application the

proposed uses for the drug. The FDA requires the manufacturer to submit clinical data and scientific information to prove the safety and effectiveness of the drug for these proposed uses and determines for which of the proposed uses the manufacturer has proven that the drug is safe and effective. If a drug is approved, it may be labeled, promoted, and advertised by the manufacturer only for those specific proposed uses of the drug that have been approved by the FDA as safe and effective. The labeling includes a description of the drug, its action, clinical pharmacology, and indications and usage for the drug. In addition, sections with the headings, "contraindications", "warnings", "precautions", and "adverse reactions" are included when applicable. All labels conclude with sections on dosage and administration and how the drug is supplied.

After a drug is approved, additional medical and scientific information may be developed by the medical community that indicates there are other appropriate uses for the drug besides those specified on a drug's label. We may cover FDA-approved drugs for uses other than those specified on their labeling if the available medical and scientific information indicates that additional uses are appropriate and accepted in the medical community, unless the uses are contraindicated on a drug's label.

As a matter of current national Medicare policy, drugs or biologicals approved for marketing by the FDA are generally considered safe and effective for purposes of meeting the "reasonable" and "necessary" criteria of section 1862(a)(1)(A) of the Act when used for indications specified in their labeling. In addition, FDA-approved drugs also may be covered when used for indications other than those specified on their labeling as long as neither FDA nor HCFA has specified such use as nonapproved, and any additional relevant medical and scientific information indicates that the additional uses are appropriate and accepted in the medical community. As stated in the April 1982 (Volume 12, Number 1) *FDA Drug Bulletin*, the FFDCA "does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. In addition, "accepted medical practice often includes drug use that is not reflected in approved drug labeling." Nevertheless, HCFA has specifically identified some indications as noncovered under Medicare, in the form of national coverage decisions published in the Coverage Issues Manual (HCFA Pub. 6). (For example, the use of (Ethylenedinitrilo)tetraacetic acid (EDTA, Edetic Acid) as a chelating agent to treat artherosclerosis, arteriosclerosis, calcinosis, or similar generalized conditions not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental.) Coverage of unlabeled uses of approved drugs is determined by HCFA contractors taking into consideration the generally accepted medical practice in the community.

As noted above, drugs that are considered by the FDA to be experimental or investigational are not covered except for certain cancer drugs distributed by the National Cancer Institute (NCI). Under its Cancer Therapy Evaluation, the Division of Cancer Treatment within NCI, in cooperation with FDA, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, are unlike other drugs distributed by the NCI, in that they are not limited to use in clinical trials for the purpose of testing their efficacy. In view of NCI controls on their distribution and use, Group C drugs, which do not include Modified Group C drugs, are covered by Medicare under current rules if all other applicable coverage requirements are satisfied.

II. The Medicare Catastrophic Coverage Act of 1988

A. Overview

In the most significant expansion of the Medicare program since its inception in 1965, the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) was enacted on July 1, 1988. Generally, this legislation provides for—

- Expanded hospital, SNF, and hospice care coverage under Part A of the program beginning January 1, 1989;
- A cap on the amount of a beneficiary's financial liability under Medicare Part B beginning January 1, 1990;
- Coverage of screening mammography and in-home respite care benefits, and improved home health benefits beginning January 1, 1990; and
- Coverage of drugs used in immunosuppressive therapy and home IV drugs and therapy services beginning January 1, 1990, and of other covered outpatient drugs, biologicals, and insulin beginning on January 1, 1991.

B. Home IV Coverage

Section 202(a) of Pub. L. 100–360 amended sections 1861(s)(2)(J) and (t) of the Act to provide general coverage for outpatient prescription drugs under Part B and to authorize Part B coverage of home IV drugs. In addition, section 203 of Pub. L. 100–360 added sections 1861(jj), 1834(d) and 1835(a)(2)(G) to the Act and amended other related sections to authorize coverage of home IV therapy services. For purposes of this new home IV benefit, under new section 1861(t)(4)(B) of the Act, we are required to publish, by January 1, 1990 and periodically thereafter, a list of covered home IV drugs, and their indications, that can be safely and effectively administered in the home.

It is this list of drugs that we are addressing in this proposed notice. Proposed rules setting forth regulations to implement the various other provisions of Pub. L. 100–360 dealing with the outpatient prescription and home IV drug benefits will be published in separate documents as follows:

- Overall coverage of outpatient prescription drugs (including drugs used in immunosuppressive therapy and home IV drugs).
- Payment methodology for covered outpatient prescription drugs (which will apply also to covered home IV drugs).
- Coverage of home IV drug therapy services.
- Conditions of participation for home IV drug therapy providers.
- Fee schedule for home IV drug therapy services.
- Deductible and coinsurance amounts and the Part B cap on out-of-pocket expenses.
- Participating pharmacies.
- Drug bill processors.
- Coverage of catastrophic Part B expenses, outpatient drug expenses, and respite care benefits for beneficiaries enrolled in pre-pay health plans, such as health maintenance organizations.

The statute provides specific definitions of "covered outpatient prescription drugs" and of what constitutes "covered home IV drugs". In order to be a covered home IV drug, the drug must first qualify as a covered outpatient prescription drug as described below.

Section 202(a) of Pub. L. 100–360 amended sections 1861(s)(2)(J) and (t) of the Act by establishing the following definition of a "covered outpatient drug", which includes drugs, biological products, and insulin.

- Drugs. A drug that may be dispensed only upon prescription and

that meets one of the following requirements:

—The Drug is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the FFDCA, or approved under section 505(j) of the FFDCA.

—The drug was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 (October 10, 1962) or it is identical, similar or related to such a drug, as defined by 21 CFR 310.6(b)(1). Nevertheless, such a drug will not be covered if the Secretary has made a final determination that it is a "new drug" and has not been approved under sections 505 or 507 of the FFDCA, or if it is subject to certain actions brought by the Secretary to enforce provisions of sections 502(f), or 505(a) of the FFDCA (21 U.S.C. 352(f), or 355(a)).

—The drug is described in section 107(c)(3) of the Drug Amendments of 1962 and is one for which the Secretary has determined there is compelling justification for its medical need, or it is identical, similar, or related to such a drug. Also, the drug must be one for which the Secretary has not issued a notice to withdraw approval for marketing, because the Secretary has determined that the drug is less than effective for all conditions of use represented, recommended, or suggested on its labeling. These are the "DESI" drugs.

• Biological products. A biological product is considered a "covered outpatient drug" if it is one that may be dispensed only upon prescription, is licensed under section 351 of the PHS Act (42 U.S.C. 262), and is produced at an establishment licensed under that Act to produce that product.

• Insulin. Insulin is covered if it is certified under section 506 of the FFDCA (21 U.S.C. 356) for the strength, quality, and purity necessary to ensure adequate safety and efficacy of use. In accordance with section 1861(t)(2)(C) of the Act, as amended by Pub. L. 100–360, insulin would be considered a "covered outpatient drug" whether or not it is dispensed under a prescription.

In addition, section 202(a)(2)(C) of Pub. L. 100–360 added sections 1861(t)(4)(A) and (B) to the Act to define "covered home IV drugs" as covered outpatient drugs that are intravenously administered to individuals in places of residence that are used as the individuals' homes. The definition includes—

• Antibiotic drugs unless the Secretary has determined, for a specific drug or for the indication for which it is applied, that the drug cannot generally be administered safely and effectively in a home setting; and

• Drugs that are not antibiotics, but only if the Secretary has determined that for a specific drug and the indications for which the drug is being applied that it can generally be administered safely and effectively in a home setting.

III. Process Followed in Compiling the Drug List

A. Description of the Process

As noted above, section 202(a)(2)(C) of Pub. L. 100–360 added section 1861(t)(4)(B) to the Act to require us to develop a list of covered home IV drugs by January 1, 1990. These drugs must meet the definitions of a "covered outpatient drug" set forth in new sections 1861(t)(2) and (2) of the Act and of a "covered home IV drug" set forth in new section 1861(t)(4)(A) of the Act.

Our task with respect to putting together a proposed list of covered home IV drugs has been twofold. First, we had to compile a list of IV drugs (both antibiotics and non-antibiotics) and their indications. Second, in accordance with section 1861(t)(4) of the Act, we had to identify from that list those IV drugs that are safe and effective for use in the home. In accordance with section 1861(t)(4)(A)(ii) of the Act, our rules for including antibiotics and non-antibiotics differed. We obtained information about IV drugs based on the following categories:

• Antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home.

• Non-antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home. We separated this category into the following groups:

—Anti-infectives (other than antibiotics);

—Hydration therapy;

—Pain management drugs;

—Antineoplastic drugs; and

—Other drugs.

In determining which drugs may be administered intravenously, we obtained the following lists from the FDA:

• All IV drugs that are currently approved by the FDA for marketing.

• DESI drugs.

• "Compliance Report for DESI-2," also referred to as the "B List" of unapproved drugs that are currently marketed.

The drugs that we considered for our proposed list had to meet the statutory definition of "covered outpatient drug" and can be found on one of these FDA generated lists. Before we reviewed a specific drug for possible inclusion as a "covered home IV drug", the drug had to meet this initial requirement, as set forth in section 1861(t) of the Act.

In listing the drugs, we decided to place together in one list all those drugs, both antibiotics and non-antibiotics, that we initially propose as being covered. We believe setting forth a comprehensive list of covered drugs for purposes of rulemaking will make it easier for the public to direct their comments appropriately to a specifically named drug or indication, as opposed to our soliciting comments on those antibiotics and their indications that we propose not to cover. As discussed below, we encountered special problems with unlabeled indications for antibiotics in this regard. Therefore, Appendix I to this notice contains a list of drugs and indications that we propose to cover. Appendix II contains a list of antibiotics and indications that we propose not to cover.

We want to emphasize that we do not have the discretion under the home IV drug benefit to pay for a drug or an indication that is not on the final list. Section 1861(t)(4)(A) of the Act, as added by section 202(a) of Pub. L. 100–360, limits coverage of home IV drugs to those drugs that the Secretary has determined are safe and effective for use in the home. Any drug or indication not addressed on the final list to be published after we consider and evaluate public comments on the attached proposed list, or any drug or indication not included in a subsequent update, would not meet this requirement and payment would not be made for that drug or indication.

To obtain advice in determining whether an IV drug should be included in our proposed list of IV drugs as being safe and effective for use in the home, we contacted the following organizations:

• The U.S. Pharmacopeia (USP).

• The American Society of Hospital Pharmacists (ASHP).

• The American Medical Association (AMA).

• Various home IV providers (recognized in the field of home IV therapy).

• The Pharmaceutical Manufacturers Association.

• Various drug manufacturers.

We requested that these sources submit a list of IV drugs that, in their opinion, could generally be safely and effectively administered in the home, and, in addition, any other information they though pertinent. Although all of

the organizations we contacted did not respond with recommendations about drugs suitable for home use, we did receive specific recommendations based on reviews by advisory panels, medical and clinical evident to support inclusion of certain drugs, lists of IV drugs that are currently being administered in the home setting, and recommendations for exclusions.

In addition, we contacted the publishers of the following compendia:

- United States Pharmacopeia Dispensing Information, Volume 1 (Drug Information for the Health Care Professional) (USP DI);
- American Medical Association's Drug Evaluations (AMA DE); and
- American Hospital Formulary Service Drug Information (AHFS DI).

Based on the information we received from all of these sources, we constructed an initial list of IV drugs that we considered for inclusion on the proposed list as being safe and effective for home use. (At this point, the list included certain antineoplastic drugs but did not include 12 of the antibiotic drugs that were included on the master list of IV drugs submitted to us by the FDA. For reasons discussed below, neither of these groups of drugs is included in Appendix I.) We then obtained from the FDA the labeled indications for these drugs.

For the purpose of determining unlabeled uses of approved drugs, we relied on the information provided by the three compendia and the suggestions of the various home IV providers.

Having put together the list of IV drugs and indications, we then submitted it to health care professionals recommended to us by the Intravenous Nurses Society and the AMA. We requested that these individuals examine the list from a clinical perspective and we received several clinical recommendations.

As noted earlier, our rules for including antibiotic and non-antibiotic drugs on the proposed list have differed. The law requires the Secretary to cover all antibiotic drugs *unless* the Secretary makes the determination that a specific antibiotic *cannot* generally be administered safely and effectively in the home. The list of IV drugs we initially obtained from the FDA included identification of all IV antibiotic drugs that are currently available on the market. Of those antibiotic drugs, there were 12 antibiotics that we are proposing as not generally being safe and effective for use in the home.

It is our understanding that the following factors may prevent these 12 drugs that we propose for exclusion from being safe or effective when administered in the home setting:

- Potential serious or life-threatening side effects;
- Stringent monitoring requirements that could not effectively be performed in the home setting; and
- Stability limitations.

We list these 12 antibiotics below and specifically solicit comments and information about these drugs and their indications that might be relevant to a final determination about their suitability for use in the home. The drugs are:

- Chloramphenicol Sodium Succinate
- Colistimethate Sodium
- Doxycycline Hyclate
- Erythromycin Gluceptate
- Erythromycin Lactobionate
- Kanamycin Sulfate
- Lincomycin Hydrochloride
- Minocycline Hydrochloride
- Moxalactum Disodium
- Oxytetracycline Hydrochloride
- Polymyxin B Sulfate
- Tetracycline Hydrochloride

In addition, we want to note that, in our administrative process of assembling the list of antibiotic drugs (covered and noncovered), we believe that we have addressed all antibiotic drugs currently on the market. However, the introduction of new drugs into the marketplace is an ongoing occurrence. In addition, it is not inconceivable that in our process, we may have inadvertently missed an antibiotic drug. Therefore, we also invite public comment concerning antibiotics that do not appear in either appendix.

For non-antibiotic drugs, the Secretary has to make a determination that a drug *can* generally be safely and effectively administered in the home. Therefore, before an IV drug could be placed on Appendix I, we had to develop evidence from which that determination could be made. We derived this list based on consultations with the USP DI and the AHFS DI, providers of home IV therapy, and a review of available medical and scientific information.

With respect to the antineoplastic drug subcategory, we initially considered the following drugs for inclusion on the list:

- Bleomycin sulfate
- Cyclophosphamide
- Cytarabine
- Daunorubicin hydrochloride
- Diethylstilbestrol diphosphate
- Doxorubicin hydrochloride
- Etoposide
- Fluorouracil
- Methotrexate sodium
- Mitomycin
- Mitoxantrone hydrochloride
- Steptozocin
- Vinblastine sulfate
- Vincristine sulfate

Concerns were raised throughout the process of developing and clearing the list about the general safety of this group of drugs when administered intravenously in the home setting. A review of the drug labels revealed that of the 14 drugs in this category, 12 of them had warnings that specified that the drug should be administered by or under the supervision of a qualified physician who is experienced in cancer therapy. In addition, several drugs had additional warnings that patients should have access to or be treated in a facility with laboratory and supportive resources sufficient to monitor drug tolerance. We also reviewed the National Institutes of Health (NIH) recommended guidelines for the "Handling of Parenteral Antineoplastic Drugs" prepared in collaboration with oncologists, the clinical center pharmacy (within NIH), oncology nurses, and National Cancer Institute staff. With these factors to consider, and mindful also of the extensive safety requirements these factors could necessitate in the conditions of participation for home IV drug providers, we concluded that we are not able to propose, at this time, that these drugs could be safely and effectively administered intravenously in the home. In order to be consistent with the approved FDA labeling, we made the decision to remove these drugs from Appendix I. Because of the concern about whether antineoplastics are safe for use in the home, we have decided to seek further advice from the Public Health Service on this matter. Coverage of antineoplastic drugs under the home IV therapy benefit will accordingly be deferred pending receipt of such advice.

B. Use of Compendia

We selected the three compendia listed above as reliable sources for some of the advice and information we needed based on the rcommendations contained in the Conference Report accompanying Pub. L. 100–360 (H.R. Report No. 661, 100th Congress, 2d Session 192 (1988)). In the report, the three compendia are suggested for consideration as references for a related purpose under the new drug benefit, that is, for purposes of the establishment of standards for covered outpatient prescription drugs, as required under the new section 1834(c)(5)(B) of the Act (as added by section 202(b)(4) of Pub. L. 100–360). Since Congress recognized these compendia as authoritative for one purpose under the new drug benefit, we believe it is appropriate to rely on

them for a related similar purpose under that benefit.

In addition, the USP DI is sponsored by the USP, an organization that includes members of schools of medicine and pharmacy, State medical and pharmacy associations, national medicine and pharmacy associations. Its listing of drugs includes virtually all drugs approved in the United States. The USP DI staff prepare monographs after a literature search and review of FDA approved labeling. (A monograph is an essay or treatise on the available data for a specified drug.) These monographs are reviewed by over 300 additional experts, plus many schools, associations, pharmaceutical companies, and government agencies. They are again reviewed by advisory panels until a consensus is developed. Proposed monographs are then published in the USP DI Review for general public comment before being published in the USP DI. The USP DI is republished annually with six supplements per year and contains individual monographs, most information from the FDA-approved label, and unlabeled uses of approved drugs.

The AHFS DI is sponsored by the American Society of Hospital Pharmacists, which represents 22,000 pharmacists. AHFS DI staff prepare monographs after a literature search and review of FDA labeling. These monographs are reviewed by over 300 specialists at the doctoral level, including physicians, pharmacologists, and biochemists selected from among experts in drug therapy. This review process continues until a consensus is developed. The AHFS DI includes individual drug monographs with some general category statements, full FDA label disclosure, and unlabeled uses of approved drugs. The AHFS DI is republished annually with three to four supplements per year.

The AMA DE is sponsored by the AMA, which represents over 293,000 physicians. The listed drugs include all drugs approved by the FDA for use in the United States. AMA staff prepare monographs after a literature search and review of FDA-approved labeling. These monographs are reviewed by about 400 consultants followed by approximately 100 designees or members of the American Society for Clinical Pharmacology and Therapeutics. The review process continues until a consensus is developed. The AMA DE includes mostly general statements with truncated drug monographs including unlabeled uses of approved drugs. The AMA DE has been published every 3 years with updates. However, beginning in late 1989, the AMA plans to publish this compendium annually with quarterly updates.

IV. Description of the List

Appendix I consists of IV drugs and their indications divided into three main categories. The categories are—biologicals, antibiotics and non-antibiotics (which is further broken down as indicated above into the four subcategories of drugs, excluding for reasons discussed above antineoplastic drugs). The list is based on our analysis and evaluation of the recommendations and information received from the various professional organizations that we contacted. Appendix II consists of the antibiotic drugs and indications not proposed for coverage.

We recognize that there is wide variation in both the type of drugs included in Appendix I as well as the indications for these drugs. This is due in part to the fact that the concept of home IV therapy has evolved to treat diverse types of patients:

- Patients who began a course of IV therapy in the hospital that has not been completed, but who are stable enough to no longer require hospitalization.
- Patients who are terminally ill and require IV therapy, but whose condition does not warrant hospitalization.
- Other types of patients who require IV therapy but do not require hospitalization.

We are proposing that all candidates for home IV therapy meet specific selection criteria as outlined in the regulations referred to earlier that deal with coverage of home IV drug therapy services and conditions of participation for home IV drug therapy providers.

While many of the drugs on the proposed list can be safely and effectively administered in the home setting and would be covered, such medications are sometimes taken orally. Payment may be denied if a more appropriate route of administration is available. When deciding that the route of administration is appropriate, the Peer Review Organization (PRO) will carefully review to determine if another route of administration would be effective (for example, oral, subcutaneous, etc.). If the PRO makes a determination that another route would be effective, the PRO would deny payment. (An example might be: a physician seeking prior approval for the administration of intravenous Aminophylline.) Payment is made for home IV therapy only when it is reasonable and necessary and there is medical justification for its use.

The proposed list includes some very toxic drugs while other less toxic drugs are excluded. We note, however, that in urging us to include virtually all IV drugs on the list, some organizations we contacted took the position that "a drug is a drug, and a cell is a cell". These organizations believe a drug that can be administered in a hospital setting can also be administered in the home setting. We take a different view. There are a variety of factors that we have considered that play a role in the determination of whether a drug is safe and effective for use in the home. These factors include, in addition to the obvious factor of potential serious or life threatening side effects, drug product stability and compatibility characteristics, and the need for close patient monitoring.

The variation of indications for each specific drug is a reflection of the varying degrees and stages of illnesses that will be treated in the home setting. We believe that we must allow flexibility to enable the physician to develop a plan of treatment appropriate for the specific medical condition of the patient. Nevertheless, we wish to make clear that the appearance of an indication for a covered drug on the listing is not intended to imply that the indication is approved under the provisions of the FFDCA.

With respect to the specific working of the indications, because there are different phrases to describe the same disease states and conditions, there may appear to be inconsistencies in our use of medical terminology when listing indications. According to medical professionals and medical texts, the following terms are examples of terms that may be used interchangeably:

- Genitourinary infections with gynecological infections; and
- Skin and soft-tissue infections with skin and skin structure infections.

Also, there may be times when a specific indication could be considered as a subset of a larger classification. Examples of these would include:

- Cystitis as part of urinary tract infections; and
- Gonorrhea as part of genitourinary infections.

Such indications may have been listed separately in Appendix I because that is the way they appeared in the recommendations that we received. In addition, because the practice of medicine is dynamic, it would not be feasible to list all indications, either labeled or unlabeled, that are not suitable for treatment in the home. For this reason, we have listed the

indications for each drug that *can* generally be treated safely and effectively in the home. The following indications are proposed for exclusion for all intravenous antibiotics because it is our understanding that the seriousness of the condition requires hospitalization.

- Biliary tract infections.
- Central nervous system infections.
- Intra-abdominal infections.
- Respiratory tract infections.
- Septicemia.

Furthermore, specific labeled indications for certain drugs have been excluded because it is our understanding that they could not be safely and effectively treated intravenously in the home.

One of our proposed sub-categories is "hydration therapy." For our purposes and purposes of home IV therapy, the term is defined as the replacement of fluids or electrolytes, or both, in the human body when the physiologic and homeostatic mechanisms, which normally preserve their balance, fail as a result of illness or disease.

Most of the drugs that appear on the proposed list have specific dosages or dose ranges and are given at specific time intervals. For example, Cimetidine, used for hypersecretory conditions has a recommended dosing schedule of 300 mg administered intravenously every 6 to 8 hours. In comparison, for hydration therapy purposes, a physician can prescribe any of numerous available solutions used for this purpose, with the addition of one or more of the listed electrolytes, in a dose he or she has determined to be appropriate (for example, dextrose 5 percent in sodium chloride 0.45 percent, 1000 ml with 7 mEq of calcium as the chloride, gluconate or glucepate salt).

The magnitude of different combinations of ingredients in this sub-category requires our format for listing drugs in hydration therapy to differ from the other categories. This means that the options available to a physician prescribing a course of hydration therapy for a Medicare beneficiary would not be limited. The only restrictions on amounts of ingredients are those placed on solutions. These limitations have been determined to be the upper limits of commercially available products that would normally be used for hydration therapy (versus parenteral nutrition).

We are aware that our list will need periodic revision as new drugs are approved by FDA for entry in the market place. The FDA has informed us that 10 to 20 new IV drugs are approved over the course of each year that we would have to consider for entry on the list. In addition, if a drug already on the list is removed from the market or if a drug is no longer considered to be appropriate for home use, we would delete the drug from the list. We will update the list at least annually through a notice in the **Federal Register**. Updates may occur more frequently, possibly as often as semi-annually.

V. Regulatory Impact Statement

A. Executive Order 12291 and Regulatory Flexibility Act

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

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

Also, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmaceutical manufacturers and physicians are considered small entities.

As noted earlier in this preamble, this notice addresses the issues of: (1) Identifying IV drugs (both antibiotics and non-antibiotics) and their indications that are approved for marketing by FDA; and (2) identifying those IV drugs that are safe and effective for use in the home. There may be some economic or other effects of the proposed list of drugs that may touch upon other proposed rules implementing other home IV provisions of the catastrophic legislation, and some of these effects are addressed here as well as in the other rules. The purpose of this duplication is to ensure that the reader may determine the effects of each document without referring to the other proposed documents.

In addressing the first issue discussed above, all of the IV drugs listed in this notice may be covered under Medicare as covered outpatient drugs because they meet the criteria defined in section 1861(t)(2) of the Act. Thus, HCFA has exercised no administrative discretion in this area.

Administrative discretion, however, was required to identify those IV drugs that are safe and effective for use in the home. As discussed earlier in this preamble, we contacted the USP, ASHP, AMA, various home IV providers, the Pharmaceutical Manufacturers Association, various drug manufacturers and the Intravenous Nurses Society in making our initial determination as to whether a certain IV drug could be proposed as safe and effective for use in the home. We believe that the information solicited from the compendia along with the advice of the other organizations constitutes a valid basis on which to conclude with reasonable assurance that a particular drug can generally be administered safely and effectively in a home setting. Furthermore, we believe that the identification of IV drugs that are safe and effective for use in the home would not result in any significant effects on the economy or on small businesses. Our reasons follow:

1. Effects on drug manufacturers

Drug manufacturers producing IV drugs that are included in this proposed list would be advantaged in competing for the Medicare market because their drugs would be covered under Medicare as home IV drugs. We recognize that manufacturers producing IV drugs that are not included in our proposed list would be adversely affected in competing for the Medicare share of the IV drug market. Although we do not have data available that allow us to determine the degree to which drug manufacturers would be affected, we do not believe that will be significantly affected. This is because IV drugs (except antineoplastics) currently being prescribed for home use would likely be included on the proposed list based on the methodology used in developing this list.

2. Effects on beneficiaries

Medicare beneficiaries who are prescribed an IV drug for home use that is on the proposed list would benefit by being eligible for Medicare coverage of that drug. Conversely, beneficiaries for whom a drug has been prescribed that is not covered by Medicare for home IV use, may have to remain in the hospital to receive covered IV therapy or may have to incur expenses for home IV therapy themselves. Since we believe that most drugs currently prescribed for home IV use are included on the list, we

do not believe beneficiaries would be significantly affected adversely.

3. Effects on physicians

If drugs commonly prescribed by a physician for use in the home are not on the list, the physician could be influenced to change his or her prescribing patterns for Medicare patients to ensure that the patient is prescribed a Medicare covered home IV drug. However, given that we have consulted with various professional organizations and compendia in developing this list, we believe that the list, with the exception of antineoplastics, contains the most frequently prescribed home IV therapy drugs. Thus, we believe it unlikely that physicians' prescribing patterns would change significantly as a result of this list.

For the reasons discussed above, we believe that this notice would not meet the $100 million criterion nor do we believe that it meets the other E.O. 12291 criteria. Therefore, we have determined that this notice is not a major rulemaking document under E.O. 12291, and a regulatory impact analysis is not required. Also, for the reasons discussed, we have determined, and the Secretary certifies, that this notice would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis would not be required under the RFA.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed notice 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

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

VI. Information Collection Requirements

This proposed notice does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

VII. Responses to Comments

In responding to this notice, we request that comments restrict their comments and suggestions to the suitability of the drugs listed in the Appendix for use in the home for the indications listed. We also request commenters about any IV drugs that are not included on the list, which commenters believe would be suitable for home use, and their indications.

Because of the large number of items of correspondence we normally receive on proposed notices, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "Date" section of this notice, and, if we proceed with a final notice, we will respond to the comments in that notice.

(Secs. 1832(a)(2)(A)(i) and 1861(s)(2)(J) and (t) of the Social Security Act (42 U.S.C. 1395k(a)(2)(A)(i) and 1395x(s)(2)(J) and (t)))

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

Dated: June 7, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

Approved: August 19, 1989.

Louis W. Sullivan,

Secretary.

Appendix I.—Proposed List of Covered Home IV Drugs and Indications

I. Antibiotics

Amdinocillin
- Urinary tract infections, bacterial

Amikacin Sulfate
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and soft-tissue infections
- Urinary tract infections, bacterial

Ampicillin Sodium
- Arthritis, gonococcal
- Bone and joint infections
- Endocarditis, bacterial
- Entercolitis, "Shigella"
- Genitourinary tract infections
- Gonorrhea
- "Hemophilus" infections
- Listeriosis
- Paratyphoid fever
- Skin and soft-tissue infections
- Urethritis, gonococcal

Ampicillin Sodium and Sulbactam Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections

Azlocillin Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Skin and skin structure infections
- Urinary tract infections, bacterial

Aztreonam
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Carbenicillin Disodium
- Genitourinary tract infections
- Skin and soft-tissue infections
- Urinary tract infections, bacterial

Cefamandole Nafate
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefazolin Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefonicid Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefoperazone Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Ceforanide
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefotaxime Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefotetan Disodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefoxitin Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Ceftazidime
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and skin structure infections
- Urinary tract infections, bacterial

Ceftizoxime Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Skin and soft-tissue infections
- Urinary tract infections, bacterial

Ceftriaxone Sodium
- Bone and joint infections
- Endocarditis, bacterial
- Genitourinary tract infections
- Lyme Disease, joint and CNS
- Skin and skin structure infections
- Urinary tract infections, bacterial

Cefuroxime Sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Gonorrhea
Skin and skin structure infections
Urinary tract infections, bacterial
Cephalothin Sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and soft-tissue infections
Urinary tract infections, bacterial
Cephapirin Sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cephradine
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Clindamycin Phosphate
Bone and joint infections
Genitourinary tract infections
Skin and soft-tissue infections
Gentamicin Sulfate
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Listeriosis
Skin and soft-tissue infections
Urinary tract infections, bacterial
Imipenem and Cilastatin Sodium
Bone and joint infections
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Methicillin Sodium
Endocarditis, bacterial
Skin and soft-tissue infections
Mezlocillin Sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Miconazole
Candidiasis, disseminated
Candidiasis, mucocutaneous, chronic
Petriellidiosis
Urinary bladder infections, fungal
Nafcillin Sodium
Endocarditis, bacterial
Skin and soft-tissue infections
Netilmicin Sulfate
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Oxacillin Sodium
Endocarditis, bacterial
Skin and soft-tissue infections
Penicillin G Potassium
Arthritis, gonococcal
Diphtheria, prophylaxis
Endocarditis, bacterial
Genitourinary tract infections
Gingivostomatitis, necrotizing ulcerative
Listeriosis
Lyme disease, joint and CNS
Syphilis
Penicillin G Sodium
Arthristis, gonococcal
Diphtheria, prophylaxis
Endocarditis, bacterial
Genitourinary tract infections
Gingivostomatitis, necrotizing ulcerative
Listeriosis
Lyme disease, joint and CNS
Syphilis
Piperacillin Sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urethritis, gonococcal
Urinary tract infections, bacterial
Ticarcillin Disodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and soft-tissue infections
Urinary tract infections, bacterial
Ticarcillin Disodium and Clavulanate Potassium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Tobramycin Sulfate
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Listeriosis
Skin and skin structure infections
Urinary tract infections,
Vancomycin Hydrochloride
Bone and joint infections
Endocarditis, bacterial

II. Non-Antibiotic Drugs

A. Anti-infectives (other than antibiotics)

Acyclovir Sodium
Herpes zoster
Herpes simplex
Pentamidine Isethionate
Pneumonia, "Pneumocystis carinii"
Leishmaniasis, visceral
Trypanosomiasis, African
Sulfamethoxazole and Trimethoprim
Bone and joint infections
Chancroid
Chlamydial infections
Enterocolitis "Shigella"
Genitourinary tract infections
Gonorrhea
"Hemophilus" infections
Lymphogranuloma venereum
Paratyphoid fever
Pneumonia, "Pneumocystis carinii"
Rheumatic fever
Urinary tract infections, bacterial

B. Hydration Therapy

Intravenous Solutions

1. dextrose in water solutions
2. sodium chloride solutions
3. dextrose/sodium chloride solutions
4. premixed potassium chloride solutions up to concentrations of 40mEq/L
5. premixed electrolyte solutions, containing any combination of the following electrolytes in their various salt forms, which are not intended for parenteral nutrition:
sodium
potassium
calcium
magnesium
chloride
phosphate

The following limitations apply for all of the above solutions:

a. concentration of dextrose in any solution is not to exceed 10%.

b. concentration of sodium chloride in any solution is not to exceed 0.9%.

The caloric content of these solutions is limited to 340 calories.

Electrolytes

calcium chloride
calcium gluconate
calcium glucepate
magnesium chloride
magnesium sulfate
potassium acetate
potassium chloride
potassium phosphate
sodium acetate
sodium bicarbonate
sodium chloride
sodium phosphate

The indications for drugs in this category are less specific than for other drugs. After referring to various clinical texts, we have determined that water depletion, and combined water and electrolyte depletion, can be the result of many disease and non-disease states, including but not limited to the following:

Extrarenal losses
1. Gastrointestinal (vomiting, diarrhea, ostomy drainage)
2. Skin losses (sweating, burns)
3. Lung losses (bronchorrhea)

Renal losses
1. Renal disease (chronic renal failure, diuretic phase of acute renal failure)
2. Diuretic excess
3. Osmotic diuresis (diabetic glycosuria)
4. Mineralcorticoid deficiency (Addison's disease, hypoaldosteronism)

There may be other instances when a patient needs hydration therapy. Patients taking antineoplastic drugs must often be hydrated to increase urine output to insure the timely excretion of the drug because of its toxic side effects.

C. Pain Management Drugs

Indication: For treatment of chronic intractable pain.

Butorphanol Tartrate
Hydromorphone Hydrochloride
Meperidine Hydrochloride
Morphine Sulfate

D. Other

Aminophylline
Asthma, bronchial
Bumetanide
Edema
Cimetidine Hydrochloride
Adenoma, multiple endocrine
Bleeding, upper gastrointestinal
Hypersecretory conditions, gastric
Mastocytosis, systemic
Pancreatic insufficiency
Reflux, gastroesophageal
Stress-related mucosal damage

- Ulcer, duodenal
- Ulcer, gastric
- Zollinger-Ellison syndrome

Deferoxamine Mesylate
- Toxicity, iron chronic
- Toxicity, aluminum

Dexamethasone Sodium Phosphate
- Adrenocortical insufficiency, chronic primary (Addison's)
- Adrenocortical insufficiency, secondary
- Adrenogenital syndrome (adrenal hyperplasia, congenital)
- Anemia, hemolytic, acquired (autoimmune)
- Anemia, hypoplastic, congenital (erythroid)
- Anemia, red blood cell (erythroblastopenia)
- Arthritis, psoriatic
- Arthritis, rheumatoid
- Bowel disease, inflammatory, including colitis, ulcerative
- Bronchitis, asthmatic, acute or chornic
- Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
- Carcinoma, breast
- Carcinoma, prostatic
- Connective tissue disease, mixed
- Dermatitis, exfoliative
- Dermitits herpetiformis bullous
- Dermatitis, seborrheic, severe
- Dermatomyositis, systemic
- Dermatoses, inflammatory, severe Enteritis, regional (Crohn's disease)
- Erythema multiforme, severe (Stevens-Johnson syndrome)
- Fever, due to malignancy
- Gouty arthritis, acute
- Hemolysis
- Hypercalcemia associated with neoplasms (or sarcoidosis)
- Increased cranial pressure due to malignancy
- Leukemia, acute or chronic
- Lupus erythematosus, systemic
- Lymphomas, Hodgkins, or non-Hodgkins
- Multiple myeloma
- Mycosis fungoides
- Nausea and vomiting, cancer-chemotherapy induced
- Pemphigoid
- Pemphigus
- Polychondritis, relapsing
- Polymyalgia, rheumatica
- Polyps, nasal
- Pulmonary disease, chronic obstructive (not controlled with theophylline and beta-adrenergic agonists)
- Reiter's disease
- Rheumatic fever
- Rhinitis, allergic, perennial, or seasonal, severe
- Thrombocytopenia, secondary, in adults
- Thrombocytopenia purpura, idiopathic, in adults
- Trichinosis

Diphenhydramine Hydrochloride
- Nausea and vomiting

Famotidine
- Adenoma, multiple endocrine
- Bleeding, upper gastrointestinal
- Hypersecrétory conditions, gastric
- Mastocytosis, systemic
- Pancreatic insufficiency
- Reflux, gastroesophageal
- Stress-related mucosal damage
- Ulcer, duodenal
- Ulcer, gastric
- Zollinger-Ellison syndrome

Furosemide
- Edema

Heparin Calcium

Heparin Sodium
- Thromboembolism

Hydrocortisone Sodium Phosphate

Hydrocortisone Sodium Succinate
- Adrenocortical insufficiency, chronic primary (Addison's)
- Adrenocortical insufficiency, secondary
- Adrenogenital syndrome (adrenal hyperplasia, congenital)
- Anemia, hemolytic, acquired (autoimmune)
- Anemia, hypoplastic, congenital (erythroid)
- Anemia, red blood cell (erythroblastopenia)
- Arthritis, psoriatic
- Arthritis, rheumatoid
- Bowel disease, inflammatory, including colitis, ulcerative
- Bronchitis, asthmatic, acute or chronic
- Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
- Carcinoma, breast
- Carcinoma, prostatic
- Connective tissue disease, mixed
- Dermatitis, exfoliative
- Dermatitis herpetiformus, bullous
- Dermatitis, seborrheic, severe
- Dermatomyositis, systemic
- Dermatoses, inflammatory, severe
- Enteritis, regional (Crohn's disease)
- Erythema multiforme, severe
- Fever, due to malignancy
- Gouty arthritis, acute
- Hemolysis
- Hypercalcemia associated with neoplasms (or sarcoidosis)
- Increased cranial pressure, due to malignancy
- Leukemia, acute or chronic
- Lupus erythematosus, systemic
- Lymphomas, Hodgkin's or non-Hodgkin's
- Multiple myeloma
- Mycosis fungoides
- Nausea and vomiting, cancer-chemotherapy induced
- Pemphigoid
- Pemphigus
- Polychondritis, relapsing
- Polymyalgia, rheumatica
- Polyps, nasal
- Pulmonary disease, chronic obstructive (not controlled with Theophylline and beta-adrenergic agonists)
- Reiter's disease
- Rheumatic fever
- Rhinitis, allergic, perennial or seasonal, severe
- Thrombocytopenia, secondary, in adults
- Thrombocytopenia purpura, idiopathic, in adults
- Trichinosis

Iron Dextran
- Iron deficiency anemia

Leucovorin Calcium
- Methotrexate toxicity (antidote to folic acid antagonist)

Mannitol
- Premedication, cancer chemotherapy

Methylprednisolone Sodium Succinate
- Adrenocortical insufficiency, chronic primary (Addison's)
- Adrenocortical insufficiency, secondary
- Adrenogenital syndrome (adrenal hyperplasia, congenital)
- Anemia, hemolytic, acquired (autoimmune)
- Anemia, hypoplastic, congenital (erythroid)
- Anemia, red blood cell (erythroblastopenia)
- Arthritis, psoriatic
- Arthritis, rheumatoid
- Bowel disease, inflammatory, including colitis, ulcerative
- Bronchitis, asthmatic, acute or chronic
- Calcium pyrophosphate deposition disease, acute (pseudogout; chondrocalcinosis articularis; synovitis, crystal-induced)
- Carcinoma, breast
- Carcinoma, prostatic
- Connective tissue disease, mixed
- Dermatitis, exfoliative
- Dermatitis, herpetiformis, bullous
- Dermatitis, seborrheic, severe
- Dermatomyositis, systemic
- Dermatoses, inflammatory, severe
- Enteritis, regional (Crohn's disease)
- Erythema multiforme, severe (Stevens-Johnson syndrome)
- Fever, due to malignancy
- Gouty arthritis, acute
- Hemolysis
- Hepatitis, chronic active
- Hepatitis, nonalcoholic, in women
- Hypercalcemia associated with neoplasms (or sarcoidosis)
- Increased cranial pressure, due to malignancy
- Leukemia, acute or chronic
- Lupus erythmatosus, systemic
- Lymphomas, Hodgkins or non-Hodgkins
- Multiple myeloma
- Mycosis fungoides
- Necrosis, hepatic, subacute
- Pemphigoid
- Pemphigus
- Polychondritis, relapsing
- Polymyalgia, rheumatica
- Polyps, nasal
- Pulmonary disease, chronic obstructive (not controlled with Theophylline and beta-adrenergic agonists)
- Reiter's disease
- Rheumatic fever
- Rhinitis, allergic, perennial or seasonal, severe
- Thrombocytopenia, secondary, in adults
- Thrombocytopenic purpura, idiopathic, in adults
- Trichinosis

Metoclopramide
- Gastroparesis
- Nausea and vomiting, cancer chemotherapy induced

Phenytoin Sodium
- Epilepsy

Prochlorperazine Edisylate
- Nausea and vomiting

Ranitidine Hydrochloride
- Adenoma, multiple endocrine
- Bleeding, upper gastrointestinal
- Hypersecretory conditions, gastric
- Mastocytosis, systemic
- Pancreatic insufficiency
- Reflux, gastroesophageal
- Stress-related mucosal damage
- Ulcer, duodenal
- Ulcer, gastric

Zollinger-Ellison syndrome

III. IV Biologicals and Indications

A. Anti-Infectives

NONE

B. Fluid Replacement

NONE

C. Pain Monogement

NONE

D. Anit-Cancer Chemotherapeutic

NONE

E. Other

Immune Globulin
Immunodeficiency Syndrome
Thrombocytopenic purpura, idiopathic
Alpha-proteinase Inhibitor, Human
Emphysema, panacinar, due to alpha-antitrypsin deficiency

Appendix II—Proposed List of Non-Covered Home IV Antibiotic Drugs and Indications

I. Antibiotic Drugs not Proposed for Coverage

Chloramphenicol Sodium Succinate
Colistimethate Sodium
Doxycycline Hyclate
Erythromycin Glucepate
Erythromycin Lactobionate
Kanamycin Sulfate
Lincomycin Hydrochloride
Minocycline Hydrochloride
Moxalactum Disodium
Oxytetracycline Hydrochloride
Polymyxin B Sulfate
Tetracycline Hydrochloride

II. Indications for Antibiotic Drugs not Proposed for Coverage

Biliary tract infections
Central nervous system infections
Intra-abdominal infections
Respiratory tract infections
Septicemia

[FR Doc. 89–21161 Filed 9–6–89; 8:45 am]

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Thursday
September 7, 1989

Part III

Department of Education

Office of Elementary and Secondary Education

34 CFR Part 222

Assistance for Local Educational Agencies in Areas Affected by Federal Activities and Arrangements for Education of Children Where Local Educational Agencies Cannot Provide Suitable Free Public Education; Final Rule

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education

34 CFR Part 222

RIN 1810-AA49

Assistance for Local Educational Agencies in Areas Affected by Federal Activities and Arrangements for Education of Children Where Local Educational Agencies Cannot Provide Suitable Free Public Education

AGENCY: Department of Education.

ACTION: Final rule.

SUMMARY: The Secretary amends the regulations governing eligibility, entitlement, and payment determinations under section 3(d)(2)(B) of the Impact Aid Program. Changes in a number of other regulatory provisions relating to payments under sections 2, 3, and 4 of this program also are made. These regulations are intended to provide guidance to local educational agencies (LEAs) applying for maintenance and operations assistance under Public Law 81-874 (the Act), and may affect the Department's calculation of assistance amounts.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments with the exception of §§ 222.3, 222.9 through 222.11, 222.14 through 222.17, 222.20, 222.22, 222.25, 222.33, 222.34, 222.36, 222.40, 222.72, 222.74, and 222.125 through 222.129. Sections 222.3, 222.9 through 222.11, 222.14 through 222.17, 222.20, 222.22, 222.25, 222.33, 222.34, 222.36, 222.40, 222.72, 222.74, and 222.125 through 222.129 will become effective after the information collection requirements contained in those sections have been submitted by the Department of Education and approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Charles E. Hansen, Acting Director, Impact Aid Program, U.S. Department of Education, 400 Maryland Avenue SW., Room 2079, Washington, DC 20202-6244. Telephone: (202) 732-3637.

SUPPLEMENTARY INFORMATION:

A. General

Public Law 81-874, as amended, 20 U.S.C. 236 through 241-1 and 242 through 244, known as the Impact Aid maintenance and operations assistance program, authorizes assistance to LEAs that are financially burdened by a reduced tax base resulting from the Federal acquisition of real property, an increased student population due to Federal activities, or both. Section 3 of the Act addresses both types of burdens by authorizing payments to LEAs that are required to provide free public education to children who live on, and/or whose parents are employed on, tax-exempt, federally owned or leased real property ("federally connected children"). These payments supplement local revenues and assist the LEAs in meeting their maintenance and operations costs.

Section 3(d)(2)(B) of the Act, 20 U.S.C. 238(d)(2)(B), provides financial assistance in addition to regular payments under section 3 of the Act, to certain heavily impacted LEAs that demonstrate eligibility for that assistance. For an applicant eligible to receive assistance under section 3(d)(2)(B), the statute provides that the Secretary will supplement the eligible LEA's section 3 payment to enable it to provide a level of education equivalent to that provided by the school districts determined to be generally comparable to it. A payment provided under section 3(d)(2)(B), however, is subject to a maximum entitlement amount.

In order to inform applicants about the operation of section 3(d)(2)(B) of the Act, the Secretary believes it is desirable to describe in regulations how the Department determines eligibility, entitlements, and payments for all LEAs applying for section 3(d)(2)(B) assistance. In addition to establishing a new subpart K, which relates specifically to section 3(d)(2)(B), a number of existing regulatory provisions are amended. Also, subpart H, containing provisions related to handicapped children and children with specific learning disabilities, is revised to clarify language and specify requirements for fiscal accountability for the use of section 3(d)(2)(C) funds.

These regulations are based upon the requirements in the Act as revised by the Hawkins-Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100-297, April 28, 1988) (Hereinafter "the Hawkins-Stafford Amendments") and Public Law 101-26, enacted on May 11, 1989. Unless otherwise indicated, the provisions in these regulations reflect the current policy and practice of the Department. The final regulations become effective starting with FY 1990.

B. Information Contained in the Notice of Proposed Rulemaking

On March 23, 1989, the Secretary published a notice of proposed rulemaking (NPRM) for the Impact Aid maintenance and operations assistance program in the **Federal Register**, 54 FR 12104-12120. Most of the explanatory statements in the NPRM remain relevant. For the sake of brevity, those statements are not being reprinted here. Readers are referred to the **Federal Register** of March 23, 1989. (54 FR 12104-12120).

C. Significant Changes

Significant changes in the final regulations from the NPRM are described below. The NPRM noted that examples concerning subpart K would not be shown in the Code of Federal Regulations. Accordingly, those examples are not included in the final regulations. Except for minor editorial and technical revisions, there are no other differences between the NPRM and these final regulations.

1. *Section 222.74.* The fiscal accountability requirements in § 222.74(d) are modified in response to public comment. The manner in which the Department tests whether section 3(d)(2)(C) funds were spent for their authorized purpose has been amended so that all expenditures on handicapped programs, including those from all Federal, State, and local funds will be factored into the average per pupil handicapped expenditure formula rather than just general State and local expenditures, as described in the NPRM. To the extent that this amendment may alter current procedure, the Department intends this modification to apply.

2. *Sections 222.124, 222.129, and 222.132.* Public Law 101-26, which became effective on May 11, 1989, made several technical amendments to the Impact Aid statute. One of the amendments changed the tax effort requirement for section 3(d)(2)(B), from 80 percent to 95 percent of the applicant's comparable LEAs' effort. As a result of this recent legislation, references to tax effort in §§ 222.124, 222.129, and 222.132 have been changed from 80 percent to 95 percent.

Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, several parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM follows.

Substantive issues are discussed under the section of the regulations to

which they pertain. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

Sections 222.9 and 222.10

Comment: One commenter stated that §§ 222.9 and 222.10 appear to be inconsistent. Section 222.9 indicates that applications are to be transmitted through State educational agencies (SEAs) while § 222.10 specifies that applications are to be simultaneously submitted to the Department and the SEA. Section 222.10 also states that SEAs must notify the Secretary by February 15 if they have any problems with an LEA's application. The commenter recommended that this review period be extended to allow SEAs 30 days to review applications.

Discussion: Section 222.10 accurately reflects the Department's proposed new practice for the submission of applications. The changes proposed are expected to reduce the incidents of applications filed too late to qualify for finding and to expedite payments.

The Secretary believes that SEAs will have sufficient time to review applications and notify the Secretary by February 15 of any concerns they have with individual applications. The Department traditionally receives applications throughout the month of January. Presumably, LEAs will maintain their usual schedules for preparing and submitting applications in the future. As a result, SEAs should have the same amount of time to review applications as in the past. In some cases, this will be more than 30 days.

Changes: The language of § 222.9 has been revised to make it consistent with § 222.10.

Section 222.33

Comment: Several commenters stated that they believe the change in the statute to allow applicants for funding under section 3(d)(2)(B) to have their payment based on three comparable LEA's should be incorporated in the regulations by revising § 222.33. They recommended that § 222.33 require groups of comparables to contain a minimum of three LEAs instead of the current minimum of ten.

Discussion: Section 222.33 describes the identification of generally comparable LEAs for all section 3 applicants, not just those seeking assistance under section 3(d)(2)(B). The statutory provision allowing the use of three comparable LEAs applies only to determinations of section 3(d)(2)(B) eligibility and payments.

Changes: None.

Section 222.36

Comment: Four commenters objected to the method proposed by the Department for identification of three comparable LEAs for section 3(d)(2)(B) purposes. One commenter complained that the statute refers to "three or more" comparables while the regulations refer to "three" comparables. This commenter recommended that section 3(d)(2)(B) applicants be allowed to select from three to nine comparables under § 222.36 using the method described in § 222.33(c)(3)(i)(A). Three commenters proposed that the regulations state that the same comparable LEAs will be used for computing local contribution rates for section 3 purposes and for computing payments under section 3(d)(2)(B).

Discussion: In one place, the statute refers to "three" comparable LEAs and in another to "three or more" comparable LEAs. The bill report from the Senate, which proposed this change, refers to three comparable LEAs. The Department uses the more specific reference in these regulations and believes this results in a distinct new option for the identification of comparable LEAs, in addition to the methods currently contained in § 222.33, including that in § 222.33(c)(3)(i)(A). Further, the apparent intention of the statutory provision is to identify the LEAs in a section 3(d)(2)(B) applicant's State that are most comparable to the applicant. The Department believes that this can best be accomplished by applying all of the objective factors incorporated in § 222.33 and then selecting three of the LEAs that most nearly match the applicant on these factors.

The Department does not believe it would be appropriate to adopt the commenter's suggestion to base a section 3(d)(2)(B) applicant's local contribution rate (for its regular section 3 payment) on the three comparable LEAs selected under the new method. The statute indicates that these three comparables may be used to determine an LEA's eligibility for a payment under section 3(d)(2)(B) but does not say they are to be used for section 3 purposes. Using different comparable LEAs for these two payment calculations would not adversely affect a district's total Impact Aid payment, because section 3(d)(2)(B) funds are added to whatever an applicant receives for a regular section 3 payment to allow the district to match the expenditures of its comparables.

Change: None.

Section 222.37

Comment: One commenter objected to applying the tax effort requirements referred to in § 222.37 to applicants for assistance under section 3(d)(3)(B)(ii), which compensates LEAs for increased expenditures resulting from unusual geographic factors. The commenter stated that this requirement should apply only to applicants under section 3(d)(2)(B) since a tax effort requirement is specifically incorporated in that provision of the statute but not in section 3(d)(3)(B)(ii).

Discussion: The Secretary believes it is appropriate to apply the tax effort requirements to both of these special assistance provisions because they are both based on financial need. A tax effort requirement under section 3(d)(3)(B)(ii) emphasizes that financial need for funds under this section must be demonstrated and helps to verify that an applicant cannot maintain a level of education equivalent to that of its comparables because of increased expenditures and not because of reduced revenues. The legislative history specifically states that "[t]he amount of the increase (in a section 3(d)(3)(B)(ii) applicant's local contribution rate) will be the amount necessary to enable it to maintain a level of education equivalent to that maintained in the school districts determined by the (Secretary) to be (generally) comparable." *See* H. Rept. 2287, 81st Cong., 2d Sess. 14 (1950). The Secretary does not believe that an LEA should be allowed to make a minimal tax effort or decrease its tax effort and expect the Impact Aid program to make up the difference by increasing the applicant's section (3)(d)(3)(B)(ii) payment.

Changes: None.

Section 222.74(b)

Comment: One commenter stated that the methods of obligation and expenditure of funds outlined in § 222.74(b) impose a significant limitation on LEAs for the expenditure of section 3(d)(2)(C) funds because the districts receive these funds late in the fiscal year. He recommends that this section be revised to allow an LEA to obligate or expend section 3(d)(2)(C) funds for the fiscal year for which the funds were appropriated or for any succeeding fiscal year provided that the LEA can demonstrate that the funds were spent on programs or projects for federally connected, handicapped children. In support of his recommendation, the commenter pointed out language in the NPRM that

discussed the rationale for removing the Tydings amendment requirement (20 U.S.C. 1225b). This requirement stated that section 3(d)(2)(C) funds must be obligated or expended by the end of the fiscal year following the fiscal year for which the funds were obligated.

Discussion: Section 222.74(b) requires that a district obligate or expend section 3(d)(2)(C) funds for, but not necessarily in, the fiscal year for which the funds were apppropriated, or reimburse itself for obligations or expenditures of local funds already made. Because districts generally receive their section 3(d)(2)(C) funds in the fiscal year for which the funds are appropriated, the Secretary believes that it is reasonable to tie the funds to that fiscal year. In addition, it is not administratively feasible to track the funds if they are not tied to a specific fiscal year.

Changes: None.

Section 222.74(b)(2)

Comment: One commenter stated that § 222.74(b)(2), which provides that an LEA may reimburse itself for obligations or expenditures of local funds, precludes LEAs in highly equalized States from utilizing the provision. He recommends that the wording be revised to include State expenditures as well as local expenditures made.

Discussion: The reference to local expenditures in this provision encompasses expenditures from local funds and general State aid. The Secretary is unable to include specific State funds in this provision because it would conflict with section 5 of the Act and § 222.75, which require that section 3(d)(2)(C) funds not supplant State funds that were or would have been available to the LEA for the free public education of children counted under section 3(d)(2)(C). However, the Secretary believes that a clarification can be added to the term "local funds."

Changes: The phrase "and general State aid" is added to the portion of § 222.74(b)(2) that refers to local funds.

Section 222.74(d)

Comment: Three commenters objected to the fiscal accountability provisions in § 222.74(d) that apply to additional payments under section 3(d)(2)(C) to LEAs that provide free appropriate public education to federally connected, handicapped children. One commenter stated he believes that the accountability provisions in § 222.74(d) make State aid for handicapped children categorical even when some State laws do not apparently specify that all State aid for handicapped children must actually be spent for such children. Two commenters indicated they feel that the fiscal accountability requirements in the NPRM do a disservice to equalized States and States that heavily compensate their LEAs for expenditures for handicapped children by focusing only on the amount of local expenditures that were made for special services for the handicapped. One commenter also believes that the effect of this test is to make Federal funds received under section 3(d)(2)(C) the "last" dollars spent on federally connected, handicapped children, and he doe snot believe there is Federal authority to compell that result. One commenter recommended that in lieu of the fiscal accountability requirements proposed, which he feels penalize LEAs in equalized States, the Department require an LEA in an equalized State to subject a budget to their SEA delineating the specific services to be provided with the 3(d)(2)(C) funds.

Discussion: The Secretary agrees that the accountability test has the potential for penalizing LEAs that have low expenditures from local sources for special education purposes but are highly compensated for these expenditures by their States either through equalization or other means. The Secretary believes that the accountability test would be strengthened by taking into consideration all funds, including Federal, State, and local, expended by the LEA for handicapped programs. The Secretary also recognizes that the test contained in the NPRM may have the effect of making State handicapped aid categorical. The Secretary does not generally believe that it is good public policy for States to provide extra money for handicapped students without specifying that the money must be spent for those students. The Secretary believes, however, that the Act does not require LEAs to spend State dollars before section 3(d)(2)(C) funds are spent. The Secretary cautions that while State funds may not necessarily be categorical, States need to be aware that they are, nevertheless, clearly prohibited from using section 3(d)(2)(C) funds to supplant State funds that would have been otherwise available to LEAs.

Changes: The Secretary has modified § 222.74(d) by deleting the provisions that separate expenditures from State funds and Federal Education of the Handicapped Act (EHA) funds from expenditures from local funds for programs or projects serving federally connected, handicapped children. The fiscal accountability test in this section has been expanded to look at the total amount of expenditures made, from all Federal, State, and local funds for handicapped programs and projects that serve federally connected, handicapped students in an LEA.

Section 222.128

Comment: Three commenters proposed that § 222.128 apply to fiscally independent districts as well as fiscally dependent school districts. This section allows, subject to the approval of the Secretary, the use of local tax sources other than real property taxes in the determination of reasonable tax effort.

Discussion: As stated in § 222.124 of the NPRM, the provisions of §§ 222.126–22.128 apply to fiscally independent school districts. Also, § 222.129 notes that applicable provisions of §§ 222.126–222.128 may be used for fiscally dependent school districts. Therefore, no change is needed in the final regulations.

Changes: None.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

List of Subjects in 34 CFR Part 222

Education, Education of the handicapped, Elementary and secondary education, Federally affected area, Grant programs-education, Public housing, Reports and recordkeeping requirements.

Dated: August 1, 1989.

Lauro F. Cavazos,

Secretary of Education.

(Catalog of Federal Domestic Assistance No. 84.041, School Assistance in Federally Affected Areas—Maintenance and Operation)

The Secretary amends Part 222 of Title 34 of the Code of Federal Regulations as follows:

PART 222—ASSISTANCE FOR LOCAL EDUCATIONAL AGENCIES IN AREAS AFFECTED BY FEDERAL ACTIVITIES AND ARRANGEMENTS FOR EDUCATION OF CHILDREN WHERE LOCAL EDUCATIONAL AGENCIES CANNOT PROVIDE SUITABLE FREE PUBLIC EDUCATION

1. The authority for part 222 is revised to read as follows:

Authority: 20 U.S.C. 236–241–1 and 242–244, unless otherwise noted.

2. The Table of Contents for part 222 is amended by revising subpart H and by adding a new subpart K to read as follows:

* * * * *

3. Section 222.3 is amended by removing the definition of "working on Federal property," revising the definitions of "applicant" (and its authority citation), "application," and "uniformed services" (and its authority citation), and by adding new definitions for "federally connected children," "local educational agency," "membership," and "parent employed on Federal property" to read as follows:

§ 222.3 Definitions.

* * * * *

Applicant means any local educational agency that files an application for financial assistance under section 2, 3, or 4 of the Act and the regulations in this part. For purposes of sections 3 and 4, a State educational agency may be an applicant only if the State agency directly operates and maintains facilities for providing free public education for the children it claims in its application.

(Authority: 20 U.S.C. 240(a) and 244(6))

Application means a properly completed and executed "Application for School Assistance in Federally Affected Areas" filed by an applicant requesting financial assistance under section 2, 3, or 4 of the Act and the regulations in this part, including amendments to the application and any supporting documents indicated by the applicant.

* * * * *

Federally connected children refers to children described in subsection 3(a) or 3(b) of the Act.

(Authority: 20 U.S.C. 238)

* * * * *

Local educational agency means a board of education or other legally constituted local school authority having administrative control and direction of free public elementary or secondary education through grade 12 in a county, township, independent, or other school district located within a State. This term includes a State educational agency so long as it also directly operates and maintains facilities for providing free public education for the children it claims in its application. Children claimed by a State educational agency must actually be attending State-operated facilities, and the State educational agency may not, through a tuition arrangement, contract, or any other means, pay another entity to operate and maintain facilities for those children.

(Authority: 20 U.S.C. 244(6))

Membership means—

(1)(i) The definition given to the term by State law; or

(ii) If State law does not define the term, the number of children listed on a local educational agency's current enrollment records on its survey date. The membership of children for whom the applicant is responsible for providing a free public education but who are attending schools other than those operated by the applicant, under a tuition arrangement described in § 222.81(d), must be included in the applicant's membership count.

(2) This term does not include children who—

(i) Have never attended classes in schools of the local educational agency or of another educational entity that the local educational agency has a tuition arrangement with;

(ii) Have permanently left the school district;

(iii) Otherwise have become ineligible to attend classes there; or

(iv) Attend the schools of the applicant under a tuition arrangement with another local educational agency that is responsible for providing them a free public education.

(Authority: 20 U.S.C. 238, 242(b), 244(10))

Parent employed on Federal property includes—

(1)(i) An employee of the Federal Government who reports to work on or whose place of work is located on Federal property;

(ii) A person not employed by the Federal Government but who spends more than 50 percent of his working time on Federal property (whether an employee or self-employed) when engaged in farming, grazing, lumbering, mining, or other operations that are authorized by the Federal Government, through a lease or other arrangement, to be carried out entirely or partly on Federal property; and

(iii) A portion, to be determined by the Secretary, of persons working on commingled Federal and non-Federal properties other than those persons covered under paragraph (a)(ii) of this definition.

(2) This term does not include a person who reports to work at a work station not on Federal property but spends more than 50 percent of his working time on Federal property providing services to operations or activities authorized to be carried out on Federal property.

(Authority: 20 U.S.C. 236, 238, 242(b))

* * * * *

Uniformed services means the United States Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanic and Atmospheric Administration, and Public Health Service.

(Authority: 20 U.S.C. 238 and 37 U.S.C. 101)

4. Section 222.9 is revised to read as follows:

§ 222.9 Application form.

Any local educational agency (LEA) seeking financial assistance under section 2, 3, or 4 of the Act shall, as a condition of entitlement, file with the Secretary an "Application for School Assistance in Federally Affected Areas." A copy of the application must be filed with the State educational agency (SEA) in accordance with the applicable filing dates established in §§ 222.10 and 222.11 and must contain information necessary to establish the LEA's entitlement under the Act and regulations. Copies of the application form may be obtained from the SEA.

(Authority: 20 U.S.C. 240(a))

5. Section 222.10 is revised to read as follows:

§ 222.10 Application filing requirements.

Beginning with fiscal year (FY) 1990, to be considered for financial assistance under section 2, 3, or 4 of the Act, an LEA must meet the following requirements:

(a) Except as provided in paragraphs (c) and (e) of this section, an LEA must—

(1) File its application for financial assistance under section 2, 3, or 4 with the Secretary on or before January 31 of the fiscal year for which assistance is sought; and

(2) Certify that it will file, and file, a copy of the application referred to in paragraph (a)(1) of this section with its SEA on or before January 31 of the fiscal year for which assistance is sought.

(b)(1) Except as provided in paragraphs (c) and (e) of this section, an SEA must notify the Secretary of any inconsistencies or other concerns it has with an LEA's application on or before February 15 of the fiscal year for which assistance is sought. If the Secretary does not receive any notification from an LEA's SEA by February 15, the Secretary assumes that the data and statements in the application are, to the best of the SEA's knowledge, true, complete, and correct.

(2) An application that is timely filed under paragraph (a)(1) of this section is not processed for payment until any concerns raised by the SEA are resolved.

(c)(1) If any of the following events, giving rise to eligibility or entitlement, occurs within the fiscal year for which assistance is sought, an LEA seeking assistance shall file an application within the time limits required by paragraph (c)(2) of this section:

(i) The United States Government initiates or reactivates a Federal activity, or acquires real property.

(ii) The United States Congress enacts new legislation.

(iii) A reorganization of school districts takes place.

(iv) Property, previously determined in writing by the Secretary not to be Federal property, is determined to be Federal property.

(2) Except as provided in paragraph (e) of this section, an LEA shall file an application as permitted by paragraph (c)(1) of this section as follows:

(i) The LEA shall file the application on or before January 31 of the fiscal year for which assistance is sought or within 60 days after the applicable event occurs, whichever date is later, but not later than September 30, the end of the Federal fiscal year.

(ii) The LEA shall also certify that it will file, and file, a copy of the application referred to in paragraph (c)(2)(i) of this section with its SEA on or before September 30 of the fiscal year for which assistance is sought.

(d)(1) Except as provided in paragraph (e) of this section, an SEA must notify the Secretary of any inconsistencies or other concerns with an LEA's application within fifteen days of the applicable filing date. If the Secretary does not receive any notification from the SEA, the Secretary assumes that the data and statements in the application are, to the best of the SEA's knowledge, true, complete, and correct.

(2) An application that is timely filed under paragraph (c)(2)(i) of this section is not processed for payment until any concerns raised by the SEA are resolved.

(e) If a filing date set forth in this section falls on a Saturday, Sunday, or Federal holiday, the deadline for filing an application is the next succeeding business day.

(f) To be timely filed under this section, an application must be—

(1) Received by the Secretary on or before the applicable filing date; or

(2) Bear a U.S. Postal Service postmark dated on or before that filing date.

(Authority: 20 U.S.C. 240(a))

Note to paragraph (f)(2): The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

6. Section 222.11 is amended by revising paragraph (a) and the introductory text of paragraph (b) to read as follows:

§ 222.11 Amendments to applications: Filing dates.

(a) An LEA may amend its application following any of the events described in § 222.10(c) by submitting a written request to the Secretary and a copy to its SEA within 60 days after the applicable event occurs, or by the end of the Federal fiscal year for which assistance is sought, whichever is earlier.

(b) The LEA may also amend its application no later than the end of the Federal fiscal year for which assistance is sought—

* * * * *

7. Section 222.12 is revised to read as follows:

§ 222.12 Applications under sections 2, 3, and 4 received after deadlines.

The Secretary does not process for payment applications for assistance under sections 2, 3, and 4 of the Act that are not timely filed with the Secretary in accordance with the applicable filing dates established by §§ 222.10 and 222.11.

(Authority: 20 U.S.C. 240(a))

8. Section 222.14 is amended by revising the heading to read as follows:

§ 222.14 Membership data: General.

* * * * *

9. Section 222.17 is amended by revising the heading, introductory text, and paragraph (a) to read as follows:

§ 222.17 Alternative methods for counting federally connected children.

An applicant may use one of the two following methods to count federally connected children and to obtain the information described in the definition of "parent-pupil survey" in § 222.3:

(a) The applicant may determine federally connected membership by conducting a parent-pupil survey.

* * * * *

10. Section 222.22 is revised to read as follows:

§ 222.22 Calculation of ADA for an LEA's federally connected children for purposes of computing entitlements and payments under section 3.

(a) This section describes the manner in which the Secretary computes the average daily attendance (ADA) of federally connected children for each category in sections 3 and 4 of the Act—for the current fiscal year—in order to determine an applicant's entitlements under those sections.

(b) If an LEA is in a State that collects actual ADA data for purposes of distributing State aid for education, the Secretary calculates the ADA of that LEA's federally connected children for the current fiscal year by—

(1) Except as provided in paragraph (b)(2) of this section—

(i) Dividing the ADA of all the LEA's children for the prior fiscal year by the LEA's total membership on its survey date for the prior fiscal year (or, in the case of an LEA that conducted two membership counts in the prior fiscal year, by the average of the LEA's total membership on the two survey dates); and

(ii) Multiplying the figure determined in paragraph (b)(1)(i) of this section by the LEA's total membership of federally connected children in each subcategory described in section 3 of the Act on the LEA's survey date for the current fiscal year (or, in the case of an LEA that conducts two membership counts in the current fiscal year, by the average of the LEA's total membership of federally connected children in each subcategory on the two survey dates).

(2)(i) For purposes of this section, "actual ADA" means raw ADA data that have not been weighted or adjusted to reflect higher costs for specific types of students for purposes of distributing State aid for education.

(ii) If an LEA provides a program of free public summer school, attendance data for the summer session are included in the LEA's ADA figure in accordance with State law or practice.

(iii) An LEA's ADA count includes attendance data for children for whom it makes tuition arrangements with other educational entities.

(3) Applicants may not count attendance data for—

(i) Any child who is not physically present at school for the daily minimum time period required by the State, unless the child is participating via telecommunication or correspondence course programs that meet State standards or is being served by a State-approved homebound instruction program for the daily minimum time period appropriate for the child; or

(ii) Any child attending the schools of the applicant under a tuition arrangement with another LEA.

(c) If an LEA is in a State that does not collect ADA data for purposes of distributing State aid for education, the LEA or SEA shall submit data necessary for the Secretary to calculate the ADA of the LEA's federally connected children as follows:

(1) If an LEA is in a State that formerly collected ADA data for purposes of distributing State aid for education, the SEA may submit the total ADA and total membership data for the State for each of the last three fiscal years that ADA data were collected. The Secretary uses these data to calculate the ADA of the LEA's federally connected children by—

(i) Dividing the total ADA data by the total membership data for each of the three fiscal years and averaging the results; and

(ii) Multiplying the average determined in paragraph (c)(1)(i) of this section by the LEA's total membership of federally connected children in the current fiscal year as described in paragraph (b)(1)(ii) of this section.

(2) An LEA may collect and submit attendance data based on sampling during the prior fiscal year. The sampling must include attendance data for all children for at least 30 school days. The data must be collected during at least three periods evenly distributed throughout the school year. Each collection period must consist of at least five consecutive school days. The Secretary uses these data to calculate the ADA of the LEA's federally connected children by—

(i) Determining the ADA of all children in the sample;

(ii) Dividing the figure obtained in paragraph (c)(2)(i) of this section by the LEA's total membership for the prior fiscal year; and

(iii) Multiplying the figure determined in paragraph (c)(2)(ii) of this section by the LEA's total membership of federally connected children for the current fiscal year, as described in paragraph (b)(1)(ii) of this section.

(3) If an LEA is in a State that distributes State aid for education based on data similar to attendance data, the SEA may request that the Secretary use those data to calculate the ADA of the LEA's federally connected children. The Secretary determines whether those data are, in effect, equivalent to attendance data and, if so, allows use of the requested data and determines the method by which the ADA of the LEA's federally connected children will be calculated.

(Authority: 20 U.S.C. 238, 239, 240(a), 244(10))

11. Section 222.30 is amended by revising paragraph (a) and the introductory text of paragraph (c) to read as follows:

§ 222.30 Determination of local contribution rates: General.

(a) In order to compute the amount to be paid to an applicant local educational agency (LEA) under section 3 of the Impact Aid program, the Secretary—after consultation with the LEA and its State educational agency (SEA)—determines the LEA's local contribution rate.

* * * * *

(c) Except for § 222.32, the provisions in § § 222.31 through 222.37 do not apply to applicant LEA's located in—

* * * * *

§ 222.31 [Amended]

12. In § 222.31, paragraph (a)(2) is removed and paragraph (a)(3) is redesignated as paragraph (a)(2).

13. Section 222.32 is amended by revising the introductory text of paragraph (a) and the authority citation and by adding a new paragraph (c) to read as follows:

§ 222.32 Local contribution rate guaranteed by the Act.

(a) Except as provided in paragraphs (b) and (c) of this section, the local contribution rate guaranteed by the Act is the greater of—

* * * * *

(c)(1) For FY 1988 and each fiscal year thereafter, the Act guarantees a special local contribution rate, as described in paragraph (c)(3) of this section, for certain LEA's whose boundaries are coterminous with the boundaries of a military installation ("coterminous LEA's").

(2) LEA's that qualify for the special guaranteed rate under paragraph (c)(3) of this section include all coterminous LEA's except—

(i) Any coterminous LEA located in a State in which the State equalization law would prohibit the LEA from retaining the additional funds resulting from a rate described in paragraph (c)(3) or (c)(4) of this section; and

(ii) Any coterminous LEA located in a State in which the State law would require that State aid to the LEA for free public education be reduced in proportion to the additional funds resulting from a rate described in paragraph (c)(3) or (c)(4) of this section.

(3) For any coterminous LEA that qualifies under paragraph (c)(2) of this section, the Act guarantees a local contribution rate that is 70 percent of the average per pupil expenditure in all of the 50 States and the District of Columbia during the second fiscal year preceding the fiscal year for which the local contribution rate is being computed unless that rate would raise the LEA's per pupil expenditure for the second preceding fiscal year above the State average per pupil expenditure for the second preceding fiscal year, in which case the LEA's rate is determined under paragraph (c)(4) of this section.

(4) If the rate described in paragraph (c)(3) of this section would raise the LEA's per pupil expenditure for the second preceding fiscal year above the State average per pupil expenditure for

the second preceding fiscal year, then the LEA receives the greater of—

(i) The rate necessary to raise the per pupil expenditure for that LEA for the second preceding fiscal year to the average per pupil expenditure in the LEA's State for the second preceding fiscal year; or

(ii) The rate described in paragraph (a)(2) of this section.

(Authority: 20 U.S.C. 238(d)(3) (B) and (h))

14. Section 222.33 is amended by revising the introductory text of paragraph (a) and paragraphs (a)(2)(i) and (b)(2) to read as follows:

§ 222.33 Identification of generally comparable LEA's.

(a) If an LEA wishes to recommend to the Secretary a rate based on appropriate data from generally comparable LEA's within its State, the SEA for that State shall, except as provided in § 222.36, use data from the second fiscal year preceding the fiscal year for which the local contribution rate is being computed to group all of its LEA's, including all applicant LEA's, as follows:

* * * * *

(2) *Grouping by Grade Span/Legal Classification and Size.* (i) Divide all LEA's into groups by grade span (or the alternative grade-span groups described in paragraph (a)(1) of this section) and legal classification, if relevant and sufficiently different from grade span and size.

* * * * *

(b) * * *

(2) Except as provided in § 222.36, the SEA may not compute a local contribution rate for any group that contains fewer than 10 LEA's.

* * * * *

§ 222.35 [Amended]

15. The undesignated, introductory language of § 222.35 is amended by inserting after the word "Act" and before the comma, the phrase "and in § 222.36".

16. Section 222.36 is revised to read as follows:

§ 222.36 Determination of additional assistance.

(a) The provisions of this section govern an LEA that applies to the Secretary for assistance under section (3)(d)(2)(B) of the Act, in addition to its application for a regular payment under section 3.

(b) An LEA that applies for funds under section 3(d)(2)(B) may have its 3(d)(2)(B) eligibility and payment based on three comparable LEAs in its State. These three comparable LEAs are identified as follows:

(1) Using data from the prior fiscal year, the SEA first follows the directions in § 222.33(a)(4). The SEA then removes from the resulting list any LEAs that are heavily impacted, as described in § 222.33(b)(1), except the applicant LEA.

(2) If the remaining LEAs are not in rank order by ADA, the SEA shall list them in that order.

(3) The LEA may then select as its generally comparable LEAs for purposes of section 3(d)(2)(B) three LEAs that are adjacent to it in size (e.g., the next three larger LEAs, the next three smaller, the next two larger and the next one smaller, or the next one larger and the next two smaller).

(4) The Secretary uses the financial data of these three LEAs and the procedures in §§ 222.130–222.132 to determine whether the applicant LEA is eligible for funding under section 3(d)(2)(B) and, if so, the amount of that funding.

(c) If an LEA does not choose to exercise the option offered by paragraph (b) of this section and if it is applying for a regular payment under section 3 based on a local contribution rate guaranteed by the Act, the Secretary—

(1) In determining the applicant LEA's eligibility for, and the amount of, any additional assistance, considers the LEA comparable to all LEAs in its State; and

(2) Uses prior year data and the procedures in §§ 222.130–222.132 to determine whether the applicant LEA is eligible for funding under section 3(d)(2)(B) and, if so, the amount of that funding.

(d) If an LEA does not choose to exercise the option offered by paragraph (b) of this section and if, in applying for a regular payment under section 3, it recommends a local contribution rate based on generally comparable LEAs in its State, the Secretary—

(1) In determining the applicant LEA's eligibility for, and the amount of, any additional assistance, considers as comparable LEAs the same LEAs that the applicant identifies as comparable in its application for a regular payment under section 3; and

(2) Uses prior year data and the procedures in §§ 222.130–222.132 to determine whether the applicant LEA is eligible for funding under section 3(d)(2)(B) and, if so, the amount of that funding.

(e) If an LEA does not choose to exercise the option offered by paragraph (b) of this section and if, in applying for a regular payment under section 3, it recommends the "hold-harmless" rate described in § 222.31(d), the Secretary—

(1) In determining the applicant LEA's eligibility for, and the amount of, any additional assistance, considers as comparable LEAs the group of LEAs that produces the highest regular section 3 rate under the generally comparable LEA method, as described in § 222.33; and

(2) Uses prior year data and the procedures in §§ 222.130–222.132 to determine whether the applicant LEA is eligible for funding under section 3(d)(2)(B) and, if so, the amount of that funding.

(Authority: 20 U.S.C. 238(d)(2)(B), 242(b))

17. Section 222.37 is amended by adding a new paragraph (e) to read as follows:

§ 222.37 Determination of compensation for unusual geographical factors.

* * * * *

(e) The Secretary does not provide compensation under section 3(d)(3)(B)(ii) unless an applicant is determined to be making a reasonable tax effort in accordance with §§ 222.124–222.129.

* * * * *

18. Section 222.42 is amended by revising paragraph (b) to read as follows:

§ 222.42 Adjustment for or recovery of overpayment.

* * * * *

(b)(1) If the LEA is not entitled to subsequent payments under the Act, the LEA shall promptly refund the amount of the overpayment to the Secretary.

(2) If the LEA does not promptly repay the amount of the overpayment or promptly enter into a repayment agreement with the Secretary, the Secretary may use the procedures set forth in the regulations contained in 34 CFR Part 30 to offset that amount against other Department programs or, under the circumstances permitted in Part 30, to request that another agency offset the debt.

* * * * *

19. Section 222.61 is amended by removing paragraph (a)(4) and by adding paragraphs (b) (4) and (5) to read as follows:

§ 222.61 Treatment of State aid programs in general.

* * * * *

(b) * * *

(4) No State, whether or not it has an equalization program that qualifies under § 222.62, may, in allocating State aid, take into consideration a local educational agency's eligibility or entitlement for payments under the Act if that local educational agency does not apply for and receive those payments.

(5) Any State that takes into consideration payments under the Act in accordance with the provisions of section 5(d)(2) in allocating State aid to local educational agencies must reimburse any local educational agency for any amounts taken into consideration for any fiscal year to the extent that the local educational agency did not in fact receive payments in those amounts during that fiscal year.

(Authority: 20 U.S.C. 240(d) (1) and (2))

§ 222.63 [Amended]

20. Section 222.63(a) is revised by removing "§ 222.62(a)(4)", in the first sentence, and inserting in lieu thereof "§ 222.62(d)".

§ 222.67 [Amended]

21. Section 222.67 is amended by removing paragraph (c) and by redesignating paragraph (d) as paragraph (c)

22. Subpart H (currently consisting of §§ 222.70 through 222.79) is revised to consist of new §§ 222.70 through 222.77 to read as follows:

Subpart H—Provisions Related to Handicapped Children and Children With Specific Learning Disabilities

§ 222.70 What are the scope and purpose of these regulations?

(a) The regulations in this subpart govern the provision of additional payments under section 3(d)(2)(C) of the Act to local educational agencies (LEAs) that provide free appropriate public education to federally connected, handicapped children who are counted under section 3(d)(2)(C) of the Act. See § 222.77 for other statutes and regulations that may be relevant.

(b) These regulations set forth the requirements, interpretations, and guidance necessary to implement section 3(d)(2)(C).

(Authority: 20 U.S.C. 238(d)(2)(C), 242(b))

§ 222.71 What definitions apply to this subpart?

In addition to the terms defined in § 222.3, the following definitions, which are generally the same as the definitions used in the Education of the Handicapped Act (20 U.S.C. 1401 *et seq.*) and in 34 CFR part 300, apply to this subpart:

Free appropriate public education means special education and related services that—

(1) Are provided at public expense, without charge, and, except for services provided to children placed in or referred to private schools or facilities by their LEAs in accordance with § 222.76, under public supervision and direction;

(2) Meet the Standards of the State educational agency (SEA), including the requirements of this part;

(3) Include preschool, elementary school, or secondary school education in the State involved; and

(4) Are provided in confirmity with an individualized education program that meets the requirements under 34 CFR 300.340–300.349.

Handicapped children is defined in 34 CFR 300.5.

Preschool program means an educational or related program encompassing the educational level from a child's birth to the time at which elementary education is provided as determined under State law, provided that this program is recognized as free public education under State law.

Related needs means those needs related to a handicap or specific learning disability for which related services, in addition to direct instructional services, are deemed necessary so that the child may effectively participate in the instructional program of the LEA.

Related services means transportation and such developmental, corrective, and supportive services (including speech pathology and audiology, psychological services, physical and occupational therapy, recreation, counseling services, and medical services for diagnostic and evaluation purposes only) required to assist a handicapped child to benefit from special education, and includes the early identification and assessment of handicapping conditions in children. (See 34 CFR 300.13 for additional information.)

(Authority: 20 U.S.C. 238(d)(2)(C), 244(10); H. Rept. 1137, 95th Cong., Sess. 2d 104–105 (1978))

§ 222.72 What requirements must an LEA meet in order to count a handicapped child for purposes of section 3(d)(2)(C)?

(a) In order that a handicapped child may be counted for the purpose of an additional payment under section 3(d)(2)(C), a child must—

(1) Have a parent on active duty in the uniformed services, as defined in § 222.3, or reside on Indian lands, as described in section 403(1)(A) of the Act;

(2) Be receiving services suited to the child's special educational and related needs; and

(3) Be enrolled in a program (including a preschool program if appropriate) that is of sufficient size, scope, and quality to give reasonable promise of substantial progress toward meeting the child's special educational and related needs and is provided as part of free public education in the LEA.

(b) An LEA shall—

(1) State in its application the number of federally connected, handicapped children it claims for an increased payment under section 3(d)(2)(C); and

(2) Meet the regular eligibility requirements of section 3(c) of the Act in order to receive an additional payment under section 3(d)(2)(C). (There is no minimum number of federally connected, handicapped children who must be served in order for the LEA to receive the additional payment under section 3(d)(2)(C).)

(c) An LEA shall provide the assurances and certifications required under § 222.73.

(d) An LEA shall have in effect a written individualized educational program for each federally connected, handicapped child claimed for an increased payment under section 3(d)(2)(C). An LEA that satisfies the requirements of 34 CFR 300.340–300.346 for children counted under section 3(d)(2)(C) has satisfied the requirements of this paragraph.

(e) The program provided for the handicapped children counted under section 3(d)(2)(C) must conform to State standards for programs for handicapped children and must encompass the specific educational and related needs of the children counted.

(Authority: 20 U.S.C. 238 (a), (b), and (d)(2)(C), 240(f), 242; S. Rept. 1026, 93d Cong., 2d Sess. 159 (1974); *Chinle Common School District v. Mathews*, Civil No. 76–1273 (D.D.C. 1976))

§ 222.73 What assurances and certifications regarding handicapped children must an LEA provide in its application?

(a) *Size, scope, and quality of programs.* (1) An LEA shall provide an assurance that federally connected, handicapped children claimed for an increased payment under section 3(d)(2)(C) are receiving services in programs (including preschool programs) that are of sufficient size, scope, and quality to give reasonable promise of substantial progress toward meeting the special educational and related needs of these children. The Secretary considers any special education program serving the special educational needs of these children that conforms to the requirements for special education programs under part B of the Education of the Handicapped Act as satisfying this assurance.

(2) The LEA shall also certify that its programs conform to State standards for

programs for the types of children served.

(b) *Education of the Handicapped Act requirements.* (1) An LEA shall provide an assurance that its programs conform to the policies, procedures, and requirements of sections 612 and 613 of the Education of the Handicapped Act.

(2) The Secretary may consult with persons in charge of special education programs for handicapped children and children with specific learning disabilities in the SEA to determine whether State standards and programs conform to the policies and procedures required under sections 612 and 613 of the Education of the Handicapped Act.

(c) *Additional information.* The Secretary may require information in addition to that contained in the application in order to substantiate compliance with these assurances.

(Authority: 20 U.S.C. 238(d)(2)(C); H. Rept. 805, 93d Cong., 2d Sess. 43–46 (1974); S. Rept. 1026, 93d Cong., 2d Sess. 45 (1974); Cong. Record, daily ed., H7396, July 31, 1974)

§ 222.74 What restrictions and requirements apply to the use of the additional payments under section 3(d)(2)(C)?

(a) *General.* The additional payment to an LEA that is related to the increase in entitlement under section 3(d)(2)(C) (hereinafter "section 3(d)(2)(C) funds") must be used for programs and projects designed to meet the special educational and related needs of the handicapped children counted under that section.

(Authority: 20 U.S.C. 240(f))

(b) *Methods of obligation and expenditure of funds.* Obligations and expenditures of section 3(d)(2)(C) funds may be incurred in either of two ways:

(1) An LEA may obligate or expend the section 3(d)(2)(C) funds for the fiscal year for which the funds were appropriated.

(2) An LEA may reimburse itself for obligations or expenditures of local and general State aid funds already made for the fiscal year for which the section 3(d)(2)(C) funds were appropriated.

(Authority: 20 U.S.C. 238(d)(2)(C), 240(f), 242(b))

(c) *Allowable expenditures.* An LEA shall use its section 3(d)(2)(C) funds for the following types of expenditures:

(1) Expenditures that are reasonably related to the conduct of programs or projects for the education of handicapped children. These expenditures may include program planning and evaluation but may not include the construction of school facilities.

(2) Acquisition cost (net invoice price) of equipment to meet the special educational and related needs of handicapped children. If section 3(d)(2)(C) funds are used for the acquisition of equipment and any financial advantage is realized through rebates, discounts, bonuses, free pieces of equipment not used in a program or project for the education of handicapped children, or other circumstances, the fair market value of that financial advantage is not an allowable expenditure and may not be credited as an expenditure of those funds. In no case may the section 3(d)(2)(C) funds be used to acquire equipment if the title to that equipment would be in a private school and not in the applicant agency.

(d) *Fiscal accountability requirements.* An LEA shall account for the use of the section 3(d)(2)(C) funds as follows:

(1) By recording, for each fiscal year, the receipt (or credit) of section 3(d)(2)(C) funds separately from other funds received under the Act, *i.e.*, on a line item basis in the general fund account or in a separate account.

(2) By demonstrating that, for each fiscal year, the total amount of expenditures for programs or projects serving federally connected, handicapped children is at least equal to the amount of section 3(d)(2)(C) funds received or credited for that fiscal year. This is done as follows:

(i) For each fiscal year, the amount of an LEA's total expenditures for programs or projects serving handicapped children is determined.

(ii) The amount determined in paragraph (d)(2)(i) of this section is divided by the ADA of the total number of handicapped children the LEA served during that fiscal year.

(iii) The amount determined in paragraph (d)(2)(ii) of this section is then multiplied by the total ADA of the LEA's federally connected, handicapped children claimed by the LEA for that fiscal year.

(3) If the amount of section 3(d)(2)(C) funds the LEA received (or was credited) for the fiscal year exceeds the amount obtained in paragraph (d)(2)(iii) of this section, an overpayment equal to the excess section 3(d)(2)(C) funds is established. This overpayment may be reduced or eliminated to the extent that the LEA chooses to and can demonstrate that the average per pupil costs for serving federally connected, handicapped children exceeded its average per pupil costs for serving non-federally connected, handicapped children.

(Authority: 20 U.S.C. 238(d)(2)(C), 240(f), 242(b); H. Rept. No. 805, 93d Cong., 2d Sess. 45 (1974))

§ 222.75 How does section 3(d)(2)(C) relate to State aid programs?

Section 3(d)(2)(C) funds may not supplant any State funds that were or would have been available to the LEA for the free public education of children counted under section 3(d)(2)(C).

(a) No section 3(d)(2)(C) funds may be paid to an LEA whose per pupil State aid for federally connected, handicapped children, either general State aid or special education State aid, has been or would be reduced as a result of eligibility for or receipt of section 3(d)(2)(C) funds, whether or not a State has a program of State aid that meets the requirements of section 5(d)(2) of the Act and subpart G of this part.

(1) A reduction in the per pupil amount of State aid for handicapped children, including children counted under section 3(d)(2)(C), from that received in a previous year raises a presumption that supplanting has occurred.

(2) The LEA may rebut this presumption by demonstrating that the reduction was unrelated to the receipt of section 3(d)(2)(C) funds.

(b) In any State in which there is only one LEA, all funds for handicapped programs other than funds from Federal sources are considered by the Secretary to be local funds.

(Authority: 20 U.S.C. 238(d)(2)(C), 240 (d) and (f), 242(b))

§ 222.76 When may an LEA count children in private schools or residential programs for the purposes of section 3(d)(2)(C)?

(a) An LEA must have placed a handicapped child in, or referred a handicapped child to, a private school or facility under the policies and procedures required by section 613 of the Education of the Handicapped Act in order to count that child under section 3(d)(2)(C). Regulations implementing those policies and procedures are set forth in 34 CFR part 300, subpart D.

(Authority: 20 U.S.C. 244(10), 1413(a)(4)(B))

(b) If placement in a public or private residential program is necessary to provide special education and related services to a handicapped child, the LEA may count that child under section 3(d)(2)(C). Regulations describing these placements are set forth in 34 CFR part 300, subpart C.

(Authority: 20 U.S.C. 244(10), 1401 (9), (10), and (18), 1413(a)(4)(B))

(c) Children who have been placed in private schools by their parents may not be counted under section 3(d)(2)(C) but may participate in public school programs that use section 3(d)(2)(C) funds.

(Authority: 20 U.S.C. 238(d)(2)(C), 240(f); H. Rept. 805, 93d Cong., 2d Sess. 45 (1974))

§ 222.77 What other statutory and regulatory requirements are relevant to section 3(d)(2)(C)?

(a) *Applicability of the Education of the Handicapped Act and related regulations.* LEAs receiving section 3(d)(2)(C) funds are generally subject to the requirements of the Education of the Handicapped Act, as amended, and related regulations (20 U.S.C. 1401 *et seq.* and 34 CFR part 300).

(b) *Applicability of general provisions regulations.* Relevant provisions contained in 34 CFR parts 75, 77, and 80 are applicable to programs conducted with section 3(d)(2)(C) funds.

(Authority: 20 U.S.C. 242(b))

23. Section 222.81 is amended by revising paragraph (a)(4) and the authority citation to read as follows:

§ 222.81 Free public education.

(a) * * *

(4) Under public supervision and direction, except with respect to—

(i) Handicapped children; and

(ii) Children who are attending schools funded under section 1128 of Public Law 95–561 (the Indian School Equalization Program operated by the Bureau of Indian Affairs, Department of the Interior) but who are not eligible for funding under that section.

* * * * *

(Authority: 20 U.S.C. 238(d)(2)(D), 244(4))

24. A new subpart K (§§ 222.120 through 222.132) is added to read as follows:

Subpart K—Provisions for Section 3(d)(2)(B)

§ 222.120 What are the scope and purpose of these regulations?

(a) The regulations in this subpart implement section 3(d)(2)(B) of the Act. Sections 222.124–222.129 also implement section 3(d)(3)(B)(ii) of the Act.

(b) The program authorized by section 3(d)(2)(B) provides financial assistance, in addition to regular payments under section 3 of the Act, to certain heavily impacted local educational agencies (LEAs) that demonstrate eligibility for that assistance.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.121 What financial data from LEAs are used to determine eligibility, entitlement, and payment under section 3(d)(2)(B)?

Final computations and determinations made with regard to an LEA's eligibility (§§ 222.122–222.130), maximum entitlement (§ 222.131), and payment (§ 222.132) under section 3(d)(2)(B) are based on final financial data for the LEA's current fiscal year and final financial data for the prior fiscal year of the LEAs determined under § 222.36 to be generally comparable to the applicant LEA (referred to in this part as "generally comparable LEAs").

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.122 What LEAs are eligible for financial assistance under section 3(d)(2)(B)?

Subject to § 222.123, an LEA is eligible for financial assistance under section 3(d)(2)(B) of the Act if the LEA is eligible for a regular section 3 payment, applies for assistance under section 3(d)(2)(B), and the Secretary determines that the LEA meets all of the following requirements:

(a) As determined under § 222.130, the LEA does not have sufficient funds to enable it to provide a level of education equivalent to that provided by its generally comparable LEAs. For the purpose of this subpart, "level of education" means average per pupil expenditure amount. (See § 222.131(a).)

(b) The LEA is making a reasonable tax effort in accordance with the requirements of §§ 222.124–222.129 and exercising due diligence in availing itself of revenues derived from State and other sources.

(c) At least 50 percent of the total number of children in average daily attendance (ADA) for whom the LEA provides free public education during its current fiscal year are federally connected children.

(d) The eligibility of the LEA for State aid and the amount of State aid are determined on a basis no less favorable than that for other LEAs in the State.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.123 How does a State's equalization program affect an LEA's eligibility for section 3(d)(2)(B) assistance?

The Secretary determines that an LEA is not eligible for financial assistance under section 3(d)(2)(B) if—

(a) The LEA is in a State that has an equalized program of State aid that meets the requirements of section 5(d)(2) of the Act; and

(b) The State, in determining the LEA's eligibility for or amount of State aid, takes into consideration the LEA's payments under section 3(d)(2)(B).

(Authority: 20 U.S.C. 238(d)(2)(B), 240(d)(2))

§ 222.124 How does the Secretary determine whether a fiscally independent LEA is making a reasonable tax effort?

(a) To determine whether a fiscally independent LEA, as defined in § 222.3, is making a reasonable tax effort as required by § 222.122, the Secretary compares the LEA's local real property tax rates for school purposes (referred to in this part as "tax rates"), as defined in § 222.3, with the tax rates of its generally comparable LEAs.

(b) For purposes of this section, the Secretary uses—

(1) Actual tax rates if all the real property in the LEA and its generally comparable LEAs is assessed at the same percentage of true value; or

(2) Tax rates computed under §§ 222.126–222.128.

(c) The Secretary determines that an LEA is making a reasonable tax effort if—

(1) The LEA's tax rate is equal to at least 95 percent of the average tax rate of its generally comparable LEAs;

(2) Each of the LEA's tax rates for each classification of real property is equal to at least 95 percent of each of the average tax rates of its generally comparable LEAs for the same classification of property;

(3) The LEA taxes all of its real property at the maximum rates allowed by the State, if those maximum rates apply uniformly to all LEAs in the State; or

(4) The LEA has no taxable real property.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.125 What information must be provided by the State educational agency?

The State educational agency (SEA) of any State with an LEA applying for assistance under section 3(d)(2)(B) shall provide the Secretary with relevant information necessary to determine whether the LEA is making a reasonable tax effort under §§ 222.126–222.129, whichever is applicable.

(Authority: 20 U.S.C. 238(d)(2)(B), 242(b))

§ 222.126 What tax rates does the Secretary use if real property is assessed at different percentages of true value?

If the real property of an LEA and its generally comparable LEAs consists of one classification of property but the property is assessed at different percentages of true value in the different LEAs, the Secretary determines whether the LEA is making a reasonable tax effort under § 222.124(c)(1) by using tax rates computed by—

(a) Multiplying the LEA's actual tax rate for real property by the percentage of true value assigned to that property for tax purposes; and

(b) Performing the computation in paragraph (a) of this section for each of its generally comparable LEAs and determining the average of those computed tax rates.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.127 What tax rates does the Secretary use if two or more different classifications of real property are taxed at different rates?

If the real property of an LEA and its generally comparable LEAs consists of two or more classifications of real property taxed at different rates, the Secretary determines whether the LEA is making a reasonable tax effort under § 222.124(c) (1) or (2) by using one of the following:

(a) Actual tax rates for each of the classifications of real property.

(b) Tax rates computed in accordance with § 222.126 for each of the classifications of real property.

(c) Tax rates computed by—

(1) Determining the total true value of all real property in the LEA by dividing the assessed value of each classification of real property in the LEA by the percentage, of true value assigned to that property for tax purposes and aggregating the results;

(2) Determining the LEA's total revenues derived from local real property taxes for school purposes;

(3) Dividing the amount determined in paragraph (c)(2) of this section by the amount determined in paragraph (c)(1) of this section; and

(4) Performing the computations in paragraphs (c) (1), (2), and (3) of this section for each of the generally comparable LEAs and determining the average of their computed tax rates.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.128 What tax rates may the Secretary use if substantial local revenues are derived from local tax sources other than real property taxes?

(a) In a State in which a substantial portion of revenues for current expenditures for educational purposes is derived from local tax sources other than real property taxes, the SEA may request that the Secretary take those revenues into account in determining whether an LEA in that State is making a reasonable tax effort under § 222.124.

(b) If, based upon the request of an SEA, the Secretary determines that it is appropriate to take the revenues described in paragraph (a) of this section into account in determining whether an LEA in that State is making a reasonable tax effort under § 222.124, the Secretary uses tax rates computed by—

(1) Dividing the assessed value of each classification of real property in the LEA by the percentage of true value assigned to that property for tax purposes and aggregating the results;

(2) Determining the LEA's total revenues derived from local tax sources for school purposes;

(3) Dividing the amount determined in paragraph (b)(2) of this section by the amount determined in paragraph (b)(1) of this section; and

(4) Performing the computations in paragraphs (b) (1), (2), and (3) of this section for each of the generally comparable LEAs and determining the average of those computed tax rates.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.129 How does the Secretary determine whether a fiscally dependent LEA is making a reasonable tax effort?

(a) If an LEA is fiscally dependent, as defined in § 222.3, the Secretary compares the LEA's imputed local tax rate, calculated under paragraph (b) of this section, with the average tax rate of its generally comparable LEAs, calculated under paragraph (c) of this section, to determine whether the LEA is making a reasonable tax effort.

(b) The Secretary imputes a local tax rate for a fiscally dependent LEA by—

(1) Dividing the assessed value of each classification of real property within the boundaries of the general government by the percentage of true value assigned to that property for tax purposes and aggregating the results;

(2) Determining the amount of locally derived revenues made available by the general government for the LEA's current expenditures for school purposes; and

(3) Dividing the amount determined in paragraph (b)(2) of this section by the amount determined in paragraph (b)(1) of this section.

(c) The Secretary performs the computations in paragraph (b) of this section for each of the fiscally dependent generally comparable LEAs and the computations in §§ 222.126–222.128, whichever is applicable, for each of the fiscally independent generally comparable LEAs and determines the average of all those tax rates.

(d) The Secretary determines that a fiscally dependent LEA is making a reasonable tax effort if its imputed local tax rate is equal to at least 95 percent of the average tax rate of its generally comparable LEAs.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.130 How does the Secretary determine whether an LEA lacks sufficient funds to enable it to provide a level of education equivalent to that provided by its generally comparable LEAs?

(a) The Secretary determines whether an LEA lacks sufficient funds to enable it to provide a level of education equivalent to that provided by its generally comparable LEAs, in accordance with § 222.122, as follows:

(1) First, the Secretary establishes the level of education equivalent to that provided by the LEA's generally comparable LEAs by—

(i) Computing the average per pupil expenditure (APPE) of the generally comparable LEAs by dividing the sum of the total current expenditures of those LEAs for their prior fiscal year by the sum of the total ADA of those LEAs for that prior fiscal year;

(ii) Increasing or decreasing the amount obtained in paragraph (a)(1)(i) of this section by the percentage the APPE of the generally comparable LEAs increased or decreased from their second preceding fiscal year to their prior fiscal year; and

(iii) Multiplying the amount determined in paragraph (a)(1)(ii) of this section by the LEA's total ADA for its current fiscal year.

(2) The Secretary next identifies the funds available to the LEA for current expenditures for its current fiscal year by—

(i) Adding the LEA's section 3 payment for the current fiscal year and all other funds available to the LEA for current expenditures for that current fiscal year; and

(ii) Subtracting from the amount obtained in paragraph (a)(2)(i) of this section the LEA's allowable carryover amount, which is that portion of the LEA's opening cash balance for the current fiscal year that does not exceed—

(A) The maximum amount of funds for current expenditures that the LEA was allowed by State law to carry over from the prior fiscal year to the current fiscal year, provided that State restrictions on carryover amounts were applied uniformly to all LEAs in the State; or

(B) If no State law governing cash balances exists, 30 percent of the LEA's "operating costs" for the prior fiscal year.

(3) The Secretary then subtracts the amount obtained in paragraph (a)(2)(ii) of this section from the figure computed in paragraph (a)(1)(iii) of this section.

(b) The Secretary determines that an LEA lacks sufficient funds to enable it to provide a level of education equivalent to that provided by its generally comparable LEAs if the amount determined in paragraph (a)(3) of this section is greater than 0.

(c) The following definitions apply to this subpart:

All other funds available to the LEA for current expenditures means—

(1) All funds received by the LEA for current expenditures from local sources (or, in the case of a fiscally dependent LEA, all funds budgeted for or made available to the LEA, whichever is greater, by the general government) and from State and Federal sources, except any payments under section 3 or section 3(d)(2)(B) of the Act received during the current fiscal year and funds granted for the purpose of Chapter 1 or Chapter 2 of Title 1 of the Elementary and Secondary Education Act of 1965; and

(2) Funds on hand for current expenditures at the beginning of the current fiscal year ("opening cash balance").

Operating costs is given the same meaning as the term "current expenditures," which is defined in § 222.3.

Section 3 payment means the total payment based on the LEA's entitlements under sections 3(d)(1), (3)(d)(2)(C)(i), and 3(d)(2)(D) of the Act.

(Authority: 20 U.S.C. 238(d)(2)(B), (C)(i), and (D), 244(5))

§ 222.131 How does the Secretary determine an LEA's maximum entitlement under section 3(d)(2)(B)?

To determine the maximum entitlement under section 3(d)(2)(B) for an LEA that meets the requirements of § 222.122, the Secretary—

(a) Computes the average per pupil expenditure of the generally comparable LEAs in accordance with § 222.130(a)(1)(i) and (ii);

(b) Multiplies the amount determined in paragraph (a) of this section by the total ADA of the LEA's federally connected children; and

(c) Subtracts from the amount computed in paragraph (b) of this section the total amount of State aid received by the LEA for its federally connected children.

(Authority: 20 U.S.C. 238(d)(2)(B))

§ 222.132 How does the Secretary determine an LEA's payment under section 3(d)(2)(B)?

(a) Except as provided in paragraph (b) of this section, an LEA that meets the requirements of § 222.122 receives a payment under section 3(d)(2)(B) in an amount equal to the lesser of—

(1) The amount determined in § 222.130(a)(3); or

(2) The LEA's maximum entitlement determined under § 222.131 minus the amount of the LEA's section 3 payment for the current fiscal year.

(b) In the case of an LEA whose tax rate is at least 95 percent but less than 100 percent of the average tax rate of its generally comparable LEAs, the Secretary reduces the LEA's payment under section 3(d)(2)(B), as determined in paragraph (a) of this section, by the percentage that the average tax rate of the generally comparable LEAs exceeds the tax rate of the LEA.

(Authority: 20 U.S.C. 238(d)(2)(B))

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Thursday
September 7, 1989

Part IV

Department of Education

34 CFR Parts 668 and 682

Student Assistance General Provisions and Guaranteed Student Loan and PLUS Program; Rule; Correction

Department of Education

34 CFR Parts 668 and 682

Student Assistance General Provisions and Guaranteed Student Loan and PLUS Programs; Correction

AGENCY: Department of Education.

ACTION: Final regulation; correction.

SUMMARY: This document corrects final regulations for the Student Assistance General Provisions and Guaranteed Student Loan and PLUS Programs, published in the **Federal Register** on June 5, 1989 (54 FR 24114).

FOR FURTHER INFORMATION CONTACT: Patricia Newcombe or Pamela A. Moran. Telephone: (202) 732–4242.

SUPPLEMENTARY INFORMATION: In the June 5, 1989 **Federal Reigster:**

PART 668—[AMENDED]

1. On pages 24118 and 24119, Appendix A the Track Record Disclosure Forms I and II are correctly added to read as follows:

BILLING CODE 4000–01–M

Form I:

HOW OUR STUDENTS ARE DOING

To help you make a good decision about whether to sign up for (name of program), (name of institution) wants you to know that, according to the latest information--

---

_____%, or ___ of the _____ students in this program scheduled to graduate in (year) went on to graduate;

*_____%, or __ of the ____ students scheduled to graduate in that year have found jobs in (name of occupation or field for which training is offered); and

_____%, or __ of the _____ students in this program taking the (name of test) administered by the State of (name of State in which the program is being offered to the student) in (year) passed that examination.

I have read and understood the graduation rate, licensing or certification examination pass rate, and job placement rate information provided above.

_____ (Prospective student's signature)

Date

*We have been told by ____ of the students that were scheduled to graduate in that year that, even though they graduated, they decided not to look for a job in that occupation. Also, ____ of the students scheduled to graduate in that year have not responded to our job placement questionnaire, so we do not know whether they have found jobs or not.

Form II:

HOW OUR STUDENTS ARE DOING

To help you make a good decision about whether to sign up for (name of program), (name of institution) wants you to know that, according to the latest information--

---

_____%, or ___ of the _____ students in this program scheduled to graduate in (year) went on to graduate; and

*_____%, or __ of the ____ students scheduled to graduate in that year have found jobs in (name of occupation or field for which training is offered).

I have read and understood the graduation rate and job placement rate information provided above.

_____ (Prospective student's signature)

Date

* We have been told by ____ of the students scheduled to graduate in that year that, even though they graduated, they decided not to look for a job in that occupation. Also, ____of the students scheduled to graduate in that year have not responded to our job placement questionnaire, so we do not know whether they have found jobs or not.

BILLING CODE 4000-01-C

2. On page 24114, in the first column, last paragraph, after (d), insert "(insofar as paragraph (d) operates to require a school to provide the information described in §§ 668.44(c)(1)(ii) through (iv))".

3. On page 24114, in the first column, last paragraph, the phrase "loans certified for" is corrected to read "students enrolled for".

4. On page 24115, in the first column, lines 24 and 31, the word "graduates" is corrected to read "students".

§ 668.15 [Corrected]

5. On page 24116, in the third column, in § 668.15(a)(3)(i), Line 1, insert the word "has" after the word "that".

6. On page 24116, in the third column, in § 668.15(b), remove "after fiscal year 1988".

7. On page 24117, in the first column, in § 668.15(b)(2)(ii)(A), the word "graduates" is corrected to read "students".

8. On page 24117, in the first column, in § 668.15(b)(2)(ii)(B), "§ 668.44(c)(3)" is corrected to read "§ 668.44(c)(1)(iii)".

9. On page 24117, in the first column, in § 668.15(b)(2)(ii)(C), "§ 668.44(c)(4)" is corrected to read "§ 668.44(c)(1)(iv)".

§ 668.44 [Corrected]

10. On page 24117, in the third column, in § 668.44(c)(1)(ii), the phrase "graduates of the program" is corrected to read "students in the program".

11. On page 24118, in the first column, in § 668.44(c)(1)(iii), the word "graduate" is corrected to read "student" each time it appears.

12. On page 24118, in the first column, in § 668.44(c)(1)(iii), Line 7, before the word "any", remove the word "for".

13. On page 24118, in the first column, in § 668.44(c)(l)(iii), Line 9, the word "graduate's" is corrected to read "student's".

14. On page 24118, in the second column, in (f)(2), after "of", "such graduates" is corrected to read "students scheduled to graduate in that year", and, after "address of the", the word "graduate" is corrected to read "student".

Appendix A to Part 34 [Corrected]

15. On page 24118, in the third column, in Appendix A introductory text, "668.44(c)(2) through (4)" is corrected to read "668.44(c)(1)(ii) through (iv)".

16. On page 24119, in the second column, before the period at the end of number 6, add "and (c)".

17. On page 24121, in the third column, in § 668.606(c)(1), Line 10, the word "upward" is corrected to read "downward".

18. On page 24121, in the third column, in § 682.606(c)(1), Line 14, the word "plus" is corrected to read "and less."

Dated: August 30, 1989.

James B. Williams,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 89-20936 Filed 9-6-89; 8:45 am]

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federal register

Thursday
September 7, 1989

Part V

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 413, 424, 482, and 483
Medicare Program; Swing-Bed Program Changes: Interim Final Rule With Comment Period

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413, 424, 482, and 483

[BERC-493-IFC]

RIN 0938-AD83

Medicare Program; Swing-Bed Program Changes

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

ACTION: Interim final rule with comment period.

SUMMARY: These interim rules revise the current Medicare rules relating to approved swing-bed hospitals. They expand the allowable rural hospital bed size from 49 beds to 99 beds. They require approved swing-bed hospitals with more than 49 beds to—

- Transfer extended care hospital patients within 5 days to an available skilled nursing facility (SNF) bed in the geographic region, unless the patient's physician certifies within the 5 day period that transfer is not medically appropriate;
- Have availability agreements with SNFs in their geographic region, concerning the availability of extended care beds and the transfer of extended care patients; and
- Not seek Medicare payment for those patient days of extended care services (in a cost reporting period) that exceed 15 percent of the product of the number of days in the period and the average number of licensed beds at the hospital. An exception to this provision is that Medicare payment will continue to be made for those patients who are receiving extended care services at the time the hospital reaches the above-mentioned limit.

These regulations also require that SNFs in the geographic region of an approved swing-bed hospital must provide notice to the hospital of the availability of SNF beds.

These provisions conform our regulations with changes made by section 4005(b) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) and section 411(b)(4)(D) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360).

DATES: *Effective date:* These regulations are effective on October 10, 1989. They are being issued in as an interim rule with comment for reasons explained in the Interim Rule with Comment section under Supplementary Information below.

Comment period: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 6, 1989.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC–493–IFC, P.O. Box 26676, Baltimore Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309–G, Huber H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC–493–IFC. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309–G of the Department's offices at 200 Indepndence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202–245–7890).

Please address a copy of comments on information collection requirements to: Office of Management and Budget, Office of Information and Regulatory Affairs, Room 3208, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron.

FOR FURTHER INFORMATION CONTACT:

Thomas Hoyer, (301) 966–4607, (Coverage Issues)

Linda McKenna, (301) 966–4530, (Reimbursement Issues)

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare and Medicaid programs cover inpatient health care services at both a hospital level of care and a skilled nursing facility (SNF) level of care. Under certain conditions and at a State's option, the Medicaid program also covers care in an intermediate care facility (ICF) for patients whose medical conditions require institutional care that is above the level of room and board, but less intensive than care provided in a hospital or SNF.

Hospitals participating in Medicare and Medicaid, in addition to providing an inpatient hospital level of care, may also provide SNF or ICF levels of care through the establishment of a separately participating "distinct part" unit. Among health, safety and other requirements, a distinct part SNF or ICF must be an entire separately identifiable unit consisting of all the beds within that unit (such as, a separate building, floor, wing, or corridor). A distinct part SNF or ICF unit is paid as an entity separate from the rest of the institution.

Small rural hospitals had difficulty in establishing identifiable units for SNF or ICF levels of care because of limitations in their physical plant and accounting capabilities. Thus, these hospitals often had an excess of hospital beds and their communities had a scarcity of SNF beds in Medicare and Medicaid participating facilities. To alleviate some of these problems, Congress enacted section 904 (the swing-bed provision) of the Omnibus Reconciliation Act of 1980 (OBRA), Pub. L. 96–499. Section 904 enacted section 1883 of the Social Security Act (the Act), under which rural hospitals with fewer than 50 beds may use their inpatient facilities to furnish SNF services to Medicare and Medicaid beneficiaries, and ICF services to Medicaid beneficiaries. These hospitals with approved swing-bed programs are paid at rates that are appropriate for those services and are generally lower than hospital rates. On July 20, 1982, we published an interim final rule in the **Federal Register** (47 FR 31518) that implemented section 1883 of the Act. The requirements contained in this section were considered in the amendments to the conditions proposed in the hospital regulations published January 4, 1983 (48 FR 299). These requirements were made final June 17, 1986 (51 FR 22010). The requirements for swing-bed hospitals are located at 42 CFR 482.66.

II. Summary of New Legislation

On December 22, 1987, the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) was enacted. Section 4005(b) of Pub. L. 100–203 amends section 1883(b)(1) of the Act by expanding the swing-bed program to rural hospitals with fewer than 100 beds.

Section 4005(b)(2)(B) of Pub. L. 100–203 amends section 1883(d) of the Act by adding the following requirements and definitions:

- Payment for extended care services furnished by hospitals with more than 49 beds but fewer than 100 beds, approved as swing-bed hospitals by Medicare after March 31, 1988, may not be made for extended care services furnished to a swing-bed hospital extended care patient more than 5 days (excluding weekends and holidays) after a bed in a SNF becomes available in the geographic region, unless the patient's physician certifies within the 5 day period, that the transfer of the patient is not medically appropriate.

• The term "extended care patient" means an individual being furnished extended care services at a swing-bed hospital under an agreement with the Secretary.

• The term "availability date" means, with respect to an extended care patient at a swing-bed hospital, any date on which a bed is available for the patient in a SNF located within the geographic region in which the hospital is located.

• The Secretary must promulgate regulations to provide for notice by SNFs of availability dates to hospitals with swing-bed agreements located within the same geographic region.

• In the case of a hospital which has more than 49 beds and a swing-bed agreement after March 31, 1988, the hospital will not seek payment in a cost reporting period for patient days of extended care services that exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period.

These swing-bed amendments do not affect providers operating under section 1883 agreements entered into before March 31, 1988.

On July 1, 1988, the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) was enacted. Section 411(b)(4)(D) of Pub. L. 100–360 adds a technical amendment to the 15 percent payment limitation by providing continued payment for those patients in the swing-bed hospital receiving extended care services at the time the limit is reached.

III. Provisions of this Interim Rule

In developing these regulations, we have essentially relied on the language of the statute, as amended by section 4005(b) of Pub. L. 100–203, and section 411(b)(4)(D) of Pub. L. 100–360.

A. Requirements Relating to Payment for Extended Care Services in a Swing-Bed Hospital

Current regulations at § 413.114 explain the reimbursement methodology for those rural hospitals that participate in the swing-bed program. In § 413.114, we are defining the terms "geographic region" and "availability date".

We define "geographic region" to mean an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether a SNF is within a hospital's geographic region, or the SNF is inaccessible to hospital patients, the HCFA Regional Office will make a determination.

We define "availability date" to mean with respect to an extended care patient in a swing-bed hospital, the later of—

• The date on which a bed is available for the patient in a SNF located within the hospital's geographic region;

• The date that a hospital learns that a SNF bed is available; or

• If the notice is prospective, the date that a SNF bed will become available.

In § 413.114, we are adding a new subsection that describes certain payment requirements for rural hospitals with more than 49 beds (but fewer than 100) that wish to participate as a swing-bed hospital. The first requirement states that if there is an available SNF bed in the geographic region, the extended care patient must be transferred within a 5 day period (excluding weekends and holidays) beginning on the availability date of the SNF bed unless the patient's physician certifies within that 5 day period that transfer is not medically appropriate.

Under the second requirement in order to receive Medicare payments, hospitals must not exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the same period. It is necessary for these hospitals to monitor the number of Medicare extended care days in order to prevent the hospital's exceeding this 15 percent payment limitation. In those States that do not license hospital beds, the hospitals must use the total average of hospital beds reported on their most recent Certificate of Need (CON) (excluding bassinets). If during the cost reporting period, there is an increase or decrease in the number of "licensed" beds, the number of "licensed" beds for each part of the period is to be multiplied by the number of days for which that number of "licensed" beds was available. After totalling the results, compute 15 percent of the total available "licensed" bed days to determine the payment limitation.

This new subsection of § 413.114 will also specify the payment restrictions that are applicable to swing-bed hospitals with more than 49 beds. The first restriction states that hospitals must not seek payment for extended care services after the end of the 5 day period (excluding weekends and holidays) beginning on the availability date of a SNF bed unless the patient's physician has certified, within that 5 day period, that the transfer of the patient to the SNF was not medically appropriate.

The second payment restriction states that swing-bed hospitals with more than 49 beds must not seek payment for extended care services in a cost reporting period to the extent that they exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period. In those States that do not license hospital beds, the hospital must use the average number of hospital beds reported on its most recent CON, excluding bassinets.

We also are adding a new § 413.114(d)(4) that describes the exception to the payment limitation. This exception states that Medicare payment will be continued for those patients who are receiving extended care services in the swing-bed hospital at the time the 15 percent limit is reached.

B. Requirements for Posthospital SNF Care

Current regulations at 42 CFR 424.20 (formerly 42 CFR 405.1632) specify the requirements for Medicare payment of posthospital SNF care. The regulations currently provide that a physician must certify that SNF care is or was needed for continued treatment of a medical condition that an individual had as an inpatient. This section also states that the certification for SNF care must be obtained at the time of admission to the SNF or as soon thereafter as is reasonable and practicable. We are revising § 424.20(a), to add the certification requirements set forth in section 1883(d) of the Act. These requirements will make it clear that if the swing-bed hospital does not timely transfer the patient to the SNF, the extended care patient's physician must certify that the transfer of the patient within 5 days of the availability date as defined in § 413.114(d), was not medically appropriate.

In addition, we are revising paragraph (b) of § 424.20, by adding a new (b)(2) concerning the timing of the physician certification. Section 424.20(b)(2) will require the physician of an extended care patient to certify within 5 days (excluding weekends and holidays) of the availability date, that transfer of the patient is not medically appropriate.

C. Special Requirements for Hospital Providers of Long Term Care Services

Current regulations at § 482.66 contain the special requirements that hospital providers of long-term care services (swing-beds) must meet in order to be approved to provide post-hospital

extended care services. Section 482.66(a)(1) requires the facility to have fewer than 50 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units. We are revising this section to expand the swing-bed program to hospitals with fewer than 100 beds, excluding beds for newborns and beds in intensive care type inpatient units or distinct parts.

We are making minor technical revisions to the section title, the introductory paragraph, paragraphs (a)(1), (4) and (5) and are adding a new paragraph (a)(6) to § 482.66 to specify the requirements of the availability agreement between hospitals and SNFs with more than 49 beds (but fewer than 100) approved after March 31, 1988.

In the title, the term "Conditions of Participation" has been dropped. Section 482.66 has been retitled as "Special Requirements" because the requirements found in this section are not traditional conditions of health and safety. Rather, they are requirements relating to approval of hospitals wishing to have swing-bed approvals.

In a new paragraph (a)(6)(i), we specify that hospitals must have an availability agreement with SNFs in their geographic region that ensures that the SNF will notify the hospital when an extended care bed becomes available.

In a new paragraph (a)(6)(ii), we specify that once the hospital learns of the availability date of a SNF bed, it must transfer the swing-bed extended care patient within 5 days (excluding weekends and holidays) of that date, unless the patient's physician certifies that the transfer is not medically appropriate. Hospitals with under 50 beds are not subject to the 5 day transfer agreement.

In a new paragraph (a)(7), we specify that we will determine the number of beds a hospital has for purposes of this section. In paragraph (a)(7)(i), we specify that a hospital bed count is calculated by excluding from the count, beds that, because of their special nature, such as newborn and intensive care beds, would not be available for swing-bed use. Also excluded from the bed count are beds in a separately certified "distinct part" as SNFs and ICFs.

At paragraph (a)(7)(ii) we specify that a hospital licensed for more than 49 or 99 beds, as the case may be, will be considered to have the number of beds that it consistently utilizes and staffs. Hospitals, at a minimum, document their count by staffing schedules and census information for the previous 12 months before application to be a swing-bed hospital. The hospital must provide written assurance to HCFA that they will not operate over 49 or over 99 beds, excluding newborn and intensive or coronary care beds, except in connection with a catastrophic event.

D. Requirements for Long Term Care Facilities

We are adding a new § 483.80 that describes the special requirements that SNFs must have with swing-bed hospitals in their geographic region. We are stating that a SNF that has an availability agreement to accept extended care patients from swing-bed hospitals with more than 49 beds, in their geographic region must provide notice of when the beds are available. In this interim regulation we have also replaced the cross references to current SNF regulations that appear in § 482.66 with references to the SNF regulations we published on February 2, 1989 (54 FR 5316). We have not changed the scope of the SNF requirements that a swing-bed hospital must meet.

E. Certification Effective Date

The statute authorizes payment for these swing-bed services, effective April 1, 1988. Therefore, hospitals that have been providing these services may request retroactive approval. This retroactive approval can be granted back to the date the hospital began providing the service but not prior to April 1, 1988, the effective date of the statutory provision. Future approvals will be not earlier than the date of the survey.

To be approved retroactively, the hospital must be found in compliance with all the swing-bed requirements at the time of the State agency survey and a review of records must provide reasonable assurance that the hospital has been continuously complying with these requirements from the date for which retroactive approval is requested.

F. Optional Reimbursement Method

Under current regulations at § 413.24(d)(5), an optional reimbursement method is available to small, rural hospitals with Medicare-participating distinct part SNFs. To qualify for this method, a hospital-SNF complex must be located in a rural area and the hospital and SNF must have a combined bed count of fewer than 50 beds. Under this method, the general routine service costs of the hospital component and SNF component are combined into a single cost center for purposes of computing the average cost per diem for hospital and SNF services. However, the two components remain as separate providers for certification and coverage purposes.

We considered extending the optional reimbursement method to those rural hospital-SNF complexes that have a combined bed count of more than 49 (but fewer than 100) beds. However, we do not believe that allowing these facilities to use the optional reimbursement method is appropriate or necessary. The optional reimbursement method was intended for use by those very small hospital-SNF complexes that, because of their size and locality, had limited resources for maintaining the distinct part components for reimbursement purposes. Because of the difficulties and the excessive strain on the resources of these hospitals, we provided for the optional reimbursement method. However, we do not believe the same problems exist to the same degree with respect to hospitals having more than 49 beds and therefore are not proposing any extension of this reimbursement method.

G. Identifying Eligible Hospitals

In administering the original swing-bed provision, HCFA considered hospitals with 49 or fewer beds in general use as eligible to participate. In other words, hospitals with 50 beds or more whose staffing and usual census showed that they routinely operated with fewer than 50 beds were considered appropriate for swing-bed approval as long as they met the other statutory and regulatory requirements for participating. We had also excluded newborn beds, intensive and coronary care beds and those associated with distinct parts and those associated with a catastrophic event. We understand that the Congress was aware of this administrative choice and that it assumed we would continue to exercise it when we implemented the new provision. Accordingly, we will look at the number of beds a hospital actually is operating to determine if it (1) is eligible for participation as a swing-bed hospital, and (2) should be considered to fall under the rules applicable to hospitals of under or over 50 beds.

H. Beneficiary Impact

Approval of swing-bed hospitals with more than 49 beds but fewer than 100 could provide beneficiaries with a new source of SNF care in rural areas. However, the statutory payment limitations on these hospitals create instances where Medicare payment may not be made and the beneficiary could be liable for the provider services. These include the following—

- A hospital that has exceeded the 15 percent payment limitation for swing-bed services will not receive Medicare

payment for any new patients admitted to a SNF swing-bed while the limitation is in effect. Therefore, a hospital, in conducting its daily census should separately account for beneficiaries receiving Medicare covered extended care services. A patient's liability for payment for extended care services in a swing-bed hospital when the hospital has reached the 15 percent payment limitation for these services is dependent upon the hospital's giving proper notice to the beneficiary of this liability. If the beneficiary is admitted directly to the swing bed hospital for extended care services after the 15 percent payment limitation has been reached, the hospital must give the beneficiary notice under section 1879 of the Act and § 405.336(d) of the regulations that the beneficiary does not require inpatient hospital care. If the hospital converts the beneficiary's status from hospital patient to long-term care patient, the hospital must give the beneficiary notice under section 1154(e) of the Act and § 412.42(c) of the regulations that the beneficiary no longer requires inpatient hospital care. ("Inpatient hospital care" can include cases in which a beneficiary needs a SNF level of care, but under Medicare criteria, a SNF level bed is not available.) These notices, which must be given prior to a change in the beneficiary's status within the hospital, or prior to admission to a swing-bed hospital for long term care, must include language indicating that the beneficiary will be liable for payment of SNF type services because the 15 percent payment limitation has been reached. This notice must point out that the beneficiary is liable only in that particular facility and that the beneficiary has the option to remain in the facility and pay for those days or request a transfer to another facility. Also included in the notice is the date Medicare would again start to pay for extended care services in that hospital (the beginning date of a hospital's new cost reporting period). The 2 day delay in the beneficiary's liability that usually applies under § 412.42(c) does not apply in connection with such changes in swing-bed status because hospital payment rules do not apply when a patient is in a swing-bed. Instead, the patient is considered for payment purposes to be a patient of a SNF and care provided is subject to SNF rules.

- Medicare payment for SNF swing-bed services ceases 5 days after a SNF bed becomes available in the geographic region, unless the beneficiary's physician certifies within that 5 day period that the beneficiary's transfer to the SNF would not be medically appropriate. The beneficiary's liability for payment for extended care services after the 5 day period has expired is dependent upon the hospital's giving prior notice to the beneficiary of this liability. These notices, which may be given at the time of admission for long term care or change of status, as appropriate, must include language indicating that the patient will be liable for payment after the expiration of the 5 days if an SNF bed is available in the geographic region and the beneficiary's physician has not certified that a transfer to that facility would be medically inappropriate.

IV. Regulatory Impact Statement

A. Executive Order 12291

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

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

We anticipate that this interim rule will result in the following costs to the Medicare and Medicaid programs.

TABLE 1.—PROJECTED MEDICARE AND MEDICAID COSTS AS A RESULT OF SWING-BED PROGRAM CHANGES [1]

	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
Medicare	$25	$25	$30	$35	$35
Medicaid	0	5	5	5	5

[1] Rounded to the nearest $5 million.

Section 1913 of the Act permits States to amend their State plans in order to make payment to Medicare swing-bed hospitals for SNF and ICF services. Medicaid payments may rise to the extent that this regulation increases the number of swing-bed hospitals in States that have adopted this Medicaid option. In conclusion, this iterim rule is not a major rule under E.O. 12291 criteria, and a regulatory impact analysis is not required.

B. Regulatory Flexibility Act

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

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if an interim rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

The provisions of this interim rule generally conform our regulations to changes made by section 4005(b) of Pub. L. 100–203 and section 411(b)(4)(D) of Pub. L. 100–360. However, we are exercising some discretion in implementing these provisions as discussed below.

First, section 4005(b) of Pub. L. 100–203 allows the Secretary to define the term "geographic region", and we have defined it as an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients.

Second, we are adding to the definition of "availability date" found in section 4005(b) of Pub. L. 100–203 in order to clarify it. We have defined it to

mean the date that a hospital learns that a SNF bed is available or if the notice is prospective, the date that a SNF bed will become available. The 5 day period begins either on the date that the hospital learns the bed is available or the date the bed becomes available, whichever is later.

We do not believe that these definitions will result in a significant impact. Because this interim rule, with few exceptions, merely conforms our policy to the statute, we have determined that a regulatory flexibility analysis and rural impact statement are not necessary.

V. Other Required Information

A. Interim Final Rule With Comment Period

Section 4039(g) of Pub. L. 100–203 provides that, if necessary, we may issue regulations to implement certain provisions of that law, including the swing bed expansion and other Medicare reforms, on an interim final basis. Congress, in Public Law 100–203, charged the agency with developing and implementing several significant and complex payment reforms. Congress recognized, however, that the agency may not be able both to develop the regulations necessary to implement these reforms and to engage in the time- and resource-consuming process entailed by the usual notice and comment procedure before the effective dates which it prescribed. Indeed, in the case of the modifications to the swing bed program contained in section 4005(b) of Pub. L. 100–203 (enacted December 22, 1987), Congress clearly intended for the Secretary to make use of interim final rules by imposing, in section 4005(b)(4), a March 31, 1988 effective date on the swing bed modifications. The usual notice and comment procedures could not have been completed in the time allowed.

The Secretary believes it necessary to exercise his option, under section 4039(g), to issue these swing bed provisions as an interim final rule in order to provide hospitals with the guidelines needed to participate in the expanded swing bed program, which statutorily became effective on March 31, 1988. The urgency contemplated by Congress in enacting section 4039(g) has not been reduced by the fact that we have been unable to develop and publish these regulations until now. Were we to go through the usual notice and comment process now, we would have to leave the current swing bed guidelines in place. Further, § 1883(d)(2)(A) of the Act, as added by section 4005(b)(2) of Public Law 100–203, requires certain criteria applicable to the expanded swing bed program to be issued by regulation. Therefore, those hospitals most affected by the expanded program (hospitals with between 50 and 100 beds) would be left with no guidelines, particularly with respect to the SNF/hospital availability agreements, to utilize in applying for swing bed participation.

Although this rule is being issued as an interim final rule, we are interested in comments and advice regarding changes that should be made to this issuance. Therefore, we are providing a 60-day comment period for public comment.

B. Response to Comments

Because of the large numbers of items of correspondence we normally receive concerning regulations, we are not able to acknowledge or respond to the comments individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "Date" section of this preamble, and we will respond to the comments in the preamble of that rule.

VI. Information Collection Requirements

Sections 413.114(d)(1)(ii), 482.66(a)(6)(ii), 482.66(a)(7) and 483.80 of this rule contain information collection and reporting requirements that are subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980. An affected hospital must identify and then make an "availability agreement" with SNFs in its area; these SNFs must report availability of SNF beds to hospitals. The hospital must also track swing-bed days as a proportion of "licensed" bed days to prevent improper payment for or transfer of patients to swing-beds. Public reporting burden for this collection of information is estimated to be 1 hour per response. Other organizations and individuals desiring to submit comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden should direct them to the office identified in the **ADDRESS** section of this preamble.

VII. List of Subjects

42 CFR Part 413

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

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

For the reasons set out in the preamble, 42 CFR Chapter IV is amended as set forth below:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Subpart F—Specific Categories of Costs

B. Part 413, Subpart F is amended as follows:

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

Authority: Secs. 1102, 1122, 1814(b), 1815, 1833(a), 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), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.114, the title and paragraphs (a) and (b) are revised; and a new paragraph (d) is added to read as follows:

§ 413.114 Payment for extended care services furnished by a swing-bed hospital.

(a) *Purpose and basis.* This section implements section 1883 of the Act, which provides for payment for extended care services furnished by rural hospitals having a swing-bed approval. Payments to these hospitals for extended care services furnished in general routine inpatient beds are based on the reasonable cost of extended care services, in accordance with paragraph (c) of this section. Swing-bed hospitals approved after March 31, 1988 with more than 49 beds must meet additional payment requirements as set forth in paragraph (d) of this section.

b. *Definitions.* For purposes of this section—"Availability date" means with respect to an extended care patient in a swing-bed hospital, the later of—

(1) Any date on which a bed is available for the patient in a SNF located within the hospital's geographic region;

(2) The date that a hospital learns that a SNF bed is available; or

(3) If the notice is prospective, the date that a SNF bed will become available.

"Geographic region" means an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether a SNF is within a hospital's geographic region or the SNF is inaccessible to hospital patients, the HCFA Regional Office makes a determination.

"Swing-bed hospital" means a hospital participating in Medicare that has an approval from HCFA to provide extended care services as defined in § 409.20 of this chapter, and meets the requirements specified in § 482.66 of this chapter.

* * * * *

(d) *Additional requirements*—(1) *General rule.* Prior to Medicare payment being made to a swing-bed hospital with more than 49 beds (but fewer than 100) the following payment requirements must be met:

(i) If there is an available SNF bed in the geographic region, the extended care patient must be transferred within 5 days (excluding weekends and holidays) of the availability date, unless the patient's physician certifies within the 5-day period that transfer is not medically appropriate.

(ii) The number of patient days for extended care services in a cost reporting period does not exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period. In those States that do not license their hospital beds, the hospitals must use the total number of hospital beds reported on their most recent Certificate of Need (CON), excluding bassinets. If during the cost reporting period, there is an increase or decease in the number of "licensed" beds, the number of "licensed" beds for each part of the period is to be multiplied by the number of days for which that number of "licensed" beds was available. After totalling the results, compute 15 percent of the total available "licensed" bed days to determine the payment limitation.

(2) *Payment restrictions.*

(i) The hospital must not seek payment for extended care services after the end of the 5 day period (excluding weekends and holidays) beginning on the availability date of a SNF bed unless the patient's physician has certified, within that 5 day period, that the transfer of the patient to the SNF was not medically appropriate.

(ii) The hospital must not seek payment for extended care services in a cost reporting period to the extent that they exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the period. In those States that do not license hospital beds, the hospital must use the average number of hospital beds reported on its most recent CON, excluding bassinets.

(3) *Payment exception.* Payment will continue to be made during the cost reporting period in which the 15 percent limit specified in paragraph (d)(1)(ii) of this section is reached for those patients who are receiving extended care services at the time the hospital reaches the limit.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

Subpart B—Physician Certification and Plan of Treatment Requirements

C. Part 424, Subpart B is amended as follows:

1. The authority citation for Part 424 is revised to read as follows:

Authority: Secs. 216(j), 1102, 1814, 1815(c), 1835, 1842(b), 1861, 1866(d), 1870 (e) and (f), 1871, 1872, and 1883(d) of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g(c), 1395n, 1395u(b), 1395x, 1395cc(d), 1395gg, 1395gg(e), 1395gg(f), 1395hh, 1395ii, and 1395tt(d).

2. In § 424.20 paragraphs (a) and (b) are revised to read as follows:

§ 424.20 Requirements for posthospital SNF care.

* * * * *

(a) *Content of certification.*—(1) *General requirements.* (i) 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; and (ii) 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.

(2) *Special requirement: A swing-bed hospital with more than 49 beds (but fewer than 100) that does not transfer a swing-bed patient to a SNF within 5 days of the availability date.* Transfer of the extended care patient to the SNF is not medically appropriate.

(b) *Timing of certification.*—(1) *General rule.* The certification must be obtained at the time of admission or as soon thereafter as is reasonable and practicable.

(2) *Special rules for certain swing-bed hospitals.* For swing-bed hospitals with more than 49 beds that are approved after March 31, 1988, the extended care patient's physician has 5 days (excluding weekends and holidays) beginning on the availability date as defined in § 413.114(b), to certify that the transfer of the extended care patient is not medically appropriate.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart E—Requirements for Specialty Hospitals

D. Part 482, Subpart E is amended as follows:

1. The authority citation for Part 482 continues to read as follows:

Authority: Secs. 1102, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396d(a)).

2. In § 482.66, the section heading is revised; the introductory text is revised; the introductory text for paragraph (a) is revised; paragraph (a)(1) is revised; the semicolons at the end of paragraphs (a)(2) and (a)(3) are removed and periods are added in their place; paragraph (a)(4) is revised; new paragraphs (a)(6) and (a)(7) are added; and paragraph (b) is revised to read as follows:

§ 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the

optional reimbursement method, see § 413.24(d)(5) of this chapter).

* * * * *

(4) The hospital does not have in effect a 24-hour nursing waiver granted under § 405.1910(c).

(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(6) A hospital with more than 49 beds (but fewer than 100) approved under this section after March 31, 1988, must—

(i) Have an availability agreement with SNFs in its geographic region that requires the SNFs to notify the hospital of the availability of extended care beds and the dates when those beds will be available; and

(ii) Transfer the extended care patient within 5 days (excluding weekends and holidays) after learning that a SNF bed is available or in the case of prospective notification by the SNF, within 5 days of the date the bed becomes available, unless the patient's physician certifies, as required under § 424.20, that the transfer is not medically appropriate.

(7) The hospital must provide written assurance to HCFA that the hospital will not operate over 49 or over 99 beds except in connection with a catastrophic event. The hospital bed count is determined as follows:

(i) A hospital bed count is calculated by excluding from the count, beds that because of their special nature such as, newborn and intensive care beds, would not be available for swing-bed use. Also excluded from the bed count are beds in separately certified "distinct part" SNFs and ICFs.

(ii) A hospital licensed for more than 49 or 99 beds, is considered to have the number of beds that it consistently utilizes and staffs. Hospitals, at a minimum, document their count by staffing schedules and census information for the previous 12 months before application to be a swing-bed hospital.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in Subpart D of Part 483 of this chapter.

(1) Patients' rights (§ 483.10(a)(1) and (a)(2), Notice of Rights and Services, § 483.10(b)(1), (b)(3), (b)(4), (b)(5), (b)(6), (b)(7), (b)(9), and (b)(10));

(2) Specialized rehabilitative services (§ 483.45);

(3) Dental services (§ 483.55);

(4) Social services (§ 483.15(g));

(5) Patient activities (§ 483.15(f)); and

(6) Discharge planning (§ 483.20(e)).

PART 483—REQUIREMENTS FOR LONG TERM CARE FACILITIES

Subpart B—Provider Agreements

E. Part 483, Subpart B is amended as follows:

1. The authority citation for Part 483 continues to read as follows:

Authority: Sec. 1102, 1861 (j) and (l), 1863, 1871, 1902(a)(28), and 1905 (a) and (c) of the Social Security Act (42 U.S.C. 1302, 1395x (j) and (l), 1395hh, 1396a(a)(28), and 1396d(c)), unless otherwise noted.

2. A new § 483.80 is added to read as follows:

§ 483.80 Special requirements for skilled nursing facility agreements with swing-bed hospitals.

SNFs must enter, as appropriate, into availability agreements as specified in § 482.66(a)(6) with swing-bed hospitals of more that 49 beds to provide notice that they have available beds and the dates these beds will become available. These agreements are only required for hospitals that are swing-bed hospitals and fall within the SNFs geographic region as defined by § 413.114.

(Catalog of Federal Domestic Assistance Program—Medicare Program: Hospital Insurance—No. 13.744.)

Dated: January 30, 1989.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: April 10, 1989.

Louis W. Sullivan,

Secretary.

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Thursday
September 7, 1989

Part VI

Environmental Protection Agency

40 CFR Parts 180, 185, and 186
Daminozide; Revocation and Amendment of Tolerances and Food Additive Regulations; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP-300202; FRL-3643-1]

Daminozide; Revocation and Amendment of Tolerances and Food Additive Regulations

AGENCY: Environmental Protection Agency ("EPA"; "the Agency").

ACTION: Proposed rule.

SUMMARY: This document proposes (1) the reduction or revocation of all tolerances for combined residues of the plant growth regulatory daminozide, trade name Alar®, Kylar®, B-Nine®, in or on all raw agricultural commodities; (2) the revocation of daminozide food/feed additive regulations for processed foods and animal feed; and (3) the establishment of expiration dates for all tolerances not revoked as of the date this rule becomes final. These proposed actions are being initiated because the Agency has determined that long term dietary exposure to daminozide and unsymmetrical dimethyl hydrazine (UDMH), a degradate and metabolite of daminozide, poses unacceptable risks to the general population.

The proposed effective dates of the tolerance revocation will vary by crop with several tolerances being revoked as of about November 30, 1989, and other tolerances being reduced as of that date and revoked by May 31, 1991. The proposed effective date of the revocation of the food/feed additive regulations is November 30, 1989, the date this proposed action is expected to be issued as a final action.

DATES: Written comments, identified by the document control number OPP-300202, must be received on or before October 23, 1989.

ADDRESS: By mail, submit comments to:

Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

In person, deliver comments to: Rm. 246, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 246 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

By mail: Lisa Engstrom, Special Review and Reregistration Division (H7508C), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Office location and telephone number: Special Review Branch, Room 1020, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703)-557-7400.

SUPPLEMENTARY INFORMATION:

I. Introduction

EPA is proposing to revoke all tolerances and food additive regulations under sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for the plant growth regulator daminozide (butanedioic acid mono (2,2-dimethylhydrazide)). For several food uses of daminozide, the tolerance will be reduced for an interim period prior to the date of final revocation.

II. Legal Background

The Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 301 *et seq.*), authorizes the establishment of tolerances and exemptions from tolerances for residues of pesticide chemicals in or on raw agricultural commodities pursuant to section 408, and the promulgation of food additive regulations for pesticide residues in processed food under section 409 of that Act (21 U.S.C. 346(a), 348). Under the Reorganization Plan, No. 3 of 1970, 4 Stat. 3086, which established EPA, the authority to set tolerances for pesticide chemicals in raw agricultural commodities and processed food under sections 408 and 409 of the FFDCA was transferred from the Food and Drug Administration (FDA) to EPA. The FDA retains the authority to enforce the tolerance and food additive provisions under this Plan.

Without such tolerances, exemptions from tolerances, or food additive regulations (sometimes also referred to as "tolerances"), a food containing pesticide residues is "adulterated" under section 402 of the FFDCA, and hence may not legally be moved in interstate commerce (21 U.S.C. 346a(a), 348(a)). Pursuant to section 402(a)(2)(C) of the FFDCA, a food additive regulation must be established for processed food if the pesticide residue in the processed food is greater than the tolerance prescribed for the raw agricultural commodity. Where, however, the pesticide residues in the processed food resulting from treatment of the raw agricultural commodity do not exceed the tolerance level established for the raw agricultural commodity, a separate food additive regulation is not necessary (21 U.S.C. 342(a)(2)(C)).

To establish a tolerance or an exemption under section 408 of FFDCA, the Agency must make a finding that the promulgation of the rule would "protect the public health" (21 U.S.C. 346a(b)). In reaching this determination, the Agency is directed to consider, among other relevant factors: (a) The necessity for the production of an adequate, wholesome and economical food supply; (b) other ways in which the consumer may be affected by the pesticide; and (c) the usefulness of the pesticide for which a tolerance is sought. Thus, in essence, section 408 of the FFDCA gives the Agency the authority to balance risks against benefits in determining appropriate tolerance levels. The Agency is permitted to set a tolerance at zero "if the scientific data before the Administrator does not justify the establishment of a greater tolerance" (21 U.S.C. 346a(b)).

The establishment of a food additive regulation under section 409 requires a finding that use of the pesticide will be "safe" (21 U.S.C. 348(c)(3)). Relevant factors in this safety determination include: (1) the probable consumption of the pesticide or its metabolites; (2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; and (3) appropriate safety factors to relate the animal data to the human risk evaluation. Section 409 contains the Delaney Clause, which specifically provides that, with very limited exceptions, no additive is deemed safe if it induces cancer when ingested by man or animals. *Id.*

Under sections 408 and 409 of the FFDCA, the proponent of a tolerance or a food additive regulation has the burden of providing data establishing the safety of the pesticide for which a tolerance (or food additive regulation) is sought (21 U.S.C. 346a(d)(1), 348(b)(2)). As noted by both the House and Senate reports:

> Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide chemical is safe from the standpoint of the consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.

H.R. Rep. No. 1385, 83d Cong., 2d Sess. at 5 (1954); S. Rep. No. 1635, 83d Cong., 2d Sess. at 4 (1954). Once a tolerance (or food additive regulation) has been established, the burden of justifying the continued safety of the pesticide residues authorized by the rule remains with the proponent of such rule (*Environmental Defense Fund* v. *Department of Health, Education and Welfare*, 428 F.2d 1083, 1092 n. 27 (DC Cir. 1970)).

For a pesticide to be sold and used in the production of a crop or an animal, the pesticide must not only have appropriate tolerances under the FFDCA but must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 *et seq.*). FIFRA requires the registration of all pesticides which are sold and distributed in the United States. The statutory standard for registration is that, among other things, the pesticide performs its intended function without causing "unreasonable adverse effects on the environment (including people)" (7 U.S.C. 136a(c)(5)). Under section 6 of FIFRA, EPA may cancel the registration for a use of a pesticide or modify the terms and conditions of registration whenever it determines that the use of the pesticide no longer satisfies the statutory standard for registration (7 U.S.C. 136d(b)).

III. Regulatory Background

Daminozide is the accepted common name for butanedioic acid mono (2,2-dimethylhydrazide). It was first registered as a pesticide under FIFRA in 1963 by the Uniroyal Chemical Company. Uniroyal registered daminozide under the trade name Alar. Daminozide is currently registered for use on a variety of crops as a plant growth regulator to control vegetative and reproductive growth of orchard crops such as apples, cherries, nectarines, peaches and pears. Daminozide affects flower bud initiation, fruit set and maturity, fruit firmness and coloring, preharvest fruit drop and the market quality of fruit at harvest and during storage, while delaying the onset of water core. Daminozide is also used to encourage shorter and more erect peanut vines, to retard stem growth in tomato transplants, and to modify the stem length and shape of ornamental plants.

All daminozide tolerances for raw agricultural commodities issued under section 408 are listed in the following Table 1:

TABLE 1—DAMINOZIDE TOLERANCES

Commodity	CFR Sec.	ppm
Apples	180.246	20.0
Cattle, Fat	180.246	0.2
Cattle, Meat Byproducts	180.246	0.2
Cattle, Meat	180.246	0.2
Cherries, Sour	180.246	55.0
Cherries, Sweet	180.246	30.0
Eggs	180.246	0.2
Goats, Fat	180.246	0.2
Goats, Meat Byproducts	180.246	0.2
Goats, Meat	180.246	0.2
Grapes	180.246	10.0
Hogs, Fat	180.246	0.2
Hogs, Meat Byproducts	180.246	0.2
Hogs, Meat	180.246	0.2
Horses, Fat	180.246	0.2
Horses, Meat Byproducts	180.246	0.2
Horses, Meat	180.246	0.2
Milk	180.246	0.02
Nectarines	180.246	30.0
Peaches	180.246	30.0
Peanuts	180.246	30.0
Peanuts, Hay	180.246	20.0
Peanuts, Hulls	180.246	10.0
Pears	180.246	20.0
Poultry, Fat	180.246	0.2
Poultry, Kidney	180.246	0.2
Poultry, Meat Byproducts (Exlcuding Kidney)	180.246	0.2
Poultry, Meat	180.246	0.2
Sheep, Fat	180.246	0.2
Sheep, Meat Byproducts	180.246	0.2
Sheep, Meat	180.246	0.2
Tomatoes	180.246	0.5

Established food and feed additive regulations under section 409 for daminozide are listed in the following Table 2:

TABLE 2—SECTION 409 FOOD AND FEED ADDITIVE REGULATIONS

Commodity	CFR Sec.	ppm
Peanuts, Meal	186.1550	90.0
Tomatoes, Concentrated Products.	185.1550	3.0
Tomatoes, Pomace (Dried).	186.1550	10.0

On July 18, 1984, EPA issued a Notice of Special Review of daminozide (49 FR 29186) based on carcinogenic concerns for both daminozide and UDMH. In September 1985 EPA submitted a Draft Preliminary/Final Determination (PD 2/3/4) and a Draft Cancellation Notice to the FIFRA Scientific Advisory Panel (SAP) and U.S. Department of Agriculture, as required by FIFRA. The SAP believed that the animal cancer studies relied upon by EPA in its risk determination were insufficient to allow a quantitative risk assessment for either daminozide or UDMH. Although EPA is not bound by the SAP's opinion, EPA concluded that, in this case, it should not proceed with the cancellation but should instead require more data and take steps to reduce daminozide/UDMH exposure in the interim.

At that time, the Agency lowered the daminozide tolerance for apples from 30 parts per million (ppm) to 20 ppm. EPA set the tolerance to expire on July 31, 1987, in the belief that some of the residue and market basket survey data to be generated would be available by then, and that a further evaluation of the tolerance could be undertaken at that time. Data available in July 1987 showed that the apple tolerance could not be lowered without potentially making some legally treated apples over tolerance and subject to seizure. Thus, the 20 ppm tolerance was extended to January 31, 1989, at which time the tolerance was to be reevaluated in light of new cancer data on daminozide and UDMH.

In January 1989, the Agency estimated the risk of daminozide use based on interim results from a 2-year mouse study using UDMH. Although the Agency found that the interim results were sufficient for a quantitative risk assessment, the Agency noted that there were limitations in the data base. Those limitations included the fact that the study results were interim and thus actual tumor response over a lifetime was not known; a carcinogenic response had only been identified in a single species; and that mice in the study were dying early at the highest dose tested which was the only dose at which a statistically significant response was observed. The quantitative risk assessment estimated the theoretical upper bound lifetime risk for the general population at 4.5×10^{-5}.

The Agency believed this lifetime risk to be unreasonable, and therefore, made plans to cancel the registration of daminozide. In light of the time required to carry out cancellation procedures, on February 10, 1989, EPA extended the 20 ppm apple tolerance for an additional 18 months (hereinafter referred to as the "February 1989 tolerance extension", 54 FR 6392). The extension was granted because EPA found that the available data indicated the risk posed by the extension was acceptable. Nonetheless, the Agency noted that the risk was of sufficient concern that it would move quickly toward cancellation under FIFRA of daminozide's registration.

On May 24, 1989, EPA issued a Preliminary Determination and Draft Cancellation Notice that proposed the cancellation of the food crop use registrations of daminozide under FIFRA (54 FR 22558). The cancellation proposal relied on the same mouse study cited in the February tolerance extension document in estimating the risk posed

by daminozide. The lifetime risk for the general population was estimated to be 4.9×10^{-5}. The Agency concluded that this risk exceeds the benefits of daminozide and thus cancellation under FIFRA was appropriate.

The risk numbers calculated in the cancellation notice varied from the February 1989 tolerance extension document (4.9×10^{-5} compared to 4.5×10^{-5}) because of two factors. First, the risk was decreased by a correction of the exposure values; exposure values had been slightly overestimated for processed foods. Second, the risk was increased on the basis of metabolism studies showing that daminozide is converted to UDMH in the digestive system. The earlier risk calculations had not taken this factor into account.

In May 1989, the Agency also received new data concerning daminozide. First, Uniroyal provided preliminary information on oncogenicity from a recently completed 2-year UDMH drinking water study in rats. In that study, significant dose-related trends were seen for hepatocellular carcinomas and combined hepatocellular carcinomas/adenomas. Second, the Agency also received monitoring data for fresh apples and processed apple commodities from several private and State organizations. Only levels of daminozide residues were reported; samples were not generally tested for UDMH residues. In general, the results of the monitoring data indicate that average daminozide residues are currently found at levels equal to or less than 1 ppm in fresh apples. Average levels of daminozide residues in processed apple commodities were found to be considerably less than 1 ppm. Although the methods of analysis used for determining the levels of residues differed in sensitivity, the Agency believes these data corroborate the applicable data sets in the 1986 market basket survey as well as EPA's estimate that usage has dropped since the time of the survey. This survey provided much of the exposure data used to estimate risks in the Agency's risk assessments.

IV. Current Proposal

A. Timing of the Current Proposal

It is generally EPA policy not to revoke pesticide tolerances under the FFDCA prior to cancellation of the registration under FIFRA (47 FR 42956; Sept. 29, 1982). The Agency's policy attempts to coordinate action under the two statutory authorities in a logical manner by ensuring that pesticides which may be legally sold, distributed, and used under FIFRA do not result in crops which are adulterated under FFDCA. The Agency believes that coordinating action under the two statutes is important for providing fair notice to growers on what pesticides they may use without the possibility of incurring legal sanctions.

In the February 1989 tolerance extension, EPA indicated that it would not take immediate action under the FFDCA citing its above-mentioned policy. Since the tolerance extension was published, however, a number of events have occurred which when considered in combination, suggest that continuing to adhere to the policy for the daminozide tolerances is unnecessary to fulfill the policy's goal of fair notice to growers. First, early in June, Uniroyal Chemical Co., Inc. of Bethany, Connecticut, the sole manufacturer of daminozide products registered for food uses, signed a formal agreement with EPA to immediately stop sales and recall all stocks of food use daminozide products including those held by users. Second, an apple industry trade association has publicly recommended that growers cease use of daminozide. Finally, EPA has provided notice at apple grower and trade association meetings that EPA would be proposing to significantly lower tolerances this summer.

Accordingly, because growers have been advised by both private and public sources not to use daminozide, and of their potential jeopardy if they do use it, as well as provided with the opportunity to return any purchased daminozide for a full refund, the Agency considers the present situation sufficiently analogous to a final cancellation action that consideration of the revocation of the daminozide tolerances at the present time is appropriate.

The Agency also believes it is important to consider revocation at this point because of the confirmatory data received recently regarding the carcinogenic risks of UDMH. First, EPA has received preliminary (unaudited) tumor data on the final results of the 2-year rat study which shows that UDMH is associated with an increased number of liver tumors at levels which do not appear to have excessive toxicity. With submission of the preliminary rat data, EPA now has evidence in two species of tumor response in studies that meet the current protocols. The results of the rat study are an important factor in the Agency's weight-of-the-evidence test for assessing the carcinogenicity of UDMH. Second, in mid-July, the Agency also received preliminary unaudited results of the 2-year "low dose" UDMH cancer study in mice. The report showed an increase in combined lung adenomas and carcinomas in female mice. Although this report adds to the qualitative evidence supporting UDMH's carcinogenicity, its usefulness in quantitatively characterizing UDMH risk can be determined only after the full report is received in September 1989.

B. Revocation

There are currently tolerances for daminozide under both section 408 and section 409. Under section 408, a pesticide tolerance may be approved if it "protects the public health." The statute requires consideration of a number of factors including the "necessity for the production of an adequate, wholesome, and economical food supply" (Section 408(b)). Thus, EPA must balance risks and benefits in assessing whether a tolerance "protects the public health." Under section 409, a pesticide tolerance may only be approved if use of the pesticide is "safe" (21 U.S.C. 348(c)).

In applying these standards, the Agency is relying on the analysis contained in the Preliminary Determination and Draft Cancellation Notice on Daminozide (54 FR 22558) and the Daminozide Special Review Technical Support Document. Copies of the Technical Support Document are available from the contact person listed under **"FOR FURTHER INFORMATION CONTACT"** above. A summary of the risk/benefit analysis from those documents is provided below.

1. *Risk considerations.* The Agency evaluated the Uniroyal data submitted in the last year in conjunction with the previously considered data on daminozide and UDMH in a weight-of-the-evidence determination. Based on this evaluation both daminozide and UDMH were classified as B2 chemicals, probable human carcinogens. In both the earlier studies and the new Uniroyal studies, daminozide produced vascular and lung tumors in mice. In the more recent Uniroyal mouse study, daminozide showed a statistically significant increase in hemangiomas/hemangiosarcomas with increasing dose (Cochran Armitage trend analysis), but not by pairwise comparison (Fischer's exact test—a statistical comparison of control and treated animals). A dose-related trend for lung tumors was also seen in male mice. The Agency believes the new data, supported by the occurrence of similar tumors in the earlier daminozide studies, are sufficient to classify daminozide as a probable human carcinogen. However, the Agency also believes the oncogenic response seen in the daminozide studies

is likely caused by the presence of UDMH in the test material and/or metabolic conversion to UDMH.

Vascular and lung tumors seen in the historical UDMH data were also seen in the 1-year interim sacrifice in mice from the new Uniroyal study at 80 and 40 ppm. The increase in vascular tumors at 80 ppm was statistically significant by pairwise comparison and trend analysis. UDMH has produced a clear oncogenic response in mice at the highest dose tested and the Agency anticipates that an increase in vascular tumors will also be seen at the lower dose at terminal sacrifice (the 40 ppm dose showed one hemangioma in both a male and female mouse at the 1-year interim sacrifice).

The Agency used data from a 1986 market basket survey, recent crop field trial data, and recently conducted animal feeding studies to estimate exposure for both daminozide and UDMH. From the interim sacrifice report of the UDMH mouse cancer study, the Agency calculated an interim carcinogenic potency factor based on the incidence of hemangiosarcomas (malignant vascular tumors) and combined hemangiomas/hemangiosarcomas of the liver. Based upon this information, the Agency estimated the lifetime risk of cancer for the general population due to dietary exposure to UDMH to be 4.9×10^{-5}. The agency is particularly concerned that a disproportionate share of the lifetime risk occurs from childhood exposure because of the high ratio of food intake per unit bodyweight and the relatively high proportion of a child's diet that is composed of foods which may contain daminozide and UDMH residues. The lifetime risk to non-nursing infants (0 to 1 year of age), the highest exposure group, from one year exposure to UDMH is estimated to be approximately 6×10^{-6}. The estimates for children are based on the same potency factor as used for adults.

Because UDMH as well as daminozide residues are considered in this document for assessing risk, it is important to note that the analytical method used to test for daminozide residues converts the parent daminozide compound to UDMH for quantitation. Thus, both daminozide and UDMH residues are determined and reported as daminozide residues.

2. *Benefits summary.* The benefits from daminozide use have been assessed in terms of economic impacts which would result if the registered uses of daminozide were cancelled. In assessing benefits, the Agency considered usage information from 1985 and 1988. The Agency concluded the overall impacts from cancellation of daminozide on food uses would be insignificant to minor. Although there are alternatives for some of daminozide's uses, no one alternative chemical provides all the benefits of daminozide. For food uses, the greatest anticipated annual impacts would be in apple production. Estimates of the economic impact on the apple industry are based on 10 percent (range of 5 to 15 percent) of the crop treated. Earlier estimates made in conjunction with the apple tolerance extension document of January 31, 1989, used a 4 to 8 percent annual crop treatment. The higher estimate (5 to 15 percent) in the PD 2/3 is a result of additional and more in-depth information gathered since the February tolerance document.

Based on 1988 usage data, impacts on the apple use, in terms of net social cost for the whole of society, could range from $18 to $81 million with the most likely impact approaching the lower end of this range. Growers of Stayman and McIntosh varieties would suffer the greatest individual impact. For other food uses, the annual impacts are anticipated to be approximately $1.5 to $5.5 million for peaches, approximately $260,000 for peanuts, and negligible impacts for nectarines, cherries, grapes, and pears.

3. *New information.* As discussed above, Uniroyal has recently submitted preliminary oncogenicity findings of a 2-year UDMH drinking water study in rats. In this study, male and female Fischer 344 rats were fed drinking water containing 0, 1, 50, and 100 ppm UDMH for 2 years. The data submitted showed that UDMH caused increased incidence of combined hepatocellular carcinomas and adenomas (malignant and benign liver tumors, respectively) and hepatocellular carcinomas in female rats at 50 and 100 ppm. Although the tumor increases were not significant by Fischer's exact test (pairwise comparison of control and treated animals), significant dose-related trends were seen for hepatocellular carcinomas and combined hepatocellular carcinomas/adenomas by Cochran Armitage trend analysis. The Agency believes these conclusions are important because the historical incidence of hepatocellular cancer in female Fischer rats at the contract laboratory which conducted the study is extremely low (2 hepatocellular adenomas out of 370 total control female Fischer rats or 0.5 percent). The incidence of liver tumors in treated males were similar to that of the control groups and are not considered to be statistically significant.

The recently received preliminary report on the results of the 2-year "low dose" (highest dose tested was 20 ppm in female mice, 10 ppm in male mice) UDMH cancer study in mice showed an increase in combined lung adenomas and carcinomas in female mice. Although these results are too preliminary for use in quantitative analysis, the results do provide further quantitative evidence supporting UDMH's carcinogenicity.

4. *Conclusion.* Based on all the data and information considered by the Agency, EPA has concluded that the daminozide tolerances do not protect the public health, taking into account, among other things, the necessity for the production of an adequate, wholesome, and economical food supply. As to the food/feed additive regulations, the Agency has concluded that these regulations do not meet the statutory standard for safe use.

C. Timing of Revocation

Although revocation of the daminozide tolerances will not be delayed until cancellation under FIFRA is final, EPA believes it is appropriate under the FFDCA to implement the revocation in a manner which minimizes disruption in the food market place to the extent that such a manner of implementation is not outweighted by the risks.

The Agency considered two options regarding the timing of the revocation.

1. Revocation of all tolerances effective immediately upon issuance of the final rule with no provision for residues from prior use. (EPA estimates that today's proposal will be made final November 30, 1989, and that date is used throughout as the projected effective date for estimating the risk posed by both of the options.)

2. A phased approach which reduces and eventually revokes tolerances as residues resulting from legal applications prior to this Summer clear the market.

The risks posed by both of these options, as well as a more detailed description of Option Two, are set forth below.

The risks posed by each option are calculated on the Agency's best estimates of the actual daminozide/UDMH exposure based on data from the Uniroyal market basket survey conducted in 1986 and crop residue studies. The Agency believes it is appropriate to calculate risk based on actual and estimated average residue levels rather than the tolerance amount for a number of reasons. First, EPA has an unusually complete data base on residue levels that reflect market basket residues. Basing risk computations on the tolerance level would thus overstate

the risk. Second, the residue levels estimated for the tolerance reduction period which this proposal would cover are for relatively short windows in time during which average residues of daminozide are unlikely to increase and in fact will probably decline further. Moreover, a number of external events (media attention to the risks of daminozide use, the apple industry trade association's recommendations against further use of daminozide, and Uniroyal's June 1989 agreement to halt sales of daminozide and recall existing stocks), while not assuring decreased exposure, probably dictate that average residues will not increase. It is unlikely, therefore, that use of actual levels will understate the risk. In fact, given EPA's current usage estimates, using actual residue levels from 1986 may overstate risk.

The Agency estimated daminozide/UDMH dietary exposure and risk for the duration of the reduced tolerance levels for the general population and the highest exposure group, non-nursing infants. The Agency estimated the lifetime dietary risks on the interim results seen in the UDMH cancer study in mice. Risks were calculated by multiplying the UDMH dietary exposure by the interim cancer potency factor (Q^*_1) for UDMH, 0.88 $(mg/kg/day)^{-1}$, and then multiplying by the period of time the tolerance would be in effect.

1. *Option One.* Option One is immediate revocation upon the date this proposed rule becomes final (estimated to be November 30, 1989). Immediate revocation should reduce exposure to daminozide to below the level of detection because all commodities above that level would be subject to seizure. Thus, all measurable risk would be eliminated. On the other hand, immediate revocation could result in a major disruption of the food market by making large numbers of legally-treated crops, particularly apples, subject to seizure. Even growers who stopped using daminozide after the 1988 season could have crops subject to seizure since daminozide's persistence may result in a significant number of commodities (and therefore processed apple products) containing detectable amounts of daminozide from previous years' treatments. The possibility for significant disruption is reflected in the results of the market basket survey conducted by Uniroyal. That study found that 56 percent of the apples and 83 percent of the processed apple products (juice and sauce) sampled contained detectable levels of daminozide. (Technical Support Document II-23 (Table 5)).

2. *Option Two.* Option Two is a phased approach which attempts to minimize making crops which were legally treated with daminozide prior to this summer subject to seizure. The timing of the reduction and revocation for each of the daminozide tolerances under this approach is discussed below. EPA has established these dates listed below based on information available to the agency on the periods of time treated crops remain in commerce either as fresh or processed commodities. EPA specifically requests comments on whether these dates are appropriate.

a. *Apples.* The Agency is proposing to lower the tolerance on apples from the current 20 ppm to 5 ppm for the period November 30, 1989 to November 30, 1990. For the following 6 months, from November 30, 1990 to May 31, 1991, the tolerance would be lowered to 1 ppm. On May 31, 1991, the tolerance would be revoked.

Treatment of apple trees with daminozide usually occurs in the Spring and Summer of the growing season. Fresh apples, harvested in the Fall, may be available for up to a year. Residues in processed apple products (juice and sauce) may be present for longer periods as such products work their way through channels of trade.

Residue data on apples from crop field trials show that most apples treated in the Spring will have residues at harvest of 5 ppm or below. Available data for most apples treated in the Summer show that residues at harvest are 10 ppm or below. EPA believes ample notice has been given to users by Agency officials at apple grower and trade association meetings that EPA would be proposing to significantly lower tolerances this summer, and that growers who did apply this summer may have crops at harvest which could be over impending lower tolerance levels. In addition, there has been informal broad-based support from growers and processors to take action on lowering the tolerance as soon as possible.

Under this Option, EPA would amend the current 20 ppm tolerance, which expires on July 31, 1990, by reducing it to 5 ppm effective November 30, 1989. The 5 ppm apple tolerance would then be lowered to 1 ppm on November 30, 1990. The 1 ppm tolerance would be in effect until May 31, 1991, and would provide tolerance coverage for fresh apple residues found in the 1990 harvest resulting from residue carryover in trees treated in the Spring of 1989. The Agency also believes any processed apple juice and sauce commodities (which should include few treated apples) made from the 1989 harvest will have cleared the marketplace by May 31, 1991 and thus will be covered by the 1 ppm tolerance.

Dietary exposure to UDMH through the consumption of apples and apple products was estimated based on the results of the 1986 market basket survey. In order to estimate the impact of the proposed 5 ppm and 1 ppm tolerances on UDMH exposure, the Agency first found the average daminozide and UDMH levels in all of the samples for the survey. The Agency then estimated UDMH exposures based on sub-samples that reflect the levels of daminozide and UDMH in the market place if the proposed tolerances are assumed. Average daminozide residues for all fresh apples found in the market basket study was 1 ppm. The average UDMH residue in these same fresh apples was 2.6 part per billion (ppb). The Agency next considered the average level of daminozide only for those samples in the survey that were less than 5 ppm to estimate the average level of daminozide if the proposed 5 ppm tolerance were in effect. The average daminozide value in the market basket survey, excluding all samples greater than 5 ppm, was 0.8 ppm. The percentage of this decline in average residue values for daminozide (20 percent), was used to estimate UDMH residues for apples as well as all apple products (adult and baby sauce and juice, dried and cooked apples) under a 5 ppm tolerance. The resultant UDMH values were used to calculate dietary exposure for the period November 30, 1989 to November 30, 1990. For the next 6 months, November 30, 1990 to May 31, 1991, a similar process for estimating UDMH residues was used. The average daminozide residues for fresh apples, excluding all values greater than 1 ppm was 0.2 ppm. The percentage of the decline in daminozide levels (80 percent) was then used to estimate the UDMH residues for all fresh apple and apple products for the 6-month period from November 30, 1990 to May 31, 1991.

A summary of average daminozide residue values used to calculate exposure for apple and apple products is presented in the following Table 3:

TABLE 3—ESTIMATES OF AVERAGE DAMINOZIDE LEVELS (IN PPM) AT THE 5 PPM AND 1 PPM TOLERANCE LEVELS

Commodity	MBS [1]	5 ppm	1ppm
apples, fresh	1.0	0.8	0.2
apple juice, baby	0.5	0.4	0.1
apple juice, adult	0.4	0.3	0.1
apple sauce, baby	0.5	0.4	0.1
apple sauce, adult	0.4	0.3	0.1
dried raw apples [2]	1.0	0.8	0.2

Commodity	MBS [1]	5 ppm	1ppm
dried cooked apples [2]	0.5	0.4	0.1

[1] = market basket survey
[2] = dried apple products were then multiplied by an 8-fold concentration factor to determine residue for exposure estimates.

A summary of the estimated average UDMH residue levels used to calculate exposure for apple and apple products is presented in the following Table 4:

TABLE 4—ESTIMATES OF AVERAGE UDMH LEVELS (IN PPB) AT THE 5 PPM AND 1 PPM DAMINOZIDE TOLERANCE LEVELS

Commodity	MBS [1]	Daminozide levels	
		5 ppm	1 ppm
apples, fresh	2.6	2.1	0.5
apple juice, baby	33.3	26.6	6.7
apple juice, adult	14.0	11.2	2.8
apple sauce, baby	44.0	35.2	8.8
apple sauce, adult	23.9	19.1	4.8
dried raw apples [2]	20.8	16.6	4.2
dried cooked apples [2]	352.0	282.0	70.4

[1] = market basket survey
[2] = dried apple products include an 8-fold concentration factor.

Carcinogenic risk from dietary exposure to UDMH was then estimated for the 18-months' exposure under these reduced tolerances to the general population and non-nursing infants, the highest exposure group, utilizing food consumption patterns from a nationwide survey conducted by the U.S. Department of Agriculture (USDA) (White et al., *Interim Report # 1: The Construction of a Raw Agricultural Commodity Consumption Data Base*, Research Triangle Institute, 1983). The average exposure to UDMH for the general population under these reduced tolerances for 18 months is 0.009199 micrograms(μg)/ kilograms(kg)/day and the lifetime risk (i.e., any cancer response could occur at any point in the person's lifetime) is 1.7×10^{-7}. For non-nursing infants, the exposure to UDMH under these reduced tolerances for 18 months is 0.158046 μg/kg/day and the lifetime risk is 3.0×10^{-6}.

EPA's best estimate of the percent of crop treated (5 to 15 percent) is less that at the time of the market basket survey (24 percent). This estimated reduced use would result in about 40 to 80 percent lower exposure. Since usage and exposure today is probably less than the market basket survey, the risk estimation for the phaseout, based on the market basket survey probably overstates current risk. Reduced usage tends to be corroborated by some recent independent surveys, such as the one by Consumer's Union, which showed a range of daminozide values in apples of 0.1 to 2.3 ppm and average daminozide values in juice of 0.11 ppm. These estimates are significantly less than the average residues from the market basket survey (0.1 to 12.0 ppm for apples and 0.5 ppm for juice). However, in one survey average daminozide residues in apples were slightly greater than the 1.0 ppm average residue found in the market basket survey.

Unlike the market basket survey, none of the recent studies was statistically designed. Many of the surveys contained just a few samples and the limit of detection varied from study to study. Furthermore, none of the independent surveys measured for UDMH, the degradate on which the Agency's assessment is based. For these reasons, EPA has used the market basket survey acknowledging that it is a likely overestimate of interim risk.

b. *Peanuts.* The Agency is proposing to lower the tolerance on peanuts to 4 ppm until May 31, 1991. The feed additive regulation on peanut meal and the tolerances on peanut hull and hay will be revoked effective November 30, 1989.

Peanut plants are generally treated with daminozide in July and August of the growing season, although wetter than normal conditions in the Eastern United States this year may have resulted in some earlier treatments. Following harvest, roasted peanuts and peanut products may remain in channels of trade for more than a year. However, the major brands of peanut butter, the primary processed product, sold at major grocery stores usually clear the market in a month or two. The market basket survey data showed residues in roasted peanuts ranging from 0.01 to 4.43 ppm daminozide. Even though there may have been some treatments prior to this Notice, the Agency believes the market basket survey data for roasted peanuts could be used to set a level of raw peanuts. Thus, under option Two the tolerance for daminozide residues on peanuts would be reduced to 4 ppm and remain in place until May 31, 1991. The 4 ppm tolerance will cover any raw peanuts treated early in 1989 and any processed product that may remain in channels of trade.

A feed additive regulation for peanut meal (90 ppm), and tolerances for peanut hulls (10 ppm), and peanut hay (20 ppm) have also been established. Although it is not clear how long these food and feed items remain in the channels of trade, the Agency believes they should clear the market rather quickly. Therefore, the Agency is proposing that the feed additive regulation for peanut meal, and the tolerances for peanut hay, and peanut hulls be revoked effective November 30, 1989.

For purposes of estimating dietary exposure during the pendency of the peanut tolerance, the Agency did not adjust the peanut, peanut butter or peanut oil residue levels downward based on the reduced tolerance levels as was done for apples. The Agency did not make these adjustments because the risk from peanut commodities is very small. The Agency utilized the same UDMH residue levels (24.9 ppb for each) used in the Technical Support Document; these consequently are likely to represent overestimates of exposure. Total UDMH exposure from peanut and peanut products to the general population for the 18-month period under Option Two was estimated to be 0.001862 μg/kg/day with a risk of 3.5×10^{-6}. Non-nursing infants would have an estimated exposure of 0.000730 μg/kg/day with a resultant risk of 1.4×10^{-6} for the 18-month period.

c. *Sweet and sour cherries.* The Agency is proposing to lower the tolerance for sweet cherries from 30 ppm to 15 ppm; for sour cherries, the tolerance would be lowered from 55 ppm to 15 ppm. Both of these tolerances would be effective from November 30, 1989 to May 31, 1991.

Both sweet and sour cherries are treated with daminozide in the Spring of the growing season. Sweet cherries are usually consumed within a short time after harvest, although small amounts may be processed. Field trial data support reducing the sweet cherry tolerance to 15 ppm from 30 ppm on November 30, 1989. Thus, under Option Two a 15 ppm tolerance for sweet cherries would be effective from November 30, 1989 to May 31, 1991. This would allow cherries legally treated this Spring to be marketed without threat of seizure and would cover any processed sweet cherry products.

Although sour cherries are used primarily for processing and, therefore, remain in channels of trade for some time, the Agency believes the tolerance could be reduced to 15 ppm from 55 ppm (based on market basket survey results) without making any legally treated cherries subject to seizure. Under this Option, the Agency would propose that the tolerance for daminozide residues on sour cherries be reduced to 15 ppm and remain in place until May 31, 1991, in order to cover any residues in processed items such as cherry pie filling.

Most of the UDMH dietary contribution from cherries comes from cherry filling and juice (more than 90

percent based on market basket survey data). Although reduced levels of UDMH residue could be expected from the lower tolerances, the Agency relied on the values used in the Technical Support Document for processed cherries to calculate dietary risk. The Agency did not make downward adjustments based on the reduced tolerances for reduced residue levels (as was done for residues in apple commodities) because the risk from sweet and sour cherry commodities is likely to be very small. The risk from 18-months' dietary exposure to UDMH residues in cherry products was estimated assuming no exposure to raw cherries. Total UDMH dietary exposure from cherries to the general population for the 18-month period was estimated to be 0.002847 $\mu g/kg/day$ with a resultant risk of 5.4×10^{-8}. Non-nursing infants will have an estimated exposure of 0.008627 $\mu g/kg/day$ with a resultant risk of 1.6×10^{-7} for the 18-month period.

d. *Grapes, peaches, pears and nectarines.* The Agency has only field trial data for the commodities grapes, peaches, pears and nectarines on which to base proposed tolerance reductions. Usage information indicates that historically very little daminozide has been used on these commodities and use in the last year has been almost nil. Crop field trial data indicate that daminozide tolerances can be reduced in November 1989 by approximately 75 percent without posing the risk of seizure to any crop treated in the Spring of 1989. To allow for the minimal use that may have occurred in 1989, the Agency is proposing that the tolerances for these commodities be reduced to the following levels with an expiration date of May 31, 1991:

Grapes—2.5 ppm
Pears—5 ppm
Peaches—7.5 ppm
Nectarines—7.5 ppm.

In estimating the dietary risk associated with these reduced tolerances, the Agency assumed that there will be no dietary exposure to UDMH residues in domestic fresh commodities after November 1989 since no treated fresh fruit would remain in commerce after that date and no carryover residue from prior years' treatment are expected. Because of a lack of data, the Agency did not reduce in its risk calculation the expected UDMH residue levels in the processed forms of these commodities and the values used (canned pears (11.9 ppb), canned peaches (21.3 ppb), grapes juice and preserves (0.2 ppb)) are the same as those in the Daminozide Technical Support Document. Thus, the actual dietary exposure and risk is likely to be lower. Combined dietary risk from exposure to processed products containing these four commodities for the duration of the reduced tolerance would be 10^{-7} to 10^{-8} for the general population and non-nursing infants.

e. *Tomatoes.* The Agency is proposing to revoke the tolerance for fresh tomatoes, which is 0.5 ppm, effective November 30, 1989. In addition, the food and feed additive regulations which currently exist for processed tomato products and dried tomato pomace (3.0 ppm and 10 ppm, respectively) will be revoked at the same time.

Daminozide is registered for use only on tomato transplants. The Agency's usage information indicates that only tomato transplants which are intended for the homeowner market are treated. Thus, it is very unlikely that there will be daminozide-UDMH exposure from tomato pomace used as animal feed. Although there may be exposure to homeowners who can or process their own tomatoes, a tolerance or food additive regulation is not necessary after the 1989 growing season is completed. Therefore, under Option Two the existing tolerance for raw tomatoes as well as the food additive regulation for processed tomato products and feed additive regulation for tomato pomace would be revoked effective November 30, 1989.

No dietary exposure or carcinogenic risk related to UDMH residues in tomatoes, tomato products, or tomato pomace was estimated since under Option Two the tolerance would be revoked in November.

f. *Meat, milk, eggs and meat by-products.* Under Option Two, the Agency is proposing to revoke the tolerances for meat, milk, eggs and meat by-products on November 30, 1989.

Animal feeding studies show that residues from treated crops used as animal feed do transfer to meat, milk and eggs, but EPA believes that any residues would be extremely small because of the anticipated reduction in treated apples this year and the correspondingly lower number of treated apples that may be processed and used as apple pomace to feed livestock. Similar reduced residues in peanut by-products used as animal feed is also anticipated. Theoretical residues for meat, meat by-products, milk and eggs accounted for more than half of the calculated risk in the Preliminary Determination to Cancel the Food Uses of Daminozide. Under Option Two the tolerance for meat, milk, eggs and meat by-products would be revoked effective November 30, 1989.

A list of the proposed tolerance levels for daminozide under Option Two, the estimated risks from these levels and their corresponding dates of expiration are presented in the following Table 5:

TABLE 5—COMPARISON OF THE CURRENT AND PROPOSED DAMINOZIDE TOLERANCES

Commodity	Current tolerance	Proposed tolerance	Effective date	Expiration date	Est. risk general pop.	Est. risk non-nursing
1. Apples	20 ppm	5 ppm	11/89	11/90	1.5×10^{-7}	2.6×10^{-6}
	(expires 7/90)	1 ppm	11/90	5/91	1.9×10^{-8}	3.3×10^{-7}
2. Peanuts	30 ppm	4 ppm	11/89	5/91	3.5×10^{-8}	1.4×10^{-6}
Peanut meal	90 ppm	none [a]	11/89			
Peanuts, hay	20 ppm	none [a]	11/89			
Peanuts, hulls	10 ppm	none [a]	11/89			
3. Cherries, sweet	30 ppm	15 ppm	11/89	5/91	5.4×10^{-8}	1.6×10^{-7}
Cherries, sour	55 ppm					
4. Grapes	10 ppm	2.5 ppm	11/89	5/91	[b]	[b]
5. Peaches	30 ppm	7.5 ppm	11/89	5/91	[b]	[b]
6. Pears	20 ppm	5 ppm	11/89	5/91	[b]	[b]
7. Nectarines	30 ppm	7.5 ppm	11/89	5/91	[b]	[b]
8. Tomatoes	0.5 ppm	none [a]	11/89			
Processed tomatoes	3.0 ppm	none [a]	11/89			
Tomato pomace	10 ppm	none [a]	11/89			
9. Meat, milk and eggs	0.02-2.0 ppm	none [a]	11/89			

[a] = revocation effective November 30, 1989.
[b] = combined risk of exposure to grapes, peaches, pears and nectarines ranges from 10^{-7} to 10^{-8} for the general population and non-nursing infants.

The aggregate dietary exposure from all treated commodities to the general population for the duration of the 18-month reduced tolerance period is 0.014268 ug/kg/day with a resultant risk of 2.7×10^{-7}. The aggregate dietary exposure from all treated commodities to non-nursing infants is 0.169471 ug/kg/day with a resultant risk of 3.2×10^{-6} for this period.

D. Risk Comparison Between the Two Options

To compare fully the risk of each of the Options it is necessary to consider the period of time from February 1, 1989, the day the apple tolerance was extended, until November 30, 1989. On February 1, 1989, when the Agency extended the apple tolerance to July 31, 1990, it was estimated that the excess lifetime risk for the tolerance extension period (18 months) would be 9.6×10^{-7} for the general population and 9×10^{-6} lifetime risk for non-nursing infants. Ten of the estimated 18 months (February–November 1989) will have passed by the time the reduced tolerances are effective. Risk for this 10-month period will be 5.0×10^{-7} for the general population and 5.0×10^{-6} for non-nursing infants.

Further, the risk estimates for the period from November 30, 1989 to May 31, 1991 must be adjusted to take into account the metabolic conversion of daminozide to UDMH in the digestive system. Based on the metabolism studies discussed in the Daminozide Technical Support Document, resultant risk from metabolic formation of UDMH was increased approximately 25 percent. Without considering metabolic conversion, risk as cited in the Technical Support Document was estimated to be 4.1×10^{-5}. The consideration of metabolic conversion increased the risk to 4.9×10^{-5}. The estimated risk in the 1989 February tolerance extension did not consider metabolic conversion. However, in that document exposure was slightly over-estimated. When reduced exposure and metabolic conversion are considered, the risk numbers are about the same as shown in the tolerance extension document.

Under Option One, the cumulative risk is simply the risk for the period from February 1, 1989 to November 30, 1989, including risk from metabolic conversion. Thus, the cumulative risk under Option One for the general population is 5.0×10^{-7} and the cumulative risk for non-nursing infants is 5.0×10^{-6}.

Under Option Two, the cumulative risk for the general population is calculated as follows: from February 1, 1989 to November 30, 1989 the risk would be 5.0×10^{-7}, including metabolic conversion. From November 30, 1989 to May 31, 1991 the risk based on the reduced tolerance would be 2.7×10^{-7} and the risk from metabolic conversion in this period would be 6.8×10^{-8} to give a total risk of 8.4×10^{-7}. The cumulative risk to non-nursing infants from February 1, 1989 to November 30, 1989 (5.0×10^{-6} including metabolic conversion), and from November 30, 1989 to May 31, 1991 (3.2×10^{-5}), including risk from metabolic conversion (8.0×10^{-7}), is 9.0×10^{-6}. Table 6 compares the risks between the two options:

TABLE 6.—COMPARISON OF RISK BETWEEN OPTION I AND OPTION II

	Risk
Option I (No tolerance after Nov. 30, 1989)	
General Population	5.0×10^{-7}
Non-Nursing Infants	5.0×10^{-6}
Option II (Phased approach)	
General Population	8.4×10^{-7}
Non-Nursing Infants	9.0×10^{-6}

V. Option Selection

Based on the available information and data, EPA believes that only Option Two (phased reduction) is a preferred approach. EPA does not view the differences in risk reduction between the two options as significant. On the other hand, Option One (immediate revocation) would have a significantly greater market disruption effect than Option Two. For these reasons, EPA is proposing Option Two, but is soliciting comment on both options.

VI. Public Comment Procedures

Any person who has registered or submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, which contains daminozide may request within 30 days after publication of this document in the **Federal Register** that this proposal to amend the daminozide tolerances listed at 40 CFR 180.246 be referred to an advisory committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA). No such procedure for an advisory committee is available under the FFDCA for the food and feed additive regulations listed at 40 CFR 185.1550 and 186.1550, respectively, which this document proposes to revoke.

Interested persons are invited to submit written comments on this proposal to amend all daminozide tolerances and food/feed additive regulations listed at 40 CFR 180.246, 185.1550, and 186.1550 for residues of daminozide. Comments must bear a notation indicating the document control number, (OPP–300202). Three copies of the comments should be submitted to facilitate the work of the Agency in reviewing the comments. All written comments filed pursuant to this notice will be available for public inspection in Rm. 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, between 8 a.m. and 4 p.m., Monday through Friday, except legal holidays.

In order to satisfy requirements for analysis as specified by Executive Order 12291 and the Regulatory Flexibility Act, the Agency has analyzed the costs and benefits of this proposal. This analysis is set forth in the Preliminary Determination and Draft Cancellation Notice on daminozide (54 FR 22558), the Daminozide Technical Support Document, and this Notice.

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, the Agency must determine whether a proposed regulatory action is "major" and, therefore, subject to the requirements of a Regulatory Impact Analysis. The Agency has determined that this proposed rule is not a major regulatory action, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed rule has been reviewed by the Office of Management and Budget as required by E.O. 12291.

B. Regulatory Flexibility Act

This proposed rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354; 94 Stat. 1164, 5 U.S.C. 601 et seq.), and it has been determined that it will not have a significant economic impact on a substantial number of small businesses, small governments, or small organizations.

Because EPA anticipates that it will issue a notice of cancellation for the registrations of daminozide with food uses in the Spring of 1990, and few treated foodstuffs will contain levels of daminozide in violation of the reduced tolerance levels, the Agency anticipates that little or no economic impact would occur at any level of business enterprise if these tolerances were revoked.

Accordingly, I certify that this regulatory action does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

C. Paperwork Reduction Act

This proposed regulatory action does not contain any information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. (Section 408(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346(m))).

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

Administrative practice and procedure, Agricultural commodities, Animal feeds, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Date: September 1, 1989.

Victor J. Kimm,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR parts 180, 185 and 186 be amended as follows:

1. In part 180:

PART 180—[AMENDED]

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

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

b. Section 180.246 is revised to read as follows:

§ 180.246 Daminozide; tolerances for residues.

Interim tolerances reflecting both daminozide and UDMH residues are established for residues of the plant growth regulator daminozide (butanedioic acid mono (2,2-dimethylhydrazide) in or on the following raw agricultural commodities and processed commodities:

Commodities	Parts per million	Expiration date
Apples	5.0	Nov. 30, 1990.
	1.0	May 31, 1991.
Cherries, sour	15.0	Do.
Cherries, sweet	15.0	Do.
Grapes	2.5	Do.
Nectarines	7.5	Do.
Peaches	7.5	Do.
Peanuts	4.0	Do.
Pears	5.0	Do.

2. In part 185:

PART 185—[AMENDED]

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

Authority: 21 U.S.C. 348.

§ 185.1550 [Removed]

b. By removing § 185.1550.

3. In part 186:

PART 186—[AMENDED]

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

Authority: 21 U.S.C. 348.

§ 186.1550 [Removed]

b. By removing § 186.1550.

[FR Doc. 89-21162 Filed 9-6-89; 8:45 am]
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