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WHEN: January 24, 2001, from 9:00 a.m. to Noon (E.S.T.)

WHERE: Office of the Federal Register
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800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

Contents

Federal Register

Vol. 66, No. 3

Thursday, January 4, 2001

Agricultural Marketing Service
RULES
Raisins grown in—
California, 705–708

Agriculture Department
See Agricultural Marketing Service
See Forest Service
See Natural Resources Conservation Service

Civil Rights Commission
NOTICES
Presidential election on November 7, 2000; allegations of voting irregularities; hearing, 777

Commerce Department
See Export Administration Bureau
See National Oceanic and Atmospheric Administration

Congressional Budget Office
NOTICES
Balanced Budget and Emergency Deficit Control Reaffirmation Act (Gramm-Rudman-Hollings):
Sequestration final report for 2001 FY; transmittal to Congress and OMB, 781

Education Department
NOTICES
Agency information collection activities:
Proposed collection; comment request, 781–782

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board—
Hanford Site, WA, 782–783
Los Alamos National Laboratory, NM, 782
Fire Safety and Preparedness Commission, 783

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States:
Arizona, 730–733
Hazardous waste program authorizations:
Indiana, 733–737
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 792–793
Water pollution control:
National pollutant discharge elimination system (NPDES)—
Region VIII; facilities/operations that generate, treat, and/or dispose of sewage sludge by land application, landfill, and surface disposal; general permit, 793–794

Export Administration Bureau
NOTICES
Meetings:
President's Export Council, 778

Federal Aviation Administration
RULES
Air traffic operating and flight rules, etc.:
Grand Canyon National Park, AZ; special flight rules in vicinity—
Special flight rules area and flight free zones; modification of dimensions, 1001–1005
NOTICES
Air traffic operating and flight rules, etc.:
Grand Canyon National Park, AZ; special flight rules in vicinity—
Commercial air tour limitation, 1005–1006

Federal Communications Commission
RULES
Radio stations; table of assignments:
Virginia and North Carolina, 737
NOTICES
Common carrier services:
Wireless telecommunications services—
Wireless antennas co-location on existing structures; programmatic agreement, 794–797

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 797

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation filings:
Cinergy Services, Inc., et al., 787–789
Hydroelectric applications, 789–792
Applications, hearings, determinations, etc.:
Cinergy Services, Inc., 783
Eastern Shore Natural Gas Co., 783–784
Iroquois Gas Transmission System, L.P., 784–785
New York Power Authority, 785
PG&E National Energy Group, LLC, et al., 785–786
Total Peaking Services, L.L.C., 786
Transwestern Pipeline Co., 786
Viking Gas Transmission Co., 786–787

Federal Housing Enterprise Oversight Office
RULES
Practice and procedure:
Civil money penalties; inflation adjustment, 709–711

Federal Maritime Commission
NOTICES
Agreements filed, etc., 797

Federal Reserve System
NOTICES
Banks and bank holding companies:
Change in bank control, 797–798
Formations, acquisitions, and mergers, 798–799
Permissible nonbanking activities, 799

Federal Trade Commission
NOTICES
Prohibited trade practices:
Black & Decker Corp. et al., 799–800

Fish and Wildlife Service
RULES
Migratory bird hunting:
Tungsten-nickel-iron shot approval as nontoxic for waterfowl and coots hunting, 737–742
NOTICES
Endangered and threatened species permit applications, 802
Urban wildland interface communities within vicinity of Federal lands that are at high risk from wildfire; list, 751–777

Food and Drug Administration
RULES
Animal drugs, feeds, and related products:
Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension, 712–713
Sponsor name and address changes—
Phoenix Scientific, Inc., 711–712
NOTICES
Medical devices:
Industry initiatives pilot program expansion, 800–801
Reports and guidance documents; availability, etc.:
Potassium iodine as thyroid blocking agent in radiation emergencies, 801–802

Forest Service
NOTICES
Environmental statements; availability, etc.:
Hiawatha National Forest, MI, 751
Urban wildland interface communities within vicinity of Federal lands that are at high risk from wildfire; list, 751–777

Geological Survey
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 802–803

Health and Human Services Department
See Food and Drug Administration
See Health Care Financing Administration

Health Care Financing Administration
RULES
Medicare and Medicaid:
Physicians' referrals to health care entities with which they have financial relationships, 855–965

Housing and Urban Development Department
See Federal Housing Enterprise Oversight Office
PROPOSED RULES
Public and Indian housing:
Public housing total development cost, 1007–1011

Indian Affairs Bureau
NOTICES
Urban wildland interface communities within vicinity of Federal lands that are at high risk from wildfire; list, 751–777

Interior Department
See Fish and Wildlife Service
See Geological Survey
See Indian Affairs Bureau
See Land Management Bureau
See National Park Service

Internal Revenue Service
RULES
Income taxes:
Corporations; liability assumptions in certain corporate transactions, 723–725
Partnership mergers and divisions; tax consequences, 715–723
Tentative carryback adjustment in consolidated return context; filing application guidance, 713–715
Procedure and administration:
Attorney's fees and other costs based upon qualified offers; awards, 725–730
PROPOSED RULES
Income Taxes:
Corporations; liability assumptions in certain corporate transactions; hearing, 748–749
Tentative carryback adjustment in consolidated return context; filing application guidance; hearing, 747–748
Procedure and administration:
Attorney's fees and other costs based upon qualified offers; awards; hearing, 749–750

International Trade Commission
NOTICES
Import investigations:
Hot-rolled steel products from—
Various countries, 805–806
Seamless carbon and alloy steel standard, line, and pressure pipe from—
Various countries, 806–807
Stainless steel bar from—
Various countries, 807–808
Synchronous dynamic random access memory devices and modules and products containing same, 808–809

Justice Department
See Justice Programs Office
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 809–810

Justice Programs Office
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 810–811

Labor Department
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 811–812

Land Management Bureau
NOTICES
Organization, functions, and authority delegations:
Salmon and Challis, ID; office address changes, 803
Urban wildland interface communities within vicinity of Federal lands that are at high risk from wildfire; list, 751–777
Wild horses removal:
Wyoming, 803

National Highway Traffic Safety Administration
PROPOSED RULES
Motor vehicle safety standards:
Head restraints for passenger cars and light multipurpose vehicles, trucks, and buses, 967–999

NOTICES
Motor vehicle safety standards; exemption petitions, etc.:
Uniroyal Goodrich Tire Manufacturing, 845

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Bering Sea/Aleutian Islands king and Tanner crabs; rebuilding overfished fisheries, 742–746
NOTICES
Meetings:
North Pacific Fishery Management Council, 778
Pacific Fishery Management Council, 778
Permits:
Exempted fishing, 778–779
Exempted fishing and scientific research, 779–780
Marine mammals, 780–781

National Park Service
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 803–804
Environmental statements; availability, etc.:
Cumberland Island National Seashore, GA; wilderness management plan, etc., 804–805
Recreation management restrictions, etc.:
Golden Gate National Recreation Area, CA; year-round closure at Fort Funston, 805
Urban wildland interface communities within vicinity of Federal lands that are at high risk from wildfire; list, 751–777

Natural Resources Conservation Service
NOTICES
Field office technical guides; changes:
Kentucky, 777

Nuclear Regulatory Commission
RULES
Nondiscrimination on basis of sex in federally assisted education programs or activities; Federal financial assistance covered by Title IX, 708–709
NOTICES
Environmental statements; notice of intent:
U.S. Army Chemical School, Fort McClellan, AL, 812–815
Meetings; Sunshine Act, 815

Office of Federal Housing Enterprise Oversight
See Federal Housing Enterprise Oversight Office

Personnel Management Office
RULES
Health and counseling programs, Federal employees:
Child care costs for lower income employees; appropriated funds use, 705
NOTICES
Meetings:
National Partnership Council, 815–816

Public Health Service
See Food and Drug Administration

Research and Special Programs Administration
NOTICES
Hazardous materials:
Exemption applications delayed; list, 845–847
Meetings:
Hazardous materials safety—
Customer service and regulatory review, 847–848
Pipeline safety—
Integrity management in high consequence areas (natural gas pipelines) and communications (natural gas and hazardous liquid pipelines), 848–849

Securities and Exchange Commission
NOTICES
Investment Company Act of 1940:
Exemption applications—
Nike Securities L.P. et al., 818–819
Scudder Weisel Capital Entrepreneurs Fund et al., 816–817
Self-regulatory organizations:
Clearing agency registration applications—
Morgan Guaranty Trust Co., 819–822
Self-regulatory organizations; proposed rule changes:
Boston Stock Exchange, Inc., 822–824
National Association of Securities Dealers, Inc., 824–834
New York Stock Exchange, Inc., 834–838
Philadelphia Stock Exchange, Inc., 838–843

State Department
NOTICES
Arms Export Control Act:
Export licenses; Congressional notifications, 843–845

Surface Transportation Board
NOTICES
Railroad operation, acquisition, construction, etc.:
Coahoma County, MS, 849–850
Mississippi Delta Railroad, 850

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration
See Research and Special Programs Administration
See Surface Transportation Board

Treasury Department
See Internal Revenue Service
NOTICES
Agency information collection activities:
Submission for OMB review; comment request, 850–853

United States Institute of Peace
NOTICES
Meetings; Sunshine Act, 853

Separate Parts In This Issue

Part II
Department of Health and Human Services, Health Care Financing Administration, 855–965

Part III
Department of Transportation, National Highway Traffic Safety Administration, 967–999

Part IV
Department of Transportation, Federal Aviation Administration, 1001–1006

Part V
Department of Housing and Urban Development, 1007–1011

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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.

5 CFR
792.....705

7 CFR
989.....705

10 CFR
5.....708

12 CFR
1780.....709

14 CFR
91.....1002
93.....1002
121.....1002
135.....1002

21 CFR
522.....711
524.....712

24 CFR
Proposed Rules:
941.....1008

26 CFR
1 (3 documents) 713, 715, 723
301.....725
Proposed Rules:
1 (2 documents) 747, 748
301.....749

40 CFR
52.....730
271.....733

42 CFR
411.....856
424.....856

47 CFR
73.....737

49 CFR
Proposed Rules:
571.....968

50 CFR
20.....737
679.....742

Rules and Regulations

Federal Register

Vol. 66, No. 3

Thursday, January 4, 2001

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 792

RIN 3206–A193

Agency Use of Appropriated Funds for Child Care Costs for Lower Income Employees

AGENCY: Office of Personnel Management.

ACTION: Technical amendment.

SUMMARY: This document contains three technical amendments to the final regulations that were originally published in the **Federal Register** on Tuesday, March 14, 2000. The first technical amendment expands the type of funds that can be used for assisting lower income Federal employees with their costs of child care to include appropriated funds used for expenses in addition to salaries. The second and third amendments extend the legislation through the end of FY 2001. These changes were enacted by Public Law 106–554, sec. 633 of the Treasury and General Government Appropriations Act, 2001, and the effective date is October 1, 2000.

EFFECTIVE DATE: October 1, 2000.

FOR FURTHER INFORMATION CONTACT: Pat Kinney, (202) 606–1313; FAX (202) 606–2091; or e-mail to *pfkinney@opm.gov.*

SUPPLEMENTARY INFORMATION: Public Law 106–58, sec. 643, enacted on September 29, 1999, allows Executive agencies to assist their lower income Federal employees with the costs of child care. Agencies could use ''appropriated funds (otherwise available to such agency for salaries) to provide child care, in a Federal or leased facility, or through contract, for civilian employees of such agency.'' The Office of Personnel Management issued regulations to implement the new authority, which were published in the **Federal Register** on March 14, 2000. The law was effective until September 30, 2000.

The current legislation expands the authority by authorizing the use of appropriated funds for expenses, in addition to appropriated funds available for salaries. It also extends the legislation until September 30, 2001.

Regulatory Flexibility Act

I certify that these changes will not have a significant economic impact on a substantial number of small entities because the regulations pertain only to Federal employees and agencies.

Lists of Subjects in 5 CFR Part 792

Alcohol abuse, Alcoholism, Day care, Drug abuse, Government employees.

Office of Personnel Management.

Janice R. Lachance,

Director.

Accordingly, OPM is amending 5 CFR part 792 as follows:

PART 792—AGENCY USE OF APPROPRIATED FUNDS FOR CHILD CARE COSTS FOR LOWER INCOME EMPLOYEES

1. The authority citation for part 792 continues to read as follows:

Authority: Sec. 201 of Pub. L. 91–616, 84 Stat. 1849, as amended and transferred to sec. 520 of the Public Health Services Act by sec. 2(b)(13) of Pub. L. 98–24 (42 U.S.C. 290dd–1) and sec. 413 of Pub. L. 92–255, 86 Stat. 84, as amended and transferred to sec. 525 of the Public Health Services Act by sec. 2(b)(16)(A) of Pub. L. 98–24 (42 U.S.C. 290ee–1); Sec. 643, Pub. L. 106–58, 113 Stat. 477; Sec. 633, Pub. L. 106–554.

2. Amend § 792.207 by revising it to read as follows:

§ 792.207 Which agency funds can be used for the purpose of this law?

You are permitted to use appropriated funds, including revolving funds, that are otherwise available to the agency for salaries and expenses.

3. Amend § 792.230 by revising it to read as follows:

§ 792.230 For how long will the tuition assistance be in effect for a Federal employee?

The tuition assistance, in the form of a reduced tuition rate, will be in effect from the time the decision for a particular Federal employee is made and the child is enrolled in the program, until the child is no longer enrolled, but not later than September 30, 2001. These funds are not available to pay for services performed after September 30, 2001.

4. Amend § 792.234 by revising it to read as follows:

§ 792.234 For how long is the law effective?

The law is effective for one year, ending September 30, 2001.

[FR Doc. 01–173 Filed 1–3–01; 8:45 am]

BILLING CODE 6325–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Docket No. FV01–989–1 IFRA]

Raisins Produced From Grapes Grown in California; Reduction in Production Cap for 2001 Diversion Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule reduces the production cap for the 2001 diversion program (RDP) for Natural (sun-dried) Seedless (NS) raisins from 2.75 to 2.5 tons per acre. The cap is specified under the Federal marketing order for California raisins (order). The order regulates the handling of raisins produced from grapes grown in California and is administered locally by the Raisin Administrative Committee (RAC). Under an RDP, producers receive certificates from the RAC for curtailing their production to reduce burdensome supplies. The certificates represent diverted tonnage. Producers sell the certificates to handlers who, in turn, redeem the certificates for reserve raisins from the RAC. The Production cap limits the yield per acre that a producer can claim an an RDP. Reducing the cap for the 2001 RDP will bring the figure in line with anticipated 2001 crop yields.

DATES: Effective January 5, 2001. Comments received by January 19, 2001, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; Fax: (202) 720–5698, or E-mail: *moab.docketclerk@usda.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.ams.usda.gov/fv/moab.html.*

FOR FURTHER INFORMATION CONTACT: Maureen T. Pello, Senior Marketing Specialist, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California 93721; telephone: (559) 487–5901, Fax: (559) 487–5906; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698, or E-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 989 (7 CFR part 989), both as amended, regulating the handling of raisins produced from grapes grown in California, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule reduces the production cap for the 2001 RDP for NS raisins from 2.75 to 2.5 tons per acre. The cap is specified in the order. Under an RDP, producers receive certificates from the RAC for curtailing their production to reduce burdensome supplies. The certificates represent diverted tonnage. Producers sell the certificates to handlers who, in turn, redeem the certificates for reserve raisins from the RAC. The production cap limits the yield per acre that a producer can claim in an RDP. Reducing the cap for the 2001 RDP will bring the figure in line with anticipated 2001 crop yields. This action was recommended by the RAC at a meeting on November 29, 2000.

Volume Regulation Provisions

The order provides authority for volume regulation designed to promote orderly marketing conditions, stabilize prices and supplies, and improve producer returns. When volume regulation is in effect, a certain percentage of the California raisin crop may be sold by handlers to any market (free tonnage) while the remaining percentage must be held by handlers in a reserve pool (reserve) for the account of the RAC. Reserve raisins are disposed of through various programs authorized under the order. For example, reserve raisins may be sold by the RAC to handlers for free use or to replace part of the free tonnage they exported; carried over as a hedge against a short crop the following year; or may be disposed of in other outlets not competitive with those for free tonnage raisins, such as government purchase, distilleries, or animal feed. Net proceeds from sales of reserve raisins are ultimately distributed to producers.

Raisin Diversion Program

The RDP is another program concerning reserve raisins authorized under the order and may be used as a means for controlling overproduction. Authority for the program is provided in § 989.56 of the order, and additional procedures are specified in § 989.156 of the order's administrative rules and regulations.

Pursuant to these sections, the RAC must meet by November 30 each crop year to review raisin data, including information on production, supplies, market demand, and inventories. If the RAC determines that the available supply of raisins, including those in the reserve pool, exceeds projected market needs, it can decide to implement a diversion program, and announce the amount of tonnage eligible for diversion during the subsequent crop year. Producers who wish to participate in the RDP must submit an application to the RAC. Such producers curtail their production by vine removal or some other means established by the RAC and receive a certificate from the RAC which represents the quantity of raisins diverted. Producers sell these certificates to handlers who pay producers for the free tonnage applicable to the diversion certificate minus the established harvest cost for the diverted tonnage. Handlers redeem the certificates by presenting them to the RAC and paying an amount equal to the established harvest cost plus payment for receiving, storing, fumigating, handling, and inspecting the tonnage represented on the certificate. The RAC then gives the handler raisins from the reserve pool in an amount equal to the tonnage represented on the diversion certificate.

Production Cap

Section 989.56(a) of the order specifies a production cap of 2.75 tons per acre for any production unit of a producer approved for participation in an RDP. When the diversion tonnage is announced, the RAC may recommend, subject to approval by the Secretary, reducing the 2.75 tons per acre production cap. The production cap limits the yield that a producer can claim. Producers who historically produce yields above the production cap can choose to produce a crop rather than participate in the diversion program. No producer is required to participate in an RDP.

Pursuant to § 989.156, producers who wish to participate in a program were to submit an application to the RAC by December 20. Producers must specify, among other things, the raisin production and the acreage covered by the application. RAC staff verifies producers' production claims using handler acquisition reports and other

available information. However, a producer could misrepresent production by claiming that some raisins produced on one ranch were produced on another, and use an inflated yield on the RDP application. Thus, the production cap limits the amount of raisins for which a producer participating in an RDP may be credited, and protects the program from overstated yields.

RAC Recommendation

On November 29, 2000, the RAC met and reviewed data relating to the quantity of reserve raisins and anticipated market needs. With a 2000–01 NS crop estimated to be the largest on record at 427,394 tons, and a computed trade demand of 233,344 tons (comparable to market needs), the RAC projects a reserve pool of 194,050 tons of NS raisins. With such a large anticipated reserve, the RAC announced that 25,000 tons of NS raisins would be eligible for diversion under the 2001 RDP.

At the meeting, RAC members evaluated the 2.75 tons per acre production cap. With this year's record crop and high yields per acre, the RAC believes that the grapevines will likely produce a smaller crop next year. In addition, RAC historical data indicates that the production cap under NS raisin diversion programs has averaged 2.24 tons per acre. Thus, the RAC recommended reducing the production cap from 2.75 to 2.5 tons per acre to more accurately reflect next year's anticipated yields. Accordingly, a new paragraph (t) is added to § 989.156 of the order's rules and regulations.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 20 handlers of California raisins who are subject to regulation under the order and approximately 4,500 raisin producers in the regulated area. Small agricultural firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those having annual receipts of less than $500,000. Thirteen of the 20 handlers subject to regulation have annual sales estimated to be at least $5,000,000, and the remaining 7 handlers have sales less than $5,000,000, excluding receipts from any other sources. No more than 7 handlers, and a majority of producers, of California raisins may be classified as small entities, excluding receipts from other sources.

This rule adds a new paragraph (t) to § 989.156 of the order's rules and regulations regarding the RDP. Under an RDP, producers receive certificates from the RAC for curtailing their production to reduce burdensome supplies. The certificates represent diverted tonnage. Producers sell the certificates to handlers who, in turn, redeem the certificates for reserve raisins from the RAC. The order specifies a production cap limiting the yield per acre that a producer can claim in an RDP. This rule reduces the cap from 2.75 to 2.5 tons per acre to accurately reflect next year's anticipated yields. Authority for this action is provided in § 989.56(a) of the order.

Regarding the impact of this action on affected entities, producers who participate in the 2001 RDP will have the opportunity to earn some income for not harvesting a 2001–02 crop. Producers will sell the certificates to handlers next fall for the free tonnage applicable to the diversion certificate minus the harvest cost for the diverted tonnage. Applicable harvest costs for the 2001 RDP were established by the RAC at $340 per ton.

Reducing the production cap will have no impact on raisin handlers. Handlers will pay producers for the free tonnage applicable to the diversion certificate minus the $340 per ton harvest cost. Handlers will redeem the certificates for 2000–01 crop NS reserve raisins and pay the RAC the $340 per ton harvest cost plus payment for receiving, storing, fumigating, handling (currently totaling $46 per ton), and inspecting (currently $9.00 per ton) the tonnage represented on the certificate. Reducing the production cap will not impact handler payments for reserve raisins under the 2001 RDP.

Alternatives to the recommended action include leaving the production cap at 2.75 tons per acre or reducing it to another figure besides 2.5 tons per acre. However, the majority of RAC members believe that a cap of 2.5 tons per acre will more accurately reflect next year's yields.

There was some discussion at the RAC's meeting that the 2.5 tons per acre production cap was too low and would discriminate against producers with high yields. In recent years, cultural practices have evolved to where some producers' yield per acre is reportedly as high as 4 tons. However, as previously stated, the program is voluntary and producers whose vines can produce 4 tons per acre have the option to produce a raisin crop rather than apply for the RDP and be subject to the production cap.

This rule imposes no additional reporting or recordkeeping requirements on either small or large raisin handlers. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection requirement referred to in this rule (i.e., the application) has been approved by the Office of Management and Budget (OMB) under OMB Control No. 0581–0178. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sectors agencies. Finally, the Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the RAC's meeting on November 29, 2000, and the RAC's Administrative Issues Subcommittee meeting on that same day but prior to the RAC meeting where this action was deliberated were public meetings widely publicized throughout the raisin industry. All interested persons were invited to attend the meetings and participate in the industry's deliberations. Finally, all interested persons are invited to submit information on the regulatory and information impact of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html*. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 15-day comment period is provided to allow interested persons to respond to this rule. Applications were due to the RAC by December 20, 2000.

After consideration of all relevant material presented, including the information and recommendation submitted by the RAC and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The submission deadline for producer applications for the 2001 RDP was December 20, 2000; (2) producers are aware of this action which was recommended by the RAC at a public meeting; (3) the program is voluntary, and any producer who objects to the reduced production cap can choose to produce a raisin crop for delivery in 2001; and (4) this interim final rule provides a 15-day comment period for written comments and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 989 is amended as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new paragraph (t) is added to § 989.156 to read as follows:

§ 989.156 Raisin diversion program.

* * * * *

(t) Pursuant to § 989.56(a), the production cap for the 2001 raisin diversion program for the Natural (sun-dried) Seedless varietal type is 2.5 tons of raisins per acre.

Dated: December 29, 2000.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 00–33462 Filed 12–29–00; 2:37 pm]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 5

RIN 3150–AG68

Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to include a list of the types of Federal financial assistance activities administered by the NRC under Title IX of the Education Amendments of 1972, as amended (Title IX). Title IX prohibits recipients of Federal financial assistance from discriminating on the basis of sex in education programs or activities. Subpart F of the Title IX common rule requires each Federal agency that awards Federal financial assistance to publish in the **Federal Register** a list of Federal financial assistance administered by that Agency.

EFFECTIVE DATE: February 5, 2001.

FOR FURTHER INFORMATION CONTACT: Irene P. Little, Director, Office of Small Business and Civil Rights, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, (301) 415–7380.

SUPPLEMENTARY INFORMATION: Title IX prohibits recipients of Federal financial assistance from discriminating on the basis of sex in education programs or activities. Subpart F of the Title IX common rule requires each Federal agency that awards Federal financial assistance to publish in the **Federal Register** a notice of the different types of Federal financial assistance covered by the Title IX regulations within sixty (60) days after the effective date of the final common rule. The final common rule for the enforcement of Title IX was published in the **Federal Register** by twenty-one (21) Federal agencies, including NRC, on August 30, 2000 (65 FR 52858–52895). NRC's portion of the final common rule will be codified at 10 CFR Part 5. Specifically, the statute states that ''[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance,'' with specific exceptions for various entities, programs, and activities. 20 U.S.C. 1681(a). Title IX and the Title IX common rule prohibit discrimination on the basis of sex in the operation of, and the provision or denial of benefits by, education programs or activities conducted not only by educational institutions but by other entities as well, including, for example, nonprofit organizations.

Because this amendment deals solely with agency practice and procedure, the notice and comment provisions of the Administrative Procedure Act do not apply under 5 U.S.C. 553(b)(A).

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provision that would impose backfits as defined in 10 CFR Chapter I.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (55 U.S.C. 3501 *et seq.*).

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 5

Administrative practice and procedure, Buildings and facilities, Civil rights, Colleges and universities, Education of individuals with disabilities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal employment opportunity, Graduate fellowship program, Grant programs-education, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements, Sex discrimination, State agreement program, Student aid, Women.

For the reasons set out in the preamble and under the authority of the

Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 5.

PART 5—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

1. The authority citation for part 5 continues to read as follows:

Authority: 20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688.

2. Appendix A is added to part 5 to read as follows:

Appendix A to Part 5—List of Federal Financial Assistance Administered by the Nuclear Regulatory Commission to Which Title IX Applies

Note: All recipients of Federal financial assistance from NRC are subject to Title IX, but Title IX's anti-discrimination prohibitions are limited to the educational components of the recipient's program or activity, if any. Failure to list a type of Federal assistance below shall not mean, if Title IX is otherwise applicable, that a program or activity is not covered by Title IX.

(a) *Conferences on regulatory programs and related matters.* Agreements for financial assistance to State and local officials, without full-cost recovery, to confer on regulatory programs and related matters at NRC facilities and offices, or other locations.

(b) *Orientations and instruction.* Agreements for financial assistance to State and local officials, without full-cost recovery, to receive orientation and on-the-job instruction at NRC facilities and offices, or other locations.

(c) *Technical training courses.* Agreements for financial assistance to State and local officials, without full-cost recovery to attend training on nuclear material licensing, inspection and emergency response regulatory responsibilities to ensure compatibility between NRC and Agreement State regulation.

(d) *Participation in meetings and conferences.* Agreements for participation, without full-cost recovery, in meetings, conferences, workshops, and symposia to assist scientific, professional or educational institutions or groups.

(e) *Research support.* Agreements for the financial support of basic and applied scientific research and for the exchanges of scientific information.

Dated at Rockville, Maryland, this 19th day of December 2000.

For the Nuclear Regulatory Commission.

William D. Travers,

Executive Director for Operations.

[FR Doc. 01–227 Filed 1–3–01; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

12 CFR Part 1780

RIN 2550–AA17

Rules of Practice and Procedure

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Final rule.

SUMMARY: The Office of Federal Housing Enterprise Oversight (OFHEO) is issuing this final rule amending its rules of practice and procedure to adjust each civil money penalty within its jurisdiction to account for inflation. OFHEO is taking this action pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996.

DATES: This rule is effective January 4, 2001.

FOR FURTHER INFORMATION CONTACT: David W. Roderer, Deputy General Counsel, (202) 414–6924, Jamey Basham, Counsel (202) 414–8906 (not toll-free numbers), 1700 G Street NW., Fourth Floor, Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is: (800) 877–8339 (TDD *only*).

SUPPLEMENTARY INFORMATION:

Background

Title XIII of the Housing and Community Development Act of 1992, Public Law No. 102–550, entitled the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, established OFHEO. OFHEO is an independent office within the Department of Housing and Urban Development (HUD) with responsibility for ensuring that Fannie Mae and Freddie Mac (collectively, the Enterprises) are adequately capitalized and operate safely and in conformity to the requirements of applicable laws, rules and regulations, including their respective charter acts. The Enterprises are government-sponsored corporations established under Federal law to effect specific public purposes.[1] These include providing liquidity to the residential mortgage market and promoting the availability of mortgage credit benefiting low- and moderate-income families and areas that are underserved by lending institutions.

The Inflation Adjustment Act

The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 (the Inflation Adjustment Act)[2] requires OFHEO, as well as other Federal agencies with the authority to issue civil money penalties (CMPs), to publish regulations to adjust each CMP authorized by law that the agency has jurisdiction to administer. The purpose of these adjustments is to maintain the deterrent effect of CMPs and promote compliance with the law. The Inflation Adjustment Act required agencies to make an initial adjustment of their CMPs upon the statute's enactment, and further requires agencies to make additional adjustments on an ongoing basis, at least once every four years following the initial adjustment. In 1997, OFHEO made the initial adjustment of its CMPs,[3] with such adjustments being applicable to any violation occurring after October 23, 1996 (the effective date of the Inflation Adjustment Act).

Under the Inflation Adjustment Act, the inflation adjustment for each applicable CMP is determined by increasing the maximum CMP amount per violation by a cost-of-living adjustment. As is described in detail below, the Inflation Adjustment Act provides that this cost-of-living adjustment is to reflect the percentage increase in the Consumer Price Index[4] since the CMPs were last adjusted or established, and rounded in accordance with rules provided in the statute.

Description of the Rule

This final rule adjusts the amount for each type of CMP that OFHEO has jurisdiction to impose, in accordance with the requirements of the Inflation Adjustment Act. Part 1780 of OFHEO's rules and regulations currently sets out the procedural rules under which OFHEO conducts proceedings to impose

[1] *See* Federal Home Loan Mortgage Corporation Act, 12 U.S.C. 1451 *et seq.;* Federal National Mortgage Association Charter Act, 12 U.S.C. 1716 *et seq.;* Act at 12 U.S.C. 4561–67, 4562 note.

[2] 28 U.S.C. 2461 note.

[3] Section 1780.71 of OFHEO's rules and regulations, 12 CFR § 1780.71.

[4] The Inflation Adjustment Act specifically identifies the Consumer Price Index for All Urban Consumers published by the United States Department of Labor (CPI–U). The Department of Labor (DOL) computes the CPI–U using two different base time periods, 1967 and 1982–1984. The Inflation Adjustment Act does not specify which of these base periods should be used to calculate the inflation adjustment. OFHEO calculated the initial adjustment of its CMPs using CPI–U data with the 1967 base period. OFHEO is using CPI–U data with the 1982–1984 base period for the adjustments adopted in this final rule, because such data now reflect the most current method of computing the CPI–U.

a civil money penalty. This final rule amends the table contained in § 1780.80, which identifies the different tiers of penalties provided in 12 U.S.C. 4636—the statute that provides OFHEO with CMP authority—and sets out the new adjusted maximum penalty amount that OFHEO may impose for that tier. The increases in maximum penalty amounts contained in this final rule may not necessarily affect the amount of any CMP that OFHEO may seek for a particular violation; OFHEO would calculate each CMP on a case-by-case basis in light of a variety of factors.

The Inflation Adjustment Act directs federal agencies to calculate each CMP adjustment as the percentage by which the CPI–U for June of the calendar year preceding the adjustment exceeds the CPI–U for June of the calendar year in which the amount of such CMP was last adjusted. Since OFHEO is making this round of adjustments in calendar year 2000,[5] and OFHEO made the last round of adjustments in calendar year 1997, the inflation adjustment amount for each CMP was calculated by comparing the CPI–U for June 1997 (160.3) with the CPI–U for June 1999 (166.2), resulting in an inflation adjustment of 3.7 percent.[6] For each CMP, the product of this inflation adjustment and the previous maximum penalty amount was then rounded in accordance with the specific requirements of the Inflation Adjustment Act,[7] then summed with the previous maximum penalty amount to determine the new adjusted maximum penalty amount. The table below sets out these items accordingly.

U.S. Code citation	Description	Previous maximum penalty amount	Inflation increase (3.7 percent)	Rounded inflation increase	New adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First Tier	5,500	203.50	0	5,500
12 U.S.C. 4636(b)(2)	Second Tier (Executive Officer or Director).	11,000	407	0	11,000
12 U.S.C. 4636(b)(2)	Second Tier (Enterprise)	27,500	1,017.50	0	27,500
12 U.S.C. 4636(b)(3)	Third Tier (Executive Officer or Director)	110,000	4,070	0	110,000
12 U.S.C. 4636(b)(3)	Third Tier (Enterprise)	1,100,000	40,700	50,000	1,150,000

Section 1780.81 states that the adjustments made in § 1780.80 apply only to violations that occur after January 4, 2001.

Public Notice and Comment and Delayed Effective Date Not Required

OFHEO finds good cause that notice and an opportunity to comment on this document are unnecessary under the Administrative Procedure Act (APA), and OFHEO is issuing these requirements as a final rule. 5 U.S.C. 553. This rulemaking conforms with and is consistent with the statutory directive set forth in the Inflation Adjustment Act, with no issues of policy discretion, and public comment is impracticable and unnecessary.

In addition, OFHEO finds good cause to make this rule effective upon publication of this document in the **Federal Register** under the Administrative Procedure Act (APA). 5 U.S.C. 553(d). This final rule does not impose any additional responsibilities on any entity. Instead, it simply adjusts CMPs as dictated by the Inflation Adjustment Act.

Regulatory Impact

Executive Order 12866, Regulatory Planning and Review

This final rule is not classified as a significant rule under Executive Order 12866 because it will not result in an annual effect on the economy of $100 million or more or a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or have 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 foreign markets. Accordingly, no regulatory impact assessment is required and this final rule has not been submitted to the Office of Management and Budget for review.

Unfunded Mandates Reform Act of 1995

This final rule does not include a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year. As a result, the final rule does not warrant the preparation of an assessment statement in accordance with the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) only applies to rules for which an agency publishes a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b) (see 5 U.S.C. 601(2)). OFHEO has determined for good cause that the APA does not require a general notice of proposed rulemaking for this regulatory action. The Regulatory Flexibility Act does not apply to this final rule.

Paperwork Reduction Act of 1995

These proposed rules contain no information collection requirements that require the approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

List of Subjects in 12 CFR Part 1780

Administrative practice and procedure, Penalties.

Accordingly, for the reasons set out in the preamble, the Office of Federal

[5] Although the adjustment is being made in calendar year 2000, the resulting CMP increases do not take effect until publication of the rule, and will only apply to conduct occurring after such date.

[6] OFHEO's last round of adjustments in 1997 applied an inflation factor of 11.8 percent, calculated by comparing June 1992 CPI–U data to June 1996 CPI–U data. The 1992 data were used as the base period in accordance with the Inflation Adjustment Act's directive to use CPI–U data from the year of a CMP's enactment if the CMP had not been previously adjusted pursuant to law. The resulting penalty increase was then rounded in accordance with the statutory rules described below and in some cases reduced by the statute's ten percent cap on initial CMP adjustments. 62 FR 68152 (December 31, 1997).

[7] The statute's rounding rules require that each increase be rounded to the nearest multiple as follows: $10 in the case of penalties less than or equal to $100; $100 in the case of penalties greater than $100 but less than or equal to $1,000; $1,000 in the case of penalties greater than $1,000 but less than or equal to $10,000; $5,000 in the case of penalties greater than $10,000 but less than or equal to $100,000; $10,000 in the case of penalties greater than $100,000 but less than or equal to $200,000; and $25,000 in the case of penalties greater than $200,000.

Housing Enterprise Oversight proposes to amend 12 CFR part 1780 as follows:

PART 1780—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for part 1780 is revised to read as follows:

Authority: 12 U.S.C. 4501, 4513, 4517, 4521, 4631–4641.

2. Revise subpart E of part 1780 to read as follows:

Subpart E—Civil Money Penalty Inflation Adjustments

§ 1780.80 Inflation adjustments.

The maximum amount of each civil money penalty within OFHEO's jurisdiction is adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 (28 U.S.C. 2461 *note*) as follows:

U.S. Code citation	Description	New adjusted maximum penalty amount
12 U.S.C. 4636(b)(1)	First tier	5,500
12 U.S.C. 4636(b)(2)	Second tier (Executive Officer or Director)	11,000
12 U.S.C. 4636(b)(2)	Second Tier (Enterprise)	27,500
12 U.S.C. 4636(b)(3)	Second Tier (Executive Officer or Director)	110,000
12 U.S.C. 4636(b)(3)	Second Tier (Enterprise)	1,150,000

§ 1780.81 Applicability.

The inflation adjustments in § 1780.80 apply to civil money penalties assessed in accordance with the provisions of 12 U.S.C. 4636 for violations occurring after January 4, 2001.

Dated: December 28, 2000.

Armando Falcon, Jr.,

Director, Office of Federal Housing Enterprise Oversight.

[FR Doc. 01–177 Filed 1–3–01; 8:45 am]

BILLING CODE 4220–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADA's) from Pfizer, Inc., to Phoenix Scientific, Inc.

DATES: This rule is effective January 4, 2001.

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, has informed FDA that it has transferred to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, ownership of, and all rights and interests in NADA 065–110 for Pro-Pen G (penicillin G procaine) in Aqueous Suspension and NADA 065–498 for Pen BP–48 (penicillin G benzathine/procaine). Accordingly, the agency is amending the regulations in 21 CFR 522.1696a and 522.1696b to reflect the transfer of ownership. The agency is also taking the opportunity to restructure the regulation to reflect current format.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1696a is revised to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 000008, 000856, 000864, 010515, and 049185 for use as in paragraph (d)(1) of this section.

(2) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000864, 010515, and 059130 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Horses, dogs, and beef cattle*—(i) *Amount*—(A) *Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations.* In beef cattle, treatment should be limited to two doses. Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle*—(i) *Amount.* 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Corynebacterium pyogenes*,

Staphylococcus aureus); upper respiratory infections such as rhinitis or pharyngitis (C*pyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations*. Limit treatment to two doses. Not for use within 30 days of slaughter.

3. Section 522.1696b is revised to read as follows.

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 000864 and 055529 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000864, 010515, 053501, and 059130: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Not for use in horses intended for food.

(A) For Nos. 000864, 010515, 053501, and 059130: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7, all other cattle—4, sheep—8, and swine—6.

(B) For No. 055529: Treatment should not exceed 4 consecutive days. Milk that has been taken during treatment and for 72 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7.

Dated: December 12, 2000.

Melanie R. Berson,

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

[FR Doc. 01–72 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension

AGENCY: Food and Drug Administration

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for veterinary prescription use of gentamicin/mometasone/clotrimazole otic suspension to treat otitis externa in dogs.

DATES: This rule is effective January 4, 2001.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141–177 that provides for veterinary prescription use of Mometamax™ gentamicin sulfate/mometasone furoate/clotrimazole) Otic Suspension for the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs. The NADA is approved as of December 5, 2000, and the regulations are amended in 21 CFR 524 by adding § 524.1044h to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning December 5, 2000, because the application contains substantial evidence of effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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—OPTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

2. Section 524.1044h is added to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

(a) *Specifications*. Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3-milligram (mg) gentamicin base, mometasone furoate monohydrate

equivalent to 1-mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsor.* See No. 000061 in § 510.6(c) of this chapter.

(c) *Conditions of use— Dogs*—(1) *Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 5- and 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 5- and 30-g bottle into the ear canal (4 drops from the 215-g bottle), twice daily for 7 days.

(2) Indications for use. For the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–140 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8919]

RIN 1545–AY57

Guidance on Filing an Application for a Tentative Carryback Adjustment in a Consolidated Return Context

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the filing of an application for a tentative carryback adjustment. These temporary regulations provide guidance to determine the time for filing such application by a consolidated group. This document also contains temporary regulations relating to the filing of an application for a tentative carryback adjustment by certain corporations for the separate return year created by their becoming a member of a consolidated group. These temporary regulations may affect all consolidated groups. The text of these temporary regulations also serves as the text of proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* January 4, 2001.

Applicability Date: For dates of applicability, see § 1.1502–78T (g)(2)(v) of these regulations.

FOR FURTHER INFORMATION CONTACT: Christopher M. Bass or Frances L. Kelly, (202) 622–7770 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains temporary amendments to the Income Tax Regulations (26 CFR Part 1) under section 1502 of the Internal Revenue Code of 1986 (Code). The amendments provide guidance as to the time for filing an application for a tentative carryback adjustment by a consolidated group. The amendments also extend the time for filing an application for a tentative carryback adjustment by certain corporations for the separate return year created by their becoming new members of a consolidated group.

Section 6411(a) requires that an application for a tentative carryback adjustment be filed on or after the date of filing for the return for the taxable year of the loss (or unused business credit) from which the carryback results and within a period of twelve (12) months after the end of such taxable year. Section 6411(c) provides that if the corporation seeking a tentative carryback adjustment made or was required to make a consolidated return for the year in which the loss or credit arose or for the preceding taxable year affected by such loss or credit, the provisions of Section 6411(a) apply only to such extent and subject to such conditions, limitations and exceptions as the Secretary may by regulations prescribe. Section 1.6411–4 refers taxpayers to the consolidated return regulations, specifically § 1.1502–78, for further rules applicable to consolidated groups filing for a tentative carryback adjustment.

Section 1.1502–78(a) addresses the proper party to file an application for a tentative carryback adjustment. However, there is no provision addressing the time for filing such application. Section 1.1502–78 does not currently alter the statutory rule as to ''when'' the end of a taxable year occurs for purposes of determining whether the twelve-month rule of section 6411 has been satisfied. Under § 1.1502–76, the due date for the separate return of a new member is generally extended until the due date of the return of the consolidated group. In certain instances, however, such separate return cannot be filed before the expiration of the twelve-month period under section 6411(a). Thus, a new member may be prevented from filing an application for a tentative carryback adjustment.

Section 1.1502–76(b)(1)(i) provides that the consolidated return must include the common parent's items of income, gain, deduction, loss, and credit for the entire consolidated year, and each subsidiary's items for the portion of the year for which it is a member. Items of a corporation for the portion of the year not included in the consolidated return must be included in a separate return (including the consolidated return of another group). Thus, the items of a new member of a consolidated group are included in two returns: first, the consolidated return for the period of time it is a member of the group; and second, a separate return (including the consolidated return of another group) for the pre-affiliation period prior to becoming a member of the consolidated group. This pre-affiliation period is a separate return year as defined in § 1.1502–1(e).

The tax returns for the periods that end and begin upon a corporation becoming (or ceasing to be) a member of a consolidated group are separate taxable years for all Federal income tax purposes. Section 1.1502–76(b)(2)(i). Although these periods are separate taxable years, items of income, gain, deduction, loss, and credit (other than extraordinary items) may be ratably allocated between such years if: (1) The corporation is not required to change its annual accounting period or its method of accounting as a result of its change in status as a member; and (2) a timely ratable allocation election is made. Section 1.1502–76(b)(2)(ii)(A). If a ratable allocation cannot be made (or is not made), the corporation must close its books at the close of the day on which its status as a member changes and its items of income, gain, deduction, loss, and credit for the pre-affiliation period are included in its separate return. Section 1.1502–76(b)(2)(ii).

Section 1.1502–76(c) determines the time for filing the new member's separate return. The provisions of this section apply only to a corporation which, immediately prior to becoming a new member of a group, was the common parent of another consolidated group, or was not required to join in the filing of a consolidated return. Under § 1.1502–76(c), the due date of the new member's separate return is dependent upon the filing of the consolidated group's tax return. If the consolidated return for the group has been filed by the due date for the new member's separate return, then the separate return must be filed no later than the due date of the consolidated group's return,

including extensions. If the consolidated return for the group has not been filed by the due date for the new member's separate return, then the separate return must be filed on or before such due date. In each case, the due date for the new member's separate return is determined with regard to extensions of time for filing but without regard to the member's new affiliated status. The close of the new member's separate return year is treated as the close of its normal taxable year. Therefore, § 1.1502–76(c) effectively extends the period of time in which a new member is required to file its separate return because otherwise, the taxable year would end on the date it becomes a member. Section 1.1502–76(b)(2).

While § 1.1502–76(c) extends the due date for filing the new member's separate return, there is no similar provision that extends the due date for filing an application for a tentative carryback adjustment for the separate return year. Neither section 6411(a) nor § 1.1502–78 interprets the close of the new member's separate return year as the close of its normal taxable year. Therefore, an application for a tentative carryback adjustment must be filed: (1) on or after the extended date for filing the return for the taxable year; and (2) within a period of twelve months after the close of such taxable year. Since the separate return year is treated as a separate taxable year for all Federal income tax purposes under § 1.1502–76(b)(2)(i), a new member that chooses to file an application for a tentative carryback adjustment under section 6411 must do so within twelve (12) months after the close of its separate return year (not its normal taxable year).

The practical effect of extending the due date for filing the new member's separate return under § 1.1502–76(c) without extending the time period for filing an application for a tentative carryback adjustment is that a corporation that becomes a member of a consolidated group early in its taxable year may effectively be precluded from filing the application. This results because the twelve-month period for filing the refund application may expire prior to the due date (extended or unextended) for the filing of the new member's separate return.

The problem is illustrated by the following example:

On April 30, 2000, 100% of the stock of Corporation X, a stand-alone corporation, is acquired by Group Y. Both Corporation X and Group Y file their returns on a calendar year basis. Under § 1.1502–76(c), Corporation X's separate return for the period, January 1-April 30, 2000 (the April 2000 Year), is due on or before September 15, 2001 (with extensions). However, its application for a tentative carryback adjustment for the April 2000 Year is due no later than April 30, 2001, twelve months after the end of the April 2000 Year.

As a practical matter, the separate return of some new members cannot be filed before the group's consolidated return is filed. As previously noted, § 1.1502–76(b)(2) provides, under certain circumstances, that the new member's items of income, gain, deduction, loss, and credit may be ratably allocated between the pre-affiliation and the post-affiliation periods. The new member may not know whether the common parent will elect to ratably allocate its items. Such allocation would alter the income or loss of the new member for its separate return year. The new member also may not know the proper amount of income and loss to report and thus cannot file its separate return or its application for a tentative carryback adjustment until the group's consolidated return has been filed. Furthermore, Rev. Rul. 75–327 (1975–2 C.B. 481) holds that, because the IRS must rely on the information provided by the taxpayer in its application for a tentative carryback adjustment and much of that information (such as NOLs) is based on the return for the loss year, section 6411(a) requires that the return for the loss year be filed before the application for a tentative refund can be filed.

This problem is not generally faced by corporations that become members of a consolidated group in the latter part of their taxable year. For example, if Corporation X had been acquired on October 15, 2000, rather than April 15, 2000, its application for a tentative carryback adjustment would be due on or before October 15, 2001, a month after its separate return is due (with extensions).

Explanation of Provisions

The consolidated return regulations do not address the time for filing an application for a tentative carryback adjustment. Rather, the consolidated return regulations rely upon the general provisions of section 6411 for guidance. The amendments to § 1.1502–78 provide a general rule for all consolidated taxpayers stating that the provisions of section 6411(a) shall apply to determine the time for filing an application for a tentative carryback adjustment by a consolidated group.

In addition, the amendments provide a special rule designed to remedy the problem faced by some corporations that become new members of a consolidated group. For such members, the amendments extend the period of time for filing an application for a tentative carryback adjustment resulting from losses or credits arising in the new member's last separate return year. For these purposes, the amendments treat the separate return year as ending on the same date as the end of the current taxable year of the consolidated group.

The special rule of these temporary regulations will apply only to a corporation that, immediately prior to becoming a new member of a group, was the common parent of another consolidated group, or was not required to join in the filing of a consolidated return. The situation not covered involves the acquisition of a member of another consolidated group. In this case, the corporation's items of income, gain, deduction, loss and credit for the period prior to becoming a member of the new consolidated group will be included in the consolidated return of its former group. The due date for the former group's consolidated return is not affected by the acquisition and the due date for its application for a tentative carryback adjustment relates back to the end of the former group's taxable year.

The approach taken attempts to provide consistency between § 1.1502–76(c) and § 1.1502–78. In addition, this approach provides certainty to taxpayers and allows for simplicity of administration by the IRS.

Special Analyses

It has been determined that this notice of temporary rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. Because no preceding notice of proposed rulemaking is required for this temporary regulation, the provisions of the Regulatory Flexibility Act do not apply.

This Treasury decision ensures that all new members of consolidated groups have the opportunity to file an application for a tentative carryback adjustment, a benefit currently unavailable to some new members. Issuing this regulation in proposed form would continue the difficulty of filing an application for a tentative carryback adjustment for affected new members. Based on these considerations, it is determined that this temporary regulation will provide taxpayers with the necessary guidance and authority to ensure equitable administration of the tax laws. Therefore, it would be contrary to the public interest to issue this Treasury decision with prior notice under section 553(b) or subject to the effective date limitation of section

553(d) of title 5 of the United States Code.

Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal authors of these temporary regulations are Christopher M. Bass and Frances L. Kelly, Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.1502–78T also issued under 26 U.S.C. 1502 and 6411(c). * * *

Par. 2. Section 1.1502–78T is added to read as follows:

§ 1.1502–78T Rules for filing applications for tentative carryback adjustments.

(a) through (f) [Reserved]. For further guidance, see § 1.1502–78(a) through (f).

(g) *Time for filing application*—(1) *General rule.* The provisions of section 6411(a) apply to the filing of an application for a tentative carryback adjustment by a consolidated group.

(2) *Special rule for new members*—(i) *New member.* A new member is a corporation that, in the preceding taxable year, did not qualify as a member, as defined in § 1.1502–1(b), of the consolidated group that it now joins.

(ii) *End of taxable year.* Solely for the purpose of complying with the twelve-month requirement for making an application for a tentative carryback adjustment under section 6411(a), the separate return year of a qualified new member shall be treated as ending on the same date as the end of the current taxable year of the consolidated group that the qualified new member joins.

(iii) *Qualified new member.* A new member of a consolidated group qualifies for purposes of the provisions of this paragraph (g)(2), if immediately prior to becoming a new member, either—

(A) It was the common parent of a consolidated group; or

(B) It was not required to join in the filing of a consolidated return.

(iv) *Examples.* The provisions of this paragraph (g)(2) may be illustrated by the following examples:

Example 1. Individual A owns 100 percent of the stock of X, a corporation filing returns on a calendar year basis. On January 31 of year 1, X becomes a member of the Y consolidated group, which also files returns on a calendar year basis. X is a qualified new member as defined in paragraph (g)(2)(iii)(B) of this section because, immediately prior to becoming a new member of the Y consolidated group, X was not required to join in the filing of a consolidated return. As a result of its becoming a new member of Group Y, X's separate return for the short taxable year (January 1 of year 1 through January 31 of year 1) is due September 15 of year 2 (with extensions). Section 1.1502–76(c). Group Y's consolidated return is also due September 15 of year 2 (with extensions). Section 1.1502–76(c). Solely for the purpose of complying with the twelve-month requirement for making an application for a tentative carryback adjustment under Section 6411(a), X's taxable year for the separate return year is treated as ending on December 31 of year 1. X's application for a tentative carryback adjustment is therefore due on or before December 31 of year 2.

Example 2. Assume the same facts as in *Example 1* except that immediately prior to becoming a new member of Group Y, X was a member of the Z consolidated group. Because X was required to join in the filing of the consolidated return for Group Z, X is not a qualified new member as defined in paragraph (g)(2)(iii) of this section. X's items for the one-month period will be included in the consolidated return for Group Z. Group Z's application for a tentative carryback adjustment, if any, continues to be due within 12 months of the end of its taxable year, which is not affected by X's change in status as a new member of Group Y.

(v) *Effective date.*

The provisions of this paragraph (g)(2) apply for applications by new members of consolidated groups for tentative carryback adjustments resulting from net operating losses, net capital losses, or unused business credits arising in separate return years of new members that begin on or after January 1, 2001.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 13, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 01–196 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8925]

RIN 1545–AX32

Partnership Mergers and Divisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the tax consequences of partnership mergers and divisions. The final regulations affect partnerships and their partners.

DATES: *Effective Date:* These regulations are effective January 4, 2001.

Applicability Date: For dates of applicability of these regulations, see §§ 1.708–1(c)(7), 1.708–1(d)(7), and 1.752–5(a).

FOR FURTHER INFORMATION CONTACT: Mary Beth Collins or Dan Carmody, (202) 622–3080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends sections 708 and 752 of the Income Tax Regulations (26 CFR part 1) regarding partnership mergers and divisions.

On January 11, 2000, a notice of proposed rulemaking and a notice of public hearing (REG–111119–99, 2000–5 I.R.B. 455) were published in the **Federal Register** (65 FR 1572) regarding sections 708, 743, and 752 of the Internal Revenue Code. No one requested to speak at the public hearing. Accordingly, the public hearing scheduled for May 4, 2000, was canceled in the **Federal Register** (65 FR 24897) on April 28, 2000. Comments responding to the proposed regulations were received. After consideration of the comments, the proposed regulations are adopted as revised by this Treasury decision.

I. Partnership Mergers

Section 708(b)(2)(A) provides that in the case of a merger or consolidation of two or more partnerships, the resulting partnership is, for purposes of section 708, considered the continuation of any merging or consolidating partnership whose members own an interest of more than 50 percent in the capital and profits of the resulting partnership. Section 1.708–1(b)(2)(i) of the Income Tax Regulations provides that if the resulting partnership can be considered a continuation of more than one of the merging partnerships, the resulting

partnership is the continuation of the partnership that is credited with the contribution of the greatest dollar value of assets to the resulting partnership. If the members of none of the merging partnerships own more than a 50 percent interest in the capital and profits of the resulting partnership, all of the merged partnerships are considered terminated, and a new partnership results. The taxable years of the merging partnerships that are considered terminated are closed under section 706(c).

II. Partnership Divisions

Section 708(b)(2)(B) provides that, in the case of a division of a partnership into two or more partnerships, the resulting partnerships (other than any resulting partnership the members of which had an interest of 50 percent or less in the capital and profits of the prior partnership) are considered a continuation of the prior partnership. Section 1.708–1(b)(2)(ii) provides that any other resulting partnership is not considered a continuation of the prior partnership but is considered a new partnership. If the members of none of the resulting partnerships owned an interest of more than 50 percent in the capital and profits of the prior partnership, the prior partnership is terminated. Where members of a partnership that has been divided do not become members of a resulting partnership that is considered a continuation of the prior partnership, such members' interests are considered liquidated as of the date of the division.

Explanation of Revisions and Summary of Comments

I. Assets-Up Form for Partnership Mergers and Divisions

The proposed regulations provide that the form of a partnership merger or division accomplished under laws of the applicable jurisdiction will be respected if the partnership undertakes the steps of one of two prescribed forms. Generally, for partnership mergers, a terminating partnership contributes its assets and liabilities to the resulting partnership in exchange for interests in the resulting partnership, and immediately thereafter, the terminated partnership distributes interests in the resulting partnership to its partners in liquidation of the terminating partnership (Assets-Over Form). Alternatively, for partnership mergers, the terminating partnership liquidates by distributing its assets and liabilities to its partners who then contribute the assets and liabilities to the resulting partnership (Assets-Up Form). The default rule for partnership mergers is the Assets-Over Form, so that if a transaction is not characterized under the Assets-Up Form, it will be characterized under the Assets-Over Form regardless of whether that form is followed.

In general, for partnership divisions, a prior partnership transfers certain assets and liabilities to a resulting partnership in exchange for interests in the resulting partnership, and immediately thereafter, the prior partnership distributes the resulting partnership interests to partners who are designated to receive interests in the resulting partnership (Assets-Over Form). Alternatively, for partnership divisions, the prior partnership distributes certain assets and liabilities to some or all of its partners who then contribute the assets and liabilities to a resulting partnership in exchange for interests in the resulting partnership (Assets-Up Form). As with partnership mergers, the default rule for partnership divisions is the Assets-Over Form, so that if a transaction is not characterized under the Assets-Up Form, it will be characterized under the Assets-Over Form regardless of whether that form is followed.

One commentator expressed concern that where the assets of an operating business are distributed to the partners as joint owners, and the partners continue to operate the business, the owners of the assets may be considered to remain partners for federal income tax purposes. Under the proposed regulations, it was intended that the Assets-Up Form would be respected where the assets are conveyed to the partners under the laws of the applicable jurisdiction and then reconveyed to the resulting partnership. An example has been added to the final regulations to confirm this result. The example also confirms that a partnership can use the Assets-Up Form for partnership mergers and divisions regardless of whether the partners could otherwise generally hold certain assets, such as undivided interests in goodwill, outside of a partnership.

The same commentator suggested that the Assets-Up Form should be respected if, rather than actually conveying ownership of the assets under applicable jurisdictional law, the partners assign their rights to receive title to the assets in liquidation of the partnership, or direct the partnership to transfer title to the assets to the resulting partnership. In providing that the Assets-Up Form would be respected in accomplishing partnership mergers and divisions, the IRS and Treasury did not intend to establish a regime whereby partners essentially could elect between the Assets-Up Form and the Assets-Over Form by creating different documents that have the same legal effect. The IRS and Treasury believe that if the Assets-Up Form is to be respected, a partnership must actually undertake the steps that are necessary, under the laws of the applicable jurisdiction, to convey ownership of the assets that are distributed to the partners. For most types of assets, this will not require the actual transfer and recording of a deed or certificate of title.

While the IRS and Treasury believe that it should be necessary for a partnership to actually convey ownership of the partnership's assets to its partners in order to follow the Assets-Up Form, it should not be necessary for the partners to actually assume the liabilities of the partnership in order to follow such form. Pursuant to section 752 and the regulations thereunder, a partner essentially is deemed to have directly incurred a share of the partnership's liabilities. Requiring the partners to actually assume debt that they already are deemed to have incurred is unnecessary. Such a requirement also could create a trap for the unwary. If a partner momentarily assumes an amount of the partnership's debt that is less than the partner's share of such debt under section 752 (and other partners momentarily assume an amount of debt in excess of their shares), the partner could inappropriately recognize gain as a result of the deemed distribution.

II. Bifurcation of Assets-Over Form and Assets-Up Form

The proposed regulations provide that the form of a partnership merger or division accomplished under laws of the applicable jurisdiction will be respected if the partnership undertakes the steps of either the Assets-Over Form or the Assets-Up Form. One commentator recommended that a single partnership merger or division be respected if the partnership undertakes the steps of the Assets-Over Form with respect to some assets and the Assets-Up Form with respect to others. For example, in a partnership merger, the terminating partnership could distribute some assets to certain partners who then contribute the assets to the resulting partnership in exchange for interests in the resulting partnership (Assets-Up Form), and simultaneously, the terminating partnership could transfer the remaining assets to the resulting partnership in exchange for interests in the resulting partnership and then distribute the interests to the remaining partners in liquidation of their interests

in the terminating partnership (Assets-Over Form).

In the preamble to the proposed regulations, the IRS and Treasury recognized that there are numerous transactions that may be undertaken pursuant to local jurisdictional law to accomplish the result of a partnership merger or division. The rules set forth in the proposed regulations were not intended to provide unlimited flexibility among the various structural alternatives for accomplishing these transactions. Instead, the proposed regulations were intended to provide a set of administrable rules that taxpayers and the IRS could apply in characterizing these transactions.

In view of this purpose, the IRS and Treasury do not believe it is appropriate for a partnership merger to be accomplished using both the Assets-Over Form and the Assets-Up Form when all the assets and liabilities of the terminated partnership are transferred to a single resulting partnership. While a partnership merger may be accomplished by using any number of transactional structures, the result is a single transaction that combines two partnerships. In the two alternatives set forth in the proposed regulations, and adopted in these final regulations, each partner must participate (or will be deemed to participate) in the partnership merger in the same manner (with the exception of those partners who are subject to the buy-out rule). Therefore, if the partners wish for a partnership merger to be characterized under the Assets-Up Form, the terminated partnership must undertake the steps of the Assets-Up Form for all of its assets when it distributes the assets to its partners. Otherwise, the transaction will be characterized under the Assets-Over Form. However, where more than two partnerships are combined, each combination will be viewed as a separate merger so that the characterization of a merger of one partnership into the resulting partnership under the Assets-Over Form will not prevent a simultaneous merger of another partnership into the same resulting partnership from being characterized under the Assets-Up Form.

For the same reasons, with respect to partnership divisions, the IRS and Treasury believe that it is appropriate to require consistency in applying either the Assets-Over Form or the Assets-Up Form to characterize a transfer of assets to a resulting partnership. However, where a single partnership is divided in a transaction that involves a transfer of assets (either actual or deemed) to multiple partnerships, the transfer to each resulting partnership should be viewed separately. As with mergers involving more than two partnerships, it is consistent with the purposes of these regulations, in the context of divisions, to allow the transfer to one resulting partnership to be characterized under the Assets-Over Form while characterizing the transfer to another resulting partnership under the Assets-Up Form. The proposed regulations provided an example that illustrates when such a division accomplished under both the Assets-Over Form and the Assets-Up Form will be respected. The final regulations do not change the example. See § 1.708–1(d)(5) Example 7 of the final regulations. The final regulations also add an example to illustrate when a division accomplished under both the Assets-Over Form and the Assets-Up Form will not be respected.

III. Clarification of Partnership Merger Buy-Out Rule

The proposed regulations contain a special buy-out rule that allows a resulting partnership in a merger to fund the purchase of one or more partners' interests in a terminating partnership without triggering the disguised sale rules, which otherwise would cause all of the partners in the terminating partnership to recognize gain or loss as a result of the purchase. Specifically, the proposed regulations provide that if the merger agreement (or similar document) specifies that the resulting partnership is purchasing the exiting partner's interest in the terminating partnership and the amount paid for the interest, the transaction will be treated as a sale of the exiting partner's interest to the resulting partnership.

Because the transaction described in the proposed regulations is treated as a sale of a partnership interest, the resulting partnership inherits the exiting partner's capital account in the terminating partnership and any section 704(c) liability of the exiting partner. Additionally, if the terminating partnership has an election in effect under section 754 (or makes an election under section 754), the resulting partnership will have a special basis adjustment regarding the terminating partnership's property under section 743. The proposed regulations provide that the resulting partnership's basis adjustments under section 743 must be allocated solely to the partners who were partners in the resulting partnership immediately before the merger.

Commentators questioned whether the exiting partner must be a party to the merger agreement in order to obtain the benefit of the special buy-out rule contained in the proposed regulations. Another commentator asked whether the exiting partner must consent to the sale treatment. The commentator explained that it may be difficult to receive consent from small investors in a large partnership whose interests are being sold to the resulting partnership.

The IRS and Treasury believe that the exiting partner does not have to be a party to the merger agreement in order to obtain the benefit of the special buy-out rule. However, to ensure that all partners to the transaction treat the transaction consistently when filing their returns, the final regulations require that, prior to or contemporaneous with the transfer, the exiting partner must consent to the sale treatment provided in the special rule.

Commentators noted that the resulting partnership's basis adjustments under section 743 should not be allocated solely to the partners who were partners in the resulting partnership immediately before the merger. As indicated in § 1.708–1(c)(4) Example 4 of the proposed regulations, where the resulting partnership has acquired an interest in the terminating partnership in accordance with the special buy-out rule, the terminating partnership, as part of the merger, distributes assets to the resulting partnership in liquidation of the resulting partnership's interest in the terminating partnership. Accordingly, the resulting partnership should take an exchanged basis in the distributed assets under section 732(b), rather than a transferred basis that includes the basis adjustment under section 743(b). In response to these comments, the IRS and Treasury have removed the proposed regulations under section 743 and have clarified the example to indicate that the basis rules under section 732(b) apply.

Commentators also asked whether a partnership termination under section 708(b)(1)(B) occurs immediately before a merger if exiting partners sell 50 percent or more of the total interests in the terminating partnership under the buy-out provision. Although not discussed in the final regulations, it follows from treating the buyout as occurring immediately prior to the merger that, if exiting partners sell 50 percent or more of the total interest in the terminating partnership's capital and profits as part of a merger, then a partnership termination under section 708(b)(1)(B) will occur immediately before the merger.

IV. Partnership Division Tax Consequences

The proposed regulations provide that the resulting partnership that is regarded as continuing shall file a return for the taxable year of the partnership that has been divided. Commentators requested that the final regulations clarify the tax consequences of a partnership that is regarded as continuing. For instance, commentators asked how a partnership files a return and which partnership retains the prior partnership's employer identification number (EIN) when more than one resulting partnership is considered a continuation of the prior partnership. Additionally, commentators asked whether subsequent elections by one resulting partnership that is regarded as continuing binds all resulting partnerships that are regarded as continuing.

In response to these comments, the final regulations clarify certain tax consequences that follow from a partnership division when more than one resulting partnership is regarded as continuing. Specifically, the final regulations provide that when more than one resulting partnership is regarded as continuing, the resulting partnership that is treated as the divided partnership will file a return for the taxable year of the partnership that has been divided and retain the EIN of the prior partnership. All other resulting partnerships that are regarded as continuing and all new partnerships (*i.e.,* resulting partnerships that are not considered continuing) will file separate returns for the taxable year beginning on the day after the date of the division with new EINs for each partnership.

The final regulations also provide that all resulting partnerships that are continuing partnerships are subject to preexisting elections that were made by the prior partnership. However, a post-division election that is made by a resulting partnership will not bind any of the other resulting partnerships.

V. Definition of Partnership Mergers and Divisions

The proposed regulations do not define what constitutes a partnership merger or division. Some commentators have requested that these terms be defined in the final regulations. Other practitioners have stated that the selectivity that would be created by attempting to draw lines in such definitions could lead to planning opportunities that would be adverse to the government's interest. The IRS and Treasury have decided not to provide comprehensive definitions of what is a partnership merger or division in these final regulations.

In addition to requesting guidance as to the general definitions of a partnership merger and division, some commentators have asked more narrowly whether a partnership division can occur when only one partner from the prior partnership is a partner in a resulting partnership. Consider the following example: ABC partnership owns X business and Y business. A and B each own a 20-percent interest, and C owns a 60-percent interest in the ABC partnership. C does not want to continue in the partnership with A and B and would like to operate X business with D. Accordingly, ABC partnership distributes X business to C in liquidation of C's interest in partnership ABC. Subsequently, C forms a partnership with D and contributes X business to the CD partnership. After the distribution and contribution of X business, AB partnership owns Y business and CD partnership owns X business.

The IRS and Treasury believe that the above transaction does not constitute a division. To have a division, at least two members of the prior partnership must be members of each resulting partnership that exists after the transaction. In the above example, C is the only member of the ABC partnership in the CD partnership. Accordingly, this transaction would not be treated as a division for Federal income tax purposes. The final regulations modify the proposed regulations to clarify this result.

VI. Application of Sections 704(c) and 737 in Partnership Divisions

In the preamble to the proposed regulations, the IRS and Treasury requested comments as to whether expanded exceptions under sections 704(c)(1)(B) and 737 would be appropriate in the context of partnership divisions. Most commentators agreed that it would not be wise to expand the current exceptions. In a related point, some commentators stated that the contribution of assets in a division should not create new section 704(c) property or section 737 net precontribution gain.

To the extent that a partnership division merely affects a restructuring of the form in which the partners hold property (that is, each partner's overall interest in each partnership property does not change), the IRS and Treasury agree that a partnership division should not create new section 704(c) property or section 737 net precontribution gain. However, it is not clear that this result is necessarily appropriate where a division is non-pro rata as to the partners, where some property is extracted from or added to the partnerships in connection with the division, or where new partners are added to the ownership group in connection with the division. The IRS and Treasury intend to study this issue and request comments in this regard.

VII. Effective Date

The proposed regulations apply to mergers and divisions occurring on or after the date final regulations are published in the **Federal Register**. Commentators requested that the final regulations allow partnerships to apply the regulations to mergers and divisions occurring on or after January 11, 2000, (the date the proposed regulations were published in the **Federal Register**). The commentators explained that the regulations provide needed clarity in an area that has lacked guidance.

The IRS and Treasury believe it is appropriate to allow partnerships to apply the final regulations retroactively to the publication date of the proposed regulations. Therefore, the final regulations apply to mergers and divisions occurring on or after January 4, 2001. However, a partnership may apply the rules in the final regulations for mergers and divisions occurring on or after January 11, 2000.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking that preceded these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Mary Beth Collins, Office of Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

§ 1.708–1 [Amended]

Par. 2. Section 1.708–1 is amended as follows:

1. Paragraph (b) is amended by removing paragraph (b)(2) and by redesignating each paragraph listed in the first column of the following table as the paragraph listed in the second column as indicated in the following table:

Old paragraph	Redesignated paragraph
(b)(1)(i)	(b)(1)
(b)(1)(i)(*a*)	(b)(1)(i)
(b)(1)(i)(*b*)	(b)(1)(ii)
(b)(1)(ii)	(b)(2)
(b)(1)(iii)	(b)(3)
(b)(1)(iii)(*a*)	(b)(3)(i)
(b)(1)(iii)(*b*)	(b)(3)(ii)
(b)(1)(iv)	(b)(4)
(b)(1)(v)	(b)(5)

2. Paragraphs (c) and (d) are added to read as follows:

§ 1.708–1 Continuation of partnership.

* * * * *

(c) *Merger or consolidation*—(1) *General rule.* If two or more partnerships merge or consolidate into one partnership, the resulting partnership shall be considered a continuation of the merging or consolidating partnership the members of which own an interest of more than 50 percent in the capital and profits of the resulting partnership. If the resulting partnership can, under the preceding sentence, be considered a continuation of more than one of the merging or consolidating partnerships, it shall, unless the Commissioner permits otherwise, be considered the continuation solely of that partnership which is credited with the contribution of assets having the greatest fair market value (net of liabilities) to the resulting partnership. Any other merging or consolidating partnerships shall be considered as terminated. If the members of none of the merging or consolidating partnerships have an interest of more than 50 percent in the capital and profits of the resulting partnership, all of the merged or consolidated partnerships are terminated, and a new partnership results.

(2) *Tax returns.* The taxable years of any merging or consolidating partnerships which are considered terminated shall be closed in accordance with the provisions of section 706(c) and the regulations thereunder, and such partnerships shall file their returns for a taxable year ending upon the date of termination, *i.e.,* the date of merger or consolidation. The resulting partnership shall file a return for the taxable year of the merging or consolidating partnership that is considered as continuing. The return shall state that the resulting partnership is a continuation of such merging or consolidating partnership, shall retain the employer identification number (EIN) of the partnership that is continuing, and shall include the names, addresses, and EINs of the other merged or consolidated partnerships. The respective distributive shares of the partners for the periods prior to and including the date of the merger or consolidation and subsequent to the date of merger or consolidation shall be shown as a part of the return.

(3) *Form of a merger or consolidation*—(i) *Assets-over form.* When two or more partnerships merge or consolidate into one partnership under the applicable jurisdictional law without undertaking a form for the merger or consolidation, or undertake a form for the merger or consolidation that is not described in paragraph (c)(3)(ii) of this section, any merged or consolidated partnership that is considered terminated under paragraph (c)(1) of this section is treated as undertaking the assets-over form for Federal income tax purposes. Under the assets-over form, the merged or consolidated partnership that is considered terminated under paragraph (c)(1) of this section contributes all of its assets and liabilities to the resulting partnership in exchange for an interest in the resulting partnership, and immediately thereafter, the terminated partnership distributes interests in the resulting partnership to its partners in liquidation of the terminated partnership.

(ii) *Assets-up form.* Despite the partners' transitory ownership of the terminated partnership's assets, the form of a partnership merger or consolidation will be respected for Federal income tax purposes if the merged or consolidated partnership that is considered terminated under paragraph (c)(1) of this section distributes all of its assets to its partners (in a manner that causes the partners to be treated, under the laws of the applicable jurisdiction, as the owners of such assets) in liquidation of the partners' interests in the terminated partnership, and immediately thereafter, the partners in the terminated partnership contribute the distributed assets to the resulting partnership in exchange for interests in the resulting partnership.

(4) *Sale of an interest in the merging or consolidating partnership.* In a transaction characterized under the assets-over form, a sale of all or part of a partner's interest in the terminated partnership to the resulting partnership that occurs as part of a merger or consolidation under section 708(b)(2)(A), as described in paragraph (c)(3)(i) of this section, will be respected as a sale of a partnership interest if the merger agreement (or another document) specifies that the resulting partnership is purchasing interests from a particular partner in the merging or consolidating partnership and the consideration that is transferred for each interest sold, and if the selling partner in the terminated partnership, either prior to or contemporaneous with the transaction, consents to treat the transaction as a sale of the partnership interest. See section 741 and § 1.741–1 for determining the selling partner's gain or loss on the sale or exchange of the partnership interest.

(5) *Examples.* The following examples illustrate the rules in paragraphs (c)(1) through (4) of this section:

Example 1. Partnership AB, in whose capital and profits A and B each own a 50-percent interest, and partnership CD, in whose capital and profits C and D each own a 50-percent interest, merge on September 30, 1999, and form partnership ABCD. Partners A, B, C, and D are on a calendar year, and partnership AB and partnership CD also are on a calendar year. After the merger, the partners have capital and profits interests as follows: A, 30 percent; B, 30 percent; C, 20 percent; and D, 20 percent. Since A and B together own an interest of more than 50 percent in the capital and profits of partnership ABCD, such partnership shall be considered a continuation of partnership AB and shall continue to file returns on a calendar year basis. Since C and D own an interest of less than 50 percent in the capital and profits of partnership ABCD, the taxable year of partnership CD closes as of September 30, 1999, the date of the merger, and partnership CD is terminated as of that date. Partnership ABCD is required to file a return for the taxable year January 1 to December 31, 1999, indicating thereon that, until September 30, 1999, it was partnership AB. Partnership CD is required to file a return for

its final taxable year, January 1 through September 30, 1999.

Example 2. (i) Partnership X, in whose capital and profits A owns a 40-percent interest and B owns a 60-percent interest, and partnership Y, in whose capital and profits B owns a 60-percent interest and C owns a 40-percent interest, merge on September 30, 1999. The fair market value of the partnership X assets (net of liabilities) is $100X, and the fair market value of the partnership Y assets (net of liabilities) is $200X. The merger is accomplished under state law by partnership Y contributing its assets and liabilities to partnership X in exchange for interests in partnership X, with partnership Y then liquidating, distributing interests in partnership X to B and C.

(ii) B, a partner in both partnerships prior to the merger, owns a greater than 50-percent interest in the resulting partnership following the merger. Accordingly, because the fair market value of partnership Y's assets (net of liabilities) was greater than that of partnership X's, under paragraph (c)(1) of this section, partnership X will be considered to terminate in the merger. As a result, even though, for state law purposes, the transaction was undertaken with partnership Y contributing its assets and liabilities to partnership X and distributing interests in partnership X to its partners, pursuant to paragraph (c)(3)(i) of this section, for Federal income tax purposes, the transaction will be treated as if partnership X contributed its assets to partnership Y in exchange for interests in partnership Y and then liquidated, distributing interests in partnership Y to A and B.

Example 3. (i) The facts are the same as in *Example 2,* except that partnership X is engaged in a trade or business and has, as one of its assets, goodwill. In addition, the merger is accomplished under state law by having partnership X convey an undivided 40-percent interest in each of its assets to A and an undivided 60-percent interest in each of its assets to B, with A and B then contributing their interests in such assets to partnership Y. Partnership Y also assumes all of the liabilities of partnership X.

(ii) Under paragraph (c)(3)(ii) of this section, the form of the partnership merger will be respected so that partnership X will be treated as following the assets-up form for Federal income tax purposes.

Example 4. (i) Partnership X and partnership Y merge when the partners of partnership X transfer their partnership X interests to partnership Y in exchange for partnership Y interests. Immediately thereafter, partnership X liquidates into partnership Y. The resulting partnership is considered a continuation of partnership Y, and partnership X is considered terminated.

(ii) The partnerships are treated as undertaking the assets-over form described in paragraph (c)(3)(i) of this section because the partnerships undertook a form that is not the assets-up form described in paragraph (c)(3)(ii) of this section. Accordingly, for Federal income tax purposes, partnership X is deemed to contribute its assets and liabilities to partnership Y in exchange for interests in partnership Y, and, immediately thereafter, partnership X is deemed to have distributed the interests in partnership Y to its partners in liquidation of their interests in partnership X.

Example 5. (i) A, B, and C are partners in partnership X. D, E, and F are partners in Partnership Y. Partnership X and partnership Y merge, and the resulting partnership is considered a continuation of partnership Y. Partnership X is considered terminated. Under state law, partnerships X and Y undertake the assets-over form of paragraph (c)(3)(i) of this section to accomplish the partnership merger. C does not want to become a partner in partnership Y, and partnership X does not have the resources to buy C's interest before the merger. C, partnership X, and partnership Y enter into an agreement specifying that partnership Y will purchase C's interest in partnership X for $150 before the merger, and as part of the agreement, C consents to treat the transaction in a manner that is consistent with the agreement. As part of the merger, partnership X receives from partnership Y $150 that will be distributed to C immediately before the merger, and interests in partnership Y in exchange for partnership X's assets and liabilities.

(ii) Because the merger agreement satisfies the requirements of paragraph (c)(4) of this section and C provides the necessary consent, C will be treated as selling its interest in partnership X to partnership Y for $150 before the merger. See section 741 and § 1.741–1 to determine the amount and character of C's gain or loss on the sale or exchange of its interest in partnership X.

(iii) Because the merger agreement satisfies the requirements of paragraph (c)(4) of this section, partnership Y is considered to have purchased C's interest in partnership X for $150 immediately before the merger. See § 1.704–1(b)(2)(iv)(*l*) for determining partnership Y's capital account in partnership X. Partnership Y's adjusted basis of its interest in partnership X is determined under section 742 and § 1.742–1. To the extent any built-in gain or loss on section 704(c) property in partnership X would have been allocated to C (including any allocations with respect to property revaluations under section 704(b) (reverse section 704(c) allocations)), see section 704 and § 1.704–3(a)(7) for determining the built-in gain or loss or reverse section 704(c) allocations apportionable to partnership Y. Similarly, after the merger is completed, the built-in gain or loss and reverse section 704(c) allocations attributable to C's interest are apportioned to D, E, and F under section 704(c) and § 1.704–3(a)(7).

(iv) Under paragraph (c)(3)(i) of this section, partnership X contributes its assets and liabilities attributable to the interests of A and B to partnership Y in exchange for interests in partnership Y; and, immediately thereafter, partnership X distributes the interests in partnership Y to A and B in liquidation of their interests in partnership X. At the same time, partnership X distributes assets to partnership Y in liquidation of partnership Y's interest in partnership X. Partnership Y's bases in the distributed assets are determined under section 732(b).

(6) *Prescribed form not followed in certain circumstances.* (i) If any transactions described in paragraph (c)(3) or (4) of this section are part of a larger series of transactions, and the substance of the larger series of transactions is inconsistent with following the form prescribed in such paragraph, the Commissioner may disregard such form, and may recast the larger series of transactions in accordance with their substance.

(ii) *Example.* The following example illustrates the rules in paragraph (c)(6) of this section:

Example. A, B, and C are equal partners in partnership ABC. ABC holds no section 704(c) property. D and E are equal partners in partnership DE. B and C want to exchange their interests in ABC for all of the interests in DE. However, rather than exchanging partnership interests, DE merges with ABC by undertaking the assets-up form described in paragraph (c)(3)(ii) of this section, with D and E receiving title to the DE assets and then contributing the assets to ABC in exchange for interests in ABC. As part of a prearranged transaction, the assets acquired from DE are contributed to a new partnership, and the interests in the new partnership are distributed to B and C in complete liquidation of their interests in ABC. The merger and division in this example represent a series of transactions that in substance are an exchange of interests in ABC for interests in DE. Even though paragraph (c)(3)(ii) of this section provides that the form of a merger will be respected for Federal income tax purposes if the steps prescribed under the assets-up form are followed, and paragraph (d)(3)(i) of this section provides a form that will be followed for Federal income tax purposes in the case of partnership divisions, these forms will not be respected for Federal income tax purposes under these facts, and the transactions will be recast in accordance with their substance as a taxable exchange of interests in ABC for interests in DE.

(7) *Effective date.* This paragraph (c) is applicable to partnership mergers occurring on or after January 4, 2001. However, a partnership may apply paragraph (c) of this section to partnership mergers occurring on or after January 11, 2000.

(d) *Division of a partnership*—(1) *General rule.* Upon the division of a partnership into two or more partnerships, any resulting partnership (as defined in paragraph (d)(4)(iv) of this section) or resulting partnerships shall be considered a continuation of the prior partnership (as defined in paragraph (d)(4)(ii) of this section) if the members of the resulting partnership or partnerships had an interest of more than 50 percent in the capital and profits of the prior partnership. Any other resulting partnership will not be considered a continuation of the prior partnership but will be considered a new partnership. If the members of none

of the resulting partnerships owned an interest of more than 50 percent in the capital and profits of the prior partnership, none of the resulting partnerships will be considered a continuation of the prior partnership, and the prior partnership will be considered to have terminated. Where members of a partnership which has been divided into two or more partnerships do not become members of a resulting partnership which is considered a continuation of the prior partnership, such members' interests shall be considered liquidated as of the date of the division.

(2) *Tax consequences*—(i) *Tax returns.* The resulting partnership that is treated as the divided partnership (as defined in paragraph (d)(4)(i) of this section) shall file a return for the taxable year of the partnership that has been divided and retain the employer identification number (EIN) of the prior partnership. The return shall include the names, addresses, and EINs of all resulting partnerships that are regarded as continuing. The return shall also state that the partnership is a continuation of the prior partnership and shall set forth separately the respective distributive shares of the partners for the periods prior to and including the date of the division and subsequent to the date of division. All other resulting partnerships that are regarded as continuing and new partnerships shall file separate returns for the taxable year beginning on the day after the date of the division with new EINs for each partnership. The return for a resulting partnership that is regarded as continuing and that is not the divided partnership shall include the name, address, and EIN of the prior partnership.

(ii) *Elections.* All resulting partnerships that are regarded as continuing are subject to preexisting elections that were made by the prior partnership. A subsequent election that is made by a resulting partnership does not affect the other resulting partnerships.

(3) *Form of a division*—(i) *Assets-over form.* When a partnership divides into two or more partnerships under applicable jurisdictional law without undertaking a form for the division, or undertakes a form that is not described in paragraph (d)(3)(ii) of this section, the transaction will be characterized under the assets-over form for Federal income tax purposes.

(A) *Assets-over form where at least one resulting partnership is a continuation of the prior partnership.* In a division under the assets-over form where at least one resulting partnership is a continuation of the prior partnership, the divided partnership (as defined in paragraph (d)(4)(i) of this section) contributes certain assets and liabilities to a recipient partnership (as defined in paragraph (d)(4)(iii) of this section) or recipient partnerships in exchange for interests in such recipient partnership or partnerships; and, immediately thereafter, the divided partnership distributes the interests in such recipient partnership or partnerships to some or all of its partners in partial or complete liquidation of the partners' interests in the divided partnership.

(B) *Assets-over form where none of the resulting partnerships is a continuation of the prior partnership.* In a division under the assets-over form where none of the resulting partnerships is a continuation of the prior partnership, the prior partnership will be treated as contributing all of its assets and liabilities to new resulting partnerships in exchange for interests in the resulting partnerships; and, immediately thereafter, the prior partnership will be treated as liquidating by distributing the interests in the new resulting partnerships to the prior partnership's partners.

(ii) *Assets-up form*—(A) *Assets-up form where the partnership distributing assets is a continuation of the prior partnership.* Despite the partners' transitory ownership of some of the prior partnership's assets, the form of a partnership division will be respected for Federal income tax purposes if the divided partnership (which, pursuant to § 1.708–1(d)(4)(i), must be a continuing partnership) distributes certain assets (in a manner that causes the partners to be treated, under the laws of the applicable jurisdiction, as the owners of such assets) to some or all of its partners in partial or complete liquidation of the partners' interests in the divided partnership, and immediately thereafter, such partners contribute the distributed assets to a recipient partnership or partnerships in exchange for interests in such recipient partnership or partnerships. In order for such form to be respected for transfers to a particular recipient partnership, all assets held by the prior partnership that are transferred to the recipient partnership must be distributed to, and then contributed by, the partners of the recipient partnership.

(B) *Assets-up form where none of the resulting partnerships are a continuation of the prior partnership.* If none of the resulting partnerships are a continuation of the prior partnership, then despite the partners' transitory ownership of some or all of the prior partnership's assets, the form of a partnership division will be respected for Federal income tax purposes if the prior partnership distributes certain assets (in a manner that causes the partners to be treated, under the laws of the applicable jurisdiction, as the owners of such assets) to some or all of its partners in partial or complete liquidation of the partners' interests in the prior partnership, and immediately thereafter, such partners contribute the distributed assets to a resulting partnership or partnerships in exchange for interests in such resulting partnership or partnerships. In order for such form to be respected for transfers to a particular resulting partnership, all assets held by the prior partnership that are transferred to the resulting partnership must be distributed to, and then contributed by, the partners of the resulting partnership. If the prior partnership does not liquidate under the applicable jurisdictional law, then with respect to the assets and liabilities that, in form, are not transferred to a new resulting partnership, the prior partnership will be treated as transferring these assets and liabilities to a new resulting partnership under the assets-over form described in paragraph (d)(3)(i)(B) of this section.

(4) *Definitions*—(i) *Divided partnership.* For purposes of paragraph (d) of this section, the divided partnership is the continuing partnership which is treated, for Federal income tax purposes, as transferring the assets and liabilities to the recipient partnership or partnerships, either directly (under the assets-over form) or indirectly (under the assets-up form). If the resulting partnership that, in form, transferred the assets and liabilities in connection with the division is a continuation of the prior partnership, then such resulting partnership will be treated as the divided partnership. If a partnership divides into two or more partnerships and only one of the resulting partnerships is a continuation of the prior partnership, then the resulting partnership that is a continuation of the prior partnership will be treated as the divided partnership. If a partnership divides into two or more partnerships without undertaking a form for the division that is recognized under paragraph (d)(3) of this section, or if the resulting partnership that had, in form, transferred assets and liabilities is not considered a continuation of the prior partnership, and more than one resulting partnership is considered a continuation of the prior partnership, the continuing resulting partnership with the assets having the greatest fair

market value (net of liabilities) will be treated as the divided partnership.

(ii) *Prior partnership.* For purposes of paragraph (d) of this section, the prior partnership is the partnership subject to division that exists under applicable jurisdictional law before the division.

(iii) *Recipient partnership.* For purposes of paragraph (d) of this section, a recipient partnership is a partnership that is treated as receiving, for Federal income tax purposes, assets and liabilities from a divided partnership, either directly (under the assets-over form) or indirectly (under the assets-up form).

(iv) *Resulting partnership.* For purposes of paragraph (d) of this section, a resulting partnership is a partnership resulting from the division that exists under applicable jurisdictional law after the division and that has at least two partners who were partners in the prior partnership. For example, where a prior partnership divides into two partnerships, both partnerships existing after the division are resulting partnerships.

(5) *Examples.* The following examples illustrate the rules in paragraphs (d)(1), (2), (3), and (4) of this section:

Example 1. Partnership ABCD is in the real estate and insurance businesses. A owns a 40-percent interest, and B, C, and D each owns a 20-percent interest, in the capital and profits of the partnership. The partnership and the partners report their income on a calendar year. On November 1, 1999, they separate the real estate and insurance businesses and form two partnerships. Partnership AB takes over the real estate business, and partnership CD takes over the insurance business. Because members of resulting partnership AB owned more than a 50-percent interest in the capital and profits of partnership ABCD (A, 40 percent, and B, 20 percent), partnership AB shall be considered a continuation of partnership ABCD. Partnership AB is required to file a return for the taxable year January 1 to December 31, 1999, indicating thereon that until November 1, 1999, it was partnership ABCD. Partnership CD is considered a new partnership formed at the beginning of the day on November 2, 1999, and is required to file a return for the taxable year it adopts pursuant to section 706(b) and the applicable regulations.

Example 2. (i) Partnership ABCD owns properties W, X, Y, and Z, and divides into partnership AB and partnership CD. Under paragraph (d)(1) of this section, partnership AB is considered a continuation of partnership ABCD and partnership CD is considered a new partnership. Partnership ABCD distributes property Y to C and titles property Y in C's name. Partnership ABCD distributes property Z to D and titles property Z in D's name. C and D then contribute properties Y and Z, respectively, to partnership CD in exchange for interests in partnership CD. Properties W and X remain in partnership AB.

(ii) Under paragraph (d)(3)(ii) of this section, partnership ABCD will be treated as following the assets-up form for Federal income tax purposes.

Example 3. (i) The facts are the same as in *Example 2*, except partnership ABCD distributes property Y to C and titles property Y in C's name. C then contributes property Y to partnership CD. Simultaneously, partnership ABCD contributes property Z to partnership CD in exchange for an interest in partnership CD. Immediately thereafter, partnership ABCD distributes the interest in partnership CD to D in liquidation of D's interest in partnership ABCD.

(ii) Under paragraph (d)(3)(i) of this section, because partnership ABCD did not undertake the assets-up form with respect to all of the assets transferred to partnership CD, partnership ABCD will be treated as undertaking the assets-over form in transferring the assets to partnership CD. Accordingly, for Federal income tax purposes, partnership ABCD is deemed to contribute property Y and property Z to partnership CD in exchange for interests in partnership CD, and immediately thereafter, partnership ABCD is deemed to distribute the interests in partnership CD to partner C and partner D in liquidation of their interests in partnership ABCD.

Example 4. (i) Partnership ABCD owns three parcels of property: property X, with a value of $500; property Y, with a value of $300; and property Z, with a value of $200. A and B each own a 40-percent interest in the capital and profits of partnership ABCD, and C and D each own a 10 percent interest in the capital and profits of partnership ABCD. On November 1, 1999, partnership ABCD divides into three partnerships (AB1, AB2, and CD) by contributing property X to a newly formed partnership (AB1) and distributing all interests in such partnership to A and B as equal partners, and by contributing property Z to a newly formed partnership (CD) and distributing all interests in such partnership to C and D as equal partners in exchange for all of their interests in partnership ABCD. While partnership ABCD does not transfer property Y, C and D cease to be partners in the partnership. Accordingly, after the division, the partnership holding property Y is referred to as partnership AB2.

(ii) Partnerships AB1 and AB2 both are considered a continuation of partnership ABCD, while partnership CD is considered a new partnership formed at the beginning of the day on November 2, 1999. Under paragraph (d)(3)(i)(A) of this section, partnership ABCD will be treated as following the assets-over form, with partnership ABCD contributing property X to partnership AB1 and property Z to partnership CD, and distributing the interests in such partnerships to the designated partners.

Example 5. (i) The facts are the same as in *Example 4*, except that partnership ABCD divides into three partnerships by operation of state law, without undertaking a form.

(ii) Under the last sentence of paragraph (d)(4)(i) of this section, partnership AB1 will be treated as the resulting partnership that is the divided partnership. Under paragraph (d)(3)(i)(A) of this section, partnership ABCD will be treated as following the assets-over form, with partnership ABCD contributing property Y to partnership AB2 and property Z to partnership CD, and distributing the interests in such partnerships to the designated partners.

Example 6. (i) The facts are the same as in *Example 4*, except that partnership ABCD divides into three partnerships by contributing property X to newly-formed partnership AB1 and property Y to newly-formed partnership AB2 and distributing all interests in each partnership to A and B in exchange for all of their interests in partnership ABCD.

(ii) Because resulting partnership CD is not a continuation of the prior partnership (partnership ABCD), partnership CD cannot be treated, for Federal income tax purposes, as the partnership that transferred assets (*i.e.,* the divided partnership), but instead must be treated as a recipient partnership. Under the last sentence of paragraph (d)(4)(i) of this section, partnership AB1 will be treated as the resulting partnership that is the divided partnership. Under paragraph (d)(3)(i)(A) of this section, partnership ABCD will be treated as following the assets-over form, with partnership ABCD contributing property Y to partnership AB2 and property Z to partnership CD, and distributing the interests in such partnerships to the designated partners.

Example 7. (i) Partnership ABCDE owns Blackacre, Whiteacre, and Redacre, and divides into partnership AB, partnership CD, and partnership DE. Under paragraph (d)(1) of this section, partnership ABCDE is considered terminated (and, hence, none of the resulting partnerships are a continuation of the prior partnership) because none of the members of the new partnerships (partnership AB, partnership CD, and partnership DE) owned an interest of more than 50 percent in the capital and profits of partnership ABCDE.

(ii) Partnership ABCDE distributes Blackacre to A and B and titles Blackacre in the names of A and B. A and B then contribute Blackacre to partnership AB in exchange for interests in partnership AB. Partnership ABCDE will be treated as following the assets-up form described in paragraph (d)(3)(ii)(B) of this section for Federal income tax purposes.

(iii) Partnership ABCDE distributes Whiteacre to C and D and titles Whiteacre in the names of C and D. C and D then contribute Whiteacre to partnership CD in exchange for interests in partnership CD. Partnership ABCDE will be treated as following the assets-up form described in paragraph (d)(3)(ii)(B) of this section for Federal income tax purposes.

(iv) Partnership ABCDE does not liquidate under state law so that, in form, the assets in new partnership DE are not considered to have been transferred under state law. Partnership ABCDE will be treated as undertaking the assets-over form described in paragraph (d)(3)(i)(B) of this section for Federal income tax purposes with respect to the assets of partnership DE. Thus, partnership ABCDE will be treated as contributing Redacre to partnership DE in

exchange for interests in partnership DE; and, immediately thereafter, partnership ABCDE will be treated as distributing interests in partnership DE to D and E in liquidation of their interests in partnership ABCDE. Partnership ABCDE then terminates.

(6) *Prescribed form not followed in certain circumstances.* If any transactions described in paragraph (d)(3) of this section are part of a larger series of transactions, and the substance of the larger series of transactions is inconsistent with following the form prescribed in such paragraph, the Commissioner may disregard such form, and may recast the larger series of transactions in accordance with their substance.

(7) *Effective date.* This paragraph (d) is applicable to partnership divisions occurring on or after January 4, 2001. However, a partnership may apply paragraph (d) of this section to partnership divisions occurring on or after January 11, 2000.

Par. 3. Section 1.752–1 is amended as follows:

1. A sentence is added to the end of paragraph (f).

2. The current *Example* in paragraph (g) is redesignated as *Example 1.*

3. *Example 2* is added in paragraph (g).

The additions read as follows:

§ 1.752–1 Treatment of partnership liabilities.

* * * * *

(f) * * * When two or more partnerships merge or consolidate under section 708(b)(2)(A), as described in § 1.708–1(c)(3)(i), increases and decreases in partnership liabilities associated with the merger or consolidation are netted by the partners in the terminating partnership and the resulting partnership to determine the effect of the merger under section 752.

(g) * * *

Example 1. * * *

Example 2. Merger or consolidation of partnerships holding property encumbered by liabilities. (i) B owns a 70 percent interest in partnership T. Partnership T's sole asset is property X, which is encumbered by a $900 liability. Partnership T's adjusted basis in property X is $600, and the value of property X is $1,000. B's adjusted basis in its partnership T interest is $420. B also owns a 20 percent interest in partnership S. Partnership S's sole asset is property Y, which is encumbered by a $100 liability. Partnership S's adjusted basis in property Y is $200, the value of property Y is $1,000, and B's adjusted basis in its partnership S interest is $40.

(ii) Partnership T and partnership S merge under section 708(b)(2)(A). Under section 708(b)(2)(A) and § 1.708–1(c)(1), partnership T is considered terminated and the resulting partnership is considered a continuation of partnership S. Partnerships T and S undertake the form described in § 1.708–1(c)(3)(i) for the partnership merger. Under § 1.708–1(c)(3)(i), partnership T contributes property X and its $900 liability to partnership S in exchange for an interest in partnership S. Immediately thereafter, partnership T distributes the interests in partnership S to its partners in liquidation of their interests in partnership T. B owns a 25 percent interest in partnership S after partnership T distributes the interests in partnership S to B.

(iii) Under paragraph (f) of this section, B nets the increases and decreases in its share of partnership liabilities associated with the merger of partnership T and partnership S. Before the merger, B's share of partnership liabilities was $650 (B had a $630 share of partnership liabilities in partnership T and a $20 share of partnership liabilities in partnership S immediately before the merger). B's share of S's partnership liabilities after the merger is $250 (25 percent of S's total partnership liabilities of $1,000). Accordingly, B has a $400 net decrease in its share of S's partnership liabilities. Thus, B is treated as receiving a $400 distribution from partnership S under section 752(b). Because B's adjusted basis in its partnership S interest before the deemed distribution under section 752(b) is $460 ($420 + $40), B will not recognize gain under section 731. After the merger, B's adjusted basis in its partnership S interest is $60.

* * * * *

Par. 4. In § 1.752–5, paragraph (a) is amended by adding two sentences after the third sentence.

§ 1.752–5 Effective dates and transition rules.

(a) *In general.* * * * In addition, § 1.752–1(f) last sentence and (g) *Example 2*, do not apply to any liability incurred or assumed by a partnership prior to January 4, 2001. Nevertheless, § 1.752–1(f) last sentence and (g) *Example 2*, may be relied on for any liability incurred or assumed by a partnership prior to January 4, 2001 and, unless the partnership makes an election under paragraph (b)(1) of this section, on or after December 28, 1991, other than a liability incurred or assumed by the partnership pursuant to a written binding contract in effect prior to December 28, 1991 and at all times thereafter. * * *

* * * * *

David A. Mader,

Acting Deputy Commissioner of Internal Revenue.

Approved: December 20, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 01–202 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8924]

RIN 1545–AY63

Liabilities Assumed in Certain Corporate Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary and final regulations.

SUMMARY: These temporary and final regulations relate to the assumption of liabilities in certain corporate transactions under section 301 of the Internal Revenue Code. The temporary and final regulations affect corporations and their shareholders. Changes to the applicable law were made by the Miscellaneous Trade and Technical Corrections Act of 1999, Public Law 106–36 (113 Stat. 127). The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective January 4, 2001.

Applicability Date: For dates of applicability, see the Effective Dates portion of the preamble under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Mary Dean, (202) 622–7550 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

A. State of the Law Before the Miscellaneous Trade and Technical Corrections Act of 1999

Section 301(b)(2) of the Internal Revenue Code (Code) provides that in a distribution of property made by a corporation to a shareholder with respect to its stock, the amount of the distribution shall be reduced (but now below zero) by (A) the amount of any liability of the corporation assumed by the shareholder in connection with the distribution and (B) the amount of any liability to which the property was subject immediately before, and after, the distribution. See also § 1.301–1(g) of the regulations.

Section 357 of the Code generally provides rules for the treatment of the assumption of liabilities in connection with transfers of property to which section 351 or 361 of the Code applies.

Prior to the Miscellaneous Trade and Technical Corrections Act of 1999 (the Act), section 357(a) provided that, except as otherwise provided, in such transfers the assumption of the transferor's liability or acquisition of property subject to a liability is not treated as money or other property, *i.e.,* is not treated as boot received by the transferor.

Prior to the Act, section 357(c) provided that in an exchange to which section 351 applies or section 361 applies by reason of a section 368(a)(1)(D) reorganization, if the sum of the amount of the liabilities assumed plus the amount of the liabilities to which the property transferred is subject exceeds the total of the adjusted basis of the property transferred pursuant to such exchange, then such excess is considered as a gain from the sale or exchange of a capital asset or of property which is not a capital asset, as the case may be.

B. Enactment of Amendments to Section 357

The Act amended the language in section 357(a) and (c) and added new section 357(d). Under the amendment to section 357(a) and (c), the reference to the acquisition of an asset subject to a liability was eliminated. Section 357(c) gain will be realized only on the excess of the amount of liabilities assumed over the adjusted basis of the property transferred in the transaction. New section 357(d) sets forth the rules for determining the amount of both recourse and nonrecourse liabilities assumed. Section 357(d) states that except as provided in regulations, a recourse liability (or portion thereof) is treated as having been assumed if, based on all the facts and circumstances, the transferee has agreed to, and is expected to, satisfy such liability, whether or not the transferor has been relieved of such liability. A nonrecourse liability is treated as having been assumed by the transferee of any asset subject to such liability, except that the amount of nonrecourse liability treated as having been assumed is reduced by the lesser of (A) the amount of such liability which an owner of other assets not transferred to the transferee and also subject to such liability has agreed with the transferee to, and is expected to, satisfy, or (B) the fair market value of such other assets. Congress provided these clarifications because certain interpretations of the existing law failed to adequately reflect the true economics of many transactions, resulting in inappropriate positions claimed by taxpayers. See S. Rep. No. 106–2, at 75 (1999).

Section 357(d)(3) directs the Secretary to prescribe regulations necessary to carry out the purposes of subsection (d). It also authorizes the Secretary to prescribe regulations which provide that the manner in which a liability is treated as assumed under subsection (d) is applied, where appropriate, elsewhere in the Code.

C. Application of Regulatory Authority to Section 301

The Treasury and the IRS have determined that it is appropriate to apply the rules of section 357(d), relating to the manner in which a liability is treated as assumed, to distributions of property under section 301 of the Code. Section 301(b)(2)(A) provides that the amount of the distribution will be reduced if the transferee assumes a liability of the corporation. Section 301(b)(2)(B) provides that the amount of the distribution will be reduced if the transferee receives property subject to a liability. These two sections do not provide specific rules for determining the amount of liabilities assumed, as contained in section 357(d). The lack of specific rules has led to interpretations of existing law that fail to reflect the true economics of certain transactions. For reasons similar to those that motivated the enactment of section 357(d), these interpretations are inappropriate for purposes of section 301. Notice 99–59, 1999–52 I.R.B. 761, illustrates one such case. In the transaction addressed in Notice 99–59, a corporation distributes property subject to a recourse liability, with the expectation that the distributee will take the position that it receives little or no net distribution, even though it is anticipated that the distributor will later satisfy its continuing primary liability on the debt.

Explanation of Provisions

Liabilities Assumed in Connection With Distributions to Shareholders

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 301 relating to liabilities assumed in connection with distributions made by a corporation to shareholders with respect to their stock. The regulations provide that the amount of a distribution under section 301 will be reduced by the amount of any liability that is treated as assumed by the distributee within the meaning of section 357(d)(1) and (2).

The Treasury and the IRS intend to propose regulations under sections 357(d) and 301 clarifying the treatment of the subsequent payment of assumed liabilities. Prior to the issuance of such regulations, the Treasury and the IRS believe that such payments generally should be treated in a manner consistent with the treatment of the liabilities assumed. Thus, in a situation where a liability is treated as assumed by the transferee under the rules of section 357(d), a later payment by the party whose liability was treated as assumed should be treated in accordance with the relationship of the parties (*e.g.,* a distribution or capital contribution). See, *e.g., Enoch* v. *Commissioner,* 57 T.C. 781 (1972), *acq. in part,* 1974–2 C.B. 2, 4, *nonacq.,* 1984–2 C.B. 5.

Effective Date

The regulations apply generally to distributions occurring after January 4, 2001. The regulations also apply to distributions occurring on or prior to January 4, 2001, if the distribution is made as part of a transaction described in, or substantially similar to, the transaction in Notice 99–59, including transactions designed to reduce gain. Under section 7805(b)(3), the Secretary may provide that any regulation may take effect or apply retroactively to prevent abuse. These regulations are being applied retroactively to prevent the abuse described in Notice 99–59. No inference should be drawn regarding the tax treatment of distributions not covered by these regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. Because no preceding notice of proposed rulemaking is required for this temporary regulation, the provisions of the Regulatory Flexibility Analysis do not apply.

This Treasury decision is issued pursuant to the grants of authority in sections 357(d)(3) and 7805 of the Internal Revenue Code. This Treasury decision provides specific rules for determining the amount by which a distribution under section 301(b) will be reduced, by applying the rules of section 357(d). Section 357(d) was intended to clarify the law because certain interpretations of existing law did not reflect the economics of certain transactions. Issuing the regulation in proposed form would continue the difficulty in ascertaining the appropriate reduction in distributions under section 301(b). Based on these considerations, it is determined that this temporary regulation will provide taxpayers with the necessary guidance and authority to ensure equitable administration of the

tax laws. Therefore, it would be contrary to the public interest to issue this Treasury decision with prior notice under section 553(b) or subject to the effective date limitation of section 553(d) of title 5 of the United States Code.

Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 1.301–1 also issued under 26 U.S.C. 357(d)(3).

Section 1.301–1T also issued under 26 U.S.C. 357(d)(3). * * *

Par. 2. Section 1.301–1 is amended by adding two new sentences at the end of paragraph (g) to read as follows:

§ 1.301–1 Rules applicable with respect to distributions of money and other property.

* * * * *

(g) * * * This paragraph (g) applies to distributions occurring on or before January 4, 2001. See § 1.301–1T for rules for distributions occurring after January 4, 2001, and for distributions made on or before January 4, 2001 if the distribution is made as part of a transaction described in, or substantially similar to, the transaction in Notice 1999–59, 1999–52 I.R.B. 761, including transactions designed to reduce gain (see § 601.601(d)(2) of this chapter).

* * * * *

Par. 3. Section 1.301–1T is added to read as follows:

§ 1.301–1T Rules applicable with respect to distributions of money and other property (temporary).

(a) through (f). [Reserved] For further guidance, see § 1.301–1(a) through (f).

(g) *Reduction for liabilities*—(1) *General rule.* For the purpose of section 301, no reduction shall be made for the amount of any liability, unless the liability is assumed by the shareholder within the meaning of section 357(d)(1) and (2).

(2) *No reduction below zero.* Any reduction pursuant to paragraph (g)(1) of this section shall not cause the amount of the distribution to be reduced below zero.

(3) *Effective dates*—(i) *In general.* This paragraph (g) applies to distributions occurring after January 4, 2001.

(ii) *Retroactive application.* This paragraph also applies to distributions made on or before January 4, 2001 if the distribution is made as part of a transaction described in, or substantially similar to, the transaction in Notice 1999–59 (1999–52 I.R.B. 761), including transactions designed to reduce gain (see § 601.601(d)(2) of this chapter).

Approved: December 20, 2000.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Jonathan Talisman,

Acting Assistant Secretary for Tax Policy.

[FR Doc. 01–200 Filed 1–3–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD8922]

RIN 1545–AX00

Awards of Attorney's Fees and Other Costs Based Upon Qualified Offers

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations relating to the circumstances under which a party, by reason of having made a qualified offer, will be entitled to an award of reasonable administrative and litigation costs in a civil tax proceeding brought in a court of the United States (including the Tax Court). The regulations implement certain changes made by section 3101(e) of the Internal Revenue Service Restructuring and Reform Act of 1998. They affect taxpayers who make qualified offers. The text of these regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Dates.* These regulations are effective January 3, 2001.

Applicability Date: These regulations apply to qualified offers made in administrative or court proceedings described in section 7430 after January 3, 2001.

FOR FURTHER INFORMATION CONTACT: Thomas D. Moffitt (202) 622–7900 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Procedure and Administration Regulations (26 CFR part 301) that reflect changes to section 7430 made by section 3101(e) of the Internal Revenue Service Restructuring and Reform Act of 1998 relating to the circumstances under which taxpayers may recover reasonable administrative and litigation costs in a court proceeding with respect to the determination or refund of any tax, interest or penalty when taxpayers have made a qualified offer.

Explanation of Provisions

In general, a prevailing party may recover the reasonable administrative and litigation costs incurred in administrative and court proceedings if the proceedings relate to the determination or refund of any tax, interest or penalty under the Internal Revenue Code. The regulations provide information concerning the circumstances under which the making of a qualified offer will result in the taxpayer being a prevailing party for purposes of a recovery of costs. In general, a taxpayer is a prevailing party by reason of making a qualified offer if the taxpayer's liability under the last qualified offer would equal or exceed the amount of the taxpayer's liability (determined without regard to interest) attributable to the adjustments included in the last qualified offer that were actually determined by the court through litigation, plus the amount of any additional adjustments included in the last qualified offer that were determined by settlements entered into after the making of the last qualified offer. Adjustments raised by any party subsequent to the making of the last qualified offer are disregarded in determining the liability of the taxpayer to be compared with the liability under the last qualified offer. These regulations apply in multiple taxpayer situations, such as joint returns, but do not set forth any special rules regarding the aggregation or segregation of the qualified offer or liability in situations that may present special circumstances, such as claims for innocent spouse relief. After study, further guidance may be issued elaborating on the treatment of such situations under these regulations.

To qualify as a prevailing party under this rule, in addition to the above,

taxpayers must also satisfy the net worth requirements of section 7430(c)(4)(A)(ii). Furthermore, to qualify for an award, taxpayers must satisfy the remaining requirements of section 7430, such as not unreasonably protracting the proceedings and, for purposes of an award of litigation costs, exhausting their administrative remedies. On the other hand, a taxpayer qualifying as a prevailing party by reason of having made a qualified offer need not substantially prevail on either the amount in controversy or the most significant issue or set of issues presented. Similarly, whether the positions of the United States in the administrative and litigation proceedings were substantially justified is not relevant for an award under the qualified offer rule. An award based upon the taxpayer having made a qualified offer is limited to those reasonable administrative and litigation costs incurred on or after the date of the last qualified offer, with respect to the adjustments that were included in the last qualified offer, and litigated to a judicial determination. If the taxpayer qualifies as a prevailing party without regard to the qualified offer rule, the reasonable administrative and litigation costs to which the taxpayer is thus entitled may not be awarded again by reason of the taxpayer having made a qualified offer.

A qualified offer is a written offer that: (1) Is made by the taxpayer to the United States during the qualified offer period; (2) establishes the taxpayer's liability (determined without regard to interest) by setting forth the amount of the taxpayer's offer on all adjustments at issue in the proceeding at the time the qualified offer is made; (3) is designated as a qualified offer at the time it is made; and (4) remains open at least until the earliest of the date the offer is rejected, the date the trial begins, or the 90th day after the date the offer is made.

The qualified offer period ends on the date which is thirty days before the date the case is first set for trial. In cases that are pending in the United States Tax Court, cases are placed upon a calendar for trial. Each case appearing on a trial calendar is to be called at the time and place scheduled. In determining when the qualified offer period ends for cases in the Tax Court and other courts of the United States using calendars for trial, a case is considered to be set for trial on the date scheduled for the calendar call. Cases may be removed from a trial calendar at any time. Thus, a case may be removed from a calendar before the date that precedes by thirty days the date scheduled for that calendar. To promote the settlement of such cases, the qualified offer period does not end until the case remains on a calendar for trial on the date that precedes by 30 days the scheduled date of the calendar call for that trial session. The qualified offer period may not be extended, although the period during which a qualified offer remains open may extend beyond the end of the qualified offer period.

A taxpayer cannot qualify as a prevailing party by reason of having made a qualified offer if the determination of the court in the proceeding with respect to the adjustments included in the last qualified offer is entered exclusively pursuant to a settlement. Neither can a taxpayer qualify as a prevailing party by reason of having made a qualified offer in any proceeding in which the amount of tax liability is not in issue, including any declaratory judgment proceeding, any proceeding to enforce or quash any summons issued pursuant to the Internal Revenue Code of 1986, and any action to restrain disclosure under section 6110(f).

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and, because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Thomas D. Moffitt, Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 301.7430–7T is added to read as follows:

§ 301.7430–7T Qualified offers (temporary).

(a) *In general.* Section 7430(c)(4)(E) (the qualified offer rule) provides that a party to a court proceeding satisfying the timely filing and net worth requirements of section 7430(c)(4)(A)(ii) shall be treated as the prevailing party if the liability of the taxpayer pursuant to the judgment in the proceeding (determined without regard to interest) is equal to or less than the liability of the taxpayer which would have been so determined if the United States had accepted the last qualified offer of the party as defined in section 7430(g). For purposes of this section, the term *judgment* means the cumulative determinations of the court concerning the adjustments at issue and litigated to a determination in the court proceeding. In making the comparison between the liability under the qualified offer and the liability under the judgment, the taxpayer's liability under the judgment is further modified by the provisions of paragraph (b)(3) of this section. The provisions of the qualified offer rule do not apply if the taxpayer's liability under the judgment, as modified by the provisions of paragraph (b)(3) of this section, is determined exclusively pursuant to a settlement, or to any proceeding in which the amount of tax liability is not in issue, including any declaratory judgment proceeding, any proceeding to enforce or quash any summons issued pursuant to the Internal Revenue Code, and any action to restrain disclosure under section 6110(f). If the qualified offer rule applies to the court proceeding, the determination of whether the liability under the qualified offer would have equaled or exceeded the liability pursuant to the judgment is made by reference to the last qualified offer made with respect to the tax liability at issue in the administrative or court proceeding. An award of reasonable administrative and litigation costs under the qualified offer rule only includes those costs incurred on or after the date

of the last qualified offer and is limited to those costs attributable to the adjustments at issue at the time the last qualified offer was made that were included in the court's judgment other than by reason of settlement. The qualified offer rule is inapplicable to reasonable administrative or litigation costs otherwise awarded to a taxpayer who is a prevailing party under any other provision of section 7430(c)(4). This section sets forth the requirements to be satisfied for a taxpayer to be treated as a prevailing party by reason of the taxpayer making a qualified offer as well as the circumstances leading to the application of the exceptions, special rules, and coordination provisions of the qualified offer rule. Furthermore, this section sets forth the elements necessary for an offer to be treated as a qualified offer under section 7430(g).

(b) *Requirements for treatment as a prevailing party based upon having made a qualified offer.*—(1) *In general.* In order to be treated as a prevailing party by reason of having made a qualified offer, the liability of the taxpayer for the type or types of tax and the taxable year or years at issue in the proceeding, as calculated pursuant to paragraph (b)(2) of this section, based on the last qualified offer, as defined in paragraph (c) of this section, made by the taxpayer in the court or administrative proceeding, must equal or exceed the liability of the taxpayer pursuant to the judgment by the court for the same type or types of tax and the same taxable year or years, as calculated pursuant to paragraph (b)(3) of this section. Furthermore, the taxpayer must meet the timely filing and net worth requirements of section 7430(c)(4)(A)(ii). If all of the adjustments subject to the last qualified offer are settled prior to the entry of the judgment by the court, the taxpayer is not a prevailing party by reason of having made a qualified offer. The taxpayer may, however, still qualify as a prevailing party if the requirements of section 7430(c)(4)(A) are met.

(2) *Liability under the last qualified offer.* For purposes of making the comparison of liability described in paragraph (b)(1) of this section, the taxpayer's liability under the last qualified offer is the change in the taxpayer's liability for the type or types of tax and the taxable year or years at issue in the proceeding from the tax shown on the return or returns (or as previously adjusted) which would have resulted from the acceptance by the United States of the taxpayer's last qualified offer on all of the adjustments at issue in the administrative or court proceeding at the time that offer was made. The portion of a taxpayer's liability that is attributable to adjustments raised by either party after the making of the last qualified offer is not included in the calculation of the liability under that offer. The taxpayer's liability under the last qualified offer is calculated without regard to adjustments to be fully resolved, by stipulation of the parties, through any other pending court or administrative proceeding. Furthermore, the taxpayer's liability under the last qualified offer is calculated without regard to interest unless the taxpayer's liability for, or entitlement to, interest is a contested issue in the administrative or court proceeding and is one of the adjustments included in the last qualified offer.

(3) *Liability pursuant to the judgment.* For purposes of making the comparison of liability described in paragraph (b)(1) of this section, the taxpayer's liability pursuant to the judgment is the change in the taxpayer's liability for the type or types of tax and the taxable year or years at issue in the proceeding from the tax shown on the return or returns (or as previously adjusted), resulting from amounts contained, or to be contained, in the judgment as a result of the court's determinations, and amounts contained in settlements not included in the judgment, that are attributable to all adjustments that were included in the last qualified offer. This liability includes amounts attributable to adjustments included in the last qualified offer and settled by the parties prior to the entry of judgment regardless of whether those amounts are actually included in the judgment entered by the court. The taxpayer's liability pursuant to the judgment does not include amounts attributable to adjustments that are not included in the last qualified offer, even if those amounts are actually included in the judgment entered by the court. The taxpayer's liability pursuant to the judgment is calculated without regard to adjustments to be fully resolved, by stipulation of the parties, through any other pending court or administrative proceeding. Furthermore, the taxpayer's liability pursuant to the judgment is calculated without regard to interest unless the taxpayer's liability for, or entitlement to, interest is a contested issue in the administrative or court proceeding and is one of the adjustments included in the last qualified offer. Where adjustments raised by either party subsequent to the making of the last qualified offer are included in the judgment entered by the court, or are settled prior to the court proceeding, the taxpayer's liability pursuant to the judgment is calculated by treating the subsequently raised adjustments as if they had never been raised.

(c) *Qualified offer*—(1) *In general.* A qualified offer is defined in section 7430(g) to mean a written offer which—

(i) Is made by the taxpayer to the United States during the qualified offer period;

(ii) Specifies the offered amount of the taxpayer's liability (determined without regard to interest, unless interest is a contested issue in the proceeding);

(iii) Is designated at the time it is made as a qualified offer for purposes of section 7430(g); and

(iv) By its terms, remains open during the period beginning on the date it is made and ending on the earliest of the date the offer is rejected, the date the trial begins, or the 90th day after the date the offer is made.

(2) *To the United States.* (i) A qualified offer is made to the United States if it is delivered to the Internal Revenue Service; Office of Appeals; Office of Chief Counsel (including field personnel), Internal Revenue Service; or Department of Justice office or personnel having jurisdiction over the tax matter at issue in the administrative or court proceeding. If those offices or persons are unknown to the taxpayer making the qualified offer, the taxpayer may deliver the offer to the appropriate office, as follows:

(A) If the taxpayer's initial pleading in a court proceeding has been answered, the taxpayer may deliver the offer to the office that filed the answer.

(B) If the taxpayer's petition in the Tax Court has not yet been answered, the taxpayer may deliver the offer to the Office of Chief Counsel, 1111 Constitution Avenue, NW., Washington, DC 20224.

(C) If the taxpayer's initial pleading in a court of the United States other than the Tax Court has not yet been answered, the taxpayer may deliver the offer to the Attorney General of the United States, 950 Pennsylvania Ave., NW., Washington, DC 20530–0001 and for a suit brought in a United States district court, a copy of the offer should also be delivered to the United States Attorney for the district in which the suit was brought.

(D) In any other situation, the taxpayer may deliver the offer to the office that sent the taxpayer the first letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals.

(ii) Until an offer is received by the appropriate personnel or office under

this paragraph (c)(2) of this section, it is not considered to have been made, with the following exception. If the offer is deposited in the United States mail, in an envelope or other appropriate wrapper, postage prepaid, properly addressed to the appropriate personnel or office under this paragraph (c)(2), the date of the United States postmark stamped on the cover in which the offer is mailed shall be deemed to be the date of receipt of that offer by the addressee. If any offer is deposited with a designated delivery service, as defined in section 7502(f)(2), in lieu of the United States mail, the provisions of section 7502(f)(1) shall apply in determining whether that offer qualifies for this exception.

(3) *Specifies the offered amount.* A qualified offer specifies the offered amount if it specifies the dollar amount for the liability of the taxpayer, calculated as set forth in paragraph (b)(2) of this section. This amount must be with respect to all of the adjustments at issue in the administrative or court proceeding at the time the offer is made and only those adjustments. The specified amount must be that amount, the acceptance of which by the United States will fully resolve the taxpayer's liability, and only that liability, (determined without regard to adjustments stipulated by the parties to be fully resolved through another pending court or administrative proceeding, or interest, unless interest is a contested issue in the proceeding) for the type or types of tax and the taxable year or years at issue in the proceeding.

(4) *Designated at the time it is made as a qualified offer.* An offer is not a qualified offer unless it is designated in writing at the time it is made that it is a qualified offer for purposes of section 7430(g). An offer made at a time when one or more adjustments not included in the first letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals have been raised by the taxpayer and remain unresolved, is not considered to be designated as a qualified offer at the time it is made unless contemporaneously or prior to the making of the qualified offer, the taxpayer has provided the United States with the substantiation and legal and factual arguments necessary to allow for informed consideration of the merits of those adjustments. For example, a taxpayer will be considered to have provided the United States with the necessary substantiation and legal and factual arguments if the taxpayer (or a qualified representative of the taxpayer described in § 601.502 of this chapter) participates in an Appeals office conference, participates in a District Counsel conference, or confers with the Department of Justice and at that time discloses all relevant information regarding the taxpayer's tax matter to the extent such information and its relevance were known or should have been known to the taxpayer at the time of such conference. All relevant information includes, but is not limited to, the legal and factual arguments supporting the taxpayer's position on any adjustments raised by the taxpayer after the issuance of the first letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals.

(5) *Remains open.* A qualified offer remains open for acceptance by the Government from the date it is made, as defined in paragraph (c)(2) of this section, at least until the earliest of the date it is rejected in writing by a person with authority to reject the settlement, the date the trial begins, or the 90th day after being received by the United States. The offer, by its written terms, may remain open after the occurrence of one or more of the above-referenced events. Once made, the period during which a qualified offer remains open may be extended by the taxpayer prior to its expiration, but such an extension cannot be used to make an offer meet the minimum period for remaining open required by this paragraph.

(6) *Last qualified offer.* A taxpayer may make multiple qualified offers during the qualified offer period. For purposes of the comparison under paragraph (b) of this section, the making of a qualified offer supersedes any previously made qualified offers. In making the comparison described in paragraph (b) of this section, only the qualified offer made most closely in time to the end of the qualified offer period is compared to the taxpayer's liability under the judgment.

(7) *Qualified offer period.* To constitute a qualified offer, an offer must be made during the qualified offer period. The qualified offer period begins on the date on which the first letter of proposed deficiency which allows the taxpayer an opportunity for administrative review in the Internal Revenue Service Office of Appeals is sent to the taxpayer. For this purpose, the date of the notice of claim disallowance will begin the qualified offer period in a refund case. If there has been no notice of claim disallowance in a refund case, the qualified offer period begins on the date on which the answer or other responsive pleading is filed with the court. The qualified offer period ends on the date which is thirty days before the date the case is first set for trial. In determining when the qualified offer period ends for cases in the Tax Court and other courts of the United States using calendars for trial, a case will be considered to be set for trial on the date scheduled for the calendar call. A case may be removed from a trial calendar at any time. Thus, a case may be removed from a calendar before the date that precedes by thirty days the date scheduled for that calendar. The qualified offer period does not end until the case remains on a calendar for trial on the date that precedes by 30 days the scheduled date of the calendar call for that trial session. The qualified offer period may not be extended beyond the periods set forth in this paragraph, although the period during which a qualified offer remains open may extend beyond the end of the qualified offer period.

(d) [Reserved]

(e) *Examples.* The following examples illustrate the provisions of this section:

Example 1. Definition of a judgment. The Internal Revenue Service audits Taxpayer A for year X and issues a notice of proposed deficiency (30-day letter) proposing to disallow deductions 1, 2, 3, and 4. A files a protest and participates in a conference with the Internal Revenue Service Office of Appeals (Appeals). Appeals allows deduction 1, and issues a statutory notice of deficiency for deductions 2, 3, and 4. A's petition to the United States Tax Court for year X never mentions deduction 2. Prior to trial, A concedes deduction 3. After the trial, the Tax Court issues an opinion allowing A to deduct a portion of deduction 4. As used in paragraph (a) of this section, the term *judgment* means the cumulative determinations of the court concerning the adjustments at issue in the court proceeding. Thus, the term judgment does not include deduction 1 because it was never at issue in the court proceeding. Similarly, the term judgment does not include deduction 2 because it was not placed at issue by A in the court proceeding. Although deduction 3 was at issue in the court proceeding, it is not included in the term judgment because it was not determined by the court, but rather by concession or settlement. For purposes of section 7430(c)(4)(e), the term judgment only includes the portion of deduction 4 disallowed by the Tax Court.

Example 2. Liability under the offer and liability under the judgment. Assume the same facts as in *Example 1* except that A makes a qualified offer after the Appeal's conference which is not accepted by the Internal Revenue Service. A's offer is with respect to all adjustments at issue at that time. Those adjustments are deductions 2, 3, and 4. At the conclusion of the litigation, A's entitlement to an award based upon the qualified offer will depend, among other things, on a comparison of the change in A's liability for income tax for year X resulting

from the judgment of the Tax Court with the change that would have resulted had the Internal Revenue Service accepted A's qualified offer. In making this comparison, the term judgment (as discussed in *Example 1*) is modified by including the amounts of settled or conceded adjustments that were at issue at the time the qualified offer was made. Any settled or conceded adjustments that were not at issue at the time the qualified offer was made, either because the settlement or concession occurred before the offer or because the adjustment was not raised until after the offer, are not included in the comparison. Thus, A's offer on deductions 2, 3, and 4 is compared with the change in A's liability resulting from the Tax Court's determination on deduction 4, and the concessions of issues 2 and 3 by A.

Example 3. Offer Must resolve full liability. Assume the same facts as in *Example 2* except that A's offer after the Appeals conference explicitly states that it is only with respect to adjustments 2 and 3 and not with respect to adjustment 4. Even if A's liability pursuant to the judgment, calculated under paragraph (b)(3) of this section as illustrated in *Example 2,* is equal to or less than it would have been had the Internal Revenue Service accepted A's offer after the Appeal's conference, A is not a prevailing party under section 7430(c)(4)(E). This is because a qualified offer must include all adjustments at issue at the time the offer is made. Since A's offer excluded adjustment 4, which was an adjustment at issue at the time the offer was made, it does not constitute a qualified offer pursuant to paragraph (b)(2) of this section.

Example 4. Qualified offer rule inapplicable when all issues settled. Taxpayer B receives a notice of proposed deficiency (30-day letter) proposing to disallow both a personal interest deduction in the amount of $10,000 (Adjustment 1), and a charitable contribution deduction in the amount of $2,000 (Adjustment 2), and to include in income $4,000 of unreported interest income (Adjustment 3). B timely files a protest with Appeals. At the Appeals conference B presents substantiation for the charitable contribution and presents arguments that the interest paid was deductible mortgage interest and that the interest received was held in trust for Taxpayer C. At the conference, B also provides the Appeals officer assigned to B's case a written offer to settle the case for a deficiency of $2,000, exclusive of interest. The offer states that it is a qualified offer for purposes of section 7430(g) and that it will remain open for acceptance by the Internal Revenue Service for a period in excess of 90 days. After considering B's substantiation and arguments, the Appeals Officer accepts the $2,000 offer to settle the case in full. Although B's offer is a qualified offer, because all three adjustments contained in the qualified offer were settled, the qualified offer rule is inapplicable.

Example 5. Qualified offer rule inapplicable when all issues contained in the qualified offer are settled; subsequently raised adjustments ignored. Assume the same facts as in *Example 4* except that B's qualified offer was for a deficiency of $1,800 and the Internal Revenue Service rejected that offer. Subsequently, the Internal Revenue Service issued a statutory notice of deficiency disallowing the three adjustments contained in *Example 4,* and, in addition, disallowing a home office expense in the amount of $5,000 (Adjustment 4). After petitioning the Tax Court, B presents the field attorney assigned to the case with a written offer, which is not designated as a qualified offer for purposes of section 7430(g), to settle the three adjustments that had been the subject of the qualified offer, plus adjustment 4, for a total deficiency of $2,500. After negotiating with B, a settlement is reached on the three adjustments that were the subject of the rejected qualified offer, for a deficiency of $1,800. Adjustment 4 is litigated in the Tax Court and the court determines that B is entitled to the full $5,000 deduction for that adjustment. Consequently, a decision is entered by the Tax Court reflecting the $1,800 settlement amount, which matches exactly the amount of B's only qualified offer in the case. Although the determined liability for adjustments 1, 2, and 3, equal that of the rejected qualified offer, because all three adjustments contained in the qualified offer were settled, the qualified offer rule is inapplicable.

Example 6. Exclusion of adjustments made after the qualified offer is made. Assume the same facts as in *Example 5* except the settlement is reached only on adjustments 1 and 2, for a liability of $1,500. Adjustments 3 and 4 are tried in the Tax Court and in accordance with the court's opinion, the taxpayer has a $300 deficiency attributable to Adjustment 3, and a $1,550 deficiency attributable to adjustment 4. Consequently, a decision is entered reflecting the $1,500 settled amount, the $300 liability on adjustment 3, and the $1,550 liability on adjustment 4. The $3,350 deficiency reflected in the Tax Court's decision exceeds the last (and only) qualified offer made by B. For purposes of determining whether B is a prevailing party as a result of having made a qualified offer in the proceeding, the liability attributable to adjustment 4, which was raised after the last qualified offer was made, is not included in the comparison of B's liability under the judgment with B's offered liability under the last qualified offer. Thus, B's $1,800 liability under the judgment, as modified for purposes of the qualified offer rule comparison, is equal to B's offered liability under the last qualified offer. Because B's liability under the last qualified offer equals or exceeds B's liability under the judgment, as calculated under paragraph (b)(3) of this section, B is a prevailing party for purposes of section 7430. Assuming B satisfies the remaining requirements of section 7430, B may recover those reasonable administrative and litigation costs attributable to adjustment 3. To qualify for any further award of reasonable administrative and litigation costs, B must satisfy the full requirements of section 7430(c)(4)(A).

Example 7. Qualified offer in a refund case. Taxpayer C timely files an amended return claiming a refund of $1,000. This refund claim results from several omitted deductions which, if allowed, would reduce D's tax liability from $10,000 to $9,000. C receives a notice of claim disallowance and files a complaint with the appropriate United States District Court. Subsequently, C makes a qualified offer for a refund of $500. The offer is rejected and after trial the court finds C is entitled to a refund of $700. The change in C's liability from the tax shown on the return that would have resulted from the acceptance of C's qualified offer is a reduction in that liability of $500. The change in C's liability from the tax shown on the return resulting from the judgment of the court is a reduction in that liability of $700. Because C's liability under the qualified offer exceeds C's liability under the judgment, C is a prevailing party for purposes of section 7430. Assuming C satisfies the remaining requirements of section 7430, C may recover those reasonable litigation costs incurred on or after the date of the qualified offer. To qualify for any further award of reasonable administrative and litigation costs C must satisfy the full requirements of section 7430(c)(4)(A).

Example 8. End of qualified offer period when case is removed from tax court trial calendar more than 30 days before scheduled trial calendar. Taxpayer E has petitioned the Tax Court in response to the issuance of a notice of deficiency. E receives notice that the case will be heard on the July trial session in E's city of residence. The scheduled date for the calendar call for that trial session is July 1st. On May 15th, E's motion to remove the case from the July trial session and place it on the October trial session for that city is granted. The scheduled date for the calendar call for the October trial session is October 1st. On May 31st, E delivers a qualified offer to the field attorney assigned to the case. On August 31st, E delivers a revised qualified offer to the field attorney assigned to the case. Neither offer is accepted. The case is tried during the October trial session, and at some time thereafter, a decision is entered by the court. Assume the judgment in the case, as calculated under paragraph (b)(3) of this section, is greater than the amount offered, as calculated under paragraph (b)(2) of this section, in the qualified offer delivered on May 31st, but less than the amount offered, as similarly calculated, in the qualified offer delivered on August 31st. Because the qualified offer period did not end until September 1st, and the offer of August 31st otherwise satisfied the requirements of paragraph (c) of this section, the last qualified offer which is compared to the judgment was the offer delivered on August 31st. Consequently, E is a prevailing party under section 7430(c)(4)(e).

Example 9. End of qualified offer period when case is removed from tax court trial calendar less than 30 days before scheduled trial calendar. Assume the same facts as in *Example 8* except that E's motion was granted on June 15th. Because the qualified offer period had ended on June 1st when the case remained on the July trial session on the date that preceded by 30 days the scheduled

date of the calendar call for that trial session, the offer delivered on May 31st was E's last qualified offer. The August 31st offer is not a qualified offer for purposes of this rule. Consequently, E is not a prevailing party under the qualified offer rule. Therefore, E must satisfy the full requirements of section 7430(c)(4)(A) to qualify for any award of reasonable administrative and litigation costs.

Example 10. When a qualified offer can be made and to whom it must be made. During the examination of Taxpayer F's return, the Internal Revenue Service issues a notice of deficiency without having first issued a 30-day letter. After receiving the notice of deficiency F timely petitions the Tax Court. The next day F mails an offer to the office that issued the notice of deficiency, which offer satisfies the requirements of paragraphs (c)(3), (4), (5) and (6) of this section. This is the only written offer made by F during the administrative or court proceeding, and by its terms it is to remain open for a period in excess of 90 days after the date of mailing to the office issuing the notice of deficiency. The office that issued the notice of deficiency transmitted the offer to the field attorney with jurisdiction over the Tax Court case. After answering the case, the field attorney refers the case to Appeals pursuant to Rev. Proc. 87–24 (1987–1 C.B. 720). After careful consideration, Appeals rejects the offer and holds a conference with F where some adjustments are settled. The remainder of the adjustments are tried in the Tax Court and F's liability resulting from the Tax Court's determinations, when added to F's liability resulting from the settled adjustments, is less than F's liability would have been under the offer rejected by Appeals. Because the Tax Court case had not yet been answered when the offer was sent, F properly mailed the offer to the office that issued the notice of deficiency. Thus, F's offer satisfied the requirements of paragraph (c)(2) of this section. Furthermore, even though F did not receive a 30-day letter, F's offer was made after the beginning of the qualified offer period, satisfying the requirements of paragraph (c)(7) of this section, because the issuance of the statutory notice provided F with notice of the Internal Revenue Service's determination of a deficiency, and the docketing of the case provided F with an opportunity for administrative review in the Internal Revenue Service Office of Appeals under Rev. Proc. 87–24 (1987–1 C.B. 720). Because F's offer satisfied all of the requirements of paragraph (c) of this section, the offer was a qualified offer and F is a prevailing party.

Example 11. Last qualified offer. Assume the same facts as in *Example 10* except that at the Appeals conference F makes a new qualified offer concerning the remaining issues. Because this subsequent qualified offer is closer in time to the end of the qualified offer period than the offer made one day after the petition was filed, the subsequent offer would be the last qualified offer made by F and it is F's liability under this offer which would be compared to F's liability under the judgment to determine whether F was a prevailing party under the qualified offer rule.

Example 12. Substitution of parties permitted under last qualified offer. Taxpayer G receives a 30-day letter and participates in a conference with the Office of Appeals but no agreement is reached. Subsequently, G receives a notice of deficiency and petitions the Tax Court. Upon receiving the Internal Revenue Service's answer to the petition, G sends a qualified offer to the field attorney that signed the answer, by United States mail. The qualified offer stated that it would remain open for more than 90 days. Thirty days after making the offer, G dies and, on motion under Rule 63(a) of the Tax Court's Rules of Practice and Procedure by G's personal representative, H is substituted for G as a party in the Tax Court proceeding. H makes no qualified offers to settle the case and the case proceeds to trial, with the Tax Court issuing an opinion partially in favor of H. Even though H was not a party when the qualified offer was made, that offer constitutes a qualified offer because by its terms, when made, it was to remain open until at least the earlier of the date it is rejected, the date of trial, or 90 days. If the liability of H under that last qualified offer, as determined under paragraph (b)(2) of this section, equals or exceeds the liability under the judgment of the Tax Court, as determined under paragraph (b)(3) of this section, H will be a prevailing party for purposes of an award of reasonable litigation costs under section 7430.

(f) *Effective date.* This section is applicable with respect to qualified offers made in administrative or court proceedings described in section 7430 after January 3, 2001 and before January 5, 2004.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 6, 2000.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 01–198 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ 004–0033; FRL–6896–8]

Revisions to the Arizona State Implementation Plan, Maricopa County Environmental Services Department

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing a limited approval and limited disapproval of a revision to the Maricopa County Environmental Services Department (MCESD) portion of the Arizona State Implementation Plan (SIP) concerning particulate matter (PM–10) emissions from open outdoor fires. Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), this action simultaneously approves local rules that regulate these emission sources and directs Arizona State to correct rule deficiencies. EPA is also finalizing a limited approval and a full approval of revisions to the MCESD portion of the Arizona SIP concerning PM–10 emissions from abrasive blasting and non-metallic mineral mining and processing, respectively. The limited approval notifies Arizona State that there are rule deficiencies. These actions were proposed in the **Federal Register** on July 11, 2000.

EFFECTIVE DATE: This rule is effective on February 5, 2001.

ADDRESSES: You can inspect copies of the administrative record for this action at EPA's Region IX office during normal business hours. You can inspect copies of the submitted rule revisions at the following locations:

Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington DC 20460.

Arizona Department of Environmental Quality, 3033 North Central Avenue, Phoenix, AZ 85012.

Maricopa County Environmental Services Department, Air Quality Division, 1001 North Central Avenue, Suite 201, Phoenix, AZ 85004.

FOR FURTHER INFORMATION CONTACT: Al Petersen, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1135.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

I. Proposed Action

On July 11, 2000 (65 FR 42649), EPA proposed a limited approval and limited disapproval of the following rule that was submitted for incorporation into the Arizona SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
MCESD	314	Open Outdoor Fires	07/18/88	01/04/90

We proposed a limited approval because we determined that this rule improves the SIP and is largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act. These provisions include the following:

• Dangerous materials in paragraph 302.2 not defined.

• Control Officer discretion in paragraphs 302.3 and 302.5.

On July 11, 2000, EPA also proposed a limited approval of the following rule that was submitted for incorporation into the Arizona SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
MCESD	312	Abrasive Blasting	07/13/88	01/04/90

We proposed a limited approval because we determined that this rule improves the SIP and is largely consistent with the relevant CAA requirements. The approval is limited, because some rule provisions conflict with section 110 of the Act, but there is no disapproval. These provisions include the following:

• Control Officer discretion in paragraphs 302.4.

On July 11, 2000, EPA also proposed a full approval of the following rule that was submitted for incorporation into the Arizona SIP.

Local agency	Rule No.	Rule title	Adopted	Submitted
MCESD	316	Nonmetallic Mineral Mining and Processing	04/21/99	08/04/99

The rule meets all of the requirements of the Act.

Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we did not receive any comments.

III. EPA Action

As authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a limited approval of Rule 314. This action incorporates the submitted rule into the Arizona SIP, including those provisions identified as deficient. As authorized under section 110(k)(3), EPA is simultaneously finalizing a limited disapproval of the rule. As a result, sanctions will be imposed unless EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the effective date of this action. These sanctions will be imposed under section 179 of the Act as described in 59 FR 39832 (August 4, 1994). In addition, EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months. Note that the submitted rule has been adopted by the MCESD, and EPA's final limited disapproval does not prevent the local agency from enforcing it.

As authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a limited approval of Rule 312. This action incorporates the submitted rule into the Arizona SIP, including those provisions identified as deficient. Sanctions and FIP requirements are not triggered by this action.

As authorized in sections 110(k)(3) and 301(a) of the Act, EPA is finalizing a full approval of Rule 316.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 13045

Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

C. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that

significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

D. Executive Order 13132

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism and 12875, Enhancing the Intergovernmental Partnership. E.O. 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under E.O. 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in E.O. 13132, because it merely acts on a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply act on requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

EPA's disapproval of the state request under section 110 and subchapter I, part D of the Clean Air Act does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect state enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action acts on pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

EPA believes that VCS are inapplicable to today's action because it does not require the public to perform activities conducive to the use of VCS.

H. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 5, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to

enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 4, 2000.

Felicia Marcus,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.120 is amended by adding paragraphs (c)(67)(i)(D) and (c)(94)(i)(D) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(67) * * *

(i) * * *

(D) Rules 312 and 314, adopted on July 13, 1998.

* * * * *

(94) * * *

(i) * * *

(D) Rule 316, adopted on April 21, 1999.

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[FR Doc. 01–117 Filed 1–3–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6925–1]

Indiana: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is granting Indiana final authorization of revisions to their hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a proposed rule on July 26, 2000 at 65 FR 45955 and provided for public comment. The public comment period ended on August 25, 2000. We received one comment, addressed below. No further opportunity for comment will be provided. EPA has determined that Indiana's revisions satisfy all the requirements needed to qualify for final authorization, and is authorizing the State's changes through this final action.

DATES: This final authorization will become effective on January 4, 2001.

ADDRESSES: You can view and copy Indiana's application from 9 am to 4 pm at the following addresses: Indiana Department of Environmental Management, 100 North Senate, Indianapolis, Indiana, (mailing address P.O. Box 6015, Indianapolis, Indiana 46206) contact Lynn West (317) 232–3593, and EPA Region 5, contact Gary Westefer at the following address.

FOR FURTHER INFORMATION CONTACT: Gary Westefer, Indiana Regulatory Specialist, U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7450.

SUPPLEMENTARY INFORMATION: On July 26, 2000, U.S. EPA published an immediate final rule granting Indiana authorization for changes to its Resource Conservation and Recovery Act program, listed in section E of that notice, which was subject to public comment. Subsequently we received one adverse comment, and therefore published a withdrawal of the immediate final rule on October 23, 2000. After reviewing the adverse comment, we hereby determine that Indiana's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization.

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Indiana's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Indiana Final authorization to operate its hazardous waste program with the changes described in the authorization application. Indiana has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before EPA authorizes the State for these requirements. Thus, EPA will implement those requirements and prohibitions in Indiana, including issuing permits, until EPA authorizes the State for these requirements and prohibitions.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Indiana subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent federal requirements. Indiana has enforcement responsibilities under its state hazardous waste program for violations of such program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Conduct inspections, and require monitoring, tests, analyses or reports;
- Enforce RCRA requirements and suspend or revoke permits;
- Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations EPA is authorizing by today's action are already effective, and are not changed by today's action.

D. Proposed Rule

On July 26, 2000 (65 FR 45955) EPA published a proposed rule. In that rule we proposed granting authorization of changes to Indiana's hazardous waste program and opened our decision to public comment. The Agency received one comment that stated that granting additional regulatory powers to the State of Indiana could not be supported. The comment criticized Indiana's handling of Clean Water Act and Clean Air Act matters, however. It did not cite any specific RCRA issues, or establish a basis for withholding authorization of a RCRA revision. U.S. EPA annually reviews the RCRA program at which

time it may convey any deficiencies to the State agency and make suggestions for improvement. U.S. EPA found Indiana's RCRA program to be satisfactory.

E. What Has Indiana Previously Been Authorized For?

Indiana initially received Final authorization on January 31, 1986, effective January 31, 1986 (51 FR 3955) to implement the RCRA hazardous waste management program. We granted authorization for changes to their program on October 31, 1986, effective December 31, 1986 (51 FR 39752); January 5, 1988, effective January 19, 1988 (53 FR 128); July 13, 1989, effective September 11, 1989 (54 FR 29557); July 23, 1991, effective September 23, 1991 (56 FR 33717); July 24, 1991, effective September 23, 1991 (56 FR 33866); July 29, 1991, effective September 27, 1991 (56 FR 35831); July 30, 1991, effective September 30, 1991 (56 FR 36010); August 20, 1996, effective October 21, 1996 (61 FR 43018); and September 1, 1999, effective November 30, 1999 (64 FR 47692).

F. What Changes Are We Authorizing With Today's Action?

On February 24, 2000, Indiana submitted a final complete program revision application, seeking authorization of their changes in accordance with 40 CFR 271.21. We now make a final decision, that Indiana's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Therefore, we grant Indiana final authorization for the following program changes:

Description of Federal requirement	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
Sharing of Information with the Agency for Toxic Substances and Disease Registry Checklist SI.	November 8, 1984, SWDA 3019(b)	IC 5–14–3; Effective April 15, 1987.
HSWA Codification Rule; Delisting Checklist 17B as amended Checklist 17B.1.	July 15, 1985, 50 FR 28702; June 27, 1989, 54 FR 27114.	329 IAC 3.1–5–3; Effective April 18, 1998.
Hazardous Waste Management Systems; Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards Checklist 112.	September 10, 1992, 57 FR 41566	329 IAC 3.1–4–1; 3.1–4–1(b); 3.1–6–1; 3.1–6–2(4); 3.1–11–1; 13–1–1; 13–1–2; 13–2; 13–3–1; 13–3–2; 13–3–3; 13–4–1; 13–4–2; 13–4–3; 13–4–4; 13–4–5; 13–5–1; 13–5–2; 13–5–3; 13–6–1; 13–6–2; 13–6–3; 13–6–4; 13–6–5; 13–6–6; 13–6–7; 13–6–8; 13–7–1; 13–7–2; 13–7–3; 13–7–4; 13–7–5; 13–7–6; 13–7–7; 13–7–8; 13–7–9; 13–7–10; 13–8–1; 13–8–2; 13–8–3; 13–8–4; 13–8–5; 13–8–6; 13–8–7; 13–8–8; 13–9–1; 13–9–2; 13–9–3; 13–9–4; 13–9–5; 13–9–6; 13–10–1; 13–10–2; 13–10–3; Effective March 5, 1997.
Recycled Used Oil Management Standards; Technical Amendments and Corrections I Checklist 122 as amended checklist 122.1.	May 3, 1993, 58 FR 26420; June 17, 1993, 58 FR 33341.	329 IAC 3.1–6–1; 3.1–9–1; 3.1–9–2(1), (2); 3.1–10–1; 3.1–10–2(1), (2), (3), (4); 13–1–1; 13–1–2; 13–2; 13–3–1; 13–3–2; 13–3–3; 13–4–2; 13–4–3; 13–4–4; 13–6–1; 13–6–3; 13–6–4; 13–6–6; 13–7–2; 13–7–3; 13–7–5; 13–8–1; 13–8–3; 13–8–5; 13–9–1; 13–9–3; 13–9–4; Effective March 5, 1997.
Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards (Technical Amendments and Corrections II) Checklist 130.	March 4, 1994, 59 FR 10550	329 IAC 13–1–1; 13–1–2; 13–2; 13–3–1; 13–4–1; 13–6–2; 13–6–5; 13–6–7; 13–7–4; 13–8–4; Effective March 5, 1997.
RCRA Expanded Public Participation Checklist 148	December 11, 1995, 60 FR 63417 ..	329 IAC 3.1–13–1; 3.1–13–2(8), (9); 3.1–13–18; 3.1–13–19; 3.1–13–20; Effective February 8, 1997.
Land Disposal Restrictions Phase III—Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners; Final Rule Checklist 151 as amended.	April 8, 1996, 61 FR 15566	329 IAC 3.1–12–1; 3.1–12–2 (1 through 9) Effective February 8, 1997.
Checklist 151.1 as amended	April 8, 1996, 61 FR 15660	Effective February 8, 1997.
Checklist 151.2 as amended	April 30, 1996, 61 FR 19117	Effective April 18, 1998.
Checklist 151.3 as amended	June 28, 1996, 61 FR 33680	Effective November 30, 1997.
Checklist 151.4 as amended	July 10, 1996, 61 FR 36419	Effective November 30, 1997.
Checklist 151.5 as amended	August 26, 1996, 61 FR 43924	Effective April 18, 1998.
Checklist 151.6	February 19, 1997, 62 FR 7502	Effective April 18, 1998.
Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators; Organic Air Emissions Standards for Tanks, Surface Impoundments, and Containers; Final Rule Checklist 154 as amended.	November 25, 1996, 61 FR 59931 ..	329 IAC 3.1–1–7; 3.1–6–1; 3.1–6–2(4); 3.1–7–1; 3.1–9–1; 3.1–10–1; 3.1–10–2 (1 through 4); 3.1–13–1; 3.1–13–2(8), (9); Effective April 18, 1998.
Checklist 154.1 as amended	December 6, 1994, 59 FR 62896.	
Checklist 154.2 as amended	May 19, 1995, 60 FR 26828.	
Checklist 154.3	September 29, 1995, 60 FR 50426.	
Checklist 154.4	November 13, 1995, 60 FR 56952.	
Checklist 154.5	February 9, 1996, 61 FR 4903.	
Checklist 154.6	June 5, 1996; 61 FR 28508.	

Description of Federal requirement	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous State authority
Military Munitions Rule: Hazardous Waste Identification and Management; Explosives Emergencies; Manifest Exemption for Transportation of Hazardous Waste on Rights-of-Ways on Contiguous Properties Checklist 156.	February 12, 1997, 62 FR 6622	329 IAC 3.1–4–1; 3.1–4–1(b); 3.1–6–1; 3.1–6–2(1), (2); 3.1–7–7; 3.1–7–2(1); 3.1–7–3; 3.1–8–1; 3.1–8–2(1); 3.1–9–1; 3.1–9–2(1), (2); 3.1–10–1; 3.1–10–2(1), (2), (3), (4); 3.1–11–1; 3.1–13–1; 3.1–13–2(1), (2), (3), (4); 3.1–13–3 through 3.1–13–17; Effective April 18, 1998.
Land Disposal Restrictions Phase IV: Treatment Standards for Wood Preserving Wastes, Paperwork Reduction and Streamlining, Exemptions from RCRA for Certain Processed Materials; and Miscellaneous Hazardous Waste Provisions Checklist 157.	May 12, 1997, 62 FR 25998	329 IAC 3.1–6–1; 3.1–6–2(1), (2), (13), (14); 3.1–12–1; 3.1–12–2 (1 through 5), (8), (10); Effective April 18, 1998.

G. Where Are the Revised State Rules Different From the Federal Rules?

There are no State requirements in this program revision considered to be either more stringent or broader in scope than the Federal requirements.

H. Who Handles Permits After the Authorization Takes Effect?

Indiana will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization until they expire or are terminated. We will not issue any more new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Indiana is not yet authorized.

I. What Is Codification and Is EPA Codifying Indiana's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. We do this by referencing the authorized State rules in 40 CFR part 272. The authorized Indiana RCRA program was incorporated by reference into 40 CFR part 272 on August 23, 1989, effective October 23, 1989 (54 FR 34988).

We reserve the amendment of 40 CFR part 272, subpart P for this authorization of Indiana's program changes until a later date.

J. Regulatory Analysis and Notices

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that section 202 and 205 requirements do not apply to today's action because this rule does not contain a Federal mandate that may result in annual expenditures of $100 million or more for State, local, and/or tribal governments in the aggregate, or the private sector. Costs to State, local and/or tribal governments already exist under the Indiana program, and today's action does not impose any additional obligations on regulated entities. In fact, EPA's approval of State programs generally may reduce, not increase, compliance costs for the private sector. Further, as it applies to the State, this action does not impose a Federal intergovernmental mandate because UMRA does not include duties arising from participation in a voluntary federal program.

The requirements of section 203 of UMRA also do not apply to today's action because this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Although small governments may be hazardous waste generators, transporters, or own and/or operate TSDFs, they are already subject to the regulatory requirements under the existing State laws that are being authorized by EPA, and, thus, are not subject to any additional significant or unique requirements by virtue of this program approval.

Certification Under the Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's action on small entities, small entity is defined as: (1) A small business as specified in the Small Business Administration regulations; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a

population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this authorization on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action does not impose any new requirements on small entities because small entities that are hazardous waste generators, transporters, or that own and/or operate TSDFs are already subject to the regulatory requirements under the State laws which EPA is now authorizing. This action merely authorizes for the purpose of RCRA section 3006 those existing State requirements.

Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Executive Order 12866.

Compliance With Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This authorization does not have federalism implications. It will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because this rule affects only one State. This action simply approves Indiana's proposal to be authorized for updated requirements of the hazardous waste program that the State has voluntarily chosen to operate. Further, as a result of this action, newly authorized provisions of the State's program now apply in Indiana in lieu of the equivalent Federal program provisions implemented by EPA under HSWA. Affected parties are subject only to those authorized State program provisions, as opposed to being subject to both Federal and State regulatory requirements. Thus, the requirements of section 6 of the Executive Order do not apply.

Compliance With Executive Order 13045

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' applies to any rule that: (1) The Office of Management and Budget determines is ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it authorizes a State program.

Compliance With Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies with consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

This rule is not subject to Executive Order 13084 because it does not significantly or uniquely affect the communities of Indian tribal governments. Indiana is not authorized to implement the RCRA hazardous waste program in Indian country. This action has no effect on the hazardous waste program that EPA implements in the Indian country within the State.

Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, Federal agencies must consider the paperwork burden imposed by any information request contained in a proposed rule or a final rule. This rule will not impose any information requirements upon the regulated community.

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be

inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: December 14, 2000.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 01–35 Filed 1–3–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91–137, RM–7494, FCC 00–409]

FM Broadcasting Services; Saltville, VA and Jefferson, NC.

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In MM Docket No. 91–137, the Commission denied an application for review filed by Smith Communications, licensee of Station WZJS(FM), Channel 264A, Banner Elk, North Carolina, of the Memorandum Opinion and Order, 61 FR 20,490, published May 7, 1996. The Commission denied review because it found no reason to depart from staff's reasoning set forth in the Memorandum Opinion and Order. It found that the staff had fully considered and rejected each of Smith's contentions that irregular terrain would prevent full signal coverage by the proposed upgraded Jefferson, North Carolina station. Additionally, since the release of the Memorandum Opinion and Order, a construction permit had been granted for an actual transmitter site at a location different from the theoretical one used previously. The Commission reexamined the expanded coverage area from that site and found the coverage to be adequate and of similar size to that predicted using the theoretical site. With this action, the proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: J. Bertron Withers, Jr., Mass Media Bureau, (202) 418–2180.

SUPPLEMENTAL INFORMATION: This is a summary of the Memorandum Opinion and Order, MM Docket 91–137, adopted November 17, 2000, and released November 28, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Information Center (room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this decision may be also purchased from the Commission's copy contractor, International Transcription Service, 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 01–127 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

RIN 1018–AH64

Migratory Bird Hunting; Approval of Tungsten-Nickel-Iron Shot as Nontoxic for Hunting Waterfowl and Coots

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We amend 50 CFR 20.21(j) to approve shot formulated of 50% tungsten, 35% nickel, and 15% iron as nontoxic for hunting waterfowl and coots. We assessed possible effects of the tungsten-nickel-iron (TNI) shot, and we believe that it is not a significant threat to wildlife or their habitats and that further testing of the shot is not necessary. In addition, approval of TNI shot may induce more waterfowl hunters to switch away from illegal use of lead shot, reducing lead risks to species and habitats.

DATES: This rule takes effect on January 4, 2001.

ADDRESSES: Copies of the Environmental Assessment are available from the Chief of the Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 634, Arlington, Virginia 22203–1610.

FOR FURTHER INFORMATION CONTACT: Jon Andrew, Chief, or Dr. George T. Allen, Division of Migratory Bird Management, 703–358–1714.

SUPPLEMENTARY INFORMATION: The Migratory Bird Treaty Act of 1918 (Act) (16 U.S.C. 703–712 and 16 U.S.C. 742 a–j) implements migratory bird treaties between the United States and Great Britain for Canada (1916 and 1996 as amended), Mexico (1936 and 1972 as amended), Japan (1972 and 1974 as amended), and Russia (then the Soviet Union, 1978). These treaties protect certain migratory birds from take, except as permitted under the Act. The Act authorizes the Secretary of the Interior to regulate take of migratory birds in the United States. Under this authority, the Fish and Wildlife Service controls the hunting of migratory game birds through regulations in 50 CFR part 20.

Since the mid-1970s, we have sought to identify shot that does not pose a significant toxicity hazard to migratory birds or other wildlife. Compliance with the use of nontoxic shot has increased over the last few years (Anderson *et al.* 2000). We believe that it will continue to increase with the approval and availability of other nontoxic shot types. Currently, steel, bismuth-tin, tungsten-iron, tungsten-polymer, and tungsten-matrix shot are permanently approved as nontoxic. We have approved tin shot for the 2000–2001 hunting season (65 FR 76886). The purpose of this rule is to approve the use of TNI shot in the tested formulation (50% tungsten, 35% nickel, and 15% iron by weight) for waterfowl and coot hunting. On October 30, 2000 (65 FR 64650) we proposed to amend 50 CFR 20.21 (j), to include TNI shot on the list of approved nontoxic shot types.

On April 9, 1999 (64 FR 17308), we announced receipt of an application from Standard Resources Corporation (Standard) of Cherry Hill, New Jersey for nontoxic approval of HEVI-METAL shot in the 50% tungsten, 35% nickel, 15% iron formulation. The density of the shot in that formulation is 11.0 grams/cm^3. The manufacturer believes that the shot does not need a coating because it is sufficiently noncorrosive under neutral pH. It is not chemically or physically altered by firing from a shotgun.

On April 19, 1999 (64 FR 19191), we announced that Standard's application did not provide sufficient information for us to conclude that the candidate shot is not a significant danger to migratory birds. We advised Standard to proceed with additional testing of the candidate shot. Subsequently, development of HEVI-METAL was transferred to ENVIRON-Metal, Inc., of Albany, Oregon (Environ-metal), and the shot was re-named HEVI-SHOT™.

On August 10, 2000, Environ-metal submitted an application for permanent approval of the tungsten-nickel-iron shot as nontoxic for hunting waterfowl and coots. The application included a description of the shot, results and a toxicological report of a preliminary 30-day dosing study of the toxicity of the shot in game-farm mallards (Ecological Planning and Toxicology, Inc. [EPT] 1999), and results of a more comprehensive 30-day acute toxicity study (Brewer and Fairbrother 2000).

Toxicity Information

Tungsten may be substituted for molybdenum in enzymes in mammals. Ingested tungsten salts reduce growth, and can cause diarrhea, coma, and death in mammals (*e.g.* Bursian *et al.* 1996, Cohen *et al.* 1973, Karantassis 1924, Kinard and Van de Erve 1941, National Research Council 1980, Pham-Huu-Chanh 1965), but elemental tungsten is virtually insoluble and therefore essentially nontoxic. In rats, a dietary concentration of 94 parts-per-million (ppm) did not reduce weight gain in growing rats (Wei *et al.* 1987). Lifetime exposure to 5 ppm tungsten as sodium tungstate in drinking water produced no discernible adverse effects in rats (Schroeder and Mitchener 1975). At 100 ppm tungsten as sodium tungstate in drinking water, rats had decreased enzyme activity after 21 days (Cohen *et al.* 1973). These studies indicate that tungsten salts are very toxic to mammals.

Chickens given a complete diet showed no adverse effects of 250 ppm sodium tungstate administered for 10 days in the diet. However, 500 ppm in the diet had detrimental effects on day-old chicks (Teekell and Watts 1959). Adult hens had reduced egg production and egg weight on a diet containing 1,000 ppm tungsten (Nell *et al.* 1981a). EPT (1999) concluded that 250 ppm in the diet would produce no observable adverse effects. Kelly *et al.* (1998) demonstrated no adverse effects on mallards dosed with tungsten-iron or tungsten-polymer shot according to nontoxic shot test protocols.

Most toxicity tests reviewed were based on soluble tungsten compounds rather than elemental tungsten. As we found in our reviews of other tungsten shot types, we believe that there is no basis for concern about the toxicity of the tungsten in TNI shot to fish, mammals, or birds.

Nickel is a dietary requirement of mammals, with necessary consumption set at 50 to 80 parts per billion for the rat and chick (Nielsen and Sandstead 1974). Though it is necessary for some enzymes, nickel can compete with calcium, magnesium, and zinc for binding sites on many enzymes. Water-soluble nickel salts are poorly absorbed if ingested by rats (Nieboer *et al.* 1988). Nickel carbonate caused no treatment effects in rats fed 1,000 ppm for 3 to 4 months (Phatak and Patwardhan 1952). Rats fed 1,000 ppm nickel sulfate for 2 years showed reduced body and liver weights, an increase in the number of stillborn pups, and decrease in weanling weights through three generations (Ambrose *et al.* 1976). Nickel chloride was even more toxic; 1,000 ppm fed to young rats caused weight loss in 13 days (Schnegg and Kirchgessner 1976).

Soluble nickel salts can be classified as very toxic to mammals, with an oral LD_{50} of 136 mg/kg in mice, and 350 mg/kg in rats (Fairchild *et al.* 1977). Nickel catalyst (finely divided nickel in vegetable oil) fed to young rats at 250 ppm for 16 months, however, produced no detrimental effects (Phatak and Patwardhan 1952).

In chicks from hatching to 4 weeks of age, 300 ppm nickel as nickel carbonate or nickel acetate in the diet produced no observed adverse effects. However, concentrations of 500 ppm or more reduced growth (Weber and Reid 1968). A diet containing 200 ppm nickel as nickel sulfate had no observed effects on mallard ducklings from 1 to 90 days of age. Diets of 800 ppm or more caused significant changes in physical condition of the ducklings (Cain and Pafford 1981). Eastin and O'Shea (1981) observed no apparent significant changes in pairs of breeding mallards fed diets containing up to 800 ppm nickel as nickel sulfate for 90 days.

Iron is an essential nutrient, so reported iron toxicosis in mammals is primarily a phenomenon of overdosing of livestock. Maximum recommended dietary levels of iron range from 500 ppm for sheep to 3,000 ppm for pigs (National Research Council [NRC] 1980). Chickens require at least 55 ppm iron in the diet (Morck and Austic 1981). Chickens fed 1,600 ppm iron in an adequate diet displayed no ill effects (McGhee *et al.* 1965). Turkey poults fed 440 ppm in the diet suffered no adverse effects. The tests in which eight #4 tungsten-iron shot were administered to each mallard in a toxicity study indicated that the 45% iron content of the shot had no adverse effects on the test animals (Kelly *et al.* 1998).

Environmental Fate

Elemental tungsten and iron are virtually insoluble in water and do not weather and degrade in the environment. Tungsten is stable in acids and does not easily form compounds with other substances. Preferential uptake by plants in acidic soil suggests uptake of tungsten when it has formed compounds with other substances rather than when it is in its elemental form (Kabata-Pendias and Pendias 1984).

Nickel is common in fresh waters, though usually at concentrations of less than 1 part per billion in locations unaffected by human activities. Pure nickel is not soluble in water. Free nickel may be part of chemical reactions, such as sorption, precipitation, and complexation. Reactions of nickel with anions are unlikely. Complexation with organic agents is poorly understood (U.S. Environmental Protection Agency [EPA] 1980). Water hardness is the dominant factor governing nickel effects on biota (Stokes 1988).

Environmental Concentrations

Calculation of the estimated environmental concentration (EEC) of a candidate shot in a terrestrial ecosystem is based on 69,000 shot per hectare (Bellrose 1959, 50 CFR 20.134). Assuming complete dissolution of the shot, the EEC for tungsten in soil is 19.3 mg/kg. The EECs for nickel and iron would be 7.7 and 3.3 mg/kg, respectively. The EEC for nickel (the only one of the three elements with an application limit) is substantially below the U.S. Environmental Protection Agency (EPA) biosolid application limit. The 3.3 mg/kg EEC for nickel also is far below the 16 to 35 mg/kg concentrations suggested as minimum sediment concentrations at which effects of the metal are likely to occur (EPA 1997, Ingersoll *et al.* 1996, Long and Morgan 1991; MacDonald *et al.* 2000, Smith *et al.* 1996). The EEC for tungsten from TNI shot is below that for the already-approved tungsten-matrix shot. The EEC for iron is less than 0.01% of the typical background concentration, and the iron is in an insoluble form.

Calculation of the EEC in an aquatic ecosystem assumes complete erosion of the 69,000 shot/hectare in water 1 foot deep. The EECs for the elements in TNI shot in water are 2,348 µg/L for tungsten, 1,643 µg/L for nickel, and 704 µg/L for iron. We concluded that a tungsten concentration of 10,500 µg/L

posed no threat to aquatic biota (62 FR 4877). The EEC for nickel, if the shot were completely dissolved, would exceed the EPA acute water quality criterion of 1,400 µg/L in fresh water, and would greatly exceed the 75 µg/L criterion for salt water. However, tests showed that corrosion of TNI shot is negligible in neutral pH fresh water. Actual tests in water with a pH of 2 showed that the EEC for nickel would be 83.98 µg/L, and in salt water it would be 7.92 µg/L; both are far below the EPA criterion of 160 µg/L for chronic exposure.

Effects on Birds

Kraabel *et al.* (1996) surgically embedded tungsten-bismuth-tin shot in the pectoralis muscles of ducks to simulate wounding by gunfire and to test for toxic effects of the shot. The authors found that the shot neither produced toxic effects nor induced adverse systemic effects in the ducks during the 8-week period of their study.

Nell *et al.* (1981a) fed laying hens *(Gallus domesticus)* 0.4 or 1.0 g/kg tungsten in a commercial mash for five months to assess reproductive performance. Weekly egg production was normal, and hatchability of fertile eggs was not affected. Exposure of chickens to large doses of tungsten either through injection or by feeding resulted in an increased tissue concentration of tungsten and a decreased concentration of molybdenum (Nell *et al.* 1981b). The loss of tungsten from the liver occurred in an exponential manner, with a half-life of 27 hours. The alterations in molybdenum metabolism seemed to be associated with tungsten intake rather than molybdenum deficiency. Death due to tungsten occurred when tissue concentrations increased to 25 ppm in the liver. At that concentration, xanthine dehydrogenase activity was zero.

Toxicity Studies

Ringelman *et al.* (1993) conducted a 32-day acute toxicity study that involved dosing game-farm mallards with a shot alloy which was 39%, 44.5%, and 16.5% by weight, respectively. No dosed birds died during the trial, and behavior was normal. Post-euthanization examination of tissues revealed no toxicity or damage related to shot exposure. Blood calcium differences between dosed and undosed birds were judged to be unrelated to shot exposure. That study indicated that tungsten presented little hazard to waterfowl.

Initial analyses of corrosion of TNI shot in 0.1N HCl and in seawater indicated that it is more corrosion resistant than copper-plated tungsten-iron shot and steel shot, and that it will release tungsten into the environment more slowly than does tungsten-iron shot. In addition, only a portion of the tungsten is soluble, and not all of that is absorbed. Therefore, EPT (1999) suggested that ingested TNI shot should pose minimal risks to migratory birds that might ingest it.

EPT conducted a preliminary 30-day oral toxicity study of TNI shot that followed the general approach outlined for a short-term acute toxicity test (50 CFR 20.134). Eight #4 TNI shot pellets were administered to each of three healthy adult male and three healthy adult female mallards by placing them in a gelatin capsule and placing the capsule in the bird's gizzard. All of the birds retained seven or eight of the pellets for the 30-day test period. During that time the birds behaved normally, and none of them exhibited signs of metal intoxication. Body weights of the birds did not change significantly during the test period.

Upon postmortem examination, all body organs looked normal. Histopathology showed that one of the females had a fatty liver, and also had elevated liver enzymes. Liver abnormalities due to fatty changes (accumulation of glycogen or fat) were considered the likely cause of the problem.

Brewer and Fairbrother (2000) reported on the outcome of more extensive corrosion/erosion testing of TNI shot, and steel and lead shot. Eight #4 TNI shot pellets were administered to each of 20 male mallards and 20 female mallards by placing the shot in a gelatin capsule and placing the capsule in the bird's gizzard. The same procedure was followed for dosing 20 male mallards and 20 female mallards with 8 #4 steel shot, and for dosing 5 males and 5 females with 8 #4 lead shot. The birds had been fasting prior to placement of the gelatin capsules to facilitate movement of the capsule to the gizzard. During the 30-day test period, the researchers monitored loss of shot through the digestive system, and they determined retention of shot in the gizzard upon necropsy. They also carefully monitored food consumption of the test birds and their health.

No mortality occurred in birds treated with TNI shot or steel shot. Nine of the ten birds dosed with lead died during the test period. Therefore, most measures of health and measures of shot erosion were not valid for the lead-dosed group. No significant differences in body weight changes emerged between the steel shot group and the TNI shot group during the test period.

The evaluation focused on corrosion/erosion of the steel shot and the TNI shot, and associated changes in organs and blood chemistry. A total of 134 of the TNI shot pellets and 138 of the steel shot were recovered from the gizzards of the test birds after 30 days. TNI shot pellets recovered from gizzards at the end of the test retained an average of 88.6% of their initial weight; steel pellets retained an average of 49.7% of their weight.

Histopathological examination of kidney tissues from the 41 ducks alive at the end of the test period revealed no significant lesions. Livers also appeared to have been unaffected by steel pellets or TNI shot. Hemoglobin, white blood cell counts, hematocrits, and blood serum chemistry results did not differ between the steel shot test group and the TNI shot test group, with the exception that the mean for plasma protein was significantly higher in the TNI shot-treated ducks.

Analytical chemistry of liver, kidney, and blood samples showed some differences between the steel shot and TNI shot test groups. Mean tungsten concentrations in blood, liver, and kidney tissues were 0.24 ppm in the blood, 0.64 ppm in kidney tissue, and 1.65 ppm in liver tissue. No tungsten was detected in tissues of mallards dosed with steel shot. Mean nickel concentrations in blood (0.03 ppm), liver (0.09 ppm), and kidney (0.44 ppm) tissues were significantly higher in ducks dosed with TNI shot than in those dosed with steel shot. Mean nickel concentrations in blood, liver, and kidney tissues of mallards treated with 800 ppm in the diet for 90 days were 0.139, 0.52, and 1.94 ppm, respectively (Eastin and O'Shea 1991). Those ducks suffered no apparent ill effects from their treatment. Mean iron concentrations in the blood and liver were higher for the ducks dosed with steel shot, but kidney concentrations did not differ.

EPT (1999) calculated that the mallards studied by Eastin and O'Shea (1981) consumed approximately 102 mg of nickel each day during the study. Under the Tier 2 protocol, each test mallard is dosed with 8 #4 shot at 0, 30, 60, and 90 days, which in the case of TNI shot would contain a total of 32 shot, and 2.3 g of nickel per bird. At pH 2, with continual grinding of ingested shot, eight #4 pellets would lose 0.176 mg of nickel per day. The maximum exposure for a mallard under such conditions would be 0.704 mg/day, substantially less than the estimated consumption by mallards in the Eastin

and O'Shea study (EPT 1999). We believe, therefore, that consumption of nickel from TNI shot is unlikely to have detrimental effects on waterfowl.

Ingestion by Fish, Amphibians, Reptiles, or Mammals

Based on the available information and past reviews of tungsten-based shot, we expect no detrimental effects due to tungsten or iron on animals that might ingest TNI shot. However, we know of no studies of ingestion of nickel by herpetofauna. In the worst case, assuming complete erosion of a #4 TNI shot pellet equal to that found in a mallard gizzard, exposure to a vertebrate would be approximately 0.022 mg of nickel per day if the shot were retained in the animal. The exposure actually would be substantially less because a shot pellet likely would not be retained in most animals that might consume one.

Nontoxic Shot Approval

The first condition for nontoxic shot approval is toxicity testing. Based on the results of the toxicological reports and the toxicity tests, we conclude that TNI shot does not pose a significant danger to migratory birds, other wildlife, or their habitats.

The second condition for approval is testing for residual lead levels. Any shot with a lead level of 1% or more will be illegal. We determined that the maximum environmentally acceptable level of lead in shot is 1%, and incorporated this requirement in the nontoxic shot approval process we published on December 1, 1997 (62 FR 63607). ENVIRON-Metal, Inc. has documented that TNI shot meets this requirement.

The third condition for approval involves enforcement. On August 18, 1995 (60 FR 43313), we stated that approval of any nontoxic shot would be contingent upon the development and availability of a noninvasive field testing device. This requirement was incorporated in the nontoxic shot approval process. TNI shotshells can be drawn to a magnet as a simple field detection method.

This final rule will amend 50 CFR 20.21(j) by approving TNI shot as nontoxic for migratory bird hunting. It is based on the toxicological reports, acute toxicity studies, and assessment of the environmental effects of the shot. Those results indicate no deleterious effects of TNI shot to ecosystems or when ingested by waterfowl.

Public Comments

We received one comment on the October 30, 2000 proposed rule to approve TNI shot for hunting waterfowl and coots. That comment supported granting approval for use of the shot.

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Required Determinations

NEPA Consideration

In compliance with the requirements of section 102(2)(C) of the NEPA and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR 1500), we prepared a final Environmental Assessment (EA) for approval of TNI shot in December 2000. The EA is available to the public at the location indicated in the **ADDRESSES** section. Based on review and evaluation of the information contained in the EA, we have determined that amending 50 CFR 20.21(j) to approve TNI shot as nontoxic for waterfowl and coot hunting would not be a major Federal action that would significantly affect the quality of the human environment within the meaning of section 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA). Accordingly, the preparation of an Environmental Impact Statement on this action is not required.

Endangered Species Act Considerations

Section 7 of the Endangered Species Act (ESA) of 1972, as amended (16 U.S.C. 1531 *et seq.*), provides that Federal agencies shall ''insure that any action authorized, funded or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of (critical) habitat * * *.'' We completed a Section 7 consultation under the ESA for this rule, which is available to the public at the location indicated in the **ADDRESSES** section. The Division of Endangered Species concurred with our determination that this rule is ''Not Likely to Affect'' endangered or threatened species.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which includes small businesses, organizations, or governmental jurisdictions. This rule approves an additional type of nontoxic shot that may be sold and used to hunt migratory birds; this rule will add one shot type to those already approved. We have determined, however, that this rule will have no effect on small entities since the approved shot will supplement nontoxic shot already in commerce and available throughout the retail and wholesale distribution systems. We anticipate no dislocation or other local effects, with regard to hunters or others.

Executive Order 12866

This rule has not been reviewed by the Office of Management and Budget (OMB) review under Executive Order 12866. OMB makes the final determination of significance under Executive Order 12866.

Paperwork Reduction Act

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. We have examined this regulation under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501) and found it to contain no information collection requirements. We have received OMB approval of continued collection of information from shot manufacturers for the nontoxic shot approval process. For further information see 50 CFR 20.134.

Unfunded Mandates Reform

We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, *et seq.*, that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It does not have an annual effect on the economy of $100 million or more; nor will it cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. This rule has the potential for reducing the present cost of nontoxic shot by making additional materials available for consumers. It does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This rule may provide beneficial effects to competition, employment, investment, productivity, innovation, and the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Civil Justice Reform—Executive Order 12988

We, in promulgating this rule, have determined that these regulations meet the applicable standards provided in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Takings Implication Assessment

In accordance with Executive Order 12630, this rule, authorized by the Migratory Bird Treaty Act, does not have significant takings implications and does not affect any constitutionally protected property rights. This rule will not result in the physical occupancy of property, the physical invasion of property, or the regulatory taking of any property. In fact, this rule will allow hunters to exercise privileges that would be otherwise unavailable; and, therefore, reduces restrictions on the use of private and public property.

Federalism Effects

Due to the migratory nature of certain species of birds, the Federal Government has been given responsibility over these species by the Migratory Bird Treaty Act. This rule does not have a substantial direct effect on fiscal capacity, change the roles or responsibilities of Federal or State governments, or intrude on State policy or administration. Therefore, in accordance with Executive Order 13132, this regulation does not have significant federalism effects and does not have sufficient federalism implications to

warrant the preparation of a Federalism Assessment.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951) and 512 DM 2, we have determined that this rule has no effects on Federally recognized Indian tribes.

Effective Date

Under the APA (5 U.S.C. 551–553) our normal practice is to publish policies with a 30-day delay in effective date. In this case, however, we use the ''good cause'' exemption under 5 U.S.C. 553(d)(3) to make this rule effective upon publication. This rule relieves a restriction, and it is not in the public interest to delay its effective date. We believe that another nontoxic shot option likely will improve hunter compliance, thereby reducing the amount of lead shot in the environment.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

For the reasons discussed in the preamble, we propose to amend part 20, subchapter B, chapter 1 of Title 50 of the Code of Federal Regulations as follows:

PART 20—[AMENDED]

1. The authority citation for part 20 continues to read as follows:

Authority: 16 U.S.C. 703–712 and 16 U.S.C. 742 a-j.

2. Section 20.21 is amended by revising paragraph (j) to read as follows:

§ 20.21 What hunting methods are illegal?

* * * * *

(j) While possessing shot (either in shotshells or as loose shot for muzzleloading) other than steel shot, or bismuth-tin (97 parts bismuth: 3 parts tin with <1 percent residual lead) shot, or tungsten-iron (40 parts tungsten: 60 parts iron with <1 percent residual lead) shot, or tungsten-polymer (95.5 parts tungsten: 4.5 parts Nylon 6 or 11 with <1 percent residual lead) shot, or tungsten-matrix (95.9 parts tungsten: 4.1 parts polymer with <1 percent residual lead) shot, or tin (99.9 percent tin with <1 percent residual lead) shot, or tungsten-nickel-iron (50% tungsten: 35% nickel: 15% iron with <1 percent residual lead), or such shot approved as nontoxic by the Director pursuant to procedures set forth in Sec. 20.134, provided that this restriction applies only to the taking of Anatidae (ducks, geese, (including brant) and swans), coots (Fulica americana) and any species that make up aggregate bag limits during concurrent seasons with the former in areas described in Sec. 20.108 as nontoxic shot zones, and further provided that:

(1) Tin shot (99.9 percent tin with 1 percent residual lead) is legal as nontoxic shot for waterfowl and coot hunting for the 2000–2001 hunting season only.

(2) [Reserved]

Dated: December 27, 2000.

Kenneth L. Smith,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–139 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 091900B]

RIN 0648-A027

Fisheries of the Exclusive Economic Zone Off Alaska; Rebuilding Overfished Fisheries

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

ACTION: Approval of a fishery management plan amendment.

SUMMARY: NMFS announces the approval of Amendment 14 to the Fishery Management Plan for the Bering Sea/Aleutian Islands King and Tanner Crabs (FMP). This amendment contains a rebuilding plan for the overfished stock of Bering Sea snow crab. This action is necessary to ensure that conservation and management measures continue to be based upon the best scientific information available. It is intended to enhance the Council's ability to achieve, on a continuing basis, optimum yield from fisheries under its authority.

DATES: The amendment was approved on December 28, 2000.

ADDRESSES: Copies of Amendment 14 to the FMP and the Environmental Assessment (EA) prepared for the amendment are available from the Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802-1668, Attn: Lori Gravel.

FOR FURTHER INFORMATION CONTACT: Gretchen Harrington, 907-586-7228 or gretchen.harrington@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS declared the Bering Sea stock of snow crab (*Chionoecetes opilio*) overfished on September 24, 1999, because the spawning stock biomass was below the minimum stock size threshold defined in the FMP. On September 24, 1999, NMFS notified the Council that the stock was overfished (64 FR 54791, October 8, 1999). The Council then took action to develop a rebuilding plan within 1 year of notification as required by section 304(e)(3) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

In June 2000, the Council adopted Amendment 14, the rebuilding plan to accomplish the purposes outlined in the national standard guidelines to rebuild the overfished stock. Amendment 14 specifies a time period for rebuilding the stock that satisfies the requirements of the Magnuson-Stevens Act. Under the rebuilding plan, the Bering Sea snow crab stock is estimated to rebuild, with a 50 percent probability, within 10 years. The stock will be considered ''rebuilt'' when it attains the maximum sustainable yield stock size level for 2 consecutive years.

The rebuilding plan consists of a framework that references the State of Alaska's harvest strategy, bycatch control measures, and habitat protection measures. The plan uses the harvest strategy developed by the Alaska Department of Fish and Game. The harvest strategy was reviewed and adopted by the Alaska Board of Fisheries. The FMP defers development of harvest strategies to the State of Alaska, with oversight by NMFS and the Council. The rebuilding harvest strategy should result in more spawning biomass because more large male crab would be conserved and fewer juveniles and females would die due to incidental catch and discard mortality. More spawning biomass would be expected to produce larger year-classes when environmental conditions are favorable. Protection of habitat and reduction of bycatch may reduce mortality of juvenile crabs, thus allowing a higher percentage of each year-class to contribute to spawning and future landings.

The Council prepared an EA for Amendment 14 that describes the management background, the purpose and need for action, the management alternatives, and the environmental and the socio-economic impacts of the

alternatives. A copy of the EA can be obtained from NMFS (see **ADDRESSES**).

A notice of availability for the proposed Amendment 14 to the FMP, which described the proposed amendment and invited comments from the public, was published in the **Federal Register** on September 29, 2000 (65 FR 58501). Comments were invited until November 28, 2000. NMFS received two comments.

Response to Comments

Comment 1: The rebuilding plan does not contain meaningful bycatch reduction measures and habitat protection measures. Given the large amount of information that is unknown about the biology of the stock, the amount of bycatch mortality from the various sources, and habitat needs of the stock, it is imperative that NMFS employ a large amount of precaution in this rebuilding plan. The commenter advanced these particular concerns about the rebuilding plan: (1) The discussion in the EA of higher probabilities of rebuilding under the alternatives is insufficient; (2) NMFS should reduce the snow crab bycatch limit in the trawl fisheries and should comprehensively study the bycatch mortality of snow crab captured in trawl gear; (3) NMFS should study snow crab bycatch mortality in the snow crab fishery and the effects of ghost fishing and the impacts of pot gear on snow crab and their habitat; (4) NMFS should determine the bycatch mortality for snow crab in the longline, groundfish pot, and scallop fisheries; (5) NMFS should study the habitat needs of snow crab to best protect essential habitats for the stock and the annual NMFS Eastern Bering Sea trawl survey is inadequate for providing information on snow crab habitat; (6) NMFS should study the current and potential effects of trawling on snow crab habitat; and (7) The preferred alternative for habitat protection does not provide meaningful habitat protection. In light of the uncertainties, NMFS must be precautionary and protect any possible snow crab habitat from adverse impacts. NMFS should consider a seasonal bottom-trawl closure from March to June in areas of highest trawl bycatch to protect snow crab during sensitive life-stages and a permanent bottom-trawl closure north of 58° N lat., protecting 82 percent of female crabs.

Response: NMFS agrees uncertainties exist about the biology of snow crab and that more scientific research needs to be conducted on its habitat, bycatch mortality in all fisheries, and the effects of all types of fishing gear on habitat. The EA highlights all of the areas where more research is needed, including those research needs identified by the commenter. The scientific uncertainties were adequately considered and accounted for in developing alternatives for the rebuilding plan. The rebuilding plan incorporates these uncertainties, provides for protection and rebuilding of the snow crab stock, and provides for a modest fishery.

NMFS has determined that the current rebuilding plan is sufficiently precautionary. The EA identifies all known sources of snow crab mortality, analyzes each one, and examines the most effective measures to rebuild the stock. By far, the largest source of mortality and bycatch of snow crab is in the directed snow crab fishery. In 1999, the directed fishery accounted for approximately 95 percent of the total snow crab bycatch in all fisheries. As the EA illustrates, the rebuilding plan greatly curtails the directed fishery. By comparison, all other sources of bycatch and bycatch mortality are minimal and amount to less than 1 percent of the snow crab population, even when assuming 100 percent mortality. Likewise, existing evidence does not indicate that the decline in snow crab abundance is due to habitat destruction by fishing gear. The vast majority of female and juvenile snow crab live in the northern regions of the Bering Sea where few or no fisheries operate.

Responses to each specific point made by the commenter are as follows: The rebuilding time period satisfies the requirements of section 304(e)(4)(A) of the Magnuson-Stevens Act. The rebuilding plan is estimated to allow snow crab to rebuild, with a 50 percent probability, to the Bmsy level within 10 years. A 50 percent rebuilding probability within 10 years is the estimated probability recommended in the NMFS technical guidance for rebuilding overfished stocks. This probability of rebuilding includes the conservative parameter that the stock will be considered 'rebuilt' when the stock size reaches the Bmsy in 2 consecutive years. NMFS and ADF&G stock assessment experts, who developed the model used to estimate the rebuilding times and probabilities, determined that a 50 percent probability best represented reality given the biology of the species and the current level of scientific information.

The EA estimates the rebuilding time of each alternative at a 10 percent, 50 percent, and 90 percent probability. The alternatives range from zero catch (no directed catch and no bycatch in the trawl fisheries) to the traditional harvest rate of 58 percent of males greater than or equal to 4 inches (102 mm). None of the alternatives, including zero catch, would achieve rebuilding at a 90 percent probability within 10 years.

The exercise of estimating rebuilding probabilities provides managers with an idea of the potential outcomes of different alternatives and helps managers predict whether the alternatives will rebuild the stock within 10 years. However, the components of the rebuilding plan were developed, taking into consideration the full breadth and depth of current scientific understanding and not solely based on the results of the models.

The EA analyzes the option of reducing the snow crab bycatch limit in the trawl fisheries. Under the existing program, NMFS closes trawl fisheries when they reach their snow crab bycatch limits. The Council considered the following points when it determined that the existing snow crab bycatch controls for the trawl fisheries are sufficient. First, reductions in bycatch most likely would not result in measurable improvements to snow crab abundance because the 7-year average annual bycatch of snow crab in the trawl fishery is only about 0.1 percent of the total abundance. Second, current bycatch limits provide incentives for the trawl fleet to avoid concentrations of snow crab, thus keeping bycatch rates well below the limit. Finally, reductions in limits would disadvantage specific sectors of the trawl fleet because of the way bycatch limits are apportioned by fishery before the fishing season. Therefore, the Council determined that the very small potential for measurable improvements in snow crab abundance did not justify the disproportional economic disadvantages that would have resulted from bycatch limit reductions.

NMFS concurs that more studies need to be conducted to determine the mortality of snow crab caught as bycatch in the trawl fisheries. Given this lack of information, a very conservative mortality rate of 80 percent was used in the analyses of alternatives. In addition, assuming that all snow crab caught in the trawl fisheries die, crab mortality caused by the trawl fisheries would equal about 0.1 percent of the total abundance of snow crab.

NMFS concurs that additional research is needed on snow crab bycatch in the directed snow crab fishery, the effects of ghost fishing (lost pots that continue to catch crab and other species), and the impacts of pot gear on habitat. As noted by the commenter, State regulations require all pots to have degradable mesh that acts as an escape mechanism to prevent ghost fishing. Also, as noted in the EA,

pot loss has greatly diminished since the State established pot limits in the crab fisheries in 1992. The rebuilding plan implements a precautionary harvest strategy that protects the stock at low abundance from the effects of the directed fishery. When abundance is very low, the rebuilding harvest strategy closes the fishery, which stops all snow crab bycatch in the snow crab fishery. Likewise, the harvest strategy provides for harvest at a reduced rate as abundance increases. A reduced harvest rate means a reduction in bycatch. In addition, because the fishing effort is greatly reduced with reductions in harvest levels, so presumably are the effects of the fishing gear on habitat. Further, the State's gear modification measures adopted under the rebuilding plan will reduce the number of females and small males caught per pot in the directed fishery. So, although scientific uncertainty exists on the effects of bycatch and pot gear on habitat, the rebuilding plan reduces bycatch and the amount of gear deployed by curtailing harvest when stock abundance is low. NMFS concurs that more research should be conducted on bycatch mortality of snow crab in the longline, groundfish pot, and scallop fisheries. However, according to observer data, bycatch of snow crab in these fisheries is minuscule. The 7-year combined average total bycatch for these fisheries is 426,950 crabs, which is 0.013 percent of the 2000 abundance estimate of 3.2 billion snow crabs. The commenter notes the increase in bycatch of snow crab in the scallop fishery. This is due to an expansion in the range of snow crabs into scallop fishery grounds during the mid-1990's when snow crab abundance was high, rather than to an expansion in the distribution of the scallop fishery. NMFS concurs that more research should be conducted on the habitat needs of snow crab. NMFS plans to conduct additional research on the habitat needs of snow crab as funding is available. NMFS also concurs that the NMFS trawl survey might be inadequate for providing information on snow crab habitat and that the survey does not cover the full extent of snow crab habitat. However, snow crab habitat that exists outside the survey area is not subject to any commercial fishing pressure. Because the survey is designed to estimate abundance of commercially important crab and groundfish species, it is conducted in those areas where commercial fishing occurs and it does not extend beyond the areas used for commercial fishing.

NMFS concurs that additional research is needed on the current and potential effects of trawling on snow crab habitat. NMFS plans to conduct additional research on the effects of trawling on snow crab habitat as funding is available.

NMFS believes the preferred alternative for habitat protection does provide adequate habitat protection. The Council may choose to develop new habitat protection measures in the future to incorporate into the rebuilding plan. However, as explained in the EA, the research conducted to date does not show substantial adverse impacts from trawling on snow crab habitat. The EA reaches this conclusion because (1) trawl effort is low in areas identified as important for females and juvenile snow crab, and (2) current bycatch control measures provide incentive for the trawl fleet to avoid areas of high concentration of snow crab, thus avoiding snow crab habitat.

The Council considered a seasonal bottom-trawl closure from March to June in areas of highest trawl bycatch. It concluded that this closure may have many unintended consequences by displacing trawl effort, including moving trawl effort to areas of sensitive habitat for other crab species, increasing bycatch of other sensitive species like halibut and Tanner crab, and concentrating trawl effort. The reported high bycatch is a function of high trawl effort and not of high snow crab abundance in that area. Further, the Council could not identify measurable benefits of this proposed time/area closure. It would not be in place during the snow crab molting and mating period. The proposed area is a relatively small portion of snow crab habitat and is not an area historically important for snow crab reproduction. The areas identified as important for snow crab reproduction extend north of 58° N lat., where some trawling occurs in limited areas. Thus the predicted benefits of closing this area would be small compared to the predicted consequences.

The EA analyzes a possible bottom-trawl closure north of 58° N lat. The commenter is correct in stating that a closure of the area north of 58° N lat. would protect approximately 82 percent of female crabs. However, less than 2 percent of the trawl effort occurs above 58° N lat. And that trawl effort occurs near the 58° N lat. line. Most of the area above 58° N lat. is not subject to any fishing effort. The Council could not find measurable benefits to moving this small amount of trawl effort to below 58° N lat.

Comment 2: NMFS should delay approving Amendment 14 until a thorough scientific analysis of the snow crab stock status and the rebuilding plan are complete because the rebuilding plan may be an over-reaction to a flawed definition of overfishing for snow crab. The commenter advanced these particular concerns about the rebuilding plan's conservative harvest strategy: (1) Snow crab are not ''overfished'' because fishing did not cause the decline in abundance. Further, the commenter quotes the Council's Scientific and Statistical Committee's opinion that NMFS should change the national standard guidelines at 50 CFR 600.310 so that stocks with low abundance are not determined to be ''overfished'' when fishing had no demonstrable effect; (2) NMFS scientists acknowledge that the time constraints set by the Magnuson-Stevens Act for developing the rebuilding plan did not allow for the new harvest strategy to benefit from a thorough analysis of many aspects of snow crab biology and that a more thorough analysis may justify a less conservative harvest strategy; (3) The traditional harvest rate of 58 percent of males 4 inches (102 mm) or greater is precautionary because the legal size for snow crab is 3.1 inches (79 mm). Thus, sexually mature males have years to fertilize females before they are captured by the fishery (The legal size limit for snow crab is 3.1 inches (79 mm), based on the size at sexual maturity of male snow crab. For market reasons, the industry standard is to only harvest males 4 inches or greater.); (4) The reduction in the harvest rate under the rebuilding plan will only increase recovery time of the stock by 6 months compared to the rebuilding time under the traditional harvest rate, as shown in the rebuilding probability simulation; and (5) The cost of the rebuilding plan, which involves hundreds of millions of pounds of foregone catch, greatly outweighs the benefit of the rebuilding plan, which is a 6-month increase in rebuilding time. Therefore, the commenter concludes that NMFS does not have adequate scientific information to reduce the harvest rate for snow crab.

Response: NMFS has determined that the rebuilding harvest strategy is based on the best scientific information available and is intended to rebuild snow crab to historic levels of abundance. As explained in the EA, existing scientific information supports a reduction in the harvest of snow crab to rebuild the stock.

The commenter assumes that a delay in approving the rebuilding plan would result in a fishery under the traditional harvest rate of 58 percent of males with a carapace width of 4 inches (102 mm) or greater. This is not the case because the harvest strategy in the rebuilding

plan was adopted into regulation by the Alaska Board of Fisheries in March of 2000.

Responses to each specific point made by the commenter are as follows: According to the national standard guidelines at 50 CFR 600.310(d)(1)(iii), the term ''overfished'' is used to describe any stock or stock complex whose size is sufficiently small enough that a change in management practices is required in order to achieve an appropriate level and rate of rebuilding. Thus, NMFS determined snow crab is overfished because snow crab abundance was below the threshold established for the stock. The cause of the decline in snow crab abundance is irrelevant to a determination that a stock or stock complex is sufficiently small that management changes are needed.

The 1-year requirement in section 304(e)(3) of the Magnuson-Stevens Act is intended to assure that action is taken in a timely manner to protect depleted populations and populations vulnerable to overfishing. Notwithstanding the short time period to protect vulnerable populations, all management actions must be based on the best science available at the time of the decision. NMFS determined that the rebuilding plan for snow crab is based on the best available scientific information that shows the population sharply declined between 1998 and 1999, that the snow crab population is aging, and that very few juvenile crab exist to grow into the fishery. In addition, as detailed in the EA, the scientific uncertainties were adequately considered and accounted for in developing alternatives for the rebuilding plan.

The framework structure of the rebuilding plan is designed so that changes can be made to the plan based on analyses conducted by NMFS, the Council, and State scientists. If the results of these analyses indicate that the harvest strategy should be modified, then it will be modified through the Board process and reviewed by NMFS and the Council, as specified in the FMP.

As explained in the EA, the traditional harvest rate of 58 percent of males 4 inches (102 mm)or greater is not precautionary and can result in overfishing during periods of poor recruitment, such as the stock has recently exhibited. Evidence suggests that continuing the previous 58 percent harvest rate on this stock may jeopardize its rebuilding by removing a majority of the largest males and causing high bycatch.

High harvest rates on large mature males may also possibly impact reproductive potential of a stock by reducing the size of males available for breeding. The low stock levels observed for eastern Bering Sea snow crab during the 1999 survey were accompanied by indications of poor reproductive potential. Mature female snow crabs examined during the 1999 survey were barren at higher than normal rates and showed lower than normal rates of full clutches. Circumstantial evidence shows fishery-induced selection for reduced size or age at maturity in males. Any of these conservation concerns related to harvesting of large males would become more acute when stocks are low because of the greater impact of chance events at low stock levels. Thus, the condition and composition of the stock were the primary considerations that lead to the conservative harvest strategy.

The rebuilding harvest strategy reduces the harvest rate because lower harvest rates must be applied to depleted stocks and those with high levels of uncertainty about their productive capacity. This reduction in the harvest rate is not only required, but it is also prudent for stocks with periodic recruitment, like snow crab. A reduced harvest rate also reduces snow crab bycatch in the directed snow crab fishery because the season is shorter and gear is on the grounds for a shorter amount of time.

The commenter is correct in stating that the rebuilding time under the rebuilding harvest strategy is estimated to be 6 months shorter than under the traditional 58 percent harvest rate. This prediction is based on the outcomes of the recruitment models used to estimate the rebuilding times of the alternatives. The EA fully explains the length-based simulation models used and the limits of the model results due to the lack of a stock-recruitment component. For these models, recruitment means the number of crab in cohort that survive from the time they are hatched until they reached 35 to 50 mm, the size at which there are abundance estimates.

The time to rebuild is highly dependent on the model's assumptions about future recruitments. None of the recruitment models used in the analyses includes any role for the effects of the spawning stock on future reproduction. This is because the relationship between the existing spawning stock size and the number of recruits this stock will produce is not known. From analyzing historic information, variability in recruitment is known to be high. Large spawning stocks are known to produce small numbers of recruits. Likewise, small spawning stocks are known to produce large numbers of recruits. At present, no studies have been performed to identify and model the factors determining or influencing recruitment to the snow crab stock. Physical-oceanographic factors probably have a strong influence on recruitment of snow crab in the eastern Bering Sea. Biological factors that are unrelated to spawning stock size could also be important determinants of the strength of recruitment.

The lack of a stock-recruitment component in the models reflects the inability of the analysts at the current time to specify a model relating spawning stock conditions to future recruitment, rather than any conclusion on the part of the analysts that no such relationship exists.

Due to this lack of a stock-recruitment component, these models do not allow for any feedback from the effects of management measures to future recruitment. The models used here are adequate for modeling the short-term (the next 15 years) recovery of the stock, because the short-term stock dynamics will not be influenced by the present reproductive potential of the stock due to the time lag from spawning to recruiting. On the other hand, the models will not adequately represent any long-term effects due to harvesting mature males.

Important conservation consequences may result from different harvest rates applied to large males. Those consequences are not revealed in the model results. First, given the nature of the recruitment models used, any conservation benefits that may result from preservation of large male crabs within the spawning population through more conservative management, will not be reflected in the model results. The rebuilding simulations were conducted to estimate rebuilding times given the current level of scientific information, not to model all of the possible effects of the alternative harvest strategies.

Second, as shown in the EA, a high harvest rate on a stock with low population levels is risky for the long-term health of the stock. Research suggests that density dependent factors and other risks associated with harvesting a high rate of large males may exist when the stock is declining. Although environmental effects are important in effecting variation in recruitment and the snow crab fishery removes only the larger mature males from the stock, the possible effects on future recruitment due to the fishery should not be discounted.

The assumption that the only benefit of the rebuilding harvest strategy is a savings of 6 months in rebuilding time is incorrect. NMFS expects that the

conservative harvest strategy will increase the abundance of snow crab by the preservation of large male crab and the reduction of bycatch of female and sublegal male crab. The primary goal of a rebuilding plan is to rebuild the stock to a biomass level that will produce maximum sustainable yield. Maximum sustainable yield provides the greatest catch and the greatest income to the fishermen and fishery-dependent communities over the long-term. Often, foregone catch in the short-term is necessary to have a high sustainable yield in the future.

The commenter states that the cost of the rebuilding harvest strategy is high levels of foregone catch. The commenter assumes that the snow crab stock would continue to support a fishery at a high harvest rate and that the fishery will rebuild if subject to a high harvest rate. As discussed above and detailed in the EA, scientific evidence shows otherwise. Continuing under the harvest rate of 58 percent runs the risk of causing the further decline of the stock.

The commenter estimates the future foregone catch based on a graph produced by ADF&G. From this graph, the commenter concludes that future harvest of snow crab will be hundreds of millions of pounds less that it would be under the traditional 58 percent harvest rate. The ADF&G graph compares the historic annual guideline harvest levels under the previous harvest rate to estimates of what the guideline harvest levels would have been if managers had applied the rebuilding harvest strategy in those years. As the graph shows, it does not model the potential increase in stock size due to greater carry-over of mature and harvestable stock that would have occurred from year-to-year under a more conservative harvest rate. This carry-over would have resulted in higher stock abundance, higher harvests than shown in the graph, and may have prevented the sharp declines in abundance that we saw under the previous harvest rate. Therefore, the assumption that, once the stock rebuilds, future harvest levels will be dramatically lower under the rebuilding harvest strategy than under the traditional 58 percent harvest rate is not accurate.

The Council has met the requirements of the Magnuson-Stevens Act and complies with the national standard guidelines by creating a rebuilding plan that reduces harvest when the stock is at low levels. The Magnuson-Stevens Act at section 303(a)(10) mandates that when the Secretary determines a stock is overfished, conservation measures to rebuild the fishery must be added to the FMP. These conservation measures are contained in the snow crab rebuilding plan.

NMFS determined that Amendment 14 to the FMP is consistent with the Magnuson-Stevens Act and other applicable laws and approved Amendment 14 on December 28, 2000. Additional information on this action is contained in the September 29, 2000, notice of availability (65 FR 58501).

No regulatory changes are necessary to implement this FMP amendment.

Dated: December 28, 2000.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

FR Doc. 01–205 Filed 1–3–01; 8:45 am]

BILLING CODE 1510–22–S

Proposed Rules

Federal Register
Vol. 66, No. 3
Thursday, January 4, 2001

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 THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–119352–00]

RIN 1545–AY58

Guidance on Filing an Application for a Tentative Carryback Adjustment in a Consolidated Return Context

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: In the rules and regulations portion of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the filing of an application for a tentative carryback adjustment by a consolidated group and by certain new members of a consolidated group. The text of those temporary regulations also serves as the text of these proposed regulations. In addition, this document provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by April 4, 2001. The public hearing has been scheduled for April 26, 2001. Outlines of topics to be discussed at the public hearing scheduled for April 26, 2001, at 10 a.m. must be received by April 5, 2001.

ADDRESSES: Send submissions to: Regulations Unit CC, room 5226 (REG–119352–00), Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may also be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to Regulations Unit CC, room 5226 (REG–119352–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet directly to the IRS Internet site at *http://www.irs.gov/tax_regs/regslist.html.* The public hearing is scheduled for April 26, 2001, and will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulation, Christopher M. Bass or Frances L. Kelly, (202) 622–7770; concerning submissions, the hearing, and/or to be placed on the building access list to attend the hearing, Guy Traynor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the Rules and Regulations sections of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR Part 1) under section 1502 of the Internal Revenue Code of 1986 (Code). The temporary regulations provide guidance as to the time for filing an application for a tentative carryback adjustment by a consolidated group. The amendments also extend the time for filing an application for a tentative carryback adjustment by certain corporations for the separate return year created by their becoming new members of a consolidated group. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

It has been determined that this notice of proposed rule making is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that these regulations will primarily affect affiliated groups of corporations that have elected to file consolidated returns, which tend to be larger businesses, and, moreover, that any burden on taxpayers is minimal. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are timely submitted to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be made available for public inspection and copying.

A public hearing has been scheduled for April 26, 2001, beginning at 10 a.m., in room 4718, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must request to speak, and submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by April 5, 2001. A period of ten minutes will be allocated to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these proposed regulations are Christopher M. Bass and Frances L. Kelly, Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding the following entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * * Section 1.1502–78 also issued under 26 U.S.C. 1502 and 6411(c). * * *

Par. 2. Section 1.1502–78, as proposed to be amended, reads as follows:

§ 1.1502–78 Tentative carryback adjustments.

[The text of the amendments to this proposed section is the same as the text of the amendments to § 1.1502–78T published elsewhere in this issue of the **Federal Register**.]

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–197 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106791–00]

RIN 1545–AY55

Liabilities Assumed in Certain Corporate Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations, and notice of public hearing.

SUMMARY: In the Rules and Regulations portion of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the assumption of liabilities in certain corporate transactions under section 301 of the Internal Revenue Code. The temporary regulations affect corporations and their shareholders. The text of those temporary regulations also serves as the text of these proposed regulations. This document also gives notice of a public hearing on these proposed regulations.

DATES: Written comments must be received by May 10, 2001. Requests to speak and outlines of topics to be discussed at the public hearing scheduled for May 31, 2001 at 10 a.m. must be received by May 10, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–106791–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–106791–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option of the IRS Home Page or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax-regs/regslist.html.* A public hearing will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Mary E. Dean, (202) 622–7550; concerning submissions and the hearings, Guy Traynor, (202) 622–7180.

SUPPLEMENTARY INFORMATION

Background

The temporary regulations amend the income tax regulations (26 CFR part 1) under section 301 relating to liabilities assumed in connection with distributions made by a corporation to shareholders with respect to their stock. These regulations provide that the amount of a distribution under section 301 will be reduced by the amount of any liability that is treated as assumed by the distributee within the meaning of section 357(d)(1) and (2). Thus, in a distribution under section 301, if a liability is treated as not having been assumed by the distributee under section 357(d)(1) and (2), the amount of the distribution will not be reduced by the amount of any liability the property is subject to under section 301(b)(2)(B). The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

It is hereby certified that these regulations do not have a significant economic impact on a substantial number of small entities. These proposed regulations under section 301 of the Internal Revenue Code (Code) address distributions by corporations in which liabilities are assumed by the shareholders or in which the distributed property is subject to liabilities. These proposed regulations provide that the amount of a distribution under section 301 will be reduced by the amount of any liability that is treated as assumed by the distributee within the meaning of section 357(d)(1) and (2).

If adopted these regulations will affect only corporations making distributions of property, in which the property is subject to a liability, or in which liabilities are assumed by the distributee. Moreover, if adopted, the proposed regulations will affect only those corporations that would have, but for the regulations, considered liabilities to have been assumed in circumstances other than those described in section 357(d)(1) and (2). Therefore, most corporations, whether large or small, will not be affected by the proposed regulations in any given year. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (preferably a signed original and eight (8) copies) or electronically generated comments that are submitted timely to the IRS. The IRS and Treasury specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 31, 2000, at 10 a.m., in room 4718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. Due to building security procedures, visitors must enter at the 1111 Constitution Avenue entrance, located between 10th and 12th streets. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by May 10, 2001. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Mary E. Dean, Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for 26 CFR part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.301–1 is amended by revising paragraph (g) to read as follows:

§ 1.301–1 Rules applicable with respect to distributions of money and other property.

* * * * *

(g) [The text of the proposed amendment to paragraph (g) of § 1.301–1 is the same as the text of paragraph (g) of § 1.301–1T published elsewhere in this issue of the **Federal Register**].

David A. Mader,

Acting Deputy Commissioner of Internal Revenue.

[FR Doc. 01–201 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–121928–98]

RIN 1545–AW99

Awards of Attorney's Fees and Other Costs Based Upon Qualified Offers

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the circumstances in which a party, by reason of having made a qualified offer, will be entitled to an award of court costs and certain fees in a civil tax proceeding brought in a court of the United States (including the Tax Court). The text of those temporary regulations also serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written comments must be received by April 4, 2001. Outlines of topics to be discussed at the public hearing scheduled for May 23, 2001, at 10 a.m., must be received by May 2, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–121928–98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–121928–98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/prod/tax__regs/regslist.html.* The public hearing will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the hearing, submission of written comments, and to be placed on the building access list to attend the hearing, Treena V. Garrett, (202) 622–7180; concerning the regulations, Thomas D. Moffitt (202) 622–7900 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** provide rules relating to the circumstances in which a party, by reason of having made a qualified offer, will be entitled to an award of court costs and certain fees in a civil tax proceeding brought in a court of the United States (including the Tax Court). The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations.

Comments are specifically requested on the rule requiring the provision of information and arguments regarding adjustments raised by taxpayers after the issuance of the first letter of proposed deficiency which provides the taxpayer with an opportunity for administrative review in the Internal Revenue Service Office of Appeals and still unresolved at the time the last qualified offer is made. The changes to section 7430 made by Congress anticipate qualified offers based upon the adjustments at issue when the first letter of proposed deficiency is sent. Adjustments subsequently raised by taxpayers would not be subject to the audit development preceding the issuance of such first letter of proposed deficiency. The proposed rule is intended to eliminate any such differences between the adjustments subject to the last qualified offer.

Comments are also specifically requested on the rule establishing the end of the qualified offer period, for courts using trial calendars, at the point where the case remains listed on a trial calendar thirty days before the scheduled date for the calendar call for that trial session. The proposed rule is intended to keep the qualified offer period open until shortly before trial while ensuring that the last day of the qualified offer period can be ascertained on that day.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and, because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility

Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 23, 2001, at 10 a.m., in room 4718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having a visitor's name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** caption.

An outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) must be submitted by any person that wishes to present oral comments at the hearing. Outlines must be received by May 2, 2001.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving requests to speak has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Thomas D. Moffitt, Office of Assistant Chief Counsel (Field Service). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is proposed to be amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.7430–0 [Removed]

Par. 2. Section 301.7430–0 is removed.

Par. 3. Section 301.7430–7 is added to read as follows:

§ 301.7430–7 Qualified offers.

[The text of this proposed section is the same as the text of § 301.7430–7T published elsewhere in this issue of the **Federal Register**.]

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–199 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

Notices

Federal Register
Vol. 66, No. 3
Thursday, January 4, 2001

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

Forest Service

Availability of a Draft Environmental Assessment for Amendment No. 21 to the Hiawatha National Forest Land and Resource Management Plan; Alger County, Michigan

AGENCY: Forest Service, USDA.

ACTION: Notice of availability of a draft environmental assessment.

SUMMARY: On December 5, 2000, Hiawatha National Forest Supervisor, Clyde N. Thompson (Responsible Official) announced his preferred alternative for a Draft Environmental Assessment that would amend the 1986 Hiawatha National Forest Land and Resource Management Plan (Forest Plan) in a 30-day pre-decision period. This amendment updates the standards and guidelines for Grand Island Research Natural Area (GI–RNA), creates a new Management Area 8.1.2 specific to GI–RNA and updates the GI–RNA Establishment Record. This notice is provided pursuant to National Forest System Land and Resource Management Planning regulations (36 CFR 219.35, 65 FR 67579, November 9, 2000). Copies of the Draft Environmental Assessment are available upon request.

DATES: On December 5, 2000, Hiawatha National Forest Supervisor, Clyde N. Thompson (Responsible Official) announced his preferred alternative for a Draft Environmental Assessment that would amend the 1986 Hiawatha National Forest Land and Resource Management Plan (Forest Plan). A legal notice was published in the Escanaba Daily Press, Escanaba, Michigan newspaper in accordance with 36 CFR 217.8(a)(2) on December 5, 2000.

ADDRESSES: Send requests for documents to: Forest Supervisor, Hiawatha National Forest, 2727 North Lincoln Road, Escanaba, MI 49829.

Alternatively, direct electronic mail to: pbeyer@fs.fed.us ATTN: GI–RNA Amendment.

FOR FURTHER INFORMATION CONTACT: Patty Beyer, Project Coordinator, at 906–228–9681. TDD 906–789–3337; or direct electronic mail to: pbeyer@fs.fed.us, or access the forest web page at *http://www.fs.fed.us/r9/hiawatha.*

Responsible Official: Clyde N. Thompson, Forest Supervisor, 2727 North Lincoln Rd., Escanaba, Michigan, 49829.

SUPPLEMENTARY INFORMATION: The proposed Forest Plan Amendment No. 21 describes site-specific standards and guidelines that allow for existing recreation use while reducing resource impacts to the GI–RNA. These standards and guidelines offer protection of soils, watershed, botanical communities, old growth, Great Lakes shoreline and heritage resources. The preferred alternative maintains the historic use patterns of Grand Island within the GI–RNA. This is non-significant amendment.

Public involvement was an important part of the decision making process for this proposal. On December 9, 1999 a public scoping letter was sent to over 700 interested parties and a notice was published in the local newspaper. A second round of public involvement occurred with the issuance of the pre-decisional environmental assessment on December 1, 2000. We published a legal notice notifying the public of the availability of the EA for review in the Escanaba Daily Press, Escanaba, Michigan on December 5, 2000. A 30-day comment period follows release of the pre-decisional EA on December 5, 2000 for review (until January 5, 2001). A final decision is expected in January 2001.

This decision will be subject to appeal pursuant to USDA Forest Service regulations 36 CFR 217.3. Any written appeal must be postmarked or submitted to the Regional Forester, USDA Forest Service, Eastern Region, 310 West Wisconsin Ave., Suite 500, Milwaukee, WI 53203, within 45 days of the date the legal notice will be published in the Escanaba Daily Press, Escanaba, Michigan in accordance with 36 CFR 217.8(a)(2). The appeal period begins the day following the legal notice publication in the Escanaba Daily Press. Appeals must meet the content requirements of 36 CFR 217.9. The Forest Service is an equal opportunity organization.

Dated: December 18, 2000.

Clyde N. Thompson,

Forest Supervisor.

[FR Doc. 01–143 Filed 1–3–01; 8:45 am]
BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Bureau of Land Management

Fish and Wildlife Service

National Park Service

Urban Wildland Interface Communities Within the Vicinity of Federal Lands That Are at High Risk From Wildfire

AGENCIES: Forest Service, USDA; Bureau of Indian Affairs, Bureau of Land Management, Fish and Wildlife Service, and National Park Service, USDI.

ACTION: Notice.

SUMMARY: This notice provides an initial list of urban wildland interface communities in the vicinity of Federal lands that are at high risk from wildfire. The list, compiled from information provided by States and Tribes, and prepared for publication by the Secretaries of Agriculture and the Interior, responds to Congressional direction to identify communities within the vicinity of Federal lands that are at high risk from wildfire, and publish a list of these communities in the **Federal Register**. States and Tribes used different criteria for selecting communities at risk. This initial list of communities is incomplete, and will be updated as additional information from the States and Tribes becomes available. The information included in the list has not been altered by the Federal agencies.

Pursuant to direction from Congress, the lists submitted by States and Tribes have been annotated by the Secretaries to identify communities around which hazardous fuel reduction treatments on Federal lands are ongoing or are planned to begin in fiscal year 2001. The Secretaries will continue to work with States, Tribes, local governments,

and other interested parties to focus fuel reduction efforts on those communities at highest risk.

This notice also provides the Federal Government's initial definition of urban wildland interface communities at high risk from wildfire, and preliminary criteria for risk evaluation and risk management that will be used by the Secretaries to rank and prioritize communities and focus implementation of fuels treatments to most effectively reduce risks. Interested members of the public may also provide additional thoughts on the list of communities, the initial definition of wildland-urban interface areas, and the preliminary criteria for risk evaluation and risk management included in this notice via the National Interagency Fire Center web page at *http://www.nifc.gov.* As a result of these suggestions, the Federal agencies will work with Tribes, States, local governments, and other interested parties to refine and narrow the initial list of communities provided in this notice, focusing on those that are at highest risk.

ADDRESSES: Paper copies of this list and related materials may be obtained by writing to: Bureau of Land Management, Office of External Affairs, National Interagency Fire Center, 3833 S. Development Avenue, Boise, Idaho 83705–5354.

FOR FURTHER INFORMATION CONTACT: Steve Bott, Fire Management Program Center, National Park Service, USDI, 3833 S. Development Avenue, Boise, Idaho 83705–5354; (208) 387–5200 (e-mail: stephen_botti@nps.gov). Information specific to individual State listings should be directed to the respective State Forester as listed with the National Association of State Foresters (NASF), 444 N. Capitol St., NW., Suite 540, Washington, DC 20001, or electronically from the NASF World Wide Web/Internet home page at *http://www.Stateforesters.org/SFlist.html.*

SUPPLEMENTAL INFORMATION:

Background

During the 2000 fire season more than 6.8 million acres of public and private lands burned, resulting in loss of property, damage to resources, and disruption of community services. Many of these fires burned in urban wildland interface areas and exceeded the fire suppression capabilities of those areas. The magnitude of these fires is the result of two primary factors: (1) Severe drought, accompanied by a series of storms that produced thousands of lightning strikes followed by windy conditions; and (2) the long-term effects of almost a century of suppressing wildfires that has led to an unnatural buildup of brush and small diameter trees in the nation's forests and rangelands.

Loss of structures due to wildland fires has been attributed to many factors, one of which is the proximity of hazardous fuels to homes and communities. During periods of hot, dry weather, the buildup of vegetation that has occurred on some Federal, State, and private lands in the vicinity of communities poses a potentially high risk of damage to homes and other structures, disruption to the local economy, or loss of life.

On August 8, 2000, the President directed the Secretaries of Agriculture and the Interior to prepare a report recommending how best to respond to this year's severe fires, reduce the impacts of those fires on rural communities, and ensure sufficient fire management resources in the future. On September 8, 2000, the President accepted their report, *Managing the Impacts of Wildfires on Communities and the Environment*, which provides an overall framework for fire management and forest health programs. The report calls for Federal agencies to increase investments in projects to reduce fire risk and to work with local communities to reduce fire hazards close to homes and communities.

Other factors—including weather conditions and patterns, and the hazardous fuels conditions in the immediate vicinity of homes, businesses, and other structures—play important roles in the spread of wildland fire. Reducing hazardous fuel near communities may reduce, but not eliminate, wildlife risks to these communities. Some risk is inherent to communities that exist in fire-dependent ecosystems. Private landowners may help reduce this risk by creating defensible space around their homes and businesses, and by using fire-resistant materials in building those structures. Without such precautionary measures, fuel reduction on Federal land in the vicinity may be ineffective in significantly reducing community risk.

The Federal land management agencies are currently in the process of forming partnerships with the States, Tribes, and local governments to plan fuels reduction treatments targeted to the urban wildland interface in the vicinity of Federal lands. These partnerships are indicative of a shared responsibility to reduce wildland fire risks to communities in the interface. Successful implementation of this fuels reduction program will require commitments from all the partners involved in this effort.

Congressional Direction and Purpose of Federal Register Notice

As directed by Title IV of the FY 2001 Appropriations Act for the Department of the Interior and Related Agencies (Public Law 106–291), the Secretaries of Agriculture and the Interior have consulted with States and Tribes about the development of a list of urban wildland interface communities within the vicinity of Federal lands, including Indian trust and restricted lands, that are at high-risk from wildfire. This initial list of communities was developed by States and Tribes, each using criteria it determined appropriate for selecting communities at risk. The list is incomplete. It will be updated as additional information from the States and Tribes becomes available. The information provided has not been altered by the Federal Agencies. The lists submitted by States and Tribes have been annotated by the Secretaries to identify communities around which hazardous fuel reduction treatments on Federal lands are ongoing or are planned to begin in fiscal year 2001. The list of communities around which treatments are planned may also be updated as the agencies further assess treatment priorities for FY 2001. Some communities may be removed from the list if further assessment and discussion among the States, Tribes and local agencies indicate it is appropriate to do so. Future updates of this list will be made available electronically from the National Interagency Fire Center World Wide Web/Internet home page at *http://www.nifc.gov.* The list is set out at the end of this notice.

This notice also provides an initial definition of urban wildland interface communities at high risk from wildfire, and the preliminary criteria for risk evaluation and risk management that will initially be used to focus hazardous fuel reduction efforts. This definition and these criteria were developed cooperatively by the Federal agencies, Tribes, and States, and may be modified through further consultation with Tribes, States, local governments, and other interested parties.

Urban Wildland Interface Community Definition

The initial definition of urban wildland interface and the descriptive categories used in this notice are modified from ''A Report to the Council of Western State Foresters—Fire in the West—The Wildland/Urban Interface Fire Problem'' dated September 18, 2000. Under this definition, ''the urban

wildland interface community exists where humans and their development meet or intermix with wildland fuel.'' There are three categories of communities that meet this description. Generally, the Federal agencies will focus on communities that are described under categories 1 and 2. For purposes of applying these categories and the subsequent criteria for evaluating risk to individual communities, a structure is understood to be either a residence or a business facility, including Federal, State, and local government facilities. Structures do not include small improvements such as fences and wildlife watering devices.

Category 1. Interface Community

The Interface Community exists where structures directly abut wildland fuels. There is a clear line of demarcation between residential, business, and public structures and wildland fuels. Wildland fuels do not generally continue into the developed area. The development density for an interface community is usually 3 or more structures per acre, with shared municipal services. Fire protection is generally provided by a local government fire department with the responsibility to protect the structure from both an interior fire and an advancing wildland fire. An alternative definition of the interface community emphasizes a population density of 250 or more people per square mile.

Category 2. Intermix Community

The Intermix Community exists where structures are scattered throughout a wildland area. There is no clear line of demarcation; wildland fuels are continuous outside of and within the developed area. The development density in the intermix ranges from structures very close together to one structure per 40 acres. Fire protection districts funded by various taxing authorities normally provide life and property fire protection and may also have wildland fire protection responsibilities. An alternative definition of intermix community emphasizes a population density of between 28–250 people per square mile.

Category 3. Occluded Community

The Occluded Community generally exists in a situation, often within a city, where structures abut an island of wildland fuels (*e.g., park or open space*). There is a clear line of demarcation between structures and wildland fuels. The development density for an occluded community is usually similar to those found in the interface community, but the occluded area is usually less than 1,000 acres in size. Fire protection is normally provided by local government fire departments.

Preliminary Criteria for Evaluating Risk to Communities

The Secretaries are required to publish in the **Federal Register,** by May 1, 2001, a second list of urban wildland interface communities within the vicinity of Federal lands that are at high risk from wildfire in which treatments will not have begun during 2001. The Federal agencies will work with Tribes, States, local governments, and other interested parties to refine and narrow the initial list of communities provided in this notice, focusing on those that are at highest risk, as determined through the application of appropriate criteria. In discussions with States, Tribes, local governments, and other interested parties, the Secretaries will suggest using the specific factors listed below, as modified through further discussion with and input from interested parties, in evaluating risk to communities. Similar risk factors will be included in interim guidance to the agencies' field units that will be required to implement urban wildland treatment projects during FY 2001.

Risk Factor 1: Fire Behavior Potential

Situation 1: In these communities, continuous fuels are in close proximity to structures. The composition of surrounding fuels is conducive to crown fires or high intensity surface fires. There are steep slopes, predominantly south aspects, dense fuels, heavy duff, prevailing wind exposure and/or ladder fuels that reduce fire fighting effectiveness. There is a history of large fires and/or high fire occurrence.

Situation 2: In these communities, there are moderate slopes, broken moderate fuels, and some ladder fuels. The composition of surrounding fuels is conducive to torching and spotting. These conditions may lead to moderate fire fighting effectiveness. There is a history of some large fires and/or moderate fire occurrence.

Situation 3: In these communities, grass and/or sparse fuels surround structures. There is infrequent wind exposure, flat terrain with little slope and/or predominantly a north aspect. There is no large fire history and/or low fire occurrence. Fire fighting generally is highly effective.

Risk Factor 2: Values At Risk

Situation 1: This situation most closely represents a community in an urban interface setting. The setting contains a high density of homes, businesses, and other facilities that continue across the interface. There is a lack of defensible space where personnel can safely work to provide protection. The community watershed for municipal water is at high risk of being burned compared to other watersheds within that geographic region. There is a high potential for economic loss to the community and likely loss of housing units and/or businesses. There are unique cultural, historical or natural heritage values at risk.

Situation 2: This situation represents an intermix or occluded setting, with scattered areas of high-density homes, summer homes, youth camps, or campgrounds that are less than a mile apart. This situation would cover the presence of lands at risk that are described under State designations such as impaired watersheds, or scenic byways. There is a risk of erosion or flooding in the community if vegetation burns.

Risk Factor 3: Infrastructure

Situation 1: In these communities, there are narrow dead end roads, steep grades, one way in and/or out routes, no or minimal fire fighting capacity, no fire hydrants, no surface water, no pressure water systems, no emergency operations group, and no evacuation plan in an area surrounded by a fire-conducive landscape.

Situation 2: In these communities, there are limited access routes, moderate grades, limited water supply, and limited fire fighting capability in an area surrounded by scattered fire-conducive landscape.

Situation 3: In these communities, there are multiple entrances and exits that are well equipped for fire trucks, wide loop roads, fire hydrants, open water sources (pools, creeks, lakes), an active emergency operations group, and an evacuation plan in place in an area surrounded by a fireproof landscape.

The Secretaries will work collaboratively with States, Tribes, local communities, and other interested parties to develop a ranking process to focus fuel reduction activities by identifying communities most at risk. Public input is welcome on the form a ranking system should take, as is input on measures that may be useful to assess the impacts of fuels treatment projects.

Preliminary Criteria for Project Selection

After the Federal agencies consult with States, Tribes, local leaders, and other interested parties on the risk to communities, the Secretaries will work collaboratively with those entities to identify and prioritize specific treatment

projects. Projects will be focused on Federal land in the urban wildland interface, and may be extended to non-Federal land that falls in close proximity. All projects will be subject to review for conformance with applicable laws, as addressed in the report to Congress that responds to section 5(B) of title IV of the report accompanying the FY 2001 Interior and Related Agencies Appropriations Act. The agencies expect the preliminary criteria for risk evaluation identified above, modified as appropriate in consultation with interested parties, to be helpful in project selection. Among other factors that may be considered in project selection is the contribution the project will make toward establishing an adequate buffer around, or defensible space for, a community at risk. By this criterion, priority would be given to projects that are adjacent to combustible structures within the interface communities. Another factor will be the degree to which the community actively supports and invests in hazardous fuel reduction activities and programs.

Support would be demonstrated by a combination of: developing partnerships with adjacent Federal agencies, States, and Tribes; sharing costs for hazardous fuels reduction and fire prevention activities; enhancing a fire-safe environment through enforcement of fire-related laws, regulations and ordinances; applying appropriate community planning practices; and participating in the organization of and support for fire safety and related environmental education.

Dated: December 27, 2000.

For the Department of Agriculture.

Dan Glickman,

Secretary of Agriculture.

Dated: December 22, 2000.

For the Department of the Interior.

Bruce Babbitt,

Secretary of the Interior.

Urban-Wildland Interface Communities in the Vicinity of Federal Lands That Are at High Risk From Wildfire

STATE RESPONSES OF THE URBAN WILDLAND INTERFACE COMMUNITIES

State	Response
Alaska	Community list provided.
Alabama	Community list provided.
Arkansas	List unavailable at this time.
Arizona	Community list provided.
California	Community list provided.
Colorado	Community list provided.
Connecticut	No high-risk communities adjacent to Federal lands.
District of Columbia	No response.
Delaware	No high-risk communities adjacent to Federal lands.
Florida	Community list provided.
Georgia	No response.
Guam	No response.
Hawaii	No response.
Iowa	Community list provided.
Idaho	Community list provided.
Illinois	No response.
Indiana	Community list provided.
Kansas	Community list provided.
Kentucky	List unavailable at this time.
Louisiana	No response.
Massachusetts	Response provided by Tribe(s), but not the State.
Maryland	Community list provided.
Maine	Community list provided.
Michigan	Community list provided.
Minnesota	Community list provided.
Missouri	No response.
Mississippi	Community list provided.
Montana	Community list provided.
North Carolina	Response provided by Tribe(s), but not the State.
North Dakota	Community list provided.
Nebraska	Community list provided.
New Hampshire	Community list provided.
New Jersey	Community list provided.
New Mexico	Community list provided.
Nevada	Community list provided.
New York	No high-risk communities adjacent to Federal lands.
Ohio	No high-risk communities were identified by the State.
Oklahoma	Community list provided.
Oregon	Community list provided.
Pennsylvania	Community list provided.
Puerto Rico	No response.
Rhode Island	No high-risk communities adjacent to Federal lands.
South Carolina	Response provided by Tribe(s). State list currently unavailable.
South Dakota	Community list provided.
Tennessee	List unavailable at this time.
Texas	Community list provided.
Utah	Community list provided.
Virginia	Community list provided.
Virgin Islands	No response.
Vermont	Community list provided.
Washington	Community list provided.

STATE RESPONSES OF THE URBAN WILDLAND INTERFACE COMMUNITIES—Continued

State	Response
Wisconsin	Community list provided.
West Virginia	Community list provided.
Wyoming	Community list provided.

Urban Wildland Community List

Listed alphabetically by State and Community.

Note, those communities where projects are ongoing or proposed are footnoted as:

[1] Ongoing fuels treatment project in Fiscal Year 2001.

[2] Proposed fuels treatment project for Fiscal Year 2001.

Alaska

Alcan, AK
Allakaket, AK
Anchor Point, AK
Anchorage, AK
Big Delta, AK
Big Lake, AK
Butte, AK
Clam Gulch, AK
College, AK
Cooper Landing, AK
Delta Junction, AK
Eagle River, AK
Fairbanks, AK
Fox River, AK
Fritz Creek, AK
Ft. Greely, AK
Funny River, AK
Happy Valley, AK
Homer, AK
Houston, AK
Kalifonsky, AK
Kasilof, AK
Kenai, AK
Lazy Mountain, AK
Lime Village, AK
McGrath, AK
Meadow Lakes, AK
Moose Creek, AK
Nikiski, AK
Ninilchik, AK
North Pole, AK
Northway, AK
Northway Junction, AK
Nulato, AK
Salamatof, AK
Soldotna, AK
Tanacross, AK
Tok, AK

Alabama

Addison, AL
Andalusia, AL
Anniston, AL
Ashland, AL
Atmore, AL
Baldon Springs, AL
Blanche, AL
Bon Secour, AL
Borden Springs, AL
Bradley, AL
Brent, AL
Bridgeport, AL
Centerville, AL
Chandler Springs, AL
Cheaha Mountain, AL
Cherokee, AL
Childresburg, AL
Choccolocco, AL
Coffeeville, AL
Curry, AL
Daleville, AL
Decatur, AL
Delta, AL
Dixie, AL [1]
Double Springs, AL
Duncanville, AL
Edwardsville, AL
Enterprise, AL
Eoline, AL
Eufaula, AL
Fort Mitchell, AL
Fort Morgan, AL
Fort Payne, AL
Freemanville, AL
Gulf Shores, AL
Haleyville, AL
Hartselle, AL
Heflin, AL
Heilberger, AL
Hollis, AL
Hollis Crossroads, AL
Huntsville, AL
Jacksonville, AL
Lawley, AL
Lineville, AL
Madison, AL
Maplesville, AL
Millerville, AL
Mooresville, AL
Moulton, AL
Munford, AL
Natural Bridge, AL
Nauvoo, AL
Newton, AL
Oak Hill, AL
Overbrook, AL
Oxford, AL
Ozark, AL
Phenix City, AL
Piedmont, AL
Plantersville, AL
Pleasant Gap, AL
Poarch, AL
Priceville, AL
Pyriton, AL
Red Oak, AL [1]
Rhodesville, AL
Scottsboro, AL
Sprott, AL
Stanton, AL
Sycamore, AL
Sylacauga, AL
Talledega, AL
Threet, AL
Triana, AL
Tuskegee, AL [1]
Waldo, AL
Wetumpka, AL
Wing, AL [1]
Winterboro, AL

Arizona

Alpine, AZ [1]
Arivaca, AZ
Bonita Creek, AZ
Camp Geronimo, AZ [1]
Cherry, AZ [2]
Chircahua, AZ
Christopher Creek, AZ
Cibola, AZ
Colcord, AZ
Crown King, AZ
Cutter, AZ
Deer Springs, AZ
Desert View, AZ [1, 2]
Eager, AZ [2]
East Rim Drive, AZ [1]
Ellision Creek, AZ
Flagstaff, AZ [1]
Forest Lakes, AZ [1]
Geronimo Estates, AZ
Globe, AZ
Golden Shores, AZ
Gordon Canyon, AZ
Grand Canyon Village, AZ [1]
Greer, AZ [1]
Groom Creek, AZ
Hawley Lake, AZ
Headquarters, AZ
Herber, AZ [2]
Hermit's Rest, AZ
Hideway, AZ [1]
Highway 64, AZ
Hondah, AZ [1]
Hunter Creek, AZ [1]
Hunters Point, AZ
Jeddito, AZ
Kaibab Lodge, AZ [2]
Keams Canyon, AZ
Kingman, AZ
Kitt Peak, AZ
Kohl's Ranch, AZ
Lakeside, AZ [1]
Linden, AZ [1]
Little Field, AZ
Maricopa Colony, AZ
McNary, AZ [1]
Mormon Lake, AZ [1]

Mount Lemmon, AZ
New River, AZ [2]
North Rim Developed, AZ [2]
North Rim Historic, AZ [2]
Nutrioso, AZ [2]
Oak Creek, AZ
Oak Springs, AZ
Oracle, AZ
Overgaard, AZ [2]
Parks, AZ [1]
Payson, AZ
Peridot, AZ
Pine, AZ [1]
Pine Springs, AZ [2]
Pinedale, AZ [1]
Pinelake, AZ [2]
Pinetop, AZ [1]
Pinewood, AZ
Pleasant Valley, AZ
Point of Pines, AZ
Polacca, AZ
Prescott, AZ [2]
Saint John, AZ
San Carlos, AZ
San Pedro, AZ
Santa Cruz, AZ
Sasabe, AZ
Second Mesa, AZ
Show Low, AZ [1]
Strawberry, AZ [1]
Summit, AZ
Supai, AZ
Third Mesa, AZ
Tonto Village, AZ [1]
Tsaile, AZ [2]
Walker, AZ
Washington Park, AZ
West Rim Drive, AZ
Whispering Pines, AZ
Whiteriver, AZ [1]
Williams, AZ [1]
Yaki Point, AZ [1]
Yavapai Prescott, AZ
Yuma, AZ

California

Acton, CA
Adelanto, CA
Agoura Hills, CA [1, 2]
Alpine, CA
Alta Sierra, CA
Altadena, CA
Amador City, CA
Angels Camp, CA
Apple Valley, CA
Arcadia, CA
Arnold, CA
Atascadero, CA
Auberry, CA
Auburn, CA
Azusa, CA
Banning, CA [1, 2]
Beale Air Force Base, CA
Beaumont, CA
Beverly Hills, CA [1, 2]
Big Bear City, CA [1]
Big Bear Lake, CA [1]
Big Oak Flat, CA
Bodfish, CA
Bolinas, CA [2]
Bootjack, CA
Boulder Creek High, CA
Boulevard, CA [1]
Bradbury, CA
Brea, CA
Burney, CA
Cabazon, CA
Cameron Park, CA
Camp Pendleton North, CA
Camp Rest, CA
Camptonville, CA [2]
Canyon Lake, CA
Carlsbad, CA
Carpinteria, CA
Cascade Oro, CA
Cathedral City, CA
Cedar Ridge, CA
Central Valley, CA
Challenge-Brownsville, CA
Cherry Valley, CA
Chester, CA [1]
Chico, CA
Chino, CA
Chula Vista, CA [2]
Claremont, CA
Clearlake, CA [2]
Cloverdale, CA
Coachella, CA
Cobb, CA
Colfax, CA
Columbia, CA [1]
Concow, CA
Corona, CA [1]
Coronado, CA
Coto de Caza, CA
Covelo, CA [1]
Crestline, CA [1, 2]
Del Monte Forest, CA
Del Rey Oaks, CA
Desert Hot Springs, CA
Devonshire, CA
Diamond Bar, CA
Diamond Springs, CA
Dollar Point, CA
Dorris, CA
Dresserville, CA
Duarte, CA
Dunsmuir, CA
East Hemet, CA
East Sonora, CA
Edwards Air Force Base, CA
El Dorado Hills, CA
El Toro, CA
El Toro Marine Corps Air Station, CA
Encinitas, CA
Escondido, CA
Etna, CA
Fallbrook, CA
Fontana, CA
Forest Knolls, CA
Foresthill, CA [1]
Fort Jones, CA [2]
Frazier Park, CA
George Air Force Base, CA
Glen Avon, CA
Glendale, CA
Glendora, CA [1]
Glenshire, CA
Grass Valley, CA
Greenville, CA
Groveland, CA [2]
Happy Camp, CA
Harbison Canyon, CA
Hayfork, CA [2]
Hemet, CA [1]
Hesperia, CA
Hidden Meadows, CA
Hidden Valley Lake, CA
Highland, CA
Homestead Valley, CA
Hoopa, CA
Idyllwild, CA [1]
Imperial Beach, CA
Indian Wells, CA
Indio, CA
Inverness, CA [2]
Ione, CA
Irvine, CA
Jamestown, CA
Jamul, CA
Julian, CA [2]
Kelseyville, CA [1]
Kernville, CA
Kings Beach, CA [1]
Klamath, CA
La Canada Flintridge, CA
La Crescenta, CA
La Habra Heights, CA
La Quinta, CA
La Verne, CA
Lagunitas, CA
Lake Arrowhead, CA [1]
Lake Elsinore, CA
Lake Isabella, CA
Lake Nacimiento, CA
Lakeland Village, CA
Lakeport, CA
Lakeside, CA [2]
Lakeview, CA
Lancaster, CA
Lewiston, CA
Littlerock, CA
Lompoc, CA
Lone Pine, CA [2]
Los Angeles, CA [1, 2]
Los Serranos, CA
Lower Lake, CA
Loyalton, CA [1]
Lucerne, CA
Magalia, CA
Mammoth Lakes, CA [2]
March Air Force Base, CA
Marina, CA
Martinez, CA
McCloud, CA
Meiners Oaks, CA
Mentone, CA
Mill Valley, CA [2]
Mira Monte, CA
Mission Viejo, CA
Mi-Wuk Village, CA
Mono Vista, CA
Monrovia, CA
Monterey, CA [2]
Montrose, CA
Moonstone, CA
Moreno Valley, CA

Morongo Valley, CA
Mount Helix, CA
Mount Shasta, CA [2]
Mountain Mesa, CA
Murphys, CA
National City, CA
Nevada City, CA [2]
Nice, CA
Norco, CA
North Auburn, CA
North Fork, CA [1, 2]
Nuevo, CA
Oakhurst, CA [2]
Oceanside, CA
Ojai, CA [2]
Ontario, CA
Oroville, CA
Oroville East, CA
Pala, CA [1]
Palermo, CA
Palm Desert, CA
Palm Springs, CA
Palmdale, CA
Paradise, CA [2]
Pasadena, CA
Perris, CA
Phoenix Lake, CA
Pine Cove, CA
Pine Valley, CA
Piru, CA
Placerville, CA
Plymouth, CA
Point Arena, CA
Point Dume, CA
Pollock Pines, CA
Pomona, CA
Porterville, CA [1]
Portola, CA
Portola Hills, CA
Poway, CA
Quail Valley, CA
Quincy-East Quincy, CA [2]
Rainbow, CA
Ramona, CA
Rancho Mirage, CA
Rancho Cucamonga, CA
Rancho Santa Margarita, CA
Redding, CA [2]
Redlands, CA
Rialto, CA
Riverside, CA
Rosamond, CA
Rowland Heights, CA
Running Springs, CA
San Andreas, CA
San Antonio Heights, CA
San Bernadino, CA
San Clemente, CA
San Diego, CA
San Diego Country Estates, CA
San Dimas, CA
San Marcos, CA
Sand City, CA
Santa Barbara, CA
Santa Clarita, CA [1]
Santa Rosa, CA [2]
Santa Ysabel, CA [1]
Santee, CA
Seaside, CA
Shingle Springs, CA [1]
Sierra Madre, CA
Simi Valley, CA
Sonora, CA
Soulsbyville, CA
South Lake, CA
South Lake Tahoe, CA
South Oroville, CA
Squaw Valley, CA
Sun City, CA
Sunnyside, CA
Susanville, CA
Sutter Creek, CA
Sycuan, CA [2]
Tahoe City, CA [1]
Tahoe Vista, CA
Tamalpais, CA
Temecula, CA
Thousand Oaks, CA
Thousand Palms, CA
Tollhouse, CA [1]
Toulumne, CA [2]
Trabuco Highlands, CA
Trinidad, CA
Truckee, CA [1]
Tuolumne, CA
Twain Harte, CA
Upland, CA
Val Verde, CA [1]
Valle Vista, CA
Valley Center, CA [1, 2]
Vandenberg Air Force Base, CA
Vandenberg Village, CA
Victorville, CA
Vista, CA
Warner Springs, CA [2]
Weed, CA
Westhaven, CA
Westlake Village, CA
Wildomar, CA
Willow Creek, CA [1]
Winchester, CA
Winterhaven, CA
Wofford Heights, CA
Woodcrest, CA
Wrightwood, CA [1]
Yosemite Lakes, CA
Yreka, CA
Yucaipa, CA
Yucca Valley, CA

Colorado

Abbeyville, CO
Acequia, CO
Adelaide, CO
Aguilar, CO
Akin, CO
Alamo, CO
Alamosa, CO
Alder, CO
Alice, CO
Allenspark, CO [1]
Allison, CO
Alma, CO
Alma Junction, CO
Almont, CO
Alpine, CO
Alpine (historical), CO
Alta, CO
Altman, CO
Altona, CO
American City, CO
Americus, CO
Ames, CO
Anaconda, CO
Angora, CO
Antero Junction, CO
Antlers, CO
Antonito, CO
Anvil Points, CO
Apex, CO
Ara, CO
Arboles, CO
Archer, CO
Arriola, CO
Arrowhead, CO
Arrowood, CO
Ashcroft, CO
Aspen, CO
Aspen Meadows, CO
Aspen Park, CO
Aspen Springs, CO
Austin, CO
Austin Post Office, CO
Avon, CO
Axial, CO
Badito, CO
Bailey, CO
Bakerville, CO
Balarat, CO
Baldwin, CO
Balltown, CO
Baltimore, CO
Bark Ranch Subdivision, CO
Barnesville, CO
Basalt, CO
Battle Creek, CO
Baxterville, CO
Bayfield, CO [2]
Beacon Hill, CO
Bear River, CO
Beaver Point, CO [2]
Bedrock, CO
Belden, CO
Belleview, CO
Bellford Mountain Heights, CO
Bellvue, CO
Bergen Park, CO
Berthoud Falls, CO
Beulah, CO [1]
Beverly Hills, CO
Big Elk Meadows, CO
Bighorn, CO [1]
Biglow, CO
Birdseye, CO
Black Eagle Mill, CO
Black Forest, CO
Black Hawk, CO
Blanca, CO
Blue Mountain, CO
Blue Mountain Subdivision, CO
Blue River, CO
Blue Valley, CO
Bonanza, CO [1]
Bonanza Mountain Estates, CO
Boncarbo, CO
Bond, CO
Bondad, CO

Bordenville, CO
Boswich Park, CO
Boulder, CO [1]
Boulder Junction, CO
Bountiful, CO
Bowie, CO
Box Prairie, CO
Bradford, CO
Breckenridge, CO [2]
Breen, CO
Breeze Basin, CO
Bridges Switch, CO
Brimstone Corner, CO
Broadmoor, CO
Broken Arrow Acres, CO
Bronquist, CO
Brook Forest, CO
Brookside, CO
Brookvale, CO
Browns Canon, CO
Brumley, CO
Buckhorn Canyon, CO
Buckskin Joe, CO
Buena Vista, CO
Buffalo Creek, CO [1]
Buford, CO
Burns, CO
Buttes, CO
Cabazon Subdivision, CO
Cameo, CO
Camp Bird, CO
Camp Hale, CO
Canon City, CO
Carbon Junction, CO
Carbondale, CO
Cardiff, CO
Cardinal, CO
Caribou, CO
Caribou City, CO
Carracas, CO
Carterville, CO
Cascade, CO
Castle Rock, CO
Cathedral, CO
Catherine, CO
Cattle Creek, CO
Cedar Cove, CO
Cedar Creek, CO
Cedar Grove, CO
Cedar Point, CO
Cedaredge, CO
Cedarwood, CO
Centerville, CO
Central City, CO [1]
Chacra, CO
Chama, CO
Chance, CO
Chandler, CO
Chattanooga, CO
Chavez Arroyo, CO
Chimney Rock Post Office, CO [2]
Chipeta, CO
Chipita Park, CO
Chromo, CO
Cimarron, CO
Clark, CO
Cleora, CO
Cliffdale, CO
Clifton, CO
Climax, CO
Coal Creek, CO
Coaldale, CO
Coburn, CO
Cody Park, CO
Cokedale, CO
Colby, CO
Cold Spring, CO
Collbran, CO
Colona, CO
Colorado City, CO
Colorado Springs, CO
Columbine, CO
Columbine Valley, CO
Columbus, CO
Commerce City, CO
Como, CO
Conejos, CO
Conifer, CO
Conifer Mountain, CO
Copper Mountain, CO
Copper Spur, CO
Copperdale, CO
Cordova Plaza, CO
Cortez, CO
Cory, CO
Cory Post Office, CO
Cotopaxi, CO
Cottonwood, CO
Coventry, CO
Cowdrey, CO
Craig, CO
Craig Place, CO
Craig South Highlands, CO
Crawford, CO
Creede, CO
Crescent, CO
Crescent Village, CO
Crested Butte, CO [1]
Crestone, CO [1]
Cripple Creek, CO
Crisman, CO
Crossons, CO
Crow Hill, CO
Crystal, CO
Crystola, CO
Cuchara, CO
Cuerna Verde Park, CO
Dallas, CO
De Beque, CO
Deckers, CO
Deermont, CO
Del Norte, CO
Delagua, CO
Dell, CO
Delta, CO
Derby Junction, CO
Dillon, CO
Dinosaur, CO [2]
Divide, CO
Dolores, CO [2]
Dome Rock, CO
Dotsero, CO
Dove Creek, CO
Dowds Junction, CO
Downieville, CO
Drake, CO
Duffield, CO
Dumont, CO
Dunckley, CO
Dunton, CO
Durango, CO [2]
Durango West, CO
Dyersville, CO
Dyke, CO
Eagle, CO
Eagles Nest, CO
East Canon, CO
East Portal, CO
East Vancorum, CO
Eastonville, CO
Echo, CO
Eckert, CO
Edgemont, CO
Edith, CO
Edwards, CO
Eggers, CO
Egnar, CO
El Jebel, CO
El Moro, CO
El Rancho, CO
El Vado, CO
Eldora, CO
Eldorado Springs, CO
Eldredge, CO
Elephant Park, CO
Elk Creek Acres, CO [1]
Elk Ridge, CO
Elkdale, CO
Elkhead, CO
Elkton, CO
Elsmere, CO
Emma, CO
Empire, CO
Engleville (abandoned), CO
Espinosa, CO
Estabrook, CO
Estes Park, CO [1, 2]
Evansville, CO
Everett, CO
Evergreen, CO [2]
Fairplay, CO
Fairview, CO
Falfa, CO
Fall River Estates Subdivision, CO
Farista, CO
Fenders, CO
Ferncliff, CO
Ferndale, CO
Fink, CO
Florence, CO
Floresta, CO
Florida, CO
Florida Mesa, CO
Florissant, CO
Fort Boettcher, CO
Fort Carson, CO
Fort Collins, CO
Fort Garland, CO
Fox Creek, CO [2]
Foxton, CO
Franktown, CO
Fraser, CO
Freeland, CO
Frisco, CO
Frost, CO
Fruita, CO
Fruitland Mesa, CO

Fulford, CO
Funston, CO
Galena, CO
Garfield (historical), CO
Gaskil, CO
Gateview, CO
Gateway, CO [1]
Gem Village, CO
Genesee, CO
Georgetown, CO
Gerrard, CO
Gillet (historical), CO
Gilman, CO
Gilpin, CO
Gilson Gulch, CO
Gilsonite, CO
Glade Park, CO
Glen Comfort, CO
Glen Cove, CO
Glen Echo, CO
Glen Eden, CO
Glen Eyie, CO
Glen Haven, CO
Glen Park, CO
Glendale, CO
Glendevey, CO
Glendevey Post Office, CO
Glenelk, CO
Glenisle, CO
Glenwood Springs, CO
Gold Hill, CO
Gold Park, CO
Gold Run Subdivision, CO
Golden, CO
Goldfield, CO
Goodell Corner, CO
Goodnight, CO
Goodpasture, CO
Gothic, CO
Gould, CO [1]
Granby, CO
Grand Island, CO
Grand Junction, CO
Grand Lake, CO [2]
Grand Mesa, CO
Grandview, CO
Granite, CO
Grant, CO
Graymount, CO
Green Mountain, CO
Green Mountain Falls, CO
Green Mountain Village, CO
Green Valley Acres, CO
Greenhorn, CO
Greenland, CO
Greenwood, CO
Ground Hog, CO
Guadalupe, CO
Guffey, CO
Gulnare, CO
Gunnison, CO
Gunston, CO
Gypsum, CO
Hahns Pear, CO
Halfway House, CO
Hamilton, CO
Hancock, CO
Happy Canyon, CO
Harris Park, CO
Haver, CO
Hay Camp, CO
Haybro, CO
Hayden, CO
Heeney, CO
Heiberger, CO
Henkel, CO
Henson, CO
Hermosa, CO
Herzman Mesa, CO
Hesperus, CO
Hessie, CO
Hidden Lake, Subdivision, CO
Hidden Valley, CO
Hideaway Park, CO
Hierro, CO
Highland Park, CO
Hillside, CO
Hiwan Hills, CO
Holiday Acres, CO
Hollywood, CO
Holy Cross City, CO
Homewood Park, CO
Hooks, CO
Hooper, CO
Hoovers Corner, CO
Horsetooth Heights, CO
Hot Sulphur Springs, CO
Hotchkiss, CO
Howard, CO
Hygiene, CO
Idaho Springs, CO
Idledale, CO
Idylwilde, CO
Ignacio, CO
Iles Grove, CO
Independence, CO
Independence (historical), CO
Indian Creek, CO
Indian Hills, CO
Indian Meadows, CO
Indian Springs Village, CO
Indian Hills, CO
Insmont, CO
Iola, CO
Iola (historical), CO
Iris, CO
Iron City (historical), CO
Ironton, CO
Irwin, CO
Ivywild, CO
Jack Springs, CO
Jacks Cabin, CO
Jamestown, CO
Jansen, CO
Jasper, CO
John Held Corner, CO
Johnson Village, CO
Juanita, CO
Juanita Junction, CO
Juniper Hot Springs, CO
Kannah, CO
Kassler, CO
Kearns, CO
Kellytown, CO
Keyhole, CO
Keystone, CO
Kiggin, CO
Kings Canyon, CO
Kinikinik, CO
Kittredge, CO
Kline, CO
Knob Hill, CO
Kobe, CO
Kokomo, CO
Kremmling, CO
La Boca, CO
La Foret, CO
La Garita, CO
La Jara, CO
La Plata, CO
La Posta, CO
La Valley, CO
La Veta, CO
La Veta Pass, CO
Lake City, CO
Lake George, CO
Lake Shore Park Subdivision, CO
Lamartine, CO
Laporte, CO
Larkspur, CO
Lawson, CO
Lazear, CO
Lazy Acres Subdivision, CO
Leadville, CO
Leadville Junction, CO
Leal, CO
Leavick, CO
Lebanon, CO
Lenado, CO
Leon, CO
Leonard, CO
Lewis, CO
Leyden, CO
Liberty, Bell, CO
Lime, CO
Lincoln, CO
Lincoln Hills, CO
Lincoln Park, CO
Little Dam, CO
Little Hills, CO
Livermore, CO
Log Hill, CO
Loma, CO
Loma Linda, CO
Lone Pine Estates, CO
Lonetree, CO
Longview, CO
Lookout Mountain, CO
Lost Acres, CO
Louviers, CO
Loveland Heights, CO
Loyd, CO
Ludlow, CO
Lujane, CO
Lynn, CO
Lyons, CO
Mad Creek, CO
Magnolia, CO [1]
Maher, CO
Malachite, CO
Malta, CO
Manassa, CO
Mancos, CO [2]
Manitou Springs, CO
Marble, CO
Marshall, CO
Marshdale, CO

Maryvale, CO
Masontown, CO
Masonville, CO
Masonville Post Office, CO
Mayday, CO
Maysville, CO
McCoy, CO
McGregor, CO
McKenzie Junction, CO
McKinley, CO
McAlamo Canyon, CO
Mears Junction, CO
Medina Plaza, CO
Meeker, CO
Meeker Park, CO [1, 2]
Meredith, CO
Mesa Lakes, CO
Mesa Lakes Resort, CO
Mesa Verde Park, CO [2]
Mid Vail, CO
Midland, CO
Midway, CO
Midway (historical), CO
Millwood, CO
Milner, CO
Minnehaha, CO
Minturn, CO
Miramonte, CO
Mishawaka, CO
Mitchell, CO
Moffat, CO
Mogote, CO
Molina, CO
Monarch, CO
Monson, CO
Montbello, CO
Monte Vista, CO
Monte Vista Estates, CO
Montezuma, CO
Montrose, CO
Montrose South, CO
Monument, CO
Monument Park, CO
Moonridge, CO
Morely, CO
Morrison, CO
Morrison Creek, CO [1]
Mount Crested Butte, CO
Mount Harris, CO
Mount Lincoln, CO
Mount Vernon Club Place, CO
Mountain Estates, CO
Mountain Meadows (subdivision), CO
Mountain View, CO
Muddy Pass, CO
Muleshoe, CO
Mulford, CO
Mystic, CO
Nathrop, CO
Naturita, CO
Nederland, CO
Needleton, CO
Nevadaville, CO
New Castle, CO
Newett, CO
Nighthawk, CO
Ninetyfour, CO
Niwot, CO
Noel, CO
Noland, CO
Norrie, CO
North Creede, CO
North Delta, CO
North Vallecito, CO
Norwood, CO
Nucla, CO
Nugget, CO
Nutria, CO
Oak Creek, CO [1]
Oak Grove, CO
Occidental, CO
Oehlmann Park, CO
Ohio, CO [1]
Olathe, CO
Olava Post Office, CO
Olympus Heights, CO
Ophir, CO
Ophir Loop, CO
Orchard City, CO
Orchard Corner, CO
Orchard Mesa, CO
Orchard Park, CO
Orodell, CO
Orsa, CO
Osier, CO
Ouray, CO
Owl Canyon, CO
Oxford, CO
Oxyoke, CO
Pactolus, CO
Pagoda, CO
Pagosa Junction, CO
Pagosa Springs, CO
Paisaje, CO
Palisade, CO
Palmer Lake, CO
Pando, CO
Pandora, CO
Paonia, CO
Papeton, CO
Parachute, CO
Paradise Hills, CO
Paradox, CO
Park Center, CO
Park City, CO
Park View, CO
Parkdale, CO
Parkville, CO
Parras Plaza, CO
Parshall, CO
Patterson Place, CO
Payne, CO
Pea Green Corner, CO
Peabodys, CO
Peaceful Valley, CO
Perigo, CO
Peyton, CO
Phillipsburg, CO
Phippsburg, CO[1]
Phoenix, CO
Picaence Rural, CO
Pictou, CO
Piedra, CO [2]
Pike-San Isabel Village, CO
Pikeview, CO
Pine, CO
Pine Brook Hill Subdivision, CO
Pine Crest, CO
Pine Junction, CO
Pine Nook, CO
Pine Valley, Co
Pinecliffe, CO
Pinewood Springs, CO
Pingree Park, CO
Pinon, CO
Pinon Acres, CO
Pitkin, CO [1]
Pittsburg, CO
Placerville, CO
Placita, CO
Plainview, CO
Platte Springs, CO
Pleasant Valley, CO
Pleasant View, CO
Pleasanton, CO
Poncha, Springs, CO
Portland, CO
Poudre Park, CO
Powderhorn, CO
Preston, CO
Primero, CO
Princeton, CO
Prospect Heights, CO
Pryor, CO
Purgatory, CO
Querida, CO
Radium, CO
Rand, CO
Range, CO
Rangely, CO
Raymond, CO
Read, CO
Red Feather Lakes, CO [2]
Red Mesa, CO
Red Mountain, CO
Red Wing, CO
Redcliff, CO
Redlands, CO
Reds Place, CO
Redstone, CO
Redvale, CO
Reilly Canyon, CO
Rex, CO
Rhone, CO
Rico, CO
Ridge at Hiwan, CO
Ridgewood Subdivision, CO
Ridgway, CO
Rifle, CO
Rio Blanco, CO
Rio Grande, CO
Rist Canyon, CO
Riverside, CO
Riverview, CO
Robinson Place, CO
Rock Creek Park, CO
Rockdale, CO
Rockvale, CO
Rockwood, CO
Rocky, CO
Roe, CO
Rogers Mesa, CO
Rollinsville, CO
Romeo, CO
Romley, CO
Rosedale, CO
Rosemont, CO

Rosevale, CO
Rosita, CO
Roswell, CO
Rouse, CO
Rowena, CO
Roxborough Park, CO
Rugby, CO
Rulison, CO
Russell Gulch, CO
Rustic, CO[1]
Rye, CO
Saguache, CO
Saint Ann Highlands Subdivision, CO
Saint Elmo, CO
Saints John, CO
Salida, CO
Salina, CO
Sample, CO
Sams, CO
San Isabel, CO
San Luis, CO
San Miguel, CO
Sanford, CO
Santa Maria, CO
Sapinero, CO
Sarcillo, CO
Sargents, CO[1]
Satank, CO
Saunders, CO
Sawpit, CO
Saxton, CO
Sedalia, CO
Segundo, CO
Seven Hills Subdivision, CO
Seven Lakes, CO
Shaffers Crossing, CO
Shamballah-Ashrama, CO
Sharpsdale, CO
Shavano, CO
Shawnee, CO
Sheephorn, CO
Sherman, CO
Shirley, CO
Sikes, CO
Sillsville, CO
Silt, CO
Silver Cliff, CO
Silver Heights, CO
Silver Plume, CO
Silver Springs, CO
Silver Springs Subdivision, CO
Silver Spruce, CO
Silverdale, CO
Silverthorne, CO
Silverton, CO
Singleton, CO
Sky Village, CO
Sleepy Cat, CO
Slick Rock, CO
Smeltertown, CO
Smith Hill, CO
Smith Place, CO
Sneffels, CO
Snow Water Springs, CO
Snowmass, CO
Snowmass Village, CO
Somerset, CO
South Fork, CO [1]
South Platte, CO
Southern Ute Indian Tribe Youth Camp, CO [1]
Spencer Heights, CO
Sphinx Park, CO
Spike Buck, CO
Springdale, CO
Spruce, CO
Sprucedale, CO
Sprucewood, CO
Stage Coach, CO [1]
Stanley Heights, CO
Subdivision, CO
Stanley Park, CO
Stapleton, CO
Starkville, CO
State Bridge, CO
Steamboat II, CO
Steamboat Springs, CO [1]
Stollsteimer, CO
Stone City, CO
Stoner, CO
Stonewall, CO
Stonewall Gap, CO
Stove Prairie, CO
Stove Prairie Landing, CO
Stratton, CO
Stratton Meadows, CO
Stringtown, CO [1]
Sugarloaf, CO
Summerville, CO
Summit, CO
Sunnyside, CO
Sunset, CO
Sunset City, CO
Sunshine, CO
Surles Meadow, CO
Swan, CO
Swissvale, CO
Switzerland Park, CO
Tabernash, CO
Tacoma, CO
Tall Timber Subdivision, CO
Tanglewood Acres, CO
Tarryall, CO
Telluride, CO
Terico, CO
Texas Creek, CO
The Pines, CO
Thomasville, CO
Thornburgh, CO
Three Bridges, CO
Three Forks, CO
Tiffany, CO
Tijeras, CO
Tincup, CO [1]
Tiny Town, CO
Tolland, CO
Tomah, CO
Toponas, CO
Tordal Estates, CO
Torres, CO
Towaoc, CO [2]
Trail Junction Picnic Grounds, CO
Trappers Crossing, CO
Treasure, CO
Trimble, CO
Trinidad, CO
Troublesome, CO
Troutdale, CO
Trujillo, CO
Trumbull, CO [1]
Trump, CO
Tuckerville, CO
Tungsten, CO
Twin Cedars, CO
Twin Forks, CO
Twin Lakes, CO
Twin Spruce, CO
Una, CO
Uncompahgre, CO
Uncompahgre Plateau, CO
Uravan, CO
Ute, CO
Vail, CO
Valdez, CO
Vallecito, CO
Valley View, CO
Vallie, CO
Vallorso, CO
Valmont, CO
Vanadium, CO
Vance Junction, CO
Vancorum, CO
Velasquez Plaza, CO
Vernal, CO
Victor, CO
Vigil, CO
Vulcan, CO
Wagon Wheel Gap, CO
Wah Keeney Park, CO
Walden, CO
Wallstreet, CO
Walsenburg, CO
Waltonia, CO
Wandcrest Park, CO
Ward, CO
Waterton, CO
Waunita Hot Springs, CO
Weasleskin, CO
Weber, CO
Webster, CO
Weller, CO
Wellsville, CO
West Creek, CO
West Dolores, CO
West Vail, CO
West Vancorum, CO
Westcliffe, CO
Weston, CO
Wetmore, CO
Wheeler Junction, CO
Wheelman, CO
Whispering Pine Subdivision, CO
White River City, CO
Whitehorn, CO
Whitepine, CO [1]
Whitewater, CO
Wideawake, CO
Widefield, CO
Wigwam, CO
Wilderness Lake, CO
Will-O–The-Wisp, CO
Winfield, CO
Wingo, CO
Winter Park, CO
Witcher Ranch, CO
Wolcott, CO

Wondervu, CO
Woodland Park, CO
Woody Creek, CO
Yampa, CO [1]
Yankee, CO
Yellow Jacket, CO
Yorkville, CO
Zamara, CO
Zapata, CO

Florida

Altonnia, FL
Astor, FL
Astor Park, FL
Avon Park, FL
Baxter, FL
Benton, FL
Big Cypress, FL [1]
Big Pine Key, FL
Blackhammock Island, FL
Brevard County, FL
Brighton, FL [1]
Bristol, FL
Buckhorn, FL
Burbank, FL
Cape Canaveral, FL
Carrabelle, FL
Carraway, FL
Cocoa Beach, FL
Copeland, FL
Crawfordville, FL
Davenport, FL
DeLand, FL
DeLeon Springs, FL
Destin, FL
Eagle Lake, FL
Everglades City, FL
Florida City, FL
Forest Corners, FL
Fort Kissimmee, FL
Fort Walton, FL
Glen Saint Mary, FL
Golden Gate, FL
Gulf Breeze, FL [1]
Gulf Islands Park Headquarters, FL
Halfmoon Island, FL [1]
Harris Fish, FL
Highland Park Fish Camp, FL
Hobe Sound, FL
Homestead, FL
Hosford, FL
Immokale, FL [1]
Indian Lake Estate, FL
Johnson, FL
Jupiter Island, FL
Kennedy Space Center, FL
Kudjoe Key, FL
Lake City, FL
Lanark, FL
Little Torch Key, FL
Lynne, FL
Macclenny, FL
Medart, FL
Merritt Island, FL
Mexico Beach, FL
Miccosukee Indian Village, FL
Miccosukee Reserved Area, FL [1, 2]
Miccosukee Trail, FL [1]
Miles City, FL
Mocassin Creek, FL
Mount Carrie, FL
Naples, FL
Navarre, FL
New Port, FL
Niceville, FL
No Name Key, FL
Oak Hill, FL
Ocala, FL
Olustee, FL [2]
Orange Springs, FL
Oyster Bay, FL
Panacea, FL
Panama City, FL
Pine Island, FL
Pittman, FL
Plantation Hill, FL
Ponciana, FL
Port Saint Johns, FL
Purify Bay, FL
Reservation Road, FL
Royal Palm, FL
Rural Miami-Date County, FL
Saint Marks, FL
Salt Springs, FL [1]
Sanderson, FL
Scottmoor, FL
Seaside, FL
Sebring, FL
Shell Point, FL
Shell Road Fish Camp, FL
Silver Springs, FL
Sopchoppy, FL [1]
Spring Creek, FL
Sugarload Key, FL
Tallahassee, FL
Taylor, FL
Titusville, FL
Umatilla, FL
Villa Venyce, FL [1, 2]
Wakulla, FL
Wakulla Beach, FL
Welaka, FL
Woodville, FL

Iowa

Beebeetown, IA
California Junction, IA
Loveland, IA
Missouri Valley, IA
Modale, IA

Idaho

Aberdeen, ID
Acequia, ID
Adrian, ID
Ahsahka, ID
Albeni, ID
Albion, ID
Almo, ID
Alpine, ID
Alta, ID
American Falls, ID
Arbon, ID
Arbon Valley, ID [2]
Arco, ID
Arimo, ID
Ashton, ID
Asotin, ID
Athol, ID
Atlanta, ID
Atomic City, ID
Avery, ID
Baker, ID
Bancroft, ID
Banida, ID
Banks, ID
Bannock Creek, ID [2]
Basalt, ID
Bayview, ID
Bearpaw, ID
Bellevue, ID
Bennington, ID
Bern, ID
Blackfoot, ID
Blanchard, ID
Bliss, ID
Bloomington, ID
Bluebell, ID
Boise, ID [2]
Bone, ID
Bonners Ferry, ID
Bovill, ID
Bowmont, ID
Bruneau, ID
Buhl, ID
Burke, ID
Burley, ID [1]
Butte City, ID
Cabinet, ID
Calder, ID
Caldwell, ID
Cambridge, ID
Carey, ID [1]
Careywood, ID
Carmen, ID
Cascade, ID
Castleford, ID
Cataldo, ID
Cavendish, ID
Centerville, ID
Challis, ID [1]
Chatcolet, ID
Chester, ID
Chubbuck, ID
Clark Fork, ID
Clarkia, ID
Clayton, ID
Clearwater, ID
Clifton, ID
Cobalt, ID
Cocolalla, ID
Coeur d'Alene, ID
Colburn, ID
Conda, ID
Conner Creek, ID
Coolin, ID
Cora, ID
Corral, ID
Cottonwood, ID
Council, ID
Craigmont, ID
Crouch, ID
Culdesac, ID
Cuprum, ID
Dalton Gardens, ID
Darlington, ID
Dayton, ID

De Smet, ID
Deary, ID
Delco, ID
Dietrich, ID [2]
Dingle, ID
Dixie, ID [1]
Donnelly, ID
Dover, ID
Downey, ID
Driggs, ID
Drummond, ID
Dubois, ID
Eagle, ID
East Hope, ID
Eastport, ID
Eden, ID
Elba, ID
Elk Bend, ID
Elk City, ID
Elk River, ID [1]
Elmire, ID
Emmett, ID
Enaville, ID
Evergreen, ID
Fairfield, ID
Farmington, ID
Felt, ID
Fenn, ID
Ferdinand, ID
Fernan Lake, ID
Fernwood, ID
Filer, ID
Firth, ID
Fish Haven, ID
Forest, ID
Fort Hall, ID
Franklin, ID
Freedom, ID
Fruitland, ID
Fruitvale, ID
Gannett, ID
Garden City, ID
Garden Valley, ID [2]
Gardena, ID
Garfield, ID
Garrison, ID
Gem, ID
Genesee, ID
Geneva, ID
Georgetown, ID
Gibbonsville, ID [1]
Gilmore, ID
Glenns Ferry, ID
Golden, ID
Gooding, ID [2]
Grace, ID
Grandview, ID
Grangemont, ID
Grangeville, ID [1]
Granite, ID
Grasmere, ID
Greencreek, ID
Greenleaf, ID
Greer, ID
Hagerman, ID
Hailey, ID
Halfway, ID
Hamer, ID
Hammett, ID
Hansen, ID
Harper, ID
Harpster, ID [1]
Harrison, ID
Harvard, ID [1]
Hatwai, ID [1]
Hauser, ID
Hayden, ID
Hayden Lake, ID
Hazelton, ID
Headquarters, ID
Heise, ID
Helmer, ID [1]
Heyburn, ID
Hill City, ID
Holbrook, ID
Hollister, ID
Homedale, ID
Hope, ID
Horseshoe Bend, ID
Howe, ID [1]
Huetter, ID
Idaho City, ID [2]
Idaho Falls, ID
Indian Valley, ID
Inkom, ID
Iona, ID
Irwin, ID
Island Park, ID [2]
Jerome, ID [2]
Jordan Valley, ID
Juliaetta, ID
Juntura, ID
Kamiah, ID [1, 2]
Kellogg, ID
Kendrick, ID
Ketchum, ID
Keutervile, ID
Kilgore, ID
Kimberly, ID
King Hill, ID
Kingston, ID
Kleinschmidt, ID
Kooskia, ID [1, 2]
Kootena, ID
Kuna, ID
Laclede, ID
Lake Fork, ID
Lakeview, ID
Lamb Creek, ID
Lane, ID
Lapwai, ID [1]
Lava Hot Springs, ID
Leadore, ID
Lenore, ID
Leon, ID
Letha, ID
Lewiston, ID
Lewisville, ID
Lincoln, ID
Lookout, ID
Lorenzo, ID
Lost River, ID
Lowell, ID [1]
Lowman, ID [2]
Lucille, ID
Machaund, ID
Mackay, ID [1]
Macks Inn, ID
Malad, ID
Malta, ID
Marsing, ID
Marysville, ID
May, ID
Mayfield, ID
McCall, ID
McCammon, ID
Meadows, ID [2]
Medimont, ID
Melba, ID
Meridian, ID
Middleton, ID
Midvale, ID
Minidoka, ID
Mink Creek, ID
Monteview, ID
Montpelier, ID
Moore, ID
Moreland, ID
Moscow, ID
Mount Idaho, ID
Mountain City, ID
Mountain Home, ID
Mud Lake, ID
Mullan, ID
Murphy, ID
Murray, ID
Murtaugh, ID
Myrtle, ID
Namps, ID
Naples, ID
New Meadows, ID
New Plymouth, ID
Newacres, ID
Newdale, ID
Nezperce, ID
Nordman, ID [2]
Norland, ID
North Bannock County, ID
North Fork, ID [1]
North Lapwai, ID
Notus, ID
Oakley, ID
Ola, ID
Oldtown, ID
Onaway, ID
Orofino, ID
Osburn, ID
Ovid, ID
Owyhee, ID
Oxford, ID
Pardee, ID
Paris, ID
Parker, ID
Parma, ID
Patterson, ID
Paul, ID
Pauline, ID
Payette, ID
Peck, ID
Picado, ID
Pierce, ID [1]
Pine, ID
Pinehurst, ID
Pineville, ID
Pingree, ID
Placerville, ID [2]
Plummer, ID [2]

Pocatello, ID [1]
Pollock, ID
Ponderay, ID
Porthill, ID
Post Falls, ID
Potlatch, ID [1]
Prairie, ID
Preston, ID
Prichard, ID
Priest Lake, ID
Priest River, ID
Princeton, ID
Quell, ID
Raft River, ID
Rathdrum, ID
Reubens, ID
Rexburg, ID
Reynolds, ID
Richfield, ID [2]
Riddle, ID
Ridgeview, ID
Rigby, ID
Riggins, ID [1]
Ririe, ID
Riverside, ID
Roberts, ID
Rock Creek, ID
Rockford, ID [1]
Rockland, ID
Rogerson, ID
Rose Lake, ID
Rupert, ID
Sagle, ID
Salmon, ID [1]
Samaria, ID
Samuels, ID
Sanders, ID
Sandpoint, ID
Santa, ID
Setters, ID
Shelley, ID
Shoshone, ID [2]
Shoup, ID
Silverton, ID
Slickpoo, ID
Smelterville, ID
Smiths Ferry, ID
Soda Springs, ID
South Mountain, ID
Southwick, ID
Spalding, ID
Spencer, ID [2]
Spirit Lake, ID
Springfield, ID
St. Anthony, ID
St. Charles, ID
St. Joe, ID
St. Maries, ID
Stanley, ID
Star, ID
State Line, ID
Sterline, ID
Stites, ID
Stone, ID
Sugar City, ID
Sun Valley, ID
Sunbeam, ID [1]
Swan Valley, ID
Swanlake, ID
Sweet, ID
Sweetwater, ID
Tendoy, ID
Tensed, ID
Terrenton, ID
Teton, ID
Tetonia, ID
Thatcher, ID
Thornton, ID
Three Creek, ID
Time, ID
Tipanuk, ID
Troy, ID
Twin Falls, ID
Ucon, ID
Victor, ID
Viola, ID
Virginia, ID
Waha, ID [1]
Wallace, ID [2]
Warm Lake, ID
Warm River, ID
Warren, ID [2]
Wayan, ID
Webb, ID
Weider, ID
Weippe, ID [2]
Weiser, ID
Wellesley, ID
Wendell, ID
Westmond, ID
Weston, ID
White Bird, ID
Wilder, ID
Winchester, ID
Woodland, ID
Worley, ID [2]
Yellow, Pine, ID [1, 2]
Yost, ID [1]

Indiana

Abydel, IN
Algiers, IN
Apalona, IN
Arlington, IN
Arthur, IN
Augusta, IN
Ayrshire, IN
Bartlettsville, IN
Bean Blossom, IN
Beatrice, IN
Beverly Shore, IN
Birdseye, IN
Bloomington, IN
Boone Grove, IN
Branchville, IN
Brandon, IN
Braodville, IN
Braxtons Siding, IN
Brownstown, IN
Burdick, IN
Burns Harbor, IN
Campbelltown, IN
Cannelton, IN
Cascade, IN
Cato, IN
Chambersburg, IN
Chesterton, IN
Chestnut Ridge, IN
Clear Creek, IN
Cobbs Corner, IN
Crisman, IN
Dabney, IN
Derby, IN
Dexter, IN
Dodd, IN
Dolan, IN
Dongola, IN
Douglas, IN
Dudleytown, IN
Dune Acres, IN [2]
Eastern Heights, IN
Ellettsville, IN
English, IN
Fleener, IN
Four Corner, IN
Francisco, IN
Freetown, IN
French Lick, IN
Fritz Corner, IN
Furnesville, IN
Garyton, IN
Gatchel, IN
Gerald, IN
Graham Woods, IN
Gray Junction, IN
Gudgel, IN
Hagland, IN
Handy, IN
Hardingtongrove, IN
Harrodsburg, IN
Hartwell, IN
Hayden, IN
Heltonville, IN
Holton, IN
Hoosier Acres, IN
Hurleburt, IN
Ironton, IN
Iva, IN
Kelley Point, IN
Kings, IN
Kirksville, IN
Kriete Corner, IN
Lacy, IN
Lake Eliza, IN
Lake of Four Seasons, IN
Lauer, IN
Leavenworth, IN
Leopold, IN
Lilly Dale, IN
Lost River, IN
Lyles, IN
Magnet, IN
Marlin Hills, IN
McCool, IN
Mentor, IN
Morgan Park, IN
Mt. Pleasant, IN
Mt. Tabor, IN
Muren, IN
Nathez, IN
New Farmington, IN
New Unionville, IN
Oak Hill, IN
Oakland City, IN
Odgen Dunes, IN
Oriolie, IN
Otwell, IN

Paoli, IN
Patoka, IN
Pikeville, IN
Pleasant Valley, IN
Portage, IN
Porter, IN
Porter Crossroad, IN
Princeton, IN
Prospect, IN
Ranger, IN
Rocky Point, IN
Roland, IN
Rome, IN
Rusk, IN
Sanders, IN
Schnellville, IN
Seymour, IN
Shoals, IN
Smithville, IN
South Haven, IN
Spraytown, IN
St. Croix, IN
Stampers Creek, IN
Stendall, IN
Stinesville, IN
Sunny Slopes, IN
Syria, IN
Tell City, IN
Terry, IN
Tobinsport, IN
Town of Pines, IN
Town of Troy, IN
Tremont, IN
Unionville, IN
West Baden Springs, IN
Western Acres, IN
Willow Creek, IN
Willow Valley, IN
Windom, IN
Winslow, IN
Woodlawn Grove, IN
Wyandotte, IN
Yenne, IN
Zelma, IN
Zoar, IN

Kansas

Blue Rapids, KS
Carneiro, KS
Clinton, KS
Delia, KS
Elkhart, KS
Glade, KS
Grandview Plaza, KS
Hartford, KS
Hillsdale, KS
Junction City, KS
Kanopolis, KS
Kanwaka, KS
Keats, KS
Kickapoo, KS
Kirwin, KS
Leavenworth, KS
Lebo, KS
Mayetta, KS
Melvern, KS
Meriden, KS
Michigan Valley, KS
Milford, KS
Neosho Rapids, KS
Ogden, KS
Olivet, KS
Oskaloosa, KS
Ottumwa, KS
Ozawkie, KS
Perry, KS
Pleasanton, KS
Powhattan, KS
Randolph, KS
Reading, KS
Reserve, KS
Riley, KS
Rock Creek, KS
Rolla, KS
Spring Hill, KS
Strong City, KS
Stull, KS
Trading Post, KS
Valley Falls, KS
Vassar, KS
Wakefield, KS
White Cloud, KS
Woodruff, KS

Massachusetts

Aquinnah, MA
Chatham, MA
Eastham, MA
Lobsterville, MA
Orleans, MA
Provincetown, MA
Truro, MA
Wampanoag Tribe, MA
Wellfleet, MA [1]

Maryland

Aberdeen, MD
Aberdeen Proving Grounds, MD
Bel Air, MD
Cambridge, MD
Carroll County, MD
Cumberland, MD
Federalsburg, MD
Fort Detrick, MD
Fort Smallwood, MD
Frederick City, MD
Frostburg, MD
Fruitland, MD
Gaithersburg, MD
Kent Island, MD
Lake Liganore, MD
LaPlata, MD
Laurel, MD
Lusby, MD
Ocean Pines, MD
Parsonsburg, MD
Port Tobacco, MD
Princess Anne, MD
Rt. 30 [1] Corridor, MD
Snow Hill, MD
Solomons, MD
St. Mary's County, MD
Waldorf, MD

Maine

Albany, ME [2]
Bar Harbor, ME [2]
Bethel, ME
Brunswick, ME
Caribou, ME
Caswell, ME
Connor, ME
Cooks Corner, ME
Cutler, ME
Edmunds, ME
Fort Fairfield, ME
Fowler, ME
Gilead, ME
Greenbush, ME
Greenfield, ME
Hall Quarry, ME [1]
Hull's Cove, ME [1, 2]
Indian Township, ME
Isle Au Haut, ME [1, 2]
Kennebunk, ME
Kennebunkport, ME
Limestone, ME
Lovell, ME
Manset, ME
Marion, ME
Milford, ME
Northeast Harbor, ME [2]
Old Town, ME
Otter Creek, ME [2]
Princeton, ME
Schoodic Point, ME
Seal Harbor, ME [2]
Southwest Harbor, ME
Stoneham, ME
Topsham, ME
Tremont, ME [1]
Trescott, ME
Waite, ME
Waterford, ME
West Tremont, ME
Whiting, ME

Michigan

Baldwin, MI [1]
Bay Millis Main, MI
Bay Mills North, MI
Dublin, MI
Glennie, MI [1]
Hannahville Main, MI
Holton, MI
Hoxeyville, MI
Irons, MI
Luzerne, MI [1]
Mack Lake, MI [1]
Mio, MI [1]
Oscoda, MI [1]
Raco, MI [2]
Rapid River, MI [1]
Saint Helen, MI
Seney, MI
South Branch, MI
Stonington, MI
Trenary, MI
Trout Lake, MI
Twin Lake, MI
Wellston, MI
Wolf Lake, MI
Woodville, MI

Minnesota

Auroa, MN
Babbit, MN

Ball Club, MN [1]
Becker, MN
Bemidji, MN
Bena, MN
Big Lake, MN
Blackduck, MN
Bowstring, MN
Boy River, MN [1]
Brimson, MN
Britt, MN [1]
Brookston, MN
Burnsville, MN
Cass Lake, MN
Chisholm, MN
Clear Lake, MN
Cloquet, MN [1]
Cook, MN [1]
Crane Lake, MN
Deer River, MN
Duluth, MN
Eagan, MN
East Bethel City, MN
East Lake, MN
Elbow Lake, MN [1]
Ely, MN
Federal Dam, MN [1]
Grand Portage, MN
Gunflint Corridor, MN [1]
Harris, MN
Hibbing, MN
Hovland, MN
Hoyt Lakes, MN
Indian Pt., MN
Inger, MN
International Falls, MN
Isabella, MN
Jessie Lake, MN
Kabetogama, MN
Linwood Township, MN
Little Rock, MN
Maple Hill, MN
Marcell, MN
McGregor, MN
Mission, MN
Motley, MN
Nashwauk, MN
Naytahwaush, MN
Nett Lake, MN
North Branch, MN
Onigum, MN
Orr, MN
Palmquist, MN [1]
Pen, MN
Pike Sandy, MN
Pine Point, MN
Poneman, MN
Ponsford, MN
Princeton, MN
Ranier, MN
Red Lake, MN
Redby, MN
Remer, MN [1]
Rice Lake, MN
Rush City, MN
Sawyer, MN
Side Lake, MN
Squaw Lake, MN
Staples, MN
Talmoon, MN
Taylor Falls, MN
Tower, MN
Vermillion, MN
Vineland, MN
Virginia, MN
Walker, MN
White Earth, MN [1]
Whiteface Reservoir, MN
Zimmerman, MN

Mississippi

Betheden, MS [2]
Bogue Chitto, MS [2]
Bogure Chitto, MS [2]
Clinton, MS [2]
Conehatta, MS [1]
Conehatta, MS [2]
Craig Springs, MS [2]
Cybur, MS [2]
French Camp, MS [2]
Gautler, MS [2]
Hanleyfield, MS [2]
Industrial, MS [2]
Kirkville, MS [2]
Koscuisko, MS [2]
Longview, MS [2]
Natchez, MS [2]
Natchez Trace R.S., MS [2]
Nicholson, MS [2]
Ocean Springs, MS [2]
Oktoc, MS [2]
Pecan, MS [2]
Picayune, MS [2]
Port Gibson, MS [2]
Raymond, MS [2]
Ridgeland, MS [2]
Saltillo, MS [2]
Singleton, MS [2]
Standing Pine, MS [2]
Standing Pine, MS [2]
Starkville, MS [2]
Tupelo, MS [2]
Warren County, MS [2]

Montana

Absarokee, MT
Alberton, MT [2]
Alzada, MT
Amsterdam, MT
Anaconda, MT
Arlee, MT
Ashland, MT [2]
Augusta, MT [2]
Avon, MT
Babb, MT [2]
Baker, MT
Belfry, MT
Belgrade, MT
Belt, MT
Big Arm, MT
Big Sandy, MT
Big Sky, MT [1]
Big Timber, MT
Bigfork, MT
Billings, MT
Birney, MT [2]
Birney Divide, MT [2]
Bonner, MT
Boulder, MT
Box Elder Crk to Smalls, MT
Box Elder Village, MT [1, 2]
Bozeman, MT
Bridger, MT
Broadus, MT
Brockton, MT [2]
Brockway, MT
Browning, MT
Busby, MT
Butte, MT [2]
Camas Prairie, MT [1]
Camerson, MT
Canyon Creek, MT
Cardwell, MT
Cascade, MT
Charlo, MT
Chester, MT
Chinook, MT
Choteau, MT
Circle, MT
Clancy, MT
Clinton, MT
Clyde Park, MT
Colstrip, MT
Columbia Falls, MT
Columbus, MT
Condon, MT
Conner, MT
Conrad, MT
Cooke City, MT [1]
Coram, MT
Corvallis, MT
Crackerville, MT
Crane, MT
Crow Agency, MT [1, 2]
Culbertson, MT
Custer, MT
Darby, MT
Dayton, MT
De Borgia, MT
Deer Lodge, MT
Dell, MT [1]
Denton, MT
Dillon, MT
Dixon, MT
Drummond, MT
Duck Creek Drainage, MT
Dutton, MT
East Glacier, MT [2]
East Helena, MT
East Shore Flathead Lake, MT [1]
Edgar, MT
Ekalaka, MT
Elliston, MT
Emmigrant, MT
Ennis, MT
Essex, MT [2]
Eureka, MT [1]
Evaro, MT
Fairfield, MT
Fairview, MT
Fallon, MT
Ferdig, MT
Fishtail, MT
Flaxville, MT
Florence, MT
Floweree, MT
Forsyth, MT
Fort Benton, MT

Fort Kipp, MT [1]
Fort Peck, MT
Fortine, MT [1]
Frazer, MT [2]
Frenchtown, MT
Froid, MT
Fromberg, MT
Gallantin Gateway, MT [1]
Gardiner, MT
Garrison, MT
Garryownen, MT
Geraldine, MT
Geyser, MT
Glasgow, MT
Glendive, MT
Grass Range, MT
Great Falls, MT
Hall, MT
Hamilton, MT
Hardin, MT
Harlem, MT
Harlowton, MT
Havre, MT
Hays, MT [1]
Haystack Loop & Villages, MT
Heart Butte, MT [2]
Helena, MT [1]
Highway 93 Corridor, MT [2]
Hilger, MT
Hobson, MT
Hot Springs, MT [2]
Hungry Horse, MT
Huntley, MT [1]
Huson, MT [1]
Hysham, MT
Ingomar, MT
Ismay, MT
Jackson, MT
Jefferson City, MT
Jocko River Corridor, MT
Joliet, MT
Joplin, MT
Jordan, MT
Judith Gap, MT [1]
Kalispell, MT
Kila, MT
Kiowa, MT [2]
Lakeside, MT [1]
Lambert, MT
Lame Deer, MT [2]
Laurel, MT
Lavina, MT
Lewistown, MT
Libby, MT [1]
Lima, MT
Lincoln, MT [1]
Little Badger, MT [2]
Livingston, MT
Lodgegrass, MT [1, 2]
Lodgepole, MT [1]
Lolo, MT
Loma, MT
Lustre, MT
Malta, MT
Manhattan, MT
Marion, MT
Martin City, MT
McAllister, MT
Mcleod, MT
Medicine Lake, MT
Melrose, MT
Miles City, MT
Milltown, MT
Missoula, MT [1]
Moore, MT
Mott, MT
Muddy Cluster, MT [2]
Mussellshell, MT
Neilhart, MT
Noxon, MT
Nye, MT
Oilmont, MT
Olney, MT
Opheim, MT
Oswego, MT [2]
Ovando, MT
Pablo, MT
Paradise, MT
Park City, MT
Parker Canyon, MT
Philipsburg, MT
Pinesdale, MT
Plains, MT
Plentywood, MT
Plevna, MT
Polaris, MT
Polebridge, MT [2]
Polson, MT [2]
Pony, MT
Poplar, MT [1]
Pray, MT
Proctor, MT
Pryor, MT [1, 2]
Ransay, MT
Rapelje, MT
Ravalli, MT
Red Lodge, MT
Reed Point, MT
Rexford, MT [1]
Richey, MT
Roberts, MT
Rocky Boy Townsite, MT
Ronan, MT
Roundup, MT
Roy, MT
Ryegate, MT
Saco, MT
Saint Xavier, MT [1, 2]
Saltese, MT
Sand Coulee, MT
Scobey, MT
Seeley Lake, MT [2]
Shelby, MT
Shepherd, MT
Sheridan, MT
Sidney, MT
Simms, MT
Somers, MT [1]
St. Ignatius, MT
St. Mary, MT [2]
St. Regis, MT
Stanford, MT
Stevensville, MT
Stryker, MT
Sula, MT
Sun River, MT
Sunburst, MT
Superior, MT
Sweetgrass, MT
Terry, MT
Thompson Falls, MT [2]
Three Forks, MT
Townsend, MT
Trego, MT [2]
Troy, MT
Twin Bridges, MT
Two Medicine, MT [2]
Ulm, MT
Valier, MT
Vaughn, MT
Victor, MT
Vigrinia City, MT
West Glacier, MT [2]
West Yellowstone, MT [1]
White Sulpher Springs, MT
Whitefish, MT
Whitehall, MT
Wibaux, MT
Wilsall, MT
Winifred, MT
Winnett, MT
Wisdom, MT
Wise River, MT
Wolf Creek, MT
Wolf Point, MT [2]
Wyola, MT [1, 2]
Yellow Bay, MT [1]
Zero, MT
Zortman, MT

North Carolina

Adams Creek, NC [2]
Goose Creek, NC [2]
Rough Branch, NC [2]
Saunooke Heights, NC [2]
Varner Estates, NC [2]

North Dakota

4-Winds, ND [2]
Belcourt, ND [1]
Bismarck, ND
Cannon Ball, ND [1]
Crow Hill, ND [2]
Devils Lake Reservation, ND
Dickinson, ND
Dunseith, ND [1]
Fargo, ND
Fort Berthold Reservation, ND
Fort Yates, ND [1]
Fourt Bears, ND [1]
Fryburg, ND
Ft. totten, ND [2]
Grassy Butte, ND
Jamestown, ND
Lake Metigoshe, ND
Lake Oahe shoreline, ND
Lake Sakakawea shoreline, ND
Lake Tschida shoreline, ND
Mandan, ND
Mandaree, ND [1]
Marmarth, ND
Medora, ND
Minot, ND
Porcupine, ND [1]
Spirit Lake Reservation, ND
St. John, ND [1]
St. Michael, ND [2]

Standing Rock Reservation, ND
Stanton, ND
Takio, ND [2]
Turtle Mountain Reservation, ND
Turtle Mountains, ND
Twin Butte, ND [1]
Valley City, ND
Watford City, ND
White Shield, ND [1]

Nebraska

Agate, NE
Alma, NE
Andrews, NE
Beatrice, NE
Belmont, NE
Bignell, NE
Blair, NE
Bodarc, NE
Bordeaux, NE
Burge, NE
Chadron, NE [2]
Cody, NE
Conterra, NE [1]
Costin, NE
Crawford, NE
Desoto, NE
Doughboy, NE
Dunning, NE
Eldorado, NE
Ft. Calhoun, NE
Gering, NE
Glen, NE
Glenover, NE
Haig, NE
Halsey, NE [1]
Harrison, NE
Hoag, NE
Hubbard Corner, NE
James, NE
Joder, NE
Kennedy, NE
Kilgore, NE
Macy, NE [1]
Marsland, NE
McGrew, NE
Melbeta, NE
Mintle, NE
Montrose, NE
Mumper, NE
Naponee, NE
Nashville, NE
Natick, NE
Nenzel, NE
Niobrara, NE
Norden, NE
Orella, NE
Orleans, NE
Pine Ridge, NE
Ponca, NE
Rackett, NE
Republican City, NE
Riford, NE
Santee, NE [1]
Scottsbluff, NE
Simeon, NE
South Bayard, NE
Sparks, NE
Stockham, NE
Story, NE
Thatcher, NE
Thedford, NE
Thomas, NE
Tiny Town, NE
Valentine, NE
Verdel, NE

New Hampshire

Amherst, NH
Bartlett, NH
Bedford, NH
Campton, NH
Charlestown, NH
Chatham, NH
Conway, NH
Cornish, NH
Dunbarton, NH
Durham, NH
Francestown, NH
Goshen, NH
Grantham, NH
Greenland, NH
Hopkinton, NH
Jefferson, NH
Lincoln, NH
Lyndeborough, NH
Madison, NH
Milford, NH
New Boston, NH
Newington, NH
Newmarket, NH
Ossipee, NH
Plymouth, NH
Portsmouth, NH
Randolph, NH [2]
Rumney, NH
Salisbury, NH
Sandwich, NH
Tamworth, NH
Thornton, NH
Unity, NH
Weare, NH
Webster, NH
Woodstock, NH

New Jersey

Barnegat, NJ
Bass River, NJ
Bernards, NJ
Bernardsville, NJ
Blairstown, NJ
Brick, NJ
Dennis, NJ
Dover, NJ
Freehold, NJ
Galloway, NJ
Hampton, NJ
Hardwick, NJ
Howell, NJ
Jackson, NJ
Jefferson, NJ
Knowlton, NJ
Lakehurst, NJ
Little Egg Harbor, NJ
Lower, NJ
Manchester, NJ
Marlboro, NJ
Middle, NJ
Montague, NJ
Pemberton, NJ
Plumstead, NJ
Port Republic City, NJ
Rockaway, NJ
Sandyston, NJ
Stafford, NJ
Stillwater, NJ
Tinton Falls, NJ
Upper, NJ
Vernon, NJ
Wall, NJ
Wantage, NJ
Washington, NJ
Woodbine, NJ
Woodland, NJ

New Mexico

Albuquerque, NM
Algodones, NM
Angel Fire, NM
Apache Summit, NM [2]
Applewood Estates, NM [2]
Bernalillo, NM [1, 2]
Black Lake, NM
Bosque Farms, NM
Budville, NM
Candy Kitchen, NM
Canon, NM
Capitan, NM [1]
Catron County Interface, NM [1]
Chama, NM
Cloudcroft, NM [1]
Cochiti Pueblo, NM [2]
Corrales, NM [1]
Dixon, NM
Dulce, NM [2]
East Mountains, NM
Escabosa, NM
Espanola, NM [2]
Espanola Bosque, NM
Fort Wingate, NM
Gallinas Watershed, NM [1]
Hernandez, NM
Isleta Pueblo, NM [2]
Jacona, NM
Jemez Pueblo, NM [1]
La Cueva, NM
La Ventanta, NM
Laguna, NM
Laguna Vista Estates, NM
Lakeview Pines, NM
Lincoln, NM [1]
Los Alamos, NM [1, 2]
Los Lunas, NM [2]
Manzano Mountains, NM
Mayhill, NM
Mescalero, NM [1]
Middle Rio Grande
Bosque, NM
Mora County Interface, NM
Mount Taylor Game Ranch, NM [2]
Nambe, NM
Ojo Caliente, NM
Paguate, NM [2]
Palmer-Pena, NM [1]
Pecos, NM [2]
Pena Blanca, NM
Penasco, NM

Pescado, NM
Picuris Pueblo, NM [1]
Pine Haven, NM [1]
Pine Hill, NM
Pojoaque, NM
Ponderosa, NM
Puye, NM
Ramah, NM
Red River, NM [1]
Ruidoso, NM [1]
Sal Ildefonso, NM
San Felipe Pueblo, NM
San Juan Pueblo, NM
San Ysidro, NM
Sandia Pueblo, NM
Santa Ana Pueblo, NM [1, 2]
Santa Clara, NM
Santa Fe Watershed, NM [1]
Santo Domingo Pueblo, NM
Shady Brook, NM
Silver City Area, NM [2]
Tamaya, NM
Taos Canyon, NM
Taos Pueblo, NM [2]
Tesuque Pueblo, NM
Three Rivers, NM
Timberon, NM [2]
Toadlena, NM [2]
Upper Brazos, NM
White Rock, NM
Zia Pueblo, NM
Zuni Pueblo, NM [1]

Nevada

Amargosa, NV
Austin, NV
Baker, NV [2]
Battle Mountain, NV [2]
Beatty, NV
Belmont, NV
Beowawe, NV
Blue Diamond, NV
Bodie Flats, NV
Boulder City, NV
Caliente, NV
Carlin, NV
Carson City, NV
Cherry Creek, NV
China Springs, NV
Churchill County, NV
Cold Springs, NV
Crescent Valley, NV
Currie, NV
Dayton, NV
Deeth, NV
Denio, NV
Eastern Washoe Valley, NV
Elko, NV
Ely, NV [1 2]
Empire, NV
Fallon, NV
Fallon Naval Air Station, NV
Fernley, NV
Gabbs, NV
Galena, NV
Gardnerville, NV
Genoa, NV
Gerlach, NV
Golconda, NV
Gold Point, NV
Goldfield, NV
Goldhill, NV
Good Springs, NV
Grass Valley, NV [2]
Hawthorne, NV
Henderson, NV
Holbrook Junction, NV
Humboldt, NV
Imlay, NV
Indian Springs, NV
Jackpot, NV
Jarbridge, NV
Jean, NV
Jiggs, NV
Kingston Canyon, NV
Lamoille, NV
Las Vegas, NV
Laughlin, NV
Lee, NV
Lee Canyon, NV [2]
Leviathan, NV
Lining, NV
Lockwood, NV
Lovelock, NV
Lund, NV
Manhattan, NV
Mason Valley, NV
McDermitt, NV
McGill, NV
Midas, NV [2]
Mill City, NV
Mina, NV
Minden, NV
Mountain City, NV
Mt. Charleston, NV
Nightingale, NV
Nixon, NV
North Las Vegas, NV
Oreana, NV
Orovada, NV
Owayee, NV
Pahrump, NV
Panaca, NV
Paradise Valley, NV [2]
Pilot Peak, NV
Pioche, NV
Pleasant Valley, NV
Reno, NV [2]
Rochester, NV
Round Mountain, NV
Ruby Valley, NV
Ruth, NV
Schurz, NV
Searchlight, NV
Silver City, NV
Silver Peak, NV
Silver Springs, NV
Six Mile Canyon, NV
Smith Valley, NV
South Lake Tahoe, NV
Sparks, NV
Sprong Creek, NV
Stagecoach, NV
Steamboat, NV
Tenabo, NV
Tonopah, NV
Topaz, NV
Tuscarora, NV [2]
Unionville, NV
Valmy, NV
Virginia City, NV
Virginia City Highlands, NV
Wadsworth, NV
Walker Lake, NV
Wells, NV
West Wendover, NV
Western Washoe Valley, NV
Whiterocks, NV [2]
Winnemucca, NV
Yerington, NV
Yomba, NV

Oklahoma

Adair, OK
Atoka, OK
Beckham, OK
Blaine, OK
Bryan, OK
Caddo, OK
Canadian, OK
Carter, OK
Cherokee, OK
Choctaw, OK
Cleveland, OK
Comanche, OK
Creek, OK
Custer, OK
Delaware, OK
Garfield, OK
Garvin, OK
Grady, OK
Grayhorse Village, OK
Haskell, OK
Hughes, OK
Jackson, OK
Johnston, OK
Kay, OK
Kenwood, OK
Kingfisher, OK
Latimer, OK
LeFlore, OK
Lincoln, OK
Logan, OK
Love, OK
Marshall, OK
Mayes, OK
McClain, OK
McCurtain, OK
McIntosh, OK
Murray, OK
Muskogee, OK
Oklahoma, OK
Okmulgee, OK
Osage, OK
Ottawa, OK
Pawnee, OK
Payne, OK
Pittsburg, OK
Pontotoc, OK
Pottawatomie, OK
Pushmataha, OK
Rogers, OK
Seminole, OK
Sequoyah, OK
Stephens, OK
Tulsa, OK

Wagoner, OK
Washington, OK
Washita, OK
Woodward, OK

Oregon

Applegate, OR[1, 2]
Ashland, OR [2]
Bear Springs, OR
Bend, OR [1]
Black Butte Ranch, OR [1]
Cave Junction, OR
Cloverdale, OR
County Line, OR [1, 2]
I–84 Corridor, OR
Kah-Nee-Tah, OR
La Pine, OR [1]
Merlin, OR [1]
Murphy, OR [1]
Ruch, OR [1]
Sams Valley, OR
Shady Cove, OR
Sidwalter Flats, OR [1, 2]
Simnasho, OR
Sisters, OR [1]
Sun River, OR [1]
Warm Springs, OR [1]
Williams, OR

Pennsylvania

Delaware, PA [2]
Dingman, PA [2]
Lehman, PA [2]
Middle Smithfield, PA [2]
Milford, PA [2]
Smithfield, PA [2]
Narragansett, RI

South Carolina

Yesehena Village, SC

South Dakota

Allen, SD [1]
Bear Creek, SD [1]
Bear Soldier, SD [1]
Belle Fourche, SD
Big Bend, SD
Big Coulee, SD
Black Hawk, SD
Boulder Park, SD
Bridger, SD [2]
Cascade Springs, SD
Central City, SD
Cherry Creek, SD [1]
Cheyenne Crossing, SD
Custer, SD
Deadwood, SD
Deerfield, SD
Dewey, SD
Doty, SD
Elmore, SD
Englewood, SD
Erskine, SD
Evergreen, SD [1]
Finley Heights, SD
Fort Thompson, SD [1]
Fox Ridge, SD [1]
Galena, SD
Georgetown, SD [1]
Grass Mountain, SD [2]
Green Grass, SD [1]
Hayward, SD
Hill City, SD
Hisega, SD
Hot Springs, SD
Iron Lightning, SD [1]
Johnson Siding, SD
Kenel, SD [1]
Keystone, SD [2]
Kyle, SD [1]
Lakeside, SD [1]
LaPlante, SD [1]
Lead, SD
Little Eagle, SD [1]
Long Hollow, SD
Lower Brule, SD [1]
Maitland, SD
Manderson, SD [1]
Marksville, SD [1]
Marty, SD
Maurice, SD
Minnekahta, SD
Nemo, SD
Number Six, SD [1]
Oglala, SD [1]
On The Tree, SD [2]
Piedmont, SD
Pine Ridge, SD [1]
Pluma, SD
Porcupine, SD [1]
Potatoe Creek, SD [1]
Pringle, SD
Promise, SD [1]
Rapid City, SD
Red Iron, SD
Red Shirt, SD [1]
Ridgeview, SD
Rochford, SD
Rock Creek, SD [1]
Rockerville, SD
Rockyford, SD [1]
Rosebud, SD [2]
Sanator, SD
Savoy, SD
Sharp's Corner, SD [1]
Silver City, SD
Soldier Creek, SD [2]
Spearfish, SC
Spring Creek, SD [2]
St. Francis, SD [2]
Sturgis, SD
Swiftbird, SD [1]
Takini, SD [1]
Thunder Butte, SD [1]
Tilford, SD
Two Strike, SD [2]
Wakpala, SD [1]
Wanblee, SD [1]
West Brule, SD [1]
Whitehorse, SD [1]
Whitewood, SD
Wolf Creek, SD [1]
Wounded Knee, SD [1]
Blackfoot, SD [1]
Parade, SD
Red Scaffold, SD [1]

Texas

Alabama Coushatta Reservation Housing, TX
Austin, TX
Bell, TX
Circle D, TX
Edwards, TX
Horizon, TX
Hutchison, TX
Lake Granbury, TX
Lake Whitney, TX
McKinney, TX
Mount Lakes, TX
Navarro, TX
Pine Forest, TX
Tahitian Village, TX
Westlake, TX
Wimberly, TX
Woodway, TX

Utah

Alpine Acres, UT [1]
Blanding, UT
Callao, UT
Canyon Meadows, UT
Canyon Terrace, UT
Castle Valley, UT
Causey Estates, UT
Cedar Fort, UT
Cedar High Lands, UT [2]
Cedar Hill, UT
Cedar Hills, UT
Cedar Mountain, UT
Center Creek, UT
Centerville, UT
Central, UT
Chekshani, UT [1]
Chournos, UT
Cisco, UT
Clear Creek, UT
Cloud Rim, UT
Color Country, UT
Copperton, UT
Cougar Canyon, UT [1]
County Landfill, UT
Cove Fort, UT
Covered Bridge, UT
Cove-Richmond Bench, UT
Dameron Valley, UT
Daniels Summit, UT
Deep Creek, UT
Deer Crest, UT
Deer Valley, UT
Defas, UT
Derffie Creek, UT
Dewey, UT
Diamond Mountain, UT [2]
Diamond Valley, UT
Dimple Dell, UT
Dixie Deer Estates, UT [2]
Docs Beach, UT
Doug Thorley, UT
Draper, UT
Dry Fork, UT [2]
Duck Creek, UT [1]
Eagle Estates, UT
Eagle Mountain, UT
Eagle Springs, UT
East Carbon, UT
Eastside of Sevier Valley, UT [2]
Elk Meadow, UT

Elk Ridge, UT
Emigration Canyon, UT
Enoch, UT
Ephraim Canyon Experiment Station, UT
Eskdale, UT
Eureka, UT [1]
Evergreen Estates, UT
Fairview Lakes, UT
Farmington, UT
Fishlake Area, UT
Flaming Gorge Acres, UT [1]
Flaming Gorge Pines, UT [1]
Forest Gardens, UT
Garden City/Bridgerland, UT
Garden City/Sweetwater, UT
Garden City/Elk Hollow, UT
Garden City/Little Switzerland, UT
Garden City/Swan Creek, UT
Garff Ranches, UT
Garrison, UT
Gold Hill, UT
Gooseberry, UT
Grafton, UT
Granite, UT
Grass Valley, UT
Green Hills, UT
Greenville, UT
Gunlock, UT
Hamilton Fort, UT
Hanksville, UT
Harmony Heights, UT
Haycock, UT
Herriman, UT
Hideaway Valley, UT
Highland, UT
Highland Estates, UT
High-Low, UT
Holiday, UT
Holiday Oaks, UT
Holiday Park, UT [1]
Ibapah, UT
Indian Creek, UT
Indian Ridge, UT [1]
Indianola, UT
Ireland Meadow, UT
Iron Town, UT
Jeremy Ranch, UT
Joes Valley, UT
Joes Valley (General Store), UT [2]
Johnson Canyon, UT
Jordanelle, UT
Kanosh, UT
Kaysville, UT
Kelly Canyon, UT
Kenilworth, UT
Khoosharem Reservoir, UT [2]
Kolob, UT
Lake Front, UT
Lake Point, UT
Laketown, UT
Lakeview, UT
Laplatta, UT
Layton, UT
LeBaron, UT
Leeds, UT
Lidias Canyon, UT
Lindon, UT
Little Cottonwood, UT
Little Ponderosa, UT
Little Reservoir, UT
Logan Canyon, UT
Long Flat, UT
Long Valley Estates, UT
Lund, UT
Mable Hills, UT
Mammoth, UT [1]
Mammoth Creek, UT [1]
Manderfield, UT
Manning Meadows, UT
Manorlands, UT
Manti Canyon, UT
Maple Hills, UT
Mapleton, UT
Meadow Lake, UT [1]
Meadow View, UT
MIA Shalom, UT
Milburn, UT
Mills Junction, UT
Mining area SW of Marysvale, UT
Mirror Lake, UT
Modena, UT
Monroe Meadows, UT
Morgan, UT
Motoqua, UT
Mountain Green, UT
Mountain Meadow, UT
Movie Ranch, UT
Mt. Tabby Springs, UT
Navajo Estates, UT
Neola/Whiterocks, UT
New Castle, UT
New Harmony, UT
North Creek, UT
North Fork, UT
North Ogden Bench, UT [1]
North Salt Lake, UT
North Valley, UT
Oak City, UT [2]
Oak Creek, UT
Oaker Hills, UT
Ogden Canyon, UT
Olympus Cove, UT
Orem, UT
Pack Creek, UT
Palisade, UT
Panguitch Lake, UT [1]
Panorama Woods, UT
Park City/Deer Valley, UT
Paroganah, UT
Parowan, UT
Partoun, UT
Pin Willies, UT
Pine Canyon, UT
Pine Creek, UT
Pine Hollow, UT
Pine Meadows, UT
Pine Plateau, UT
Pine Valley, UT [1]
Pine View, UT
Pines Ranches/Pine Mt., UT
Pinto, UT
Pintura, UT
Plesant Grove, UT
Pleasant View, UT
Pole Patch, UT
Ponderosa Estates, UT
Ponderosa Villa, UT
Porterville, UT
Poverty Flat, UT [2]
Provo, UT
Puffer Lake, UT
Quitchapah, UT
Rabbit Gulch, UT
Rainbow Meadow, UT
Red Hawk, UT
Reeders, UT
Reservation Ridge, UT
Reservoir Road, UT
River Forest, UT
Rockport Estates, UT
Rocky Ridge, UT
Rush Valley, UT
Salt Lake City, UT
Sandy, UT
Santaquin, Ut
Scare Canyon, UT
Schofield, UT
Schofield Reservoir, UT
Sheep Creek, UT
Silver Creek/Tollgate, UT
Silver Reef, UT
Silver Valley, UT
Skull Valley, UT
Sky Haven, UT
Skyline Mountain Resort, UT
Soldier Creek, UT
South Ogden Bench, UT
South Weber, UT
Spirit Lake Lodge, UT
Spring Canyon/Helper, UT
Spring City Ranchero, UT
Spring Glen, UT
Spring Mountain, UT
Springville, UT
Strawberry Valley, UT
Summit, UT
Summit Park/Pinebrook, UT
Sundance, UT [1]
Sunnyside, UT
Swains Creek, UT
Swiss Mountain, UT
Sylvin Canyon, UT
Taylor Flat, UT [2]
Teasdale/Torrey, UT
Terra, UT [2]
Third Mound, UT
Thompson, UT
Three Creek, UT
Timber Trails, UT
Tintic, UT [1]
Tommy Creek, UT
Tooele, UT
Trappers Loop, UT
Trout Creek, UT
Turkey Farm, UT [1]
Two Bears, UT
Uintah Bench, UT [1]
Uintah Canyon, UT
Uintalands, UT
Upton/Gas Plant, UT
Veyo, UT
Vista Grande, UT
WECCO, UT
West Water, UT [1]
Whispering Pines, UT
White Mesa, UT

Williams, UT
Willow Basin, UT
Winchester Hills, UT
Woodland Hills, UT
Woodruff, UT
Yellow Pine, UT
Zion View, UT

Virginia

3 Creek Knoll, VA
Advance Mills, VA
Albin Acres, VA
Apline Acres, VA
Alpine Farm, VA
AM Club, VA
Amhest Plantation, VA
Anna Coves, VA
Anna High View, VA
Antler Trail, VA
Apple Mountain Lake, VA
Arrowhead, VA
Ashby Run Estates, VA
Ashcroft, VA
Ashmere, VA
Aspen Hill, VA
Aspen Hill Farm, VA
Aubrey Lee Subdivision, VA
Auburn Hills, VA
Ballard Woods, VA
Baptist Dan, VA
Battle Creek Forest, VA
Beacon Hill, VA
Bear Castle, VA
Bear Creek, VA
Bear Hollow Ridge, VA
Beaver Creek, VA
Beechwood Estates, VA
Belarispring, VA
Bell Farm Estates, VA
Bien Venue, VA
Big Hill Estates, VA
Big Reed, VA
Big Run Estates, VA [2]
Bishop Hill, VA
Black Walnut, VA
Blackwell, VA
Blandemar, VA
Blue Berry Hill, VA
Blue Mountain, VA
Blue Ridge, VA
Blue Ridge Acres, VA
Blue Ridge Forest, VA
Blue Ridge Shores, VA
Blue Springs Farm, VA
Blue Water, VA
Bonnie Brae, VA
Both Waters, VA
Brandy Run, VA
Brandywood Estates, VA
Breaks International Park, VA
Breamers Brook, VA
Brierwood Bluff, VA
Briery Branch, VA [2]
Brocks Gap, VA
Broken Back, VA
Brookmill, VA
Brookshire, VA
Bryce Mountain, VA
Buck Hill, VA
Buck Mountain, VA
Bull Run Mountain, VA
Bull Yearling, VA
Calalpa, VA
Caldwell Lake, VA
Calf Mountain, VA
Calmes Neck, VA
Camp Friends, VA
Cardinal Forest, VA
Carefree Acres, VA
Carringan Property, VA
Cascade Mountain, VA
Castle Rock Mountain, VA
Cedar Creek Estates, VA
Cedar Grove, VA
Cedar Hill Estates, VA
Celestine Acre, VA
Centennial Heights, VA
Central Valley, VA
Chalet High, VA
Chatmoss, VA
Cherry Ridge, VA
Chest Mountain Estates, VA
Chesterfield
Subdivision, VA
Chestnut Creek, VA
Chestnut Grove, VA
Chestnut Manor, VA
Chestnut Park, VA
Chimney Hill, VA
Chinuapin Estates, VA
Clairmont Manor, VA
Clay Banks, VA
Claymont, VA
Clearfield Heights, VA
Cloud Land, VA
Cobble Mountain, VA
Coleman, VA
Collier Hill, VA
Collinsville Landing, VA
Contrary Creek, VA
Contrary Forest, VA
Cooks Creek, VA
Cornwall, VA
Countryside Estates, VA
County View, VA
Courtland, VA
Covington, VA
Crimora Mill, VA
Crystal Springs, VA
Daniel Mountain, VA
Dawn Heights, VA
Deer Lick Ridge, VA
Deer Rapids, VA
Deerhead, VA
Delawder, VA
Dogwood Mountain, VA
Dogwood Valley, VA
Draper Mountain, VA
Dry Run Acres, VA
Duck Run, VA
Duffield-Sunbranch, VA
Dunlop Farm, VA
Earlysville Forest, VA
Echo Hills, VA
Edgewood, VA
Elk Ridge, VA
Emerald Ridge, VA
Estates, VA
Fairgrove 1&2, VA
Farm Colony, VA
Faw/Boseley Lake, VA
Fingerlake Estates, VA
First Blue Ridge, VA
Fisher Tract, VA
Flacon Ridge, VA
Flat Top Mountain, VA [2]
Forest Acres, VA
Forest Springs, VA
Forest View, VA
Fort Mason, VA
Fort Pasage, VA
Fortune Mountain, VA
Foster Falls Mill, VA
Fox Chase, VA
Fox Hollow, VA
Fox Run, VA
Foxcroft, VA
Foxwood, VA
Frazier Hill, VA
Fruland Orchard, VA
Furnace Mill, VA [2]
Georgetown Lane, VA
Gilbert Heights, VA
Gladstone, VA
Glass II, VA
Glaydin Acres, VA
Glenmore, VA
Glenmore Heights, VA
Goose Creek, VA
Gore Subdivision, VA
Graham Subdivision, VA
Granch Acres, VA
Grants Hollow, VA
Green Hill Forest, VA
Green Hill Heights, VA
Green Hill Terrace, VA
Green Mountain, VA
Green Mountain Acres, VA
Greene Land, VA
Greene Valley, VA
Greene Valley, VA
Greenwood Farm, VA
Griffinsburg, VA
Haley, VA
Hardwick Mountain, VA
Harper Valley, VA
Hazel River Estates, VA
Henly Mountain, VA
Henry Hill, VA
Hensley Hollow, VA
Herdman Hill, VA
Hickory Hills, VA
Hickory Ridge, VA
Hidden Pass, VA
Hidden Valley, VA
Hideaway Hills, VA
Hideway Lake, VA
High Knob, VA
High View Manor, VA
High View Woods, VA
Highland Estates, VA
Highland Lake, VA
Highland Park, VA
Hightop Mountain, VA
Highview, VA
Hill Top, VA
Hillendale, VA

Hillwood Estates, VA
Hinson's Ford, VA
Holbrook, VA
Holmes Run, VA
Hone Quarry, VA
Hoover, VA
Hoover Mountain, VA
Huckelberry Mountain, VA
Hunters Lake, VA
Hunters Valley, VA
Hunting Hill, VA
Huntington, VA
Irisburg Heights, VA
Ivy Creek, VA
Jackson Woods, VA
Jarman Gap Estates, VA
Jefferson Hunting Trail, VA
Kawana Valley, VA
Kire, VA
Knolls, VA
La-Go-Ha, VA
Lake Country, VA
Lake Holiday, VA
Lake Isaac, VA
Lake Monticello, VA
Lake Saint Claire, VA
Lake Serene, VA
Lakeridge, VA
Lakewood, VA
Lamma, VA
Laney Cemetary, VA
Laurel Mountain, VA
Laurel Ridge, VA
Laurel Wood, VA
Lawson Estates, VA
Layside Estates, VA
LeBaron Estates, VA
LeeHigh, VA
Leeland Heights, VA
Liberty Hill, VA
Lincoln Estates, VA
Little Gun Mountain, VA
Little North Mountain, VA
Loch Linden, VA
Locust Hill, VA
Lodebar, VA
Log Cabin Estates, VA
Lookout, VA
Lookout Mountain Community, VA
Loren's Camp, VA
Lost Valley, VA
Loudon Valley, VA
LOW, VA
Lowry Lest, VA
Manvel Subdivision, VA
Massanulten Forest, VA
Massanutten, VA
Matney Flats, VA
McGuire Hills, VA
Meadowfield, VA
Meadowlands, VA
Meadowview, VA
Melory Lake, VA
Merrimac South, VA
Merry Meadow, VA
Middle River, VA
Middlebranch, VA
Midlick, VA
Milford Height, VA
Mill Creek, VA
Millon Heights, VA
Milton Hills, VA
Mocassin Gap, VA
Monkey Run, VA
Moonshine Mountain, VA
Mount Gile, VA
Mount Joy, VA
Mount Pleasant, VA
Mount Wea, VA
Mountain Falls Park, VA
Mountain Hollow, VA
Mountain Run, VA
Mountain Run Lake, VA
Mountain Terrace, VA
Mountain View, VA
Mountain View Estates, VA
Mountain View Park, VA
Musterfield Road, VA
Normandy, VA
North Deans, VA
North Fork Farms, VA
North Mountain Properties, VA
North Ridge, VA
North White Oak, VA
Oak Manor, VA
Oakridge, VA
Oakwood Estates, VA
Oakwood Lake, VA
Outback, VA
Overlook, VA
Overlook Mountain, VA
Page Valley Estates, VA
Paige, VA
Pamunkey Creek, VA
Paradise Haven, VA
Paris Heights, VA
Park View Acres, VA
Partridge Run, VA
Patterson Road, VA
Peacock Hill, VA
Pinecrest, VA
Pleasant Valley, VA
Point O'Wood, VA
Pond Mountain, VA
Potts Mountain, VA
Powell Mountain, VA
Preston Gap, VA
Quail Ridge, VA
Quality Row, VA
R. Durham, VA
Rag Mountain, VA
Randle Ridge, VA
Rappahannoc, VA
Rawley Spring, VA
Rebel Acres, VA
Red Bud, VA
Red Hills, VA
Redfields, VA
Reynards Crossing, VA
Richardville South, VA
Ridgecrest Heights, VA
Riggory Ridge, VA
Rillhurst I&II, VA
Ritter Mountain Subdivision, VA
Riverbend Estates, VA
Riverdale, VA
Rock Branch, VA
Rock Mills, VA
Rolling Hills, VA
Roundhead Mountain, VA
Route 6 Cohasselo, VA
Route 637, VA
Route 644, VA
Route 651, VA
Route 655, VA
Route 676, VA
Route 683, VA
Running Deer, VA
Saddle Run, VA
Saddlebrook, VA
Saddlewood Forest, VA
Sand Mountain Estates, VA
Sandy Brook Reserve, VA
Sanford Tract, VA
Sanville Estates, VA
Scenic Green, VA
Seigen Forest, VA
Senger Mountain, VA
Seven Fountain, VA
Seven Springs, VA
Sexton Hills, VA
Shadwell Estates, VA
Shady Forest, VA
Shadybrook, VA
Shawneeland, VA
Shenandoah Farm, VA
Shenandoah Farms, VA
Shenandoah Forest, VA
Shenandoah Gap, VA
Shenandoah Highlands, VA
Shenandoah Retreat, VA
Shenandoah Shores, VA
Sherwood Forest, VA
Shipwreck Farm, VA
Signal Hill, VA
Sile Heights, VA
Singer Tree Hill, VA
Ski & Hunt, VA
Skyland Estates, VA
Skyline Crest, VA
Skyline Lakes, VA [2]
Skyline Orchard, VA
Skyview & Brook, VA
Slate Hill, VA
Slate Mountain, VA
Sleepy Hollow, VA
South Keswick, VA
South River Estates, VA
South Wales, VA
South White Oak, VA
Sparkling Spring, VA
Spoon Creek, VA
Spotswood Farm, VA
Spradlin Properties, VA
Spring Valley, VA
Stage Coach, VA
Stoney Fork Ranch, VA
Stoney Mountain, VA
Stony Point, VA
Stony Point Hills, VA
Stratford, VA
Stroupe Mountain, VA
Summer Place, VA
Sundance, VA
Sundance Creek, VA
Sundance Mountain, VA
Sundance Retreat, VA

Sundance West, VA
Sunny Ridge, VA
Sunset Ridge, VA
Sunvalley (lower), VA
Sunvalley (upper), VA [2]
Supin Lick, VA
Surreyfield, VA
Swan Ridge Estates, VA
Swan Woods, VA
Swift Run Estates, VA
Swift Run Haven, VA
Tall Pines, VA
Tannery Hills, VA
Tara Woods, VA
Taylors Gap, VA
Taylors Mountain Farm, VA
The Homestead, VA
The Ledges, VA
Thompson Hollow, VA
Thunder Oak, VA
Thunderbird Farm, VA
Thunderbird Ridge, VA
Thurston, VA
Tillman, VA
Timber Ridge Forest, VA
Timber Ridge Springs, VA
Timberlain, VA
Tobacco Row, VA
Totier Hills, VA
Trails End, VA
Turner Run, VA
Twin Coves, VA
Twin Falls Subdivision, VA
Twin Run Estates, VA
Vallee Viedeo, VA
Valley Estates, VA
Vance Subdivision, VA
Vias Estates, VA
Village of Springfield, VA
Village Square, VA
Virginia Farms, VA
Walnut Hills, VA
Walnut Hills Estates, VA
Walnut Mountains, VA
Walnut Run, VA
Waterford Subdivision, VA
Waterloo Woods, VA
Watts Station, VA
Wavertree Hollow, VA
WDS Landing, VA
Weatherwood, VA
Weber City, VA
Weslern Ridge, VA
Wesley Chapel, VA
West, VA
West Brice, VA
West Calvert, VA
West Lakes, VA
Westwood Acres, VA
Wexford, VA
Whip Por Ridge, VA
Whipporwill Hollow, VA
White Oak, VA
Whiteland, VA
Whitestone Estates, VA
Wilchpole Mountain, VA
Wilderness Park, VA
Wilderness Shores, VA
Wildwood, VA
Wildwood Forest, VA
Windrift, VA
Windy Gap, VA
Winnbrook, VA
Winter Hill, VA
Wintergreen, VA
Winterwood, VA
Wolf Lots, VA
Wolftrap Woods, VA
Woodcreek, VA
Woodcrust, VA
Woodlands Subdivision, VA
Woodlawn, VA
Woods Lodge, VA
Woodshire, VA
Woody Court, VA
Yates, VA
Yearwood, VA

Vermont

Bristol, VT
Dorset, VT
Dover, VT
Granville, VT
Jamaica, VT
Lincoln, VT
Mendon, VT
Mount Tabor, VT
Ripton, VT
Somerset, VT
Stockbridge, VT
Sunderland, VT
Wardsboro, VT
Warren, VT
Wilmington, VT
Windall, VT

Washington

9-Mile Rogers Bar, WA
Acme, WA
Addy, WA
Allyn, WA
Amboy, WA
Ariel, WA
Arlington, WA
Ashford, WA
Bainbridge Island, WA
Baring, WA
Battle Ground, WA
Belfair, WA
Bellingham, WA
Bickleton, WA
Bingen, WA
Boyds, WA
Bremerton, WA
Brewster, WA
Brinnon, WA
Brush Prairie, WA
Burlington, WA
Camas, WA
Cameron Lake, WA
Carlton, WA
Carnation, WA
Carson, WA
Cashmere, WA
Castle Rock, WA
Cathlamet, WA
Centerville, WA
Chattaroy, WA
Cheney, WA
Chewelah, WA
Clayton, WA
Cle Elum, WA
Colbert, WA
Colville, WA [1]
Cowiche, WA
Curlew, WA
Cusick, WA
Dayton, WA [1]
Deer Park, WA
Deming, WA
Desautel, WA
East Wenatchee, WA
Eatonville, WA
Elbe, WA
Elk, WA
Ellensburg, WA
Elma, WA
Entiat, WA [1]
Enumclaw, WA
Etueville, WA [2]
Evans, WA
Fairchild Air Force Base, WA
Fall City, WA
Ford, WA
Ford Cluster, WA [2]
Fort Simcoe Job Corp. Ctr., WA [2]
Friday Harbor, WA
Fruitland, WA
Georgeville, WA [2]
Gifford, WA
Goldendale, WA
Granite Falls, WA
Grapeview, WA
Greenacres, WA
Hansville, WA
Highway 21 Corridor, WA
Highway 97 Corridor, WA
Hoodsport, WA
Hunters, WA
Ilwaco, WA
Inchelium Rural, WA
Inchelium Urban, WA [2]
Issaquah, WA
Kalama, WA
Keller, WA
Kelso, WA
Kettle Falls, WA
Kingston, WA
Klickitat, WA
Lake Roosevelt Corridor, WA
Leavenworth, WA [1]
Liberty Lake, WA [2]
Lilliwaup, WA
Long Beach, WA
Long Island, WA
Longview, WA
Loomis, WA
Loon Lake, WA
Lyle, WA
Malaga, WA
Malo, WA
Manson, WA [1]
Marblemount, WA [1]
Matlock, WA
Mazama, WA
Mead, WA
Medical Lake, WA

Methow, WA
Mica, WA
Monroe, WA
Moses Meadows, WA
Mossyrock, WA
Naches, WA
Naselle, WA
Nespelem, WA [2]
Newman Lake, WA
Newport, WA
Nine Mile Falls, WA [1]
North Ahtanum, WA [2]
North Bend, WA
Ocean Park, WA
Okanogan Chelan, WA
Olalla, WA
Olga, WA
Olympia, WA
Omak, WA
Omak Rural, WA
Omak Urban, WA
Oroville, WA
Otis Orchards, WA
Packwood, WA
Pateros, WA [1]
Peshastin, WA [1]
Pomeroy, WA
Port Angeles, WA
Port Hadlock, WA
Port Orchard, WA
Port Townsend, WA
Poulsbo, WA
Quilcene, WA
Randle, WA
Ravensdale, WA
Reardan, WA
Republic, WA [1]
Reservation Road, WA [1, 2]
Rice, WA
Ridgefield, WA
Riverside, WA
Rockford, WA
Roosevelt, WA
Roy, WA
Seabeck, WA
Selah, WA
Sequim, WA
Shelton, WA
Silverdale, WA
Silverlake, WA
Skykomish, WA
Snoqualmie, WA
Spangle, WA
Spokane, WA [1]
Springdale, WA
Stehekin, WA [1, 2]
Stevenson, WA
Sultan, WA
Suquamish, WA
Tahuya, WA
Thorp, WA
Tieton, WA
Tonasket, WA
Toutle, WA
Tumtum, WA
Twin Lakes, WA
Twisp, WA [1]
Underwood, WA
Union, WA
Usk, WA
Valley, WA
Valleyford, WA
Vancouver, WA
Veradale, WA
Waitsburg, WA
Washougal, WA
Wauconda, WA
Wellpinit, WA [2]
Wenatchee, WA [1, 2]
White Salmon, WA
Winthrop, WA [1]
Woodland, WA
Yacolt, WA
Yakima, WA
Yelm, WA

Wisconsin

Alvin, WI
Argonne, WI
Armstrong Creek, WI
Babcook, WI
Barnes, WI
Birch Hill, WI
Blackwell, WI
Blue Wing, WI
Bowler, WI
Camp Douglas, WI
Carter, WI
Clam Lake, WI
Clear Lake, WI
Clearwater Lake, WI
Conover, WI
Crooked Lake, WI
Dairyland, WI
Danbury, WI
Drummond, WI
Dry Town, WI
Eagle River, WI
Fence Lake, WI
Finley, WI
Fort McCoy, WI
Franks Field, WI
Gordon, WI
Grand View, WI
Hayward, WI
Hiles, WI
Horizon, WI
Iron River, WI
Kekoskee, WI
Keshena, WI [1]
Keshena, WI
Lac du Flambeau, WI
LacCourte Oreilles Tribal Center, WI
Lacdu, WI
Lakewood, WI
Langlade, WI
Laona, WI
Long Lake, WI
Meadow Valley, WI
Middle Village, WI [1]
Minocqua, WI
Mission, WI
Morgan, WI
Mountain, WI
Necedah, WI
Nelma, WI
Neopit, WI
Newald, WI
Oakedale, WI
Phelps, WI
Reserve, WI
Riverside, WI
Sand Pillow, WI
South Branch, WI [1]
Sprague, WI
Three Lakes, WI
Tipper, WI
Townsend, WI
Valley Junction, WI
Wabeno, WI
West Branch, WI
Woodruff, WI

West Virginia

Alpena, WV
Alvon, WV
Amboy, WV
Anthony, WV
Arbovale, WV
Arden, WV
Aurora, WV
Auto, WV
Baker, WV
Bakerton, WV
Ballard, WV
Bartow, WV
Beckwith, WV
Bemis, WV
Bismark, WV
Blue Bend, WV
Bolair, WV
Bolivar, WV
Bowen, WV
Boyer, WV
Branchland, WV
Brandywine, WV
Cabins, WV
Camben on Gauley, WV
Canvas, WV
Cass, WV
Cedar Grove, WV
Cheat Bridge, WV
Cherry Grove, WV
Circleville, WV
Clarksburg, WV
Clear Fork, WV
Clearco, WV
Cloverlick, WV
Coketon, WV
Craigsville, WV
Cunard, WV
Curtin, WV
Cyrus, WV
Dailey, WV
Davis, WV
Deep Water, WV
Denmar, WV
Dorcas, WV
Droop, WV
Dunlow, WV
Dunmore, WV
Durbin, WV
East Bank, WV
East Lynn, WV
Edray, WV
Eglon, WV
Eleanor, WV

Elgood, WV
Elkins, WV
Elkwater, WV
Elliton, WV
Erwin, WV
Etam, WV
Fayetteville, WV
Fenwick, WV
Flemington, WV
Frank, WV
Franklin, WV
Friars, WV
Frost, WV
Ft. Gay, WV
Ft. Seybert, WV
Galloway, WV
Gassaway, WV
Gauley Bridge, WV
Genoa, WV
Gilbert, WV
Glady, WV
Glasgow, WV
Glen Ferris, WV
Gormania, WV
Grafton, WV
Green Bank, WV
Hambleton, WV
Handley, WV
Harman, WV
Harpers Ferry, WV
Hendricks, WV
Henry Hill, WV
Hillsboro, WV
Hunterville, WV
Huttonsville, WV
Jerryville, WV
Job, WV
Jordan Run, WV
Judy Gap, WV
Justice, WV
Keslers Cross Lane, WV
Kiahsville, WV
Kline, WV
Landes Sutton, WV
Lavalette, WV
Leivasy, WV
Lerona, WV
Lobelia, WV
London, WV
Lost City, WV
Lost River, WV
Mace, WV
Macomber, WV
Mammoth, WV
Marlinton, WV
Mathias, WV
Maxwelton, WV
Melissa, WV
Mill Creek, WV
Mill Point, WV
Mingo, WV
Minnehaha Springs, WV
Monterville, WV
Montrose, WV
Moyers, WV
Mt. Nebo, WV
Neola, WV
Nettie, WV
Nutter Fort, WV
Oak Flat, WV
Onego, WV
Parsons Robson, WV
Perry, WV
Petersburg, WV
Pierce, WV
Pipestem, WV
Pratt, WV
Radnor, WV
Ranger, WV
Red Creek, WV
Red House, WV
Renick, WV
Richwood, WV
Riverton, WV
Salt Rock, WV
Scherr, WV
Seebert, WV
Seneca Rocks, WV
Sheperdstown, WV
Silver Lake, WV
Simpson, WV
Slatyfork, WV
Snowshoe, WV
Spring Creek, WV
St. George, WV
Stonewood, WV
Sugar Grove, WV
Sully, WV
Summersville, WV
Thomas, WV
Thornwood, WV
Thurmond, WV
Upper Tract, WV
Valley Bend, WV
Valley Head, WV
Waiteville, WV
Ward, WV
Wardensville, WV
White Sulpher Springs, WV
Whitmer, WV
Wilson, WV
Winfield, WV
Wolf Summit, WV
Wymer, WV

Wyoming

Albany, WY
Alpine, WY
Alta, WY
Antelope Butte Ski Lodge, WY
Aspen Highlands
Estates, WY
Atlantic City, WY
Backcountry, WY
Baker Canyon, WY
Battle Lake
Subdivision, WY [1]
Beaver Creek, WY [2]
Beaver Creek, Area, WY
Big Block cabins, WY
Big Goose Creek, WY
Big Goose Creek, Work Center, WY
Bighorn Sum. Homes, WY
Billy Creek, WY
Billy Creek homes & cabins, WY
Black Buttes, WY
Bondurant, WY
Boulder Ridge Estates, WY
Breakneck, WY
Buckhorn, WY
Burgess Junction Lodge, WY [1]
Burgess Work Center, WY [1]
Camp Grace, WY
Canyon Creek Cabins #1, WY
Canyon Creek Cabins #2, WY
Canyon Creek County, WY [1]
Canyon Junction, WY
Casper Mountain, WY
Cedar Mountain, WY
Centennial, WY [1]
Clear Creek, WY
Colter Bay, WY [2]
Community, WY
Cottonwood Acres, WY [1]
Crandall, WY
Crooked Creek, WY [1]
Crystal Lake, WY
Curt Gowdy, WY
Dayton, WY
Deer Haven, WY
Devils Tower, WY
Devils Tower Visitor Center, WY
Dome Lake, WY
Dull Knife Reservoir, WY
East of Hunter Hwy 16, WY
East Upton, WY
Elk Ridge Estates, WY
Esterbrook, WY [1]
Ethete, WY
Ferguson Canyon, WY
Fontenelle, WY
Fort Washakie, WY
Fox Park, WY [1]
Freedom, WY
French Creek, WY
Glendo State Park, WY
Granite Springs, WY
Grave Springs, WY
Green Creek Subdivision, WY
Greybull River, WY
Guernsey State Park, WY
Harriman, WY
Hazelton, WY
Hazelton Area (East), WY
Hoback Ranches, WY
Homestead Park Subdivision, WY [1]
Hulett, WY
Hyatt Ranch Area, WY
Indian Hills, WY
Jackson, WY [2]
Jackson Lake Lodge, WY
JY Ranch, WY [2]
Keyhole, WY
Keystone, WY
Kortes Dam Camp, WY
Limestone Mountain Area, WY
Little Big Horn Cabins, WY
Loop Road, WY
Mammoth, WY
Meadowlark, WY
Meadowlark Lake Complex, WY
Middle Fork Powder River, WY
Moose Haven Subdivision, WY
Mountain Home, WY
New Haven, WY
Newcastle, WY
North Blacktail, WY

North Fork Shoshone River, WY
Old Faithful, WY
Osage, WY [1]
Overlook Retreats, WY
Painter Estates, WY
Paradise Guest Ranch, WY
Park County, WY
Pine Bluffs, WY
Pine Creek Area on South Pass, WY
Pine Grove Estates, WY
Pomeroy Subdivision, WY
Porcupine Ranger Station & Cabins WY
Porcupine Shell Work Center, WY [1]
Porcupine Subdivision, WY
Rattlesnake, WY
Remount, WY
Resorts, WY
Rice Subdivision, WY [1]
Rinkerlank Forest Subdivision, WY
Round Hill Ranch, WY
Ryan Park, WY [1]
Sage Valley, WY
Sage Valley Subdivision, WY
Sand Creek, WY
Seminoe Reservoir Area, WY
Shadow Mountain, WY [1, 2]
Shell Ranger Station & Cabins, WY [1]
Signal Mountain, WY [1, 2]
Sinks Canyon, WY
Soda Butte, WY
South Fork Shoshone River, WY
South Pass City, WY
Star Valley, WY
Story, WY
Sundance, WY
Sunlight, WY
Sweetwater, WY
Tensleep-Special Use Area, WY
Tongue River, WY
Tyrell Work Center & Cabins, WY [2]
Union Pass Area, WY
Upper Wood River, WY
Upton, WY [1]
Urban Thermopolis, WY
Wapiti Subdivision, WY [1]
Warm Springs, WY
Warm Springs Mountain, WY
Waywest Subdivision, WY
West Thumb, WY
White Rock Estates, WY
Wigwam, WY
Wind River, WY
Wold Subdivision, WY
Wood River, WY [1]
Woodedge, WY

[FR Doc. 01–52 Filed 1–3–01; 8:45 am]

BILLING CODE 3410–11–M; 4310–70–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Change to Section IV of the Field Office Technical Guide (FOTG) of the Natural Resources Conservation Service in Kentucky

AGENCY: Natural Resources Conservation Service (NRCS) in Kentucky, U.S. Department of Agriculture.

ACTION: Notice of availability of proposed changes in Section IV of the FOTG of the NRCS in Kentucky for review and comment.

SUMMARY: It is the intention of the NRCS in Kentucky to issue a revised conservation practice standard for: Nutrient Management (Code 590).

DATES: Comments will be received on or before February 5, 2001.

FOR FURTHER INFORMATION CONTACT: Inquire in writing to David G. Sawyer, State Conservationist, Natural Resources Conservation Service (NRCS), 771 Corporate Drive, Suite 110, Lexington, KY 40503–5479. Copies of the practice standards are made available upon written request. Persons with Internet capability may access the Kentucky NRCS homepage to obtain a copy of the revised 590 standard. The Internet address is *http://www.ky.nrcs.usda.gov* and click on Standards and Specifications.

SUPPLEMENTARY INFORMATION: Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS State Technical Guides used to carry out highly erodible land and wetland provisions of the law shall be made available for public review and comment. For the next 30 days the NRCS in Kentucky will receive comments relative to the proposed changes. Following that period a determination will be made by the NRCS in Kentucky regarding deposition of those comments and a final determination of change will be made.

Dated: December 20, 2000.

David G. Sawyer,

State Conservationist, Natural Resources Conservation Service, Lexington, KY.

[FR Doc. 01–138 Filed 1–3–01; 8:45 am]

BILLING CODE 3410–16–M

COMMISSION ON CIVIL RIGHTS

Hearing on Allegations of Voting Irregularities in the Presidential Election on November 7, 2000

AGENCY: Commission on Civil Rights.

ACTION: Amended notice of hearings.

SUMMARY: Notice is hereby given pursuant to the provisions of the Civil Rights Commission Amendments Act of 1994, Section 3, Public Law 103–419, 108 Stat. 4338, as amended, and 45 CFR 702.3., that public hearings before the U.S. Commission on Civil Rights will commence on Thursday, January 11, 2001, beginning at 9 a.m., in the morning in Tallahassee, FL, and on subsequent days in Miami, FL, Jacksonville, FL, and Tampa, FL. The January 11 and 12, 2001, hearing will take place at the Holiday Inn Select Hotel, 316 West Tennessee Street, Tallahassee, Florida 32301. The purpose of these hearings is to collect information within the jurisdiction of the Commission, under Public Law 98–183, Section 5(a)(1) and Section 5(a)(5), related particularly to allegations that eligible persons in Florida were denied the right to vote or to have their votes properly counted in the election of the Presidential electors on November 7, 2000.

The original notice for the hearings was announced in the **Federal Register** on Wednesday, December 13, 2000, FR Doc. 00–31904, Vol. 65, No. 2401, p. 77850.

The Commission is authorized to hold hearings and to issue subpoenas for the production of documents and the attendance of witnesses pursuant to 45 CFR 701.2. The Commission is an independent bipartisan, fact finding agency authorized to study, collect, and disseminate information, and to appraise the laws and policies of the Federal Government, and to study and collect information with respect to discrimination or denials of equal protection of equal protection of the laws under the Constitution because of race, color, religion, sex, age, disability, or national origin, or in the administration of justice. The Commission has broad authority to investigate allegations of voting irregularities even when alleged abuses do not involve discrimination.

Hearing impaired persons who will attend the hearings and require the services of a sign language interpreter, should contact Pamela Dunston, Administrative Services and Clearinghouse Division at (202) 376–8105 (TDD (202) 376–8116), at least five (5) working days before the scheduled date of the hearings.

FOR FURTHER INFORMATION CONTACT: Les Jin, Office of the Staff Director (202) 376–7700.

Dated December 28, 2000.

Edward A. Hailes, Jr.,

Acting General Counsel.

[FR Doc. 01–142 Filed 1–3–01; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

President's Export Council Subcommittee on Encryption; Notice of Meeting Change

Federal Register citation of previous announcement: p. 80833, December 22, 2000.

Previously announced time of meeting: 9:30 a.m., January 10, 2001.

New time of meeting: 9:00 a.m., January 30, 2001, Room 3407.

Dated: December 28, 2000

Lee Ann Carpenter,

Committee Liaison Officer.

[FR Doc. 01–193 Filed 1–3–01; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122700D]

North Pacific Fishery Management Council; Teleconference

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

ACTION: Notice of plan team teleconference.

SUMMARY: The North Pacific Fishery Management Council's (Council) Bering Sea/Aleutian Islands King and Tanner Crab Plan Team will hold a teleconference.

DATES: The teleconference will begin at 1 p.m., Alaska Time, on Thursday, January 25, 2001.

ADDRESSES: The teleconference will be held at the North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501-2252.

FOR FURTHER INFORMATION CONTACT: David Witherell, NPFMC, 907-271-2809.

SUPPLEMENTARY INFORMATION: The Plan Team will review bycatch amounts of *C. opilio* taken inside and outside the *C. opilio* Bycatch Limitation Zone (COBLZ) and prepare recommendations for the Council regarding overall bycatch limits, as well as accounting for crabs taken outside the COBLZ, and whether or not they should accrue toward the bycatch limit that triggers closure of the COBLZ.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Helen Allen, 907-271-2809, at least 5 working days prior to the meeting date.

Dated: December 28, 2000.

Valerie Chambers,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–208 Filed 1–3–00; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122700C]

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Council) Coastal Pelagic Species Management Team (CPSMT) and Coastal Pelagic Species Advisory Subpanel (CPSAS) will hold work sessions, which are open to the public.

DATES: The CPSMT will meet on Tuesday, January 30, 2001, 10 a.m. to 5 p.m. and Wednesday, January 31, 2001, 8 a.m. until business for the day is completed. The CPSAS will convene on Thursday, February 1, 2001, 10 a.m. until business for the day is completed.

ADDRESSES: The work sessions will be held at NMFS Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, CA 92038-0271; (619) 546-7000.

On Tuesday, January 30, 2001, the CPSMT will meet in room A-214; on Wednesday, January 31, 2001, the CPSMT will meet in the small conference room. On Thursday, February 1, 2001, the CPSAS will meet in the large conference room.

Council address: Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Dan Waldeck, Pacific Fishery Management Council; (503) 326-6352.

SUPPLEMENTARY INFORMATION: The primary purpose of these meetings is to continue work on several issues relative to capacity in the finfish limited entry fishery. This work is in response to a Council request for the CPSMT and CPSAS to develop recommendations for a capacity goal for the limited entry fishery and several other capacity-related issues, including transferability of limited entry permits. The CPSMT and CPSAS are scheduled to provide their recommendations to the Council at the April 2001 Council meeting.

Although non-emergency issues not contained in the CPSMT/CPSAS meeting agenda may come before the CPSMT and/or CPSAS for discussion, those issues may not be the subject of formal CPSMT nor CPSAS action during these meetings. CPSMT and/or CPSAS action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the CPSMT's and/or CPSAS's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 326-6352 at least 5 days prior to the meeting date.

Dated: December 28, 2000.

Valerie Chambers,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–207 Filed 1–3–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 080100B]

Coral, Golden Crab, Shrimp, Spiny Lobster, Red Drum, Coastal Migratory Pelagic Resources, and Snapper-Grouper Fisheries of the South Atlantic

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

ACTION: Issuance of an exempted fishing permit.

SUMMARY: NMFS announces the issuance of an exempted fishing permit (EFP) for the South Carolina Aquarium (applicant), located in Charleston, South Carolina. The EFP would authorize the applicant, with certain conditions, to collect for public display annually, for two years, an average of 25 specimens each of numerous species of marine invertebrates and marine fish from Federal waters off South Carolina. This EFP is similar to the previous EFP issued to the applicant that expired on June 30, 2000.

DATES: The newly issued EFP is effective January 1, 2001, through December 31, 2002.

ADDRESSES: Copies of the EFP are available from Peter Eldridge, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Peter Eldridge, 727–570–5305; fax 727–570–5583; e-mail: peter.eldridge@noaa.gov.

SUPPLEMENTARY INFORMATION: The EFP is issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and the regulations at 50 CFR 600.745(b).

The South Carolina Aquarium (SCA), located in Charleston, is a public, non-profit, self-supporting institution for the understanding and conservation of South Carolina's natural aquatic habitats, with extensive field study and outreach programs and with free admission to groups of school children.

The applicant intends, over a period of 2 years, to collect annually for public display an average of 25 specimens each of 76 species of marine invertebrates and 221 species of marine fish from the EEZ off South Carolina, using a variety of fishing gears and the fish anesthetic, quinaldine.

The proposed collection involves activities otherwise prohibited by regulations implementing the Fishery Management Plans for Coral, Coral Reefs, and Live/Hard Bottom Habitats, Golden Crab, Shrimp, Spiny Lobster, Red Drum, Coastal Migratory Pelagics, and Snapper-Grouper Fisheries of the South Atlantic Region (FMPs). The EFP authorizes the applicant, consistent with the terms of the EFP, to harvest and possess corals, live rock, golden crab, rock shrimp, red drum, wreckfish, warsaw grouper, and other snapper-grouper species taken from Federal waters off South Carolina. In addition, the EFP authorizes, consistent with the terms of the EFP, the use of quinaldine in a coral area and the possession of spiny lobster, bluefish, cobia, king and Spanish mackerel, groupers and snappers, greater amberjack, hogfish and red porgy below the minimum size limit in excess of established bag limits or taken with prohibited gear.

The EFP has a number of conditions concerning the harvest of prohibited species and corals and the gear that can be employed, including bycatch restrictions. The EFP requires an annual report to NMFS that lists specimens that have been taken.

The applicant also intends to collect a large number of species that are either not subject to Federal fishery management in the South Atlantic Region or included under a fishery management plan that contains no management measures restricting possession or harvest. The applicant was referred to the NMFS Highly Migratory Species Division for authorization to collect Atlantic highly migratory species, such as sharks and tunas, for public display.

A notice of receipt of the application for this permit was published in the **Federal Register** on August 30, 2000 (65 FR 52701). In addition to announcing the receipt of the application, public comments were requested; no public comments were received. Also, consistent with the requirements of 50 CFR 600.745(b)(3)(i), NMFS provided copies of the EFP application to the State of South Carolina, the South Atlantic Fishery Management Council, and U.S. Coast Guard along with the following required information: Information on the EFP's effects on target and incidental species; citations of the regulations that, without the EFP, would prohibit the proposed collection activity; and other biological information relevant to the EFP proposal. None of these consulted entities expressed any objections to the issuance of the EFP.

Failure of the permittee to comply with the terms and conditions of the EFP may be grounds for revocation, suspension or modification of this EFP or for civil or criminal sanctions.

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

Dated: December 26, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–203 Filed 1–3–01; 8:45 am]

BILLING CODE: 3510–22 –S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122800D]

Magnuson-Stevens Act Provisions; Atlantic Highly Migratory Species; Exempted Fishing and Scientific Research Permits

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

ACTION: Issuance of 2001 Exempted Fishing and Scientific Research Permits; request for comments.

SUMMARY: NMFS announces the intent to issue exempted fishing permits (EFPs) and scientific research permits (SRPs) for the collection of Atlantic highly migratory species. These EFPs/SRPs would authorize collections of a limited number of tunas, swordfish, billfishes, and sharks from Federal waters in the Atlantic Ocean and Gulf of Mexico for the purposes of scientific data collection and public display. The EFPs will be valid through May 31, 2001, at which time revised regulations regarding permit issuance procedures and conditions are scheduled to go into effect and revised permits may be issued. NMFS also announces the intent to issue EFPs upon receiving applications from U.S. fishermen whose vessels fish for Atlantic highly migratory species while operating under contract with interests in other fishing nations. These EFPs would allow a U.S. fishing vessel to fish so as to be consistent with another country's regulations without violating U.S. regulations, and would ensure that such vessels report to the proper authorities.

DATES: Written comments on these collection, research and fishing activities will be considered by NMFS in issuing such EFPs/SRPs if received on or before January 19, 2001.

ADDRESSES: Send comments to Christopher Rogers, Acting Chief, Highly Migratory Species Management Division (F/SF1), NMFS, 1315 East-West Highway, Silver Spring, MD 20910. The EFP/SRP applications and copies of the regulations under which EFPs/SRPs are issued may also be requested from this address. Comments also may be sent via facsimile (fax) to (301)713-1917. Comments will not be accepted if submitted via e-mail or Internet.

FOR FURTHER INFORMATION CONTACT: Sari Kiraly, 301-713-2347; fax: 301-713-1917.

SUPPLEMENTARY INFORMATION: EFPs and SRPs are requested and issued under the

authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and/or the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). Regulations at 50 CFR 600.745 and 50 CFR 635.32 govern scientific research activity, exempted fishing, and exempted educational activity with respect to Atlantic highly migratory species.

Issuance of EFPs and/or SRPs may be necessary because possession of certain shark species is prohibited, possession of billfishes on board commercial fishing vessels is prohibited, and because the commercial fisheries for bluefin tuna, swordfish and large coastal sharks may be closed for extended periods, during which collection of live animals and/or biological samples would otherwise be prohibited. In addition, NMFS regulations at 50 CFR 635.32 regarding implantation or attachment of archival tags in Atlantic highly migratory species require prior authorization and a report on implantation activities.

NMFS also seeks public comment on its intention to issue EFPs for the purpose of collecting biological samples under at-sea fisheries observer programs. NMFS intends to issue EFPs to any NMFS or NMFS-approved observer to bring onboard and possess, for scientific research purposes, biological sampling, measurement, etc., any Atlantic swordfish, Atlantic shark, or Atlantic billfish, provided the fish is a recaptured tagged fish, a dead fish prior to being brought onboard, or specifically authorized for sampling by the Director of the Office of Sustainable Fisheries at the request of the Southeast Fisheries Science Center or Northeast Fisheries Science Center. In total, 169 swordfish and 44 sharks were collected by at-sea observers under such EFPs in 2000.

Collection of bluefin tuna would be authorized for scientific research age and growth, genetic, and spawning studies. In 2000, five permits for bluefin tuna archival tagging and research were issued. In 2001, pursuant to ICCAT recommendations calling for research that addresses bluefin tuna spawning locations, NMFS intends to issue SRPs and/or EFPs for U.S. participation in an international program that could involve the landing of up to 15 metric tons of bluefin tuna for scientific sampling. This would be in addition to SRPs and EFPs issued for other tuna research.

NMFS also intends to continue to issue EFPs to vessel operators requesting offloading windows in the Atlantic Swordfish fishery, in the event the swordfish fishery is closed and a vessel is not equipped with a vessel monitoring system that would enable it to remain at sea after the announced closure date. NMFS anticipates that commercial EFP applicants would be captains of larger vessels out on extended trips at the time of a closure announcement. These applicants would benefit from delayed offloading by avoiding market gluts and cold storage problems.

Several EFPs have been issued in the past authorizing the retention of Atantic Skipjack tuna as an allowable incidental species while fishing for other species using coastal driftnet gear. Comments have been received that vessels intend to participate in this fishery during 2001, and NMFS intends to issue a limited number of EFPs again to collect vessel effort information and to monitor bycatch of all species caught by coastal driftnetters while fishing for other species.

NMFS also seeks public comment on its intention to issue EFPs for distant water pelagic longline vessels for the purpose of expanding access of U.S. vessels into other markets while continuing to collect information about U.S. fishing effort and landings. NMFS would consider applications from any U.S. Atlantic pelagic longline vessel. NMFS intends to issue such EFPs to any U.S. vessel fishing under contract to another nation, provided its landings and discards are consistent with ICCAT recommendations and, due to the requirements of the contract, those landings are being reported to ICCAT by that other nation or otherwise appropriately accounted for.

NMFS is also seeking public comment on its intention to issue EFPs for the collection of restricted species of sharks for the purposes of public display. In the HMS FMP, NMFS established a public display quota of 60 metric tons wet stweight for this purpose. NMFS has preliminarily determined that up to 3,000 sharks could be taken with this current quota and such harvest would be consistent with the most recent environmental impact statement prepared for this fishery. NMFS believes that harvesting this amount for public display will have a minimal impact on the stock. In 2000, 14 EFPs were issued for the collection of sharks for display purposes.

Generally, the authorized collections or exemptions would involve activities otherwise prohibited by regulations implementing the Final Fishery Management Plan for Atlantic Tunas, Swordfish and Sharks (HMS FMP) and Amendment 1 to the Atlantic Billfish Management Plan. The EFPs, if issued, would authorize recipients to fish for and possess tunas, billfishes, swordfish and sharks outside the applicable Federal commercial seasons, size limits and retention limits, or to fish for and possess prohibited species.

In the near future, NMFS intends to undertake rulemaking to revise general aspects of the procedures for issuing EFPs. Permits will be issued under the current regulations and be valid until new regulations become effective, which is expected to be June 1, 2001, at which time revised permits may be issued. A final decision on issuance of any EFPs/SRPs will depend on the submission of all required information about the proposed activities, NMFS' review of public comments received on this notice, conclusions of any environmental analyses conducted pursuant to the National Environmental Policy Act, and on any consultations with any appropriate Regional Fishery Management Councils, states, or Federal agencies. NMFS does not anticipate any environmental impacts from the issuance of these EFPs other than impacts already assessed in the Final Environmental Impact Statement (EIS) and any subsequent Environmental Assessments or EISs contained in the Final HMS FMP (64 FR 13575; March 19, 1999).

Authority: 16 U.S.C. 971 *et seq.*and 16 U.S.C. 1801 *et seq.*

Dated: December 28, 2000.

Valerie L. Chambers,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–204 Filed 1–3–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 121900B]

Marine Mammals; File No. 924-1484.

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

ACTION: Issuance of permit amendment.

SUMMARY: Notice is hereby given that Permit No. 924-1484-00, issued to Marsha Green, Ph.D., Albright College, P.O. Box 15234, Reading, PA 19612-5234, was amended.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits and Documentation Division, Office of Protected Resources, NMFS,

1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713-2289);

Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213 (562/980-4027); and

Pacific Islands Area Office, National Marine Fisheries Service, NOAA, 1601 Kapiolani Boulevard, Suite 1110, Honolulu HI 96814-4700 (808/973-2935).

FOR FURTHER INFORMATION CONTACT: Trevor Spradlin or Jill Lewandowski, 301/713-2289.

SUPPLEMENTARY INFORMATION: The subject amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of § 216.39 of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the provisions of § 222.306 of the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

The permit has been amended to (1) change the expiration date to August 31, 2005; (2) authorize the close approach to spinner dolphins (*Stenella longirostris*), spotted dolphins (*Stenella attenuata*) and bottlenose dolphins (*Tursiops truncatus*) that are associating with humpback whales; and (3) increase the number of annual humpback whale takes to 350 for controlled vessel approaches and 700 for audio/video recordings.

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of the endangered species which is the subject of this permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: December 28, 2000.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–206 Filed 1–3–01; 8:45 am]

BILLING CODE 3510–22–S

CONGRESSIONAL BUDGET OFFICE

Notice of Transmittal of Final Sequestration Report for Fiscal Year 2001 to Congress and the Office of Management and Budget

Pursuant to section 254(b) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 904(b)), the Congressional Budget Office hereby reports that it has submitted its Final Sequestration Report for Fiscal Year 2001 to the House of Representatives, the Senate, and the Office of Management and Budget.

Dan L. Crippen,

Director.

[FR Doc. 01–295 Filed 1–2–01; 9:59 am]

BILLING CODE 00–0702–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Leader, Regulatory Information Management, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by January 5, 2001.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Acting Desk Officer: Department of Education, Office of Management and Budget; 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.,* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on respondents, including through the use of information technology.

Dated: December 28, 2000.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: New.

Title: Application for the Transition to Teaching Program.

Abstract: The Transition to Teaching Program provides grants to local educational agencies, state educational agencies, educational service agencies, nonprofit agencies and organizations to support their efforts to recruit talented and capable individuals from other fields to become licensed or certified classroom teachers.

Additional Information: Due to the unexpected delay in passage of an appropriations law, ED is requesting an emergency review of this information collection in order to make awards in sufficient time for applicants to participate in the Transition for Teaching Program. Based upon the occurrence of this unanticipated event, and the public harm that might otherwise occur with delaying grant awards so that the opportunity is missed to support efforts in recruiting

individuals from other fields to become licensed or certified classroom teachers, OMB approval is requested by January 5, 2001, so that the application notice can be published and the application be made available to eligible applicants. We anticipate that this time schedule will allow eligible applicants 60 days to prepare grant applications, and the Department to award grants by mid-May.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 200

Burden Hours: 2,400

Requests for copies of the proposed information collection request should be directed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov, or should be faxed to 202–708–9346.

Comments regarding burden and/or the collection activity requirements, contact Kathy Axt at her internet address Kathy_Axt@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–176 Filed 1–3–01; 8:45 am]

BILLING CODE 4000–1–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Los Alamos; Notice of Open Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Los Alamos. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Wednesday, January 24, 2001, 6:00 p.m.–9:00 p.m.

ADDRESSES: St. Vincent Hospital, 455 St. Michael's Drive, Santa Fe, NM.

FOR FURTHER INFORMATION CONTACT: Ann DuBois, Northern New Mexico Citizens' Advisory Board, 1640 Old Pecos Trail, Suite H, Santa Fe, NM 87505. Phone (505) 989–1662; fax (505) 989–1752 or e-mail: *adubois@doeal.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

1. Opening Activities 6:00–6:30 p.m.
2. Public Comments 6:30–7:00 p.m.
3. Reports 7:00–9:00 p.m.
   LANL's RCRA Permit, Part B—James Bearzi, Chief of Hazardous Waste Division, New Mexico Environment Department
4. Committee Reports: Waste Management Environmental Restoration Monitoring and Surveillance Community Outreach Budget
5. Other Board business will be conducted as necessary.

This agenda is subject to change at least one day in advance of the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Ann DuBois at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments at the beginning of the meeting.

Minutes: Minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Public Reading Room located at the Board's office at 1640 Old Pecos Trail, Suite H, Santa Fe, NM. Hours of operation for the Public Reading Room are 9:00 a.m.-4:00 p.m. on Monday through Friday. Minutes will also be made available by writing or calling Ann DuBois at the Board's office address or telephone number listed above. Minutes and other Board documents are on the Internet at: *http:www.nnmcab.org.*

Issued at Washington, DC on December 29, 2000.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–245 Filed 1–3–01; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford; Notice of Open Meeting

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, February 1, 2001: 9:00 a.m.–4:30 p.m.; Friday, February 2, 2001: 8:30 a.m.–3:00 p.m.

ADDRESSES: West Coast Hotel (formerly Cavanaugh's), 1101 North Columbia Center Boulevard, Kennewick, WA (509–783–0611).

FOR FURTHER INFORMATION CONTACT: Gail McClure, Public Involvement Program Manager, Department of Energy Richland Operations Office, P.O. Box 550 (A7–75), Richland, WA, 99352; Phone: (509) 373–5647; Fax: (509) 376–1563.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

Thursday, February 1, 2001

Morning

- Hanford Advisory Board Chair Transition
- Spent Fuel—Update from the Department of Energy
- New Tank Waste Treatment Contract (EPA)
- Overview of contract—technical, financial, regulatory (EPA)

Afternoon

- Reconsideration of committee structure (Board discussion)
- Discussion of FY 2003 Budget Development Process and product from the Board

Friday, February 2, 2001

Morning

- Emerging Tri-Party Agreement (TPA) Issues
- SSAB Issue
- February SSAB Chairs Meeting
- Discussion on Proposing a SSAB Groundwater/Vadoze Workshop

Afternoon

- Status of Solid (Radioactive and Hazardous) Waste Draft EIS
- Update on Contracts, e.g., Fluor Hanford Extension
- Discussion of 2012 Advice issued by the Board in December

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gail McClure's office at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided equal time to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9:00 a.m. and 4:00 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to Gail McClure, Department of Energy Richland Operation Office, P.O. Box 550, Richland, WA 99352, or by calling her at (509) 373–5647.

Issued at Washington, DC on December 29, 2000.

Rachel M. Samuel,

Deputy, Advisory Committee Management Officer.

[FR Doc. 01–246 Filed 1–3–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Commission on Fire Safety and Preparedness

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Commission on Fire Safety and Preparedness. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770), requires that public notice of the meetings be announced in the **Federal Register**.

DATES: Thursday, January 11, 2001, 9:00 am to 4:30 pm.

ADDRESSES: Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Amina Khan, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, telephone number 202–586–6982, email: *amina.khan@ns.doe.gov*

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting:

To provide advice to the Department of Energy on the state of the fire safety and protection programs; to review the scope and results of a special internal investigation led by the Department on fire protection and safety; and to provide guidance, advice and information on the readiness of the complex from the threat of wildland and facility fires.

Tentative Agenda:

Welcome Remarks

Brief Overview of the Federal Advisory Committee Act

Debrief on the 60 Day Review

Status Quo of Fire Protection Programs at the Department of Energy

Office of Environment, Safety and Health Follow-on Study

Public Comment Period

Public Participation: The meeting is open to the public on a first-come, first-served basis because of limited seating. Written statements may be filed with the committee before of after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Amina Khan at the numbers above. Requests to make oral statements must be made and received five days prior to the meeting; reasonable provision will be made to include the statement in the agenda. The Chair of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. This notice is being published less than 15 days before the date of the meeting due to the holidays.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 am and 4 pm, Monday through Friday, except holidays.

Issued in Washington, DC on December 29, 2000.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–244 Filed 1–3–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–585–000]

Cinergy Services, Inc.; Notice of Filing

December 28, 2000.

Take notice that on December 12, 2000, Cinergy Services, Inc. (Cinergy), tendered for filing a Service Agreement under Cinergy's Resale, Assignment or Transfer of Transmission Rights and Ancillary Service Rights Tariff (the Tariff) entered into between Cinergy and Duke Power. This Service Agreement has been executed by both parties and is to replace the existing unexecuted Service Agreement.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 8, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–172 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–193–000]

Eastern Shore Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

December 28, 2000.

Take notice that on December 21, 2000, Eastern Shore Natural Gas Company (ESNG), tendered for filing

certain revised tariff sheets in the above captioned docket as part of its FERC Gas Tariff, Second Revised Volume No. 1, that bear a proposed effective date of January 1, 2001.

The purpose of this instant filing is to track rate changes attributable to storage services purchased from Columbia Gas Transmission Corporation (Columbia) under its Rate Schedules FSS and SST. The costs of the above referenced storage service comprise that rates and charges payable under ESNG's respective Rate Schedule CFSS. This tracking filing is being made pursuant to Section 3 of ESNG's Rate Schedule CFSS.

In addition to the above referenced tracking charges this instant filing also reflects the December 15, 2000 tracking rate charges attributable to storage services purchased from Transcontinental Gas Pipe Line Corporation (Transco) under its Rate Schedules GSS and LSS. The costs of the above referenced storage service comprise the rates and charges payable under ESNG's respective Rate Schedules GSS and LSS. This tracking filing is being made pursuant to Section 3 of ESNG's Rate Schedules GSS and LSS.

ESNG states that copies of the filing have been served upon its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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 proceedings. 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. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–164 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–07–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP00–232–001]

Iroquois Gas Transmission System, L.P.; Notice of Amendment

December 28, 2000.

Take notice that on December 15, 2000, Iroquois Gas Transmission System, L.P. (Iroquois), One Corporate Drive, Suite 600, Shelton, Connecticut 06484, tendered for filing in docket No. CP00–232–001 an amendment to its original application filed on April 28, 2000 to modify the proposed terminus of its Eastchester Expansion Project, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may be viewed at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Specifically, Iroquois now seeks to alter the route of its Eastchester Expansion Project so that the terminus will now be at a proposed interconnection with Consolidated Edison Company of New York, Inc. (Con Ed) near Lafayette Boulevard in the Throgs Neck area of the Bronx section of New York City. Originally, Iroquois had proposed that its Eastchester Expansion Project would terminate at a proposed interconnection with Con Ed near the intersection of Steenwick and Hollers Avenues in the Bronx section of New York City. The modified cost of the Eastchester Expansion Project is approximately $173.9 million.

Any questions regarding the application should be directed to Jeffrey A. Bruner, Vice President, General Counsel, and Secretary for Iroquois, One Corporate Drive, Suite 600, Shelton, Connecticut 06484 at 203–925–7200, or Beth L. Webb, attorney for Iroquois, Dickstein Shapiro Morin & Oshinsky, LLP, 2101 L Street, NW., Washington, DC 20037 at 202–785–9700.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status be becoming a party to the proceedings for this project should, on or before January 18, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commmenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community

and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–168 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2216–046–NY]

New York Power Authority; Notice of Application for Amendment of License to Delete Certain Non-Jurisdictional Transmission Facilities, and Soliciting Comments, Motions to Intervene, and Protests

December 28, 2000.

a. *Type of Filing:* Amendment of license to delete the 187-mile-long (Cross-State Line) transmission line from the license as non-jurisdictional because it is now under control of the New York Independent System Operator (ISO).

b. *Project No:* 2216–046.

c. *Date Filed:* December 1, 2000.

d. *Applicant:* New York Power Authority.

e. *Name of Project:* Niagara Project.

f. *Location:* The project is located on the Niagara River in Niagara County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 USC 791(a)–825(r), section 4.201 of the Commission's Regulations.

h. *Applicant Contact:* Keith Silliman, New York Power Authority, 30 South Pearl Street, Albany, NY 12207–3425

(i) *FERC Contact:* William Guey-Lee, (202) 219–2808, or william.gueylee@ferc.fed.us.

j. *Deadline for filing comments, motions to intervene or protests:* February 2, 2001.

All documents (original and eight copies) should be filed with: David Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The applicant requests that the license for the Niagara Project No. 2216 be amended to delete a 187-mile-long, 345–kV, Cross-State transmission line from the license. The Cross-State line consists of two adjacent single circuit lines, running from the switchyard at the Niagara Project to Niagara Mohawk Power Corporation's Edic Substation in the vicinity of New Power Authority's Clark Energy Center at Marcy, New York, and is currently under the direct operational control of the New York Independent System Operator.

l. *Location of the Filing:* A copy of the filing is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm [call (202) 208–2222 for assistance]. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but not only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–162 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–49–000]

PG&E National Energy Group, LLC, PG&E National Energy Group, Inc. On Behalf of Themselves and Their Public Utility Subsidiaries; Notice of Filing

December 28, 2000.

Take notice that on December 28, 2000, PG&E National Energy Group, LLC (NEG LLC) and PG&E National Energy Group, Inc. (NEG), tendered for filing on behalf of themselves and their public utility subsidiaries, an application under Section 203 of the Federal Power Act seeking authorization for the transfer of all the outstanding stock of NEG from PG&E Corporation to NEG LLC.

A copy of this Application was served upon the California Public Utilities Commission.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or January 8, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will

not serve to make protestants parties to the proceedings. 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. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–195 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–175–001]

Total Peaking Services, L.L.C.; Notice of Tariff Change

December 28, 2000.

Take notice that on December 19, 2000, Total Peaking Services, L.L.C. (Total Peaking), tendered for filing Revised Tariff Sheets Nos. 64 and 82 of Total Peaking's FERC Gas Tariff, Original Volume No. 1. The Revised Sheets remove language from Total Peaking's Tariff that currently subjects customers to imbalance penalties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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 proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–166 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–288–007]

Transwestern Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

December 28, 2000.

Take notice that on December 20, 2000, Transwestern Pipeline Company (Transwestern), tendered for filing to become part of Transwestern's FERC Gas Tariff, the following tariff sheets, proposed to become effective on December 19, 2000:

Second Revised Volume No. 1

Fourth Revised Sheet No. 5B.05
Third Revised Sheet No. 5B.07

The above sheets are being filed to implement a specific negotiated rate transaction in accordance with the Commission's Policy Statement on Alternatives to Traditional Cost-of-Service Ratemaking for Natural Gas Pipelines.

Transwestern further states that copies of the filing have been mailed to each of its customers and interested State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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 proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims. htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–167 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–194–000]

Viking Gas Transmission Company; Notice of Filing

December 28, 2000.

Take notice that on December 19, 2000, Viking Gas Transmission Company (Viking), tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets proposed to be effective January 1, 2001:

Seventh Revised Sheet No. 141
Second Revised Sheet No. 142
Second Revised Sheet No. 143
Third Revised Sheet No. 144
Second Revised Sheet No. 145
Third Revised Sheet No. 146

The purpose of this filing is to revise Viking's Electronic Bulletin Board Access Service Agreement (EBB Agreement) to reflect the replacement of Viking's Webshipper computer system. The revised EBB Agreement does not identify a particular EBB computer system so that Viking will not have to modify the EBB Agreement every time it upgrades its EBB computer system. Replacement of Webshipper for EBB purposes has no effect other than to change the specific technology used for EBB communication. Viking will continue to comply with all EBB requirements established by the Commission. Viking is filing these sheets under section 4 of the Natural Gas Act, 15 U.S.C. 717c (1996).

Viking requests an effective date of January 1, 2001, the date the new computer system will be in service, and accordingly requests such waivers of Part 154 and the Commission's regulations under the Natural Gas Act as may be necessary to place the tariff sheets in effect on the proposed date. Accordingly, Viking requests expedited consideration so that the revised EBB Service Agreement may be executed prior to the January 1, 2001 date on which Viking's EBB system is implemented. Viking will employ the agreement effective January 1, 2001, subject to any changes required by the Commission. Viking states that copies of the filing have been mailed to all its

jurisdictional customers and to affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. 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 proceedings. 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. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–165 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–698–000, et al.]

Cinergy Services, Inc., et al.; Electric Rate and Corporate Regulation Filings

December 22, 2000

Take notice that the following filings have been made with the Commission:

1. Cinergy Services, Inc.

[Docket No. ER01–698–000]

Take notice that on December 18, 2000, Cinergy Services, Inc. (Provider), tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Cinergy Services, Inc., (Customer).

This service agreement has a yearly firm transmission service with Louisville Gas & Electric Company via the Gibson Unit No. 5 Generating Station.

Provider and Customer are requesting an effective date of January 1, 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. California Power Exchange Corporation

[Docket No. ER01–719–000]

Take notice that on December 18, 2000, the California Power Exchange Corporation (CalPX), tendered for filing its proposed Tariff Amendment No. 21, consisting of a change of Section 3.5 of Schedule 6 of its Tariff. The sole purpose of Tariff Amendment No. 21 is to track the changes proposed by the California Independent System Operator Corporation (CAISO) in its unbundled Grid Management Charge (GMC) filing in the docket ER01–313–000. CalPX proposes to use the same allocation methodology for the GMC as that proposed by the CAISO.

CalPX requests waiver of the Commission's Regulations to permit an effective date of January 1, 2001 or such other date as the Commission permits CAISO's filing in docket No. ER01–313–000 to become effective.

CalPX states that it has served this filing on the California Public Utilities Commission and on its participants and has also posted this filing on its website (*www.calpx.com*).

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. MidAmerican Energy Company

[Docket No. ER01–716–000]

Take notice that on December 19, 2000, MidAmerican Energy Company (MidAmerican), 666 Grand Ave, Des Moines, Iowa 50309, tendered for filing with the Commission a Termination of Assignment of Neal 3 Transmission Assignments for Capacity Schedule entered into by MidAmerican and Alliant Energy dated October 27, 2000.

MidAmerican requests an effective date of November 1, 2000 for the Termination and seeks a waiver of the Commission's notice requirement. MidAmerican has served a copy of the filing on the Iowa Utilities Board, the Illinois Commerce Commission and the South Dakota Public Utilities Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Commonwealth Edison Company

[Docket No. ER01–715–000]

Take notice that on December 19, 2000, Commonwealth Edison Company (ComEd), tendered for filing a Firm Transmission Service Agreement (Agreement) supplemented by Network Upgrade Agreement with Wisconsin Electric Power Company (WEP), and two firm Agreements with Commonwealth Edison Company, in its wholesale merchant function (WMD) under the terms of ComEd's Open Access Transmission Tariff (OATT).

ComEd requests an effective date of February 1, 2001, for the Agreement with WEP and an effective date of February 1, 2001, for the corresponding Network Upgrade Agreement with WEP; and an effective date of January 1, 2001 and January 8, 2001 for the Agreements with WMD, and accordingly, seeks waiver of the Commission's notice requirements.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Wisconsin Public Service Corporation

[Docket No. ER01–701–000]

Take notice that on December 18, 2000, Wisconsin Public Service Corporation (WPSC or the Company), tendered for filing a modified rate schedule for its service to the City of Marshfield, Wisconsin (Marshfield). The purpose of this filing is to include updated generation capability ratings for the combustion turbine unit that supplies power to Marshfield.

WPSC requests a January 1, 2001 effective date.

Copies of the filing were served upon Marshfield, the Public Service Commission of Wisconsin and the Michigan Public Service Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Consumers Energy Company

[Docket No. ER01–714–000]

Take notice that on December 19, 2000, Consumers Energy Company (Consumers), tendered for filing a Service Agreement with Northern Indiana Public Service Company, (Customer) under Consumers' FERC Electric Tariff No. 9 for Market Based Sales.

Consumers requested that the Agreement be allowed to become effective December 19, 2000.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Tampa Electric Company

[Docket No. ER01–713–000]

Take notice that on December 19, 2000, Tampa Electric Company (Tampa Electric), tendered for filing a service agreement with Enron Power Marketing, Inc. (Enron) under Tampa Electric's market-based sales tariff.

Tampa Electric proposes that the service agreement be made effective on December 1, 2000, and gives notice of its termination as of January 1, 2001.

Copies of the filing have been served on Enron and the Florida Public Service Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. PECO Energy Company

[Docket No. ER01–711–000]

Take notice that on December 18, 2000, PECO Energy Company (PECO), tendered for filing under Section 205 of the Federal Power Act, 16 U.S.C. S 792 et seq., an Agreement dated December 18, 2000 with Calpine Corporation. (CALPINE) under PECO's FERC Electric Tariff Original Volume No. 1 (Tariff).

PECO requests an effective date of December 18, 2000 for the Agreement.

PECO states that copies of this filing have been supplied to Calpine Corporation and to the Pennsylvania Public Utility Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Consumers Energy Company

[Docket No. ER01–709–000]

Take notice that on December 19, 2000 Consumers Energy Company (Consumers), tendered for filing a Service Agreement with FirstEnergy Corp., (Customer) under Consumers' FERC Electric Tariff No. 9 for Market Based Sales.

Consumers requested that the Agreement be allowed to become effective December 19, 2000.

Copies of the filing were served upon the Customer and the Michigan Public Service Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Pennsylvania Electric Company

[Docket No. ER01–707–000]

Take notice that on December 19, 2000, Pennsylvania Electric Company (doing business as GPU Energy), tendered for filing a letter agreement (Agreement) between GPU Energy and American Cooperative Services, Inc., (American Coop.). Under the Agreement, American Coop., has agreed to the operational and financial responsibilities set forth in the GPU Energy Manuals in connection with American Coop., becoming the Load Serving Entity (LSE) for the Pennsylvania Borough of East Conemaugh.

Copies of the filing were served upon American Coop., PJM and regulators in the Commonwealth of Pennsylvania.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Otter Tail Power Company

[Docket No. ER01–706–000]

Take notice that Otter Tail Power Company (OTP) on December 13, 2000, tendered for filing a transmission service agreement between itself and Split Rock Energy LLC. The agreement establishes Split Rock Energy LLC as a customer under OTP's transmission service tariff (FERC Electric Tariff, Original Volume No.7).

OTP respectfully requests an effective date sixty days after filing. OTP is authorized to state that Split Rock Energy LLC, joins in the requested effective date.

Copies of the filing have been served on Split Rock Energy LLC, Minnesota Public Utilities Commission, North Dakota Public Service Commission, and the South Dakota Public Utilities Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Commonwealth Edison Company and Commonwealth Edison Company of Indiana

[Docket No. ER01–99–001]

Take notice that on December 19, 2000, Commonwealth Edison Company and Commonwealth Edison Company of Indiana, Inc. (collectively ComEd), tendered for filing revised Attachment K for ComEd's Open Access Transmission Tariff (OATT) in compliance with the Commission's December 8, 2000 Order issued in above-captioned docket. *Commonwealth Edison Company,* 93 FERC ¶ 61,237 (2000).

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Carolina Power & Light Company

[Docket No. ER00–3537–002 and OA96–198–005]

Take notice that on December 19, 2000, Carolina Power & Light Company (CP&L), tendered for filing the refund report.

Copies of the filing were served upon the North Carolina Utilities Commission and the South Carolina Public Service Commission.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. New York Independent System Operator, Inc.

[Docket No. ER97–1523–005, ER97–1523–006, OA97–470–006, ER97–4234–004 and EC99–31–001]

Take notice that on December 19, 2000, the New York Independent System Operator, Inc., tendered for filing a Report on Governance Issuance in the above-captioned dockets.

A copy of this filing was served upon all parties in the above-captioned dockets.

Comment date: January 10, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Cinergy Services, Inc.

[Docket No. ER01–699–000]

Take notice that on December 18, 2000, Cinergy Services, Inc. (Provider) tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Cinergy Services, Inc., (Customer).

This service agreement has a yearly firm transmission service with American Electric Power via the Zimmer Unit No. 1 Generating Station.

Provider and Customer are requesting an effective date of January 1, 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Central Maine Power Company

[Docket No. ER01–700–000]

Take notice that on December 11, 2000, Central Maine Power Company (CMP) tendered for filing the executed Service Agreement for Local Network Transmission Service (LNSA) and the Local Network Operating Agreement (LNOA) between CMP and Champion International. The Executed LNSA and Executed LNOA replace the unexecuted agreements filed on March 30, 2000, further supplemented on April 20, 2000 and accepted for filing on May 26, 2000.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. American Transmission Company LLC

[Docket No. ER01–702–000]

Take notice that on December 18, 2000, American Transmission Company LLC (ATCLLC), tendered for filing the Standards of Conduct for ATCLLC to be effective January 1, 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company

[Docket No. ER01–703–000]

Take notice that on December 18, 2000, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (individually doing business as GPU Energy), tendered for filing a Notice of Cancellation of the Service Agreement between GPU Service, Inc. and Western Power Services, Inc., FERC Electric Tariff, Original Volume No. 1, Service Agreement No. 56.

GPU Energy requests that cancellation be effective the 14th day of February 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Wisconsin Electric Power Company

[Docket No. ER01–710–000]

Take notice that on December 18, 2000, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing a short-term firm Transmission Service Agreement and a non-firm Transmission Service Agreement between itself and (MG&E). The Transmission Service Agreements allow MG&E to receive transmission services under Wisconsin Energy Corporation Operating Companies' FERC Electric Tariff, Volume No. 1. Wisconsin Electric requests the Commission assign these service agreements as Nos. 188 and 189 under its Tariff.

Wisconsin Electric requests an effective date of May 1, 2002, coincident with MG&E's power supply transactions. Wisconsin Electric requests waiver of the Commission's notice requirements in order to accommodate MG&E's power supply transactions.

Copies of the filing have been served on MG&E, the Public Service Commission of Wisconsin and the Michigan Public Service Commission.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company

[Docket No. ER01–704–000]

Take notice that on December 18, 2000, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (individually doing business as GPU Energy), tendered for filing a Notice of Cancellation of the Service Agreement between GPU Service Corporation and Public Service Electric and Gas Company (now PSEG Energy Resources & Trade LLC), FERC Electric Tariff, Original Volume No. 1, Service Agreement No. 9.

GPU Energy requests that cancellation be effective the 14th day of February 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company

[Docket No. ER01–705–000]

Take notice that on December 18, 2000, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company (individually doing business as GPU Energy), tendered for filing a Notice of Cancellation of the Service Agreement between GPU Energy and Eastern Power Distribution, Inc. (now Amerada Hess Corp.), FERC Electric Tariff, Original Volume No. 1, Service Agreement No. 75.

GPU Energy requests that cancellation be effective the 14th day of February 2001.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. Madison Gas and Electric Company

[Docket No. ER01–708–000]

Take notice that on December 18, 2000, Madison Gas and Electric Company (MGE), tendered for filing a service agreement under MGE's Market-Based Power Sales Tariff with Southern Illinois Power Company.

MGE requests the agreement be effective on the date it was filed with the FERC.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. Arizona Public Service Company

[Docket No. ER01–717–000]

Take notice that on December 18, 2000, Arizona Public Service Company tendered for filing Notice that effective June 29, 2000, APS' FERC Rate Schedule No. 116, effective date July 25, 1984 and filed with the Federal Energy Regulatory Commission is to be canceled.

Copies of the proposed notice of cancellation have been served upon Plains Electric Generation & Transmission, The Arizona Corporation Commission and The New Mexico Public Service Commission.

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

24. Indianapolis Power & Light Company

[Docket No. ER01–718–000]

Take notice that on December 18, 2000, Indianapolis Power & Light Company tendered for filing the First Amendment to the Interconnection, Operation and Maintenance Agreement between DTE Georgetown, L.L.C., and Indianapolis Power & Light Company in the above-captioned

Comment date: January 9, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 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 the comment date. 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 these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–194 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 28, 2000.

a. *Application Type:* Application to Amend License for the Big Creek No. 3 Project.

b. *Project No.:* 120–017.

c. *Date Filed:* January 12, 2000.

d. *Applicant:* Southern California Edison Company (SCE).

e. *Name of Project:* Big Creek No. 3 Project.

f. *Location:* The project is located on the San Joaquin River in Fresno, Tulare, and Kern Counties. The project utilizes lands of the Sierra National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Stephen E. Pickett, Vice President and General Counsel, Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, CA 91770, (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Vedula Sarma at (202) 219–3273 or by e-mail at vedula.sarma@ferc.fed.us.

j. *Deadline for filing comments and/or motions:* February 2, 2001.

Please include the project number (120–017) on any comments or motions filed.

k. *Description of Filing:* SCE proposes to delete one 220kV transmission line because it is part of SCE's Transmission System Network. The licensee filed revised exhibits M, K, and L to reflect changes to transmission facilities, and other revisions to project facilities to reflect as-built conditions of the project. The proposed modifications reduce the amount of federal lands used by the project by 530 acres.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm [call (202) 208–2222 for assistance]. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

n. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–163 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 28, 2000.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of License to Change Project Boundary and Approve Revised Exhibits.

b. *Project No.:* 372–009.

c. *Date Filed:* January 12, 2000, and November 9, 2000.

d. *Applicant:* Southern California Edison Company.

e. *Name of Project:* Lower Tule River.

f. *Location:* The project is located on the Tule River near the Town of Springville, in Tulare County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a), 825(r) and 799 and 801.

h. *Applicant Contact:* Stephen E. Pickett, Vice President and General Counsel, Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, CA 91770, (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Mohamad Fayyad at (202) 219–2665, or e-mail address: mohamad.fayyad@ferc.fed.us.

j. *Deadline for filing comments and or motions:* February 2, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Please include the project number (P–372–009) on any comments or motions filed.

k. *Description of Request:* SCE is proposing to include within the project boundary an existing access road used for project purposes. This would increase the amount of federal lands within the project boundary by 1.58 acres. In addition, SCE is proposing to delete from the license a 2.04-mile-long, 66-kV transmission line, which SCE says is part of its interconnected transmission system. The subject transmission line does not affect any federal lands.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in

all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

n. Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–169 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions to Intervene, and Protests

December 28, 2000.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of License to Change Project Boundary and Approve Revised Exhibits.

b. *Project No:* 2174–010.

c. *Date Filed:* January 12, 2000, and November 9, 2000.

d. *Applicant:* Southern California Edison Company.

e. *Name of Project:* Portal Water Power.

f. *Location:* The project is located on the Rancheria Creek and Big Creek, in Fresno County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a), 825(r), 799 and 801.

h. *Applicant Contact:* Stephen E. Pickett, Vice President and General Council, Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, CA 91770, (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Mohamad Fayyad at (202) 219–2665, or e-mail address: mohamad.fayyad@ferc.fed.us.

j. *Deadline for filing comments and or motions:* February 2, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426.

Please include the project number (P–2174–010) on any comments or motions filed.

k. *Description of Request:* SCE is proposing to delete from the license the 7.58-mile-long, 33-kV Big Creek #1—Portal transmission line, which SCE says is part of its interconnected transmission system. The subject transmission line occupies 47.05 acres of federal lands. In addition, SCE is proposing to include within the project boundary an existing forebay control line. This would increase the amount of federal lands within the project boundary by 11.11 acres. SCE says that due to a more accurate computer mapping, the revised acreage of federal lands within the project boundary is 126.6 acres.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on *http://www.ferc.fed.us/online/rims.htm* (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

n. Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–170 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions to Intervene, and Protests

December 28, 2000.

a. *Application Type:* Revised Exhibit K, L, and M Drawings for Mammoth Pool Project.

b. *Project No.:* 2085–010.

c. *Dates Filed:* November 24, 1999; supplemented November 9, 2000.

d. *Applicant:* Southern California Edison.

e. *Name of Project:* Mammoth Pool Project.

f. *Location:* The Mammoth Pool Project is on the San Joaquin River,

Rock Creek, and Ross Creek in Fresno and Madera Counties California, and affecting navigable waters and lands of the United States within Sierra National Forest.

g. *Filed Pursuant to:* 18 CFR section 4.201(c).

h. *Applicant Contact:* Bryant C. Danner, Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, California 91770; (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Robert Shaffer at (202) 208–0944 or by e-mail at Robert.Shaffer@ferc.fed.us.

j. *Deadline for filing comments and/or motions:* February 02, 2001.

Please include the project number (P–2085–010) on any comments or motions filed.

k. *Description of Filing:* Southern California Edison Company (SCE) filed revised exhibits K, L, and M on November 24, 1999, and November 9, 2000, to reflect as-built conditions of the project. SCE is proposing to increase the project boundary by 6.16 acres (4.92 acres for an existing access road, and 1.24 acres due to more accurate computer mapping), also increasing the acreage of federal lands administered by the U.S. Forest Service.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on *http://www.ferc.fed.us/online/rims.htm* [call (202) 208–2222 for assistance]. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

n. Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–171 Filed 1–3–01; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6928–9]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Combined Sewer Overflow Control Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) renewal has been forwarded to the Office of Management and Budget (OMB) for review and approval: Information Collection Request for the Combined Sewer Overflow Control Policy (OMB Control Number 2040–0170; EPA ICR Number 1680.03; Expiration Date: December 31, 2000. The renewal ICR describes the nature of the information collection and its expected burden and cost.

DATES: Comments must be submitted on or before February 5, 2001.

ADDRESSES: Send comments, referencing EPA ICR No. 1680.03 and OMB Control Number 2040–0170, to the following addresses: Sandy Farmer, U.S. Environmental Protection Agency, Office of Environmental Information, Collection Strategies Division (Mail Code 2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For a copy of the ICR contact Sandy Farmer at EPA by phone at (202) 260–2740, by email at *farmer.sandy@epamail.epa.gov,* or download off the Internet at *http://www.epa.gov/icr* and refer to EPA ICR No. 1680.03. For technical question about the ICR contact Timothy Dwyer, EPA Office of Wastewater Management (Mail Code 4203M), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Title: Information Collection Request for the Combined Sewer Overflow Control Policy (OMB Control Number 2040–0170; EPA ICR Number 1680.03; Expiration Date: December 31, 2000.

Abstract: The information to be collected under this request is the information recommended in the CSO Control Policy that will be developed by municipalities with combined sewer systems that have combined sewer overflows (CSOs). Specifically, the information is the documentation that the municipalities have implemented the nine minimum controls specified in the CSO policy, the long-term control plan that the municipalities must develop and implement to achieve compliance with the requirements of the Clean Water Act and applicable State water quality standards (WQS), and compliance monitoring data for demonstrating compliance with applicable WQS and National Pollutant Discharge Elimination System (NPDES) permit conditions. The first two information submittals are one-time submittals; the last element will be submitted semi-annually as part of the municipalities' Discharge Monitoring Reports (DMRs). EPA will use this information to determine how well the CSO Control Policy is being implemented at the State and local level and to prepare the performance reports required under the Government Performance and Results Act (GPRA).

The information to be collected under this information collection is necessary to determine the program's achievement of GPRA performance measures. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on 07/03/00 (65 FR 41065); no comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 624 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information; processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Municipalities with combined sewer systems that have combined sewer overflows (CSOs).

Estimated Number of Respondents: 930.

Frequency of Response: One time for selected items and semi-annually for other items.

Estimated Total Annual Hour Burden: 580,044 hours.

Estimated Total Annualized Capital and Operating & Maintenance Cost Burden: $182,000.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 1680.03 and OMB Control No. 2040–0170 in any correspondence.

Dated: December 27, 2000.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 01–222 Filed 1–3–01; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6929–2]

Public Notice of Draft NPDES General Permits for Facilities/Operations That Generate, Treat, and/or Use/Dispose of Sewage Sludge by Means of Land Application, Landfill, and Surface Disposal in EPA Region VIII

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to issue NPDES general permits and request for comments.

SUMMARY: Region VIII of EPA is hereby giving notice of its tentative determination to issue National Pollutant Discharge Elimination System (NPDES) general permits for facilities or operations that generate, treat, and/or use/dispose of sewage sludge by means of land application, landfill, and surface disposal in the States of CO, MT, ND, and WY and in Indian country in the States of CO, MT, ND, SD, WY and UT (except for the Goshute Indian Reservation and the Navajo Indian Reservation).

On June 21, 2000 and September 21, 2000, U.S. District Judge Donald W. Molloy issued orders stating that until all necessary total maximum daily loads under section 303(d) of the Clean Water Act are established for a particular water quality limited segment, the EPA is not to issue any new permits or increase permitted discharges under the NPDES program. (The orders were issued in the lawsuit *Friends of the Wild Swan, Inc., et al.*, v. *U.S. E.P.A., et al.*, CV 97–35–M–DWM, District of Montana, Missoula Division.) EPA finds that the issuance of these proposed general permits does not conflict with this order, because (1) the proposed permits would not authorize any point source discharges into waters of the United States and (2) as discussed under the ''Protection of Public Health and The Environment'' section of the Fact Sheet, the use and/or disposal of sewage sludge in compliance with the conditions of these permits is not likely to have any adverse effect on any waterbody in Montana that has been listed under section 303(d) of the Clean Water Act. If any member of the public believes that EPA should interpret the District Court's order otherwise, EPA requests that this issue be brought to its attention during the public comment period on these proposed permits.

Region VIII is proposing to use general permits instead of individual permits for permitting such sewage sludge related activities in order to reduce the Region's administrative burden of issuing separate individual permits. The administrative burden for the regulated sources is expected to be about the same under the general permits as with individual permits, but it will be much quicker to obtain permit coverage with general permits than with individual permits. The permit requirements would be essentially the same with an individual permit or under the general permit. Facilities or operations that incinerate sewage sludge are not eligible for coverage under these general permits and must apply for an individual permit. Wastewater lagoon systems that are not using/disposing of sewage sludge do not need to apply for permit coverage unless notified by the permit issuing authority. The deadlines for applying for coverage under the general permits are given in the permits and the Fact Sheet. For most facilities/operations the deadline is 90 days after the effective date of the permit.

DATES: Public comments on this proposal must be received, in writing, on or before March 5, 2001.

ADDRESSES: Public comments should be sent to: State Assistance Program (8P–SA); Attention: NPDES Permits; U.S. EPA, Region VIII; 999 18th Street, Suite 300; Denver, CO 80202–2466.

FOR FURTHER INFORMATION CONTACT: For a copy of the draft permit and Fact Sheet, please write William Kennedy at the above address or telephone (303) 312–6285. Copies of the draft permit and Fact Sheet may also be downloaded from the EPA Region VIII web page at *http://www.epa.gov/region08/water/wastewater/biohome/biohome.html.* Questions regarding the specific permit requirements may be directed to Bob Brobst, telephone (303) 312–6129.

Public Comment Period

Public comments are invited. Comments must be written and must be received by no later than March 5, 2001. Comments should be sent to: State Assistance Program (8P–SA); Attention: NPDES Permits; U.S. EPA, Region VIII; 999 18th Street, Suite 300; Denver, CO 80202–2466. Each comment should cite the page number and, where possible, the section(s) and/or paragraph(s) in the draft permit or Fact Sheet to which each comment refers. Commenters should use a separate paragraph for each issue discussed.

SUPPLEMENTARY INFORMATION: On February 19, 1993, (58 FR 9248) the EPA promulgated ''Standards for the Use or Disposal of Sewage Sludge'' (40 CFR part 503) and made revisions to the NPDES regulations to include the permitting of facilities/operations that generate, treat, and/or use/disposal of sewage sludge. The 503 regulations were amended on August 4, 1999 (64 FR 42551). The State of Utah currently is the only State in Region VIII that has been authorized to administer the biosolids (sludge) program. However, the State of South Dakota has applied for authorization to administer the biosolids program and Region VIII has public noticed (65 FR 59385) its intent to approve the application. Since the State's application is being processed, Region VIII does not plan to issue a general permit for South Dakota unless the State's application is denied. It is proposed that general permits be issued for facilities or operations that generate, treat, and/or use/dispose of sewage sludge by means of land application, landfill, and surface disposal within the following areas:

State	Permit No.	Area covered by the general permit
Colorado	COG650000	State of Colorado except for Federal Facilities and Indian country.
	COG651000	Indian country within the State of Colorado and the portions of the Ute Mountain Indian Reservation located in New Mexico and in Utah.
	COG652000	Federal Facilities in the State of Colorado, except those located in Indian country, which are covered under permit COG51000.
Montana	MTG650000	State of Montana except for Indian country.
	MTG651000	Indian country in the State of Montana.
North Dakota	NDG650000	State of North Dakota except for Indian country.
	NDG651000	Indian country within the State of North Dakota (except for Indian country located within the former boundaries of the Lake Traverse Indian Reservation, which are covered under permit SDG651000) and that portion of the Standing Rock Indian Reservation located in South Dakota.
South Dakota	SDG651000	Indian country within the State of South Dakota (except for the Standing Rock Indian Reservation, which is covered under permit NDG651000), that portion of the Pine Ridge Indian Reservation located in Nebraska, and Indian country located in North Dakota within the former boundaries of the Lake Traverse Indian Reservation.
Utah	UTG651000	Indian country within the State of Utah except for the Goshute Indian Reservation, Navajo Indian Reservation, and Ute Mountain Indian Reservation (which is covered under permit COG651000).
Wyoming	WYG650000	State of Wyoming except for Indian country.
	WYG651000	Indian country within the State of Wyoming.

The State of Utah has been delegated permitting authority for sewage sludge and the State of South Dakota has applied for that authority, therefore general permits will be issued only for Indian country in those States. The general permit for Indian country in Utah does not include the portions of the Goshute Indian Reservation and the Navajo Indian Reservation in Utah because the permitting activities for these reservations are done by Region IX of EPA. The State of Colorado has not been delegated permitting authority for Federal facilities, so a general permit is proposed for Federal facilities not located in Indian country.

Authorization under the general permits may be for one of the following three categories: Category 1—Facilities/operations that generate and/or partially treat sewage sludge, but do not use/dispose of sewage sludge; Category 2—Facilities/operations that use/dispose of sewage sludge and may also generate and/or treat sewage sludge; and Category 3—Wastewater lagoon systems that need to land apply sewage sludge on an occasional, restricted basis. Authorization under the general permit will be limited to one of the three categories, but authorization may be granted to one or more subcategories under Category 2. In applying for authorization under the general permit, the applicant will be required to specify under which category or subcategory(s) authorization is being requested. However, the permit issuing authority will have the final determination as to which category or subcategory(s) the authorization will be granted. The requirements in the permit for the use/disposal of sewage sludge are based primarily on 40 CFR part 503.

Since these permits do not involve discharges to waters of the United States, certification under section 401(a)(1) of the Clean Water Act is not necessary for the issuance of these permits and certification will not be requested.

Economic Impact (Executive Order 12866): EPA has determined that the issuance of this general permit is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735 (October 4, 1993)) and is therefore not subject to formal OMB review prior to proposal.

Paperwork Reduction Act: EPA has reviewed the requirements imposed on regulated facilities in these proposed general permits under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* The information collection requirements of these permits have already been approved by the Office of Management and Budget in submissions made for the NPDES permit program under the provisions of the Clean Water Act.

Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., as amended by the Small Business regulatory Enforcement Fairness Act (SBREFA): The RFA requires that EPA prepare a regulatory flexibility analysis for rules subject to the requirements of 5 U.S.C. 553(b) that have a significant impact on a substantial number of small entities. The permit proposed today, however, is not a ''rule'' subject to the requirements of 5 U.S.C. 553(b) and is therefore not subject to the RFA.

Unfunded Mandates Reform Act: Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104–4, generally requires Federal agencies to assess the effects of their ''regulatory actions'' defined to be the same as ''rules'' subject to the RFA on tribal state, and local, governments and the private sector. The permit proposed today, however, is not a ''rule'' subject to the RFA and is therefore not subject to the requirements of the UMRA.

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: December 22, 2000.

Kerrigan G. Clough,

Assistant Regional Administrator, Office of Partnerships and Regulatory Assistance.

[FR Doc. 01–220 Filed 1–3–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 00–2907]

The Wireless Telecommunications Bureau Seeks Comment on a Draft Programmatic Agreement With Respect to Co-Locating Wireless Antennas on Existing Structures

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this public notice, we request comments on a Nationwide Programmatic Agreement that would adopt streamlined procedures for review of co-locations of antennas under the National Historic Preservation Act (NHPA), 16 U.S.C. 470 *et seq.* This Nationwide Programmatic Agreement is being considered for potential execution by the Federal Communications Commission, the National Conference of State Historic Preservation Officers, and the Advisory Council on Historic Preservation on or about January 29, 2001.

DATES: Comments are due on or before January 23, 2001.

ADDRESSES: All comments should reference DA 00–2907 and should be filed with the Office of the Secretary, Federal Communications Commission, 445 Twelfth Street, SW., TW B204, Washington, DC 20554. A copy of each filing should be sent to International Transcription Services, Inc. (ITS), 445 Twelfth Street, SW., Room CY–B402, Washington, DC 20554. In addition, parties should send two copies to Joel Taubenblatt, Federal Communications Commission, Wireless Telecommunications Bureau, Commercial Wireless Division, 445 Twelfth Street, SW., Room 4A260, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joel Taubenblatt, Wireless Telecommunications Bureau, at (202) 418–1513.

SUPPLEMENTARY INFORMATION: This is a summary of the *Public Notice,* DA 00–2907, released December 26, 2000. The *Public Notice* is available for inspection and copying during normal business hours in the FCC Reference Center, 445 Twelfth Street, SW., Washington DC. The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 445 Twelfth Street, SW., Room CY–B402, Washington DC 20554, (202) 857–3800. The document is also available via the internet at: *http://www.fcc.gov/Bureaus/Wireless/Public_Notices/2000* under the DA 00–2907 file.

Appendix A to the Public Notice

Draft Nationwide Programmatic Agreement among the Federal Communications Commission, the National Conference of State Historic Preservation Officers and the Advisory Council on Historic Preservation for the Co-location of Antennas

Whereas, the Federal Communications Commission (FCC) establishes rules and procedures for licensing wireless communications systems in the United States and its Possessions and Territories; and,

Whereas, the FCC has deregulated the review of applications for the construction of individual wireless communications antennas and, under this framework, licensees are required to prepare an environmental assessment (EA) when the licensee determines that the proposed construction falls within one of certain environmental categories, including situations which may affect historical sites listed or eligible for listing in the National Register; and,

Whereas, Section 106 of the National Historic Preservation Act requires federal agencies to take into account the effects of their undertakings on historic properties and to give the Advisory Council on Historic Preservation (Council) a reasonable opportunity to comment; and,

Whereas, Section 36 CFR 800.14(b) of the Council's regulations, ''Protection of Historic Properties'' (36 CFR Part 800), allows for programmatic agreements to streamline and tailor the Section 106 review process to particular federal programs; and,

Whereas, in August 2000, the Council established a Telecommunications Working Group to provide a forum for the FCC, Industry representatives, State Historic Preservation Officers (SHPOs) and Tribal Historic Preservation Organizations (THPOs), and the Council to discuss improved coordination of Section 106 compliance regarding wireless communications projects involving historic properties; and,

Whereas, the FCC, the Council and Working Group have developed this Programmatic Agreement in accordance with 36 CFR 800.14(b) to address the Section 106 review process as it applies to the co-location of antennas (*i.e.,* the placement of antennas on existing towers and existing buildings and other non-tower structures); and,

Whereas, the FCC encourages licensees to consider co-location of antennas where technically and economically feasible, in order to minimize the need for new tower construction; and,

Whereas, the execution of this Nationwide Programmatic Agreement will streamline the Section 106 review of co-location proposals and thereby minimize the need for the construction of new towers, thus limiting potential effects on historic properties resulting from the construction of new towers; and,

Whereas, the FCC and the Council have agreed that measures should be incorporated into a Nationwide Programmatic Agreement to better manage the Section 106 consultation process and streamline reviews for co-location of antennas; and,

Whereas, the FCC has consulted with the National Conference of State Historic Preservation Officers (NCSHPO) and requested its signature on this Nationwide Programmatic Agreement in accordance with 36 CFR 800.14(b)(2)(iii); and,

Whereas, the FCC has consulted with Indian Tribes regarding the terms of this Nationwide Programmatic Agreement and clarified that the terms of this Programmatic Agreement do not apply on tribal lands, nor does it preclude Indian tribes or Native Hawaiian Organizations from requesting consultation with the FCC regarding co-location activities; and,

Whereas, the execution and implementation of this Nationwide Programmatic Agreement will not preclude members of the public from filing complaints regarding Section 106 with the FCC or the Council regarding the construction of any existing tower or any activity covered under the terms of this Programmatic Agreement.

Now Therefore, the FCC, the Council, and NCSHPO agree that the FCC will meet its Section 106 compliance responsibilities for the co-location of antennas involving historic properties as follows.

Stipulations

The FCC, in coordination with licensees or tower construction companies, will ensure that the following measures are carried out. For the purpose of this Programmatic Agreement, ''towers'' are defined as structures built for the primary purpose of siting equipment used for radio communications services.

I. Co-Location of Antennas on Existing Towers Constructed on or Before December 31, 2000

A. A licensee or tower construction company may place new antennas on existing towers constructed on or before December 31, 2000 without such undertakings having to be reviewed under the consultation process set forth under Subpart B of 36 CFR Part 800, unless:

1. The mounting of the antenna will result in a substantial increase in the size of the tower as defined in Attachment A; or

2. The construction of the tower has been determined to have an effect on historic properties by the FCC, unless such effect has been avoided, minimized or mitigated through an existing conditional No Adverse Effect determination or Memorandum of Agreement; or

3. The tower is the subject of a pending environmental review or related proceeding before the FCC involving compliance with Section 106 of the National Historic Preservation Act; or

4. The licensee or tower construction company or its authorized representative has received written or electronic notice from any source, which notice can be provided at any time, that the FCC is in receipt of a pending complaint or allegation from a member of the public, a SHPO/THPO or the Council that the co-location has an adverse effect on historic properties.

II. Co-Location of Antennas on New Towers Constructed After December 31, 2000

A. A licensee or tower construction company may mount antennas on towers constructed after December 31, 2000 without such undertakings having to be reviewed under the consultation process set forth under Subpart B of 36 CFR Part 800, unless:

1. The Section 106 review process for the tower set forth in 36 CFR Part 800 and any associated environmental reviews required by the FCC have not been completed; or

2. The mounting of the new antenna will result in a substantial increase in the size of the tower as defined in Attachment A; or

3. The construction of the tower has been determined to have an effect on historic properties by the FCC, unless such effect has been avoided, minimized or mitigated through a conditional No Adverse Effect determination or execution of a Memorandum of Agreement; or

4. The licensee or tower construction company or its authorized representative has received written or electronic notice from any source, which notice can be provided at any time, that the FCC is in receipt of a pending complaint or allegation from an interested person, a SHPO/THPO or the Council that the co-location has an adverse effect on historic properties.

III. Co-Location of Antennas on Buildings and Non-Tower Structures Outside of Historic Districts

A. A licensee may mount antennas on buildings or non-tower structures without such undertakings having to be reviewed under the consultation process set forth under Subpart B of 36 CFR Part 800, unless:

1. The building or structure is over 45 years old; or

2. The building or structure is inside the boundary of a historic district or, if visible from the ground level of the historic district, is within 250 feet of the boundary of the historic district; or

3. The building or non-tower structure is a designated National Historic Landmark, designated as an historic property by the local jurisdiction, listed in the State register of historic properties, or listed in or eligible for listing in the National Register of Historic Places based upon the review of the licensee or tower construction company; or

4. The mounting of the antenna on the non-tower structure or building is the subject of a pending environmental review or related proceeding before the FCC involving compliance with Section 106 of the National Historic Preservation Act; or

5. The licensee or tower construction company or its authorized representative has received written or electronic notice from any source, which notice can be provided at any time, that the FCC is in receipt of a pending complaint or allegation from an interested person, a SHPO/THPO or the Council that the mounting of the antenna on the building or other non-tower structure has an adverse effect on historic properties.

B. Should the SHPO/THPO or Council determine that the co-location of an antenna or its associated equipment installed under the terms of Stipulation III has resulted in an adverse effect on historic properties, the SHPO/THPO or Council shall notify the FCC accordingly. The FCC shall comply with the requirements of Section 106 and 36 CFR Part 800 for this particular undertaking.

IV. Monitoring

A. Licensees and tower construction companies shall retain records of the placement of all their antennas, including co-locations subject to this Nationwide Programmatic Agreement, consistent with FCC rules and procedures.

B. The Council will forward to the FCC any written objections it receives from members of the public regarding a co-location activity or general compliance with the provisions of this Nationwide Programmatic Agreement within thirty (30) days following receipt of the written objection. The FCC will forward a copy of the written objection to the appropriate licensee or tower company.

V. Termination

A. If the FCC determines that it cannot implement the terms of this Nationwide Programmatic Agreement, or if the NCSHPO or Council determines that the Programmatic Agreement is not being properly implemented, the FCC, NCSHPO or Council may propose to other signatories that the Programmatic Agreement be terminated.

B. The party proposing to terminate the Programmatic Agreement shall so notify all signatories in writing, explaining the reasons for the proposed termination and affording them at least thirty (30) days to consult and seek alternatives to termination. Should the consultation fail, the Programmatic Agreement will be terminated.

C. In the event that the Programmatic Agreement is terminated, the FCC shall advise its licensees and tower construction companies of the termination and of the need to comply with Section 106 on a case-by-case basis for co-location activities.

VI. Duration of the Programmatic Agreement

A. This Programmatic Agreement for co-location shall remain in force unless the Programmatic Agreement is terminated or superseded by a comprehensive Programmatic Agreement for wireless communications antennas.

Execution of this Nationwide Programmatic Agreement by the FCC, NCSHPO and the Council, and implementation of its terms, evidence that the FCC has afforded the Council an opportunity to comment on the co-location of antennas covered under the FCC's rules, and that the FCC has taken into account the effects of these undertakings on historic properties in accordance with Section 106 of the National Historic Preservation Act and its implementing regulations, 36 CFR Part 800.

Federal Communications Commission

Date: _____

Advisory Council on Historic Preservation

_____

Date: _____

National Conference of State Historic Preservation Officers

_____

Date: _____

Attachment A

Definition of ''Substantial Increase in the Size of the Tower''

For purposes of this document, the term ''substantial increase in the size of the tower'' means:

(1) The mounting of the proposed antenna on the tower would increase the existing height of the tower by more than 10%, or by the height of one additional antenna array with separation from the nearest existing antenna not to exceed twenty feet, whichever is greater; or

(2) The mounting of the proposed antenna would involve the installation of more than the standard number of new equipment cabinets for the technology involved, not to exceed four, or more than one new equipment shelter; or

(3) The mounting of the proposed antenna would involve adding an appurtenance to the body of the tower that would protrude from the edge of the tower more than twenty feet, or more than the width of the tower structure at the level of the appurtenance, whichever is greater; or

(4) The mounting of the proposed antenna would involve excavation outside the current tower site, defined as the current boundaries of the leased or owned property surrounding the tower and any access or utility easements currently related to the site.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 01–126 Filed 1–3–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

DATE & TIME: Tuesday, January 9, 2001 at 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g. Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration Internal personnel rules and procedures or matters affecting a particular employee.

DATE & TIME: Thursday, January 11, 2001 at 10:00 a.m.

PLACE: 999 E Street, N.W., Washington, D.C. (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED: Correction and Approval of Minutes.

Advisory Opinion 2000–27: United Citizens Party of South Carolina by Michael Avey, Vice Chairman.

Final Audit Report on Schumer '98.

Administrative Matters.

FOR FURTHER INFORMATION CONTACT: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 01–394 Filed 1–2–01; 3:30 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011742

Title: P&O Nedlloyd-Farrell/Hapag-Lloyd/Zim Mediterranean Space Charter Agreement.

Parties: P&O Nedlloyd Limited, P&O Nedlloyd B.V., Farrell Lines, Inc., Hapag-Lloyd Linie GmbH, Zim Israel Navigation Co. Ltd.

Synopsis: The proposed agreement authorizes the parties to establish a cooperative arrangement to discuss and agree on the number, size, and characteristics of vessels deployed, and to exchange and charter vessel space between the parties in the trade between the U.S. East and Gulf coast ports, and major ports in the Mediterranean, including Atlantic ports of Portugal.

Agreement No.: 011743

Title: Global Transportation Network Agreement.

Parties: APL Co. PTE Ltd., CP Ships Holding Inc., Crowley Maritime Corporation, Hanjin Shipping Co., Ltd., Hyundai Merchant Marine Co., Ltd., Kawasaki Kisen Kaisha, Ltd., Mitsu O.S.K. Lines, Ltd., Senator Line GmbH, Yangming Marine Transport Corp., Zim Israel Navigation Company.

Synopsis: The proposed agreement authorizes members to establish and operate an Internet Portal so they and other user carriers may provide information and offer services to their respective customers worldwide.

By Order of the Federal Maritime Commission.

Dated: December 28, 2000.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 01–161 Filed 1–3–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have 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 the 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. The notices also will be available for inspection at the office 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 January 19, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Lyle P. Campbell, Downers Grove, Illinois, Craig L. Campbell, Danville, Illinois, and Thomas E. Malone and Verna C. Malone, Scottsdale, Arizona; to acquire voting shares of Terrapin Bancorp, Inc., Elizabeth, Illinois, and thereby indirectly acquire voting shares of Elizabeth State Bank, Elizabeth, Illinois.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Kevin J. Kavanaugh, Lawrenceville, Illinois; to acquire voting shares of HBancorporation, Inc., Lawrenceville, Illinois, and thereby indirectly acquire voting shares of Heritage National Bank, Lawrenceville, Illinois.

Board of Governors of the Federal Reserve System, December 28, 2000.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01–158 Filed 1–3–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have 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 the 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. The notices also will be available for inspection at the office 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 January 16, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. James Albert Kaldenberg, Albia, Iowa; and Caryl Kaldenberg Sharp, Edina, Minnesota; to retain voting shares of First Iowa State Shares, Inc., Albia, Iowa, and thereby indirectly retain voting shares of First Iowa State Bank, Albia, Iowa.

Board of Governors of the Federal Reserve System, December 29, 2000.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01–242 Filed 1–3–00; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 29, 2001.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Gateway Financial Corporation, Elizabeth City, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Gateway Bank & Trust Co., Elizabeth City, North Carolina.

B. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303–2713:

1. United Financial Holdings, Inc., Saint Petersburg, Florida; to acquire 100 percent of the voting shares of First Security Bank, Sarasota, Florida.

C. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Thumb National Bank & Trust Company Employee Stock Ownership Plan and Trust, Pigeon, Michigan; to become a bank holding company by acquiring 30.52 percent of the voting shares of Thumb Bancorp, Inc., Pigeon, Michigan, and thereby indirectly acquiring voting shares of Thumb National Bank & Trust Company, Pigeon, Michigan.

D. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. Waukomis Bancshares, Inc., Yukon, Oklahoma; to become a bank holding company by acquiring 100 percent of the voting shares of Covington First State Bancshares, Inc., Covington, Oklahoma, and thereby indirectly acquiring First State Bank, Covington, Oklahoma.

E. Federal Reserve Bank of San Francisco (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105–1579:

1. The Charles Schwab Corporation, San Francisco, California, and U.S. Trust Corporation, New York, New York; to merge with Resource Companies, Inc., Minneapolis, Minnesota, and thereby indirectly acquire Resource Trust Company, Minneapolis, Minnesota.,

2. Franklin Resources, Inc., San Mateo, California; to become a bank holding company by acquiring 100 percent of the voting shares of Fiduciary Trust Company International, New York, New York.

In connection with this application, Applicant also has applied to acquire Franklin Templeton Bank & Trust, F.S.B., Salt Lake City, Utah, and thereby engage in trust company activities pursuant to § 225.28(b)(5) of Regulation Y.

Board of Governors of the Federal Reserve System, December 28, 2000.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01–159 Filed 1–3–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of

a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 26, 2001.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Republic Bancorp, Inc., Louisville, Kentucky; to acquire 100 percent of the voting shares of Republic Bank and Trust Company of Indiana (in organization), Clarksville, Indiana.

B. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. American National Corporation, Omaha, Nebraska; to acquire 100 percent of the voting shares of American National Bank, Lincoln, Nebraska (in organization).

2. Colorado Business Bankshares, Inc., Denver, Colorado; to acquire 100 percent of the voting shares of First Capital Bank of Arizona, Phoenix, Arizona.

Board of Governors of the Federal Reserve System, December 29, 2000.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01–243 Filed 1–3–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 29, 2001.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. Westdeutsche Landesbank Girozentrale, Dusseldorf, Germany; to acquire voting shares of Boullioun Aviation Services, Inc., Bellevue, Washington, and thereby engage in leasing personal property or acting as agent, broker, or adviser in leasing such property, pursuant to § 225.28(b)(3) of Regulation Y; providing financial and investment advice pursuant to § 225.28(b)(6) of Regulation Y; making, acquiring, brokering or servicing loans or other extensions of credit, pursuant to § 225.28(b)(1) of Regulation Y; and engaging under contract with a third party in asset management, servicing and collection of assets of a type that an insured depository institution may originate and own, pursuant to § 225.28(b)(2)(vi) of Regulation Y.

Board of Governors of the Federal Reserve System, December 28, 2000.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01–160 Filed 1–3–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

[File No. 002 3194]

The Black & Decker Corporation, et al.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 29, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Elaine Kolish or Laura Koss, FTC/S–4302, 600 Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–3042 or 326–2890.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for December 28, 2000), on the World Wide Web, at *http://www.ftc.gov/os/2000/12/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room H–130, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondents The Black & Decker Corporation and its wholly-owned subsidiary, Kwikset Corporation.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns advertising, packaging, labeling, and promotional practices related to the sale of Kwikset Corporation's lockset products, including locksets, deadbolts, knobs, and handles. The Commission's complaint charges that respondents misrepresented on packaging and in advertising that certain Kwikset Corporation products are all or virtually all made in the United States. In truth and in fact, these products are actually made with significant foreign content and/or processing.

The proposed consent order contains a provision that is designed to remedy the charges and to prevent the respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Kwikset Corporation from misrepresenting the extent to which any Kwikset lockset is made in the United States. The order defines Kwikset lockset products as any product that is manufactured or sold by Kwikset Corporation that is used to secure doors, including but not limited to locksets, deadbolts, knobs, and handles. The proposed order would allow Kwikset Corporation to represent that such products are made in the United States as long as all, or virtually all, of the components of the products are of U.S. origin, and all, or virtually all, of the labor in manufacturing them is performed in the United States.

The proposed order also prohibits Kwikset Corporation from representing that its products are ''All American Made'' or ''All American Made and Proud of it'' or otherwise entirely made in the United States, unless such products are in fact 100% made in the United States.

Part II of the proposed order requires respondents to maintain materials relied upon in disseminating any representation covered by the order. Part III of the proposed order requires Kwikset Corporation to distribute copies of the order to certain company officials and employees. Part IV of the proposed order requires the respondents to notify the Commission of any change in the corporation that may affect compliance obligations under the order. Part V of the proposed order requires the respondents to file one or more compliance reports. Part VI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed consent order. If is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 01–247 Filed 1–3–01; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1678]

Expansion of Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing some changes in its standard practices for medical device, drug, food, and biologics inspections based on the outcome of the expansion of the medical device industry initiatives pilot program. FDA is discontinuing the practice of post-inspection notification letters for all inspections because the agency now provides inspected establishments with a copy of the establishment inspection report (EIR) when the inspection is deemed closed. FDA has decided to maintain pre-announced inspections and annotations of the inspectional observations (FDA 483) as standard practices for medical device inspections but with respect to inspections of other program areas, to apply these initiatives at the discretion of district management.

DATES: The changes to the medical device and expansion programs are effective January 1, 2001, with the publication of FDA's 2001 edition of the Investigations Operations Manual (IOM). Written comments may be submitted at any time in accordance with FDA's good guidance practices.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION: During the FDA/medical device industry grassroots forums in 1995, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to consider action on three of the inspectional issues discussed. These included instituting: (1) Pre-announced inspections, (2) listing promised or completed corrective actions on FDA 483 items, and (3) post-inspection notification to establishments regarding their compliance status.

In fiscal year (FY) 1996, FDA initiated a pilot program for the medical device industry, implementing these three changes. The pilot program took place during the 1996 calendar year and was limited to inspections of medical device manufacturers that did not manufacture products that crossed other program areas such as drugs or biologics. Pre-announced inspections were offered to those medical device firms that met the criteria for inclusion in the pilot program. The criteria included nonviolative current good manufacturing practices inspectional histories and a history that records and individuals were available at earlier pre-announced inspections. FDA 483 annotations and the post-inspection notification were done for all medical device inspections whether or not the inspection was pre-announced.

Based on industry input, FDA initiated another year-long pilot program in January 1999, to provide similar coverage for program areas including drugs (both human and animal) and biologics. Food inspections were limited to FDA 483 annotations and post-inspection notification. In FY 2000, FDA considered the impact of the second pilot's effects on field operations. The intent of the medical device pilot program was to optimize resource utilization, enhance FDA/industry communications, and provide firms prompt closure for nonviolative inspections and for corrected inspection observations. However, FDA determined that the additional burdens placed on field staff by the expansion into other program areas failed to capitalize resources and reduced overall field inspectional productivity.

FDA believes that the new inspection method for medical device firms (the quality system inspection technique) implemented in October 1999 provides

a clear direction in the inspection of these establishments, and provides logical stopping points, thus making the time it takes to complete an inspection more predictable. FDA concludes that pre-announcement of medical device inspections will remain standard procedure based on the defined criteria. For other establishments, pre-announcement of inspections remains voluntary at the discretion of the local FDA office. FDA will continue generally not to pre-announce inspections of food, blood bank, and plasmapheresis centers, but this, too, will be left to the district's discretion.

FDA investigators traditionally have discussed their observations with appropriate management at the establishment at the conclusion of the inspection. These discussions are reported in the Establishment Inspection Report. FDA will continue that practice, and will rely on the discretion of the investigator/team to determine whether to annotate the FDA 483. Since the medical device industry specifically asked FDA for annotations of the FDA 483, and since FDA has not found this practice to adversely affect the inspection process for medical devices, annotations will remain standard procedure for medical device inspections only.

In April 1997, FDA implemented a Field Management Directive (FMD 145) that requires FDA field offices to provide a copy of the EIR to the inspected establishment once the inspection is deemed closed. The copy of the EIR is provided along with a letter referred to as the ''FMD 145 letter.'' FDA has found that the issuance of both a post-inspection notification (PIN) letter and a FMD 145 letter is redundant. Because of this redundancy and the burden this puts on the field, the PIN letters will be discontinued in all program areas. FMD 145 will remain in place and these letters will continue to be issued. Establishments will receive a copy of their EIR when the inspection is deemed closed based on 21 CFR 20.64(d).

The 2001 IOM will be posted to FDA's website at www.fda.gov/ora under Inspection References/Investigations Operations Manual. The IOM sections that apply are: 510, 512.3, 516, 529 and 551.1. FMD 145 is posted to FDA's website at www.fda.gov/ora under Inspection References/Field Management Directives.

Dated: December 27, 2000.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–141 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1681]

Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This draft guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In the draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified condition for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency.

DATES: February 5, 2001.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Executive Operations (HFD–06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.''

The Federal Emergency Management Agency has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are expected to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, the DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

FDA is announcing the availability of a draft guidance that updates the notice of availability, ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use,'' published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency. In this draft guidance, FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization (WHO), as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), though they differ from those of the WHO in two areas.

First, for the sake of logistical simplicity, FDA recommends the 65-milligram (mg) dose of KI for all school-age children while allowing for the full adult dose of 130 mg in adolescents approaching adult size. WHO recommends 130 mg KI for adults and adolescents (over 12 years of age). Second, FDA recommends that KI prophylaxis in those under age 19 and in pregnant or lactating women be triggered at a predicted thyroid radioiodine exposure of 5 centiGray (cGy), while WHO establishes 1 cGy as the threshold for intervention. FDA has concluded from the Chernobyl data that the most reliable evidence demonstrates

a significant increase in risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The recommendations in the draft guidance were prepared by scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health of FDA in consultation with other governmental experts.

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on use of potassium iodide as a thyroid blocking agent in radiation emergencies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–189 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*). Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Applicant: Mitchel Kalmanson, Maitland, Florida, PRT–034041.

The applicant request a permit to export 4.8 captive born tigers (*Panthera tigris*) to Juan M. L. Salazar aka Johnny Lam, Mexico for the purpose of enhancement of the survival of the species through propagation.

Applicant: Institute for the Conservation of Tropical Environments, Stony Brook, NY, PRT–035632.

The applicant request a permit to import biological samples of diademed sifka (*Propithecus diadema*), lesser bamboo lemur (*Hapalemur griseus*), golden bamboo lemur (*Hapalemur aureus*), and greater bamboo lemur (*Hapalemur simus*) for the purpose of enhancement of the survival of the species through scientific research. This notification covers activities conducted by the applicant for a period of five years.

The U.S. Fish and Wildlife has information collection approval from OMB through February 28, 2001. OMB Control Number 1018–0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358–2104); Fax: (703/358–2281).

Dated: December 29, 2000.

Anna Barry,

Branch of Permits, Division of Management Authority.

[FR Doc. 01–226 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological survey

Request for Public Comments on Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below has been submitted to the Office of Management 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 may be obtained by contacting the USGS Clearance Officer at the phone number listed below. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days; therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration. Comments and suggestions on the requirement should be made directly to the Desk Officer for the Interior Department, Office of Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 and to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: Production Estimate, Quarterly Construction Sand and Gravel and Crushed and Broken Stone.

Current OMB approval number: 1028–0065.

Abstract: The collection is required to provide data on mineral production for annual reports published by commodity for use by Government agencies, industry, education programs, and the general public. One publication is the ''Mineral Commodity Summaries,'' the first preliminary publication to furnish estimates covering the previous year's nonfuel mineral industry.

Bureau form numbers: 9–4042–A and 9–4124–A.

Frequency: Quarterly and Annual.

Description of respondents: Producers of industrial minerals and metals.

Annual Responses: 3,450.

Annual burden hours: 742.

Bureau clearance officer: John Cordyack, 703–648–7313.

John H. DeYoung, Jr.,

Chief Scientist, Minerals Information Team.

[FR Doc. 01–185 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–Y7–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection Submitted to the Office of management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below has been submitted to the Office of Management 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 may be obtained by contacting the USGS Clearance Officer at the phone number listed below. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days; therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration. Comments and suggestions on the requirement should be made directly to the Desk Officer for the Interior Department, Office of Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 and to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;
2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The utility, quality, and clarity of the information to be collected; and,
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: Industrial Mineral Surveys.

Current OMB approval number: 1028–0062.

Abstract: Respondents supply the U.S. Geological Survey with domestic production and consumption data on nonfuel mineral commodities. This information will be published as Annual Reports, Mineral Industry Surveys, and in Mineral Commodity Summaries for use by Government agencies, industry, and the general public.

Bureau form numbers: Various (40 forms).

Frequency: Monthly, Quarterly, Semiannual, and Annual.

Description of respondents: Producers and Consumers of Industrial Minerals.

Annual Responses: 19,008.

Annual burden hours: 13,185.

Bureau clearance officer: John Cordyack, 703–648–7313.

John H. DeYoung, Jr.,

Chief Scientist, Minerals Information Team.

[FR Doc. 01–186 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–Y7–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–080–1110–XG]

Notice of Address Change for Salmon and Challis (Idaho) Offices

AGENCY: Bureau of Land Management, Upper Columbia—Salmon Clearwater District, Idaho.

ACTION: Notice of address changes for Salmon and Challis (Idaho) Offices.

SUMMARY: Due to recent moves, the addresses for the Bureau of Land Management (BLM) offices in Salmon and Challis, Idaho have changed. The new addresses are as follows and are effective immediately:

Bureau of Land Management, Salmon Field Office, 50 Highway 93 S., Salmon, Idaho 83467

Bureau of Land Management, Challis Field Office, HC 63, Box 1670, Challis, Idaho 83226–9304

FOR FURTHER INFORMATION CONTACT: Jenifer Arnold (208) 769–5000.

Dated: December 27, 2000.

Ted Graf,

Acting District Manager.

[FR Doc. 01–181 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–GG–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–930–1060–PC]

Notice of Intent to Remove Wild Horses on the Public Lands in Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Wild, Free Roaming Horse and Burro Act (Pub. L. 92–195), as amended, provides, among other things, that excess wild horses shall be removed from the public lands.

The Bureau of Land Management (BLM) plans to continue removal operations according to the following schedule: Beginning February 1, 2001, remove 500 horses from the following areas: Antelope Hills, Lost Creek/I80 North, Stewart Creek, Divide Basin, and Salt Wells. Beginning August 6, 2001, remove 400 horses from the Salt Wells Herd Management Area (HMA). Beginning August 6, 2001, remove 350 horses from the Lander HMA. Beginning August 27, 2001, remove 150 horses from the Little Colorado HMA. Beginning September 10, 2001, remove 300 horses from the Divide Basin and Lost Creek HMAs. Dates are approximate depending on weather and soil conditions, and other factors unforseen at this time. BLM plans to remove a total of 1700 horses from public lands according to the above schedule.

Pursuant to the requirements noted above, the BLM will conduct a public hearing on the use of helicopters in gathering operations during the calendar year of 2001 on January 30, 2001, at 3 p.m. MST in the large conference room of the Rawlins Field Office of the BLM located at 1300 North Third Street in Rawlins, Wyoming.

FOR FURTHER INFORMATION CONTACT: Don Glenn, Wild Horse Specialist, Bureau of Land Management, Wyoming State Office, 5353 Yellowstone, Cheyenne, WY 82009. Phone (307) 775–6097.

Dated: December 27, 2000.

Alan Rabinoff,

Acting State Director.

[FR Doc. 01–182 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Submission of Study Package to Office of Management and Budget; Opportunity for Public Comment

AGENCY: National Park Service and Hopewell Culture National Historical Park, Department of the Interior.

ACTION: Notice and request for comments.

ABSTRACT: The National Park Service is conducting a study to assess the attitudes and perceptions of community members regarding the significance of archeological resources at Hopewell Culture National Historical Park (HOCU) and in southern Ohio. This information will be used to help the staff at HOCU evaluate the effectiveness of its outreach program and to modify

and improve the Park's outreach efforts. The following specific study objectives have been identified:

1. Determine community attitudes towards the perceived significance and importance of the park's archeological resources;

2. Determine the effect of the park's outreach program on the attitudes of people in the community regarding archeological resources;

3. Determine community awareness of visitor services offered at the park;

4. Determine potential benefits of the park to the community;

5. Determine the importance and value of archeology to community members;

6. Determine community perspectives concerning the protection of archeological sites.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 and 5 CFR part 1320, Reporting and Record Keeping Requirements, the NPS invites public comment on the proposed information collection request (ICR). Comments are invited on: (1) The need for the information including whether the information has practical utility; (2) the accuracy of the reporting burden estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The purpose of the proposed ICR is to assess the attitudes and perceptions of community members concerning the importance of archeological resources at HOCU and in southern Ohio. This information will be used to help the staff at HOCU enhance the effectiveness of their outreach programs to better educate the public about the importance of cultural resources in the region. There were no public comments received as a result of publishing in the **Federal Register** a 60-day notice of intention to request clearance of information collection for this survey.

DATES: Public comments will be accepted on or before February 5, 2001.

Send Comments to: Office of Information and Regulatory Affairs of OMB, Attention Desk Officer for the Interior Department, Office of Management and Budget, Washington, DC 20530. Please also send comments to Dorothy H. Anderson, Ph.D., Professor and Program Leader, Cooperative Park Studies Program, Department of Forest Resources, University of Minnesota, 115 Green Hall, 1530 Cleveland Ave. N., St. Paul, MN 55108–6124.

The OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, to ensure maximum consideration, OMB should receive public comments within thirty days of the date on which this notice is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For a copy of the study package submitted for OMB review, contact: Dorothy H. Anderson, phone: 612–624–2721.

SUPPLEMENTARY INFORMATION:

Title: Hopewell Culture National Historical Park Community Survey.

Form: Not applicable.

OMB Number: To be assigned.

Expiration Date: To be assigned.

Type of Request: Request for new clearance.

Description of Need: The National Park Service needs information concerning public attitudes and perceptions about the significance of archeological resources at Hopewell Culture National Historical Park and southern Ohio. The information is needed to help the staff at HOCU evaluate the effectiveness of its outreach program and to enhance and improve education and interpretation programs offered by the park. The end result will be better management and protection of the park's and the community's cultural resources.

The proposed information to be collected regarding the local public served by this park is not available from existing records, sources, or observations.

Automated Data Collection: At the present time, there is no automated way to gather this information, since it includes asking residents about their attitudes and perceptions related to archeological resources at HOCU.

Description of Respondents: A sample of residents in Ross County, Ohio and the town of Circleville in Pickaway County, Ohio.

Estimated Average Number of Respondents: 500.

Estimated Average Number of Responses: Each respondent will respond only one time, so the number of responses will be the same as the number of respondents.

Estimated Average Burden Hours Per Response: 15 minutes.

Frequency of Response: One time per respondent.

Estimated Annual Reporting Burden: 125 hours.

Dated: December 20, 2000.

Betsy Chittenden,

Information Collection Clearance Officer, WASO Administrative Program Center, National Park Service.

[FR Doc. 01–188 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of Draft Wilderness Management Plan, Commercial Services Plan, Interpretive Plan, and Resource (Cultural and Natural) Management Plan and Draft Environmental Impact Statement (DPlans/DEIS) for Cumberland Island National Seashore, St. Marys, Georgia

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 (16 U.S.C. 410ccc–4; 42 U.S.C. 4371; 40 CFR 1503) the National Park Service (NPS) announces the availability of the DPlans/DEIS.

These documents have been prepared in cooperation with a committee of the National Park System Advisory Board. The Board forwarded its recommendations to the Director of the National Park Service and the Secretary of the Interior.

This DPlans/DEIS presents a range of alternatives for guiding future management of the national seashore and balancing resource protection and public use. It also includes an analysis of the potential consequences of these actions. The major subject areas are natural and cultural resources management, wilderness management, long range interpretation, and commercial services.

DATES: There will be a 120-day comment period beginning with the Environmental Protection Agency's publication of its notice in the **Federal Register**.

ADDRESSES: Comments should be mailed to the Southeast Regional Office, National Park Service, 1924 Building, 100 Alabama Street, SW, Atlanta, Georgia 30303. The National Park Service will host public meetings on the Draft Plans and Draft EIS at the following locations:

January 17, 2001—5 to 7 p.m.—Camden County Library, 1410 Georgia Highway 40E, Kingsland, Georgia 31548

January 18, 2001—1 to 3 p.m.—Martin Luther King, Jr. NHS, Visitor Center, 450 Auburn Avenue, N.E., Atlanta, Georgia 30312

January 18, 2001—6 to 8 p.m.—Same location above.

The DPlans/DEIS will be available for review at the public libraries and National Park Service sites listed below:
St. Marys Public Library, 101 Herb Bauer Drive, St. Marys, Georgia 31558
Jacksonville Library, 122 North Ocean Street, Jacksonville, Florida 32202
Atlanta-Fulton County Library, Sandy Springs Branch, 395 Mount Vernon Highway, Atlanta, Georgia 30328
Camden County Library, 1410 Highway 40 East, Kingsland, Georgia 31548
Fernandina Beach Library, 25 North 4th Street, Fernandina Beach, Florida 32034
Cumberland Island National Seashore, Museum-Conference Room, 129 Osborne Street, St. Marys, Georgia 31558
Brunswick (Glynn County) Library, 208 Glouchester Street, Brunswick, Georgia 31250
Atlanta-Fulton County Library, 1 Margaret Mitchell Square, 2nd Floor, Atlanta, Georgia 30303
Cumberland Island National Seashore Visitor Center, 107 St. Marys Street, St. Marys, Georgia 31558
St. Simons Library, 530 Beachview Drive, Unit A, St. Simons Island, Georgia 31522
Southeast Regional Office, National Park Service, 1924 Building, 100 Alabama Street, SW, Atlanta, Georgia 30303
Atlanta-Fulton County Library, Buckhead Branch, 269 Buckhead Avenue, Atlanta, Georgia 30305
Cumberland Island National Seashore, Sea Camp Ranger Station, On the Island

FOR FURTHER INFORMATION CONTACT: Arthur Frederick, Superintendent, Cumberland National Seashore, P.O. Box 806, St. Marys, Georgia 31558, telephone (912) 882–4336.

SUPPLEMENTARY INFORMATION: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. If you wish for us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: December 19, 2000.

Charlie L. Powell,

Regional Director, Southeast Region.

[FR Doc. 01–213 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Year-Round Closure at Fort Funston, Golden Gate National Recreation Area

DATE: December 21, 2000.

ACTION: Notice of closure.

SUMMARY: In accordance with the resource protection mandate of the National Park Service (NPS), the Golden Gate National Recreation Area, NPS, is announcing its decision to close year-round approximately 12 acres of Fort Funston to off-trail recreational use by the public. The closure is located in the northwest portion of Fort Funston. This closure is necessary to protect habitat for the California threatened bank swallows (*Riparia riparia*), enhance significant native plant communities, improve public safety and reduce human-induced impacts to the coastal bluffs and dunes, a significant geological feature.

Background: Consistent with section 1.5 of Title 36 of the Code of Federal Regulations, authorizing the Superintendent to effect closures and public use permits within a national park unit, the proposed 12-acre year-round closure and solicitation of comments was noticed by publication in the **Federal Register** on July 18, 2000 (65 FR 44546). Details of the proposed closure were made available to the public in the form of a public document entitled ''Proposed Habitat Protection Closure, Fort Funston, Golden Gate National Recreation Area,'' as stated in the **Federal Register** on July 18, 2000 (65 FR 44546). The public comment period closed on October 6, 2000. The public provided approximately 1,500 comments on the proposed closure. Upon consideration of the public comments, and the recommendations of the Golden Gate National Recreation Area Advisory Commission, NPS has determined that the proposed year-round 12-acre closure is the least restrictive means to meet the four goals and objectives for the project and that the project will be implemented as described in the document entitled, ''Proposed Habitat Protection Closure, Fort Funston, Golden Gate National Recreation Area.''

Reference: Public Law 92–589 of October 27, 1972, as amended, as codified in Title 16 United States Code Sections 460bb through 460bb–5. Title 16 United States Code Sections 1 and 1a–1. Title 36 Code of Federal Regulations sections 1.5, 1.7, 2.1, and 2.15. *Ft. Funston Dog Walkers* v. *Babbitt*, No. C00–00877 WHA, N.D. Cal., Preliminary Injunction, May 16, 2000.

FOR FURTHER INFORMATION CONTACT: Rich Weideman, Office of Public Affairs, Golden Gate National Recreation Area at 415–561–4730.

Dated: December 21, 2000.

George Turnbull,

Acting General Superintendent, Golden Gate National Recreation Area.

[FR Doc. 01–187 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–404–408 (Preliminary) and 731–TA–898–908 (Preliminary)]

Hot-Rolled Steel Products from Argentina, China, India, Indonesia, Kazakhstan, Netherlands, Romania, South Africa, Taiwan, Thailand, and Ukraine

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission determines, pursuant to section 703(a) of the Tariff Act of 1930 (the ''Act'') (19 U.S.C. 1671b(a)), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from Argentina, India, Indonesia, South Africa, and Thailand of hot-rolled steel products that are alleged to be subsidized by the Governments of Argentina, India, Indonesia, South Africa, and Thailand. The Commission also determines, pursuant to section 733(a) of the Act (19 U.S.C. 1673b(a)), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from Argentina, China, India, Indonesia, Kazakhstan, the Netherlands, Romania, South Africa, Taiwan, Thailand, and Ukraine of hot-rolled steel products that are alleged to be sold in the United States at less than fair value (LTFV).

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling which will be published in the **Federal Register** as provided in section 207.21 of the

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Commission's rules upon notice from the Department of Commerce (Commerce) of affirmative preliminary determinations in the investigations under sections 703(b) and 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) and 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On November 13, 2000, petitions were filed with the Commission and the Department of Commerce on behalf of Bethlehem; Gallatin; IPSCO; LTV; National; Nucor; SDI; USX; Weirton; [2] and the labor union representing the organized workers at Weirton Steel Corp. known as the Independent Steelworkers Union, alleging that an industry in the United States is materially injured, and is threatened with material injury, by reason of subsidized imports of hot-rolled steel products from Argentina, India, Indonesia, South Africa, and Thailand and by reason of LTFV imports of the same from Argentina, China, India, Indonesia, Kazakhstan, the Netherlands, Romania, South Africa, Taiwan, Thailand, and Ukraine. Accordingly, effective November 13, 2000, the Commission instituted countervailing duty investigations Nos. 701–TA–404–408 (Preliminary) and antidumping duty investigations Nos. 731–TA–898–908 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference 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 November 22, 2000 (65 FR 70364). The conference was held in Washington, DC, on December 4, 2000, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on December 28, 2000. The views of the Commission are contained in USITC Publication 3381 (December 2000), entitled Hot-Rolled Steel Products from Argentina, China, India, Indonesia, Kazakhstan, Netherlands, Romania, South Africa, Taiwan, Thailand, and Ukraine: Investigations Nos. 701–TA–404–408 (Preliminary) and 731–TA–898–908 (Preliminary).

Issued: December 29, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–234 Filed 1–3–01; 8:45 am]

BILLING CODE 7020–02–P

[2] Weirton is not a petitioner in the investigation involving the Netherlands.

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–362 and 731–TA–707–710 (Review)]

Certain Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Argentina, Brazil, Germany, and Italy

AGENCY: International Trade Commission.

ACTION: Scheduling of full five-year reviews concerning the countervailing duty order on certain seamless carbon and alloy steel standard, line, and pressure pipe from Italy and the antidumping duty orders on certain seamless carbon and alloy steel standard, line, and pressure pipe from Argentina, Brazil, Germany, and Italy.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) (the Act) to determine whether revocation of the countervailing duty order with regard to certain seamless carbon and alloy steel standard, line, and pressure pipe from Italy and/or the revocation of the antidumping duty orders with regard to certain seamless carbon and alloy steel standard, line, and pressure pipe from Argentina, Brazil, Germany, and Italy would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: Effective Date: December 28, 2000.

FOR FURTHER INFORMATION CONTACT: Christopher J. Cassise (202–708–5408), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*).

SUPPLEMENTARY INFORMATION:

Background

On October 5, 2000, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews pursuant to section 751(c)(5) of the Act should proceed (65 FR 63889, October 25, 2000). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's web site.

Participation in the reviews and public service list

Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under

the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report

The prehearing staff report in the reviews will be placed in the nonpublic record on April 11, 2001, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing

The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on May 1, 2001, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before April 23, 2001. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on April 26, 2001, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written submissions

Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is April 20, 2001. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is May 10, 2001; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before May 10, 2001. On May 30, 2001, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before June 1, 2001, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

Issued: December 29, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–235 Filed 1–3–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 701–TA–413 and 731–TA–913–918 (Preliminary)]

Stainless Steel Bar from France, Germany, Italy, Korea, Taiwan, and the United Kingdom

AGENCY: International Trade Commission.

ACTION: Institution of countervailing duty and antidumping investigations and scheduling of preliminary phase investigations.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase countervailing duty investigation No. 701–TA–413 (preliminary) and antidumping investigations Nos. 731–TA–913–918 (preliminary) under sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from France, Germany, Italy, Korea, Taiwan, and the United Kingdom of stainless steel bar, provided for in subheadings 7222.11.00, 7222.19.00, 7222.20.00, and 7222.30.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be subsidized by the Government of Italy or that are alleged to be sold in the United States at less than fair value. Unless the Department of Commerce extends the time for initiation pursuant to sections 702(c)(1)(B) or 732(c)(1)(B) of the Act (19 U.S.C. § 1671a(c)(1)(B) or 1673a(c)(1)(B)), the Commission must reach preliminary determinations in countervailing duty and antidumping investigations in 45 days, or in this case by February 12, 2001. The Commission's views are due at the Department of Commerce within five business days thereafter, or by February 20, 2001.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: December 28, 2000.

FOR FURTHER INFORMATION CONTACT: Fred Fischer (202–205–3179), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server *(http://www.usitc.gov).*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on December 28, 2000, by Carpenter Technology Corp. (Wyomissing, PA); Crucible Specialty Metals (Syracuse, NY); Electralloy Corp. (Oil City, PA); Empire Specialty Steel, Inc. (Dunkirk, NY); Slater Steels Corp.,

Specialty Alloys Division (Fort Wayne, IN); and the United Steelworkers of America, AFL–CIO/CLC (Pittsburgh, PA).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission countervailing duty and antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Operations has scheduled a conference in connection with these investigation for 9:30 a.m. on January 18, 2001, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Fred Fischer (202–205–3179) not later than January 16, 2001, to arrange for their appearance. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before January 23, 2001, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: December 29, 2000.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–236 Filed 1–3–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–437]

In the Matter of Certain Synchronous Dynamic Random Access Memory Devices and Modules and Products Containing Same; Notice of Decision to Terminate the Investigation Based on Withdrawal of the Complaint

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to terminate the above-captioned investigation based on withdrawal of the complaint by complainant Rambus Inc. The Commission vacated the presiding administrative law judge's (ALJ's) initial determination (ID) with respect to all other issues. (Commissioners Bragg and Askey dissenting with respect to the ID's condition on termination.)

FOR FURTHER INFORMATION CONTACT: Tim Yaworski, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3096. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD Terminal on 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 5, 2000, based on a complaint filed by Rambus Inc. of Mountain View, California. The complaint alleged a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, based on infringement of claims of three U.S. patents (U.S. Letters Patent 6,038,195, U.S. Letters Patent 5,953,263, and U.S. Letters Patent 6,034,918) owned by complainant. The respondents named in the investigation were Hyundai Electronics Industries Co., Ltd. of Korea and Hyundai Electronics America of San Jose, California (collectively ''Hyundai''). The investigation was assigned to Administrative Law Judge Sidney Harris. 65 FR 60684. On October 6, 2000, complainant Rambus moved to withdraw its complaint and terminate the investigation. Rambus' motion was responded to by Hyundai and the Commission investigative attorney (''IA''). On November 8, 2000, the ALJ issued an ID terminating the investigation based on Rambus' withdrawal of its complaint, but with the condition that, if the Commission institutes a subsequent investigation based on a complaint filed by Rambus involving one or more of the same patents, then such investigation should be assigned to the same ALJ, unless exceptional circumstances require assignment to another ALJ. The ALJ found that Rambus had engaged in impermissible judge shopping. Rambus and the IA petitioned for review of the ID. On December 11, 2000, the Commission determined to review the ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and section 210.45(c) of the Commission's Rules of Practice and Procedure, 19 CFR 210.45(c).

Copies of the Commission's Order, the ID, and all other nonconfidential documents filed in connection with this investigation are or will be 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 202–205–2000. Copies of these documents may also be downloaded from the Commission's Internet server at *http://www.usitc.gov.*

Issued: December 26, 2000.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–233 Filed 1–3–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Justice Management Division

Agency Information Collection Activities: Existing Collection: Common Request

ACTION: Notice of information collection under review: Extension of previously approved collection, Department of Justice procurement blanket clearance.

Office of Management and Budget approval is being sought for the information collection listed below. This collection was previously published in the **Federal Register** on October 3, 2000, Vol. 65, page 59015, allowing for a 60 day public comment period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 5, 2001. This process is conducted in accordance with 5 CFR 3120.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs: Attention: Mr. Nathan Knuffman, 202–395–5871, Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile on 202–395–7285. Written comments and suggestions from the public and affected agencies concerning this collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Comments may also be submitted to the Department of Justice, Justice Management Division, Information Management and Security Staff, Attention: Department Deputy Clearance Officer.

Overview of this Collection

(1) *Type of information collection:* Extension of Current Collection.

(2) *The title of the form/collection:* Department of Justice Procurement Blanket Clearance.

(3) *The agency form number, if any, and applicable component of the Department sponsoring the collection:* Procurement Solicitation Documents, Justice Management Division, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract. Primary:* Commercial organizations and individuals who voluntarily submit offers and bids to compete for contract awards to provide supplies and services required by the Government. All work statements and pricing data are required to evaluate the contractors bid or proposal.

(5) *An estimate of the total number of respondents and the amount of time for an average respondent to respond:* 7,462 respondents, 20 hours average response time.

(6) *An estimate of the total public burden (in hours) associated with this collection:* 149,240 hours annually.

If additional information is required contact: Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place, 1331 Pennsylvania Avenue, NW., Washington, DC 20530.

Dated: December 20, 2000.

Brenda E. Dyer,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–229 Filed 1–3–01; 8:45 am]

BILLING CODE 4410–26–M

DEPARTMENT OF JUSTICE

Justice Management Division

Agency Information Collection Activities: Proposed Collection; Comment Request; Certification of Identity

ACTION: Reinstatement, with change, of a previously approved collection of which approval has expired.

Office of Management and Budget approval is being sought for the information collection listed below. This collection was previously published in the **Federal Register** on October 3, 2000, (Vol. 65, page 59015), allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 5, 2001. This process is conducted in accordance with 5 CFR 3120.10.

Written comments and/or suggestions regarding the item contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proposed performance of the functions of the Agency, including whether the information will have practical utility.

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Certification of Identity.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form DOJ–361. Facilities and Administrative Services Staff, Justice Management Division, U.S. Department of Justice.

(4) *Affected public who will be asked or required to responsed, as well as a brief abstract:* Primary: Individuals. The information collection will be used by the Department to identify individuals requesting certain records under the Privacy Act. Without this form an individual cannot obtain the information requested.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 153,333 respondents at 15 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 38,333 annual burden hours.

If additional information is required contact: Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place Building, 1331 Pennsylvania Avenue, NW., Washington, DC 20530.

Dated: December 20, 2000.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 01–230 Filed 1–3–01; 8:45 am]

BILLING CODE 4410–26–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Approval of a New Collection Comment Request

ACTION: Notice of information collection under review; extension of a currently approved collection. VOI/TIS 96/ NEPA Guidance.

The Department of Justice, Office of Justice Programs, Corrections Program Office, has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. Office of Management and Budget approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register,** Volume 65, page 41097 on July 3, 2000, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment until February 5, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the Ms. Brenda E. Dyer, Deputy Clearance Office, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place Building, 1331 Pennsylvania Avenue, NW., Washington, DC 20530. Additional comments may be submitted to DOJ via facsimile to (202) 514–1590.

Written comments and/or suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technology collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the form/collection:* Program Guidance on Environmental Protections Requirements and Violent Offender Incarceration/Truth-in-Sentencing Project Status Report.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Department of Justice, Office of Justice Programs, Corrections Program Office.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: State and Local Government.

Other: None. The Violent Offender Incarceration/Truth-in-Sentencing Grant Program was authorized under Title II, Subtitle A of the Violent Crime Control and Law Enforcement Act of 1994, as amended, to assist states in their efforts to remove violent offenders from the community and to encourage states to implement truth-in-sentencing.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* The time burden of the 550 respondents to complete the surveys is 60 minutes per survey, the approximate burden of completing an Environmental Assessment or Environmental Impact Statement or a combination of the two can be up to 24 months (hours may vary).

(6) *An estimate of the total public burden (in hours) associated with the collection:* Average time burden for each respondent can be up to 24 months.

If additional information is required contact: Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place Building, 1331 Pennsylvania Avenue, NW., Washington, DC 20530.

Dated: December 20, 2000.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 01–231 Filed 1–3–01; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comment Request; Fiscal Year 1999 State Domestic Preparedness Equipment Program Needs Assessment

The Department of Justice, Office of Justice Programs (OJP), Office for State and Local Domestic Preparedness Support (OSLDPS), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. Office of Management and Budget approval is being sought for the information collection listed below. This proposed information collection

was previously published in the **Federal Register** on June 8, 2000, Volume 65, page 36467, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comment until February 5, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to (202) 395–7285. Comments may also be submitted to the Department of Justice (DOJ), Office of Justice Programs, Office for State and Local Domestic Preparedness Support (OSLDPS), Attention: Frank Lepage, Chief, Grants Management Operations Branch, 810 7th Street, NW., Washington, DC 20531. Additionally, comments may be submitted to OSLDPS via facsimile at (202) 616–2922.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information:

(1) *Type of Information Collection:* New collection.

(2) *The Title of the Form/Collection:* Fiscal Year 1999 State Domestic Preparedness Equipment Program Needs Assessment.

(3) *The Agency Form Number, if any, and the Applicable Component of the Department Sponsoring the Collection:* U.S. Department of Justice, Office of Justice Programs, Office for State and Local Domestic Preparedness Support.

(4) *Affecting Public who will be Asked or Required to Respond, as well as a Brief Abstract:*

Primary: Federal Government, State, and Local

Abstract: Section 1404 of the Defense Against Weapons of Mass Destruction Act of 1998 (Title XIV of Public Law 105–261; 50 U.S.C. 2301) as amended by section 1064 of the National Defense Authorization Act of 2000 (Title X of Public Law 106–65; 50 U.S.C. 2301) authorizes the Department of Justice to collect information from state and local jurisdictions to assess the threat and risk of terrorist employment of weapons of mass destruction against cities and other local areas. This data collection is a one-time event that will allow states to: (1) Report current jurisdictional needs for equipment, training, exercises, and technical assistance; (2) forecast projected needs for this support; and (3) identify the gaps that exist at the jurisdictional level in equipment, training, exercises, and technical assistance that OJP/OSLDPS funding will be used to address. Additionally, the information collected will guide OJP/OSLDPS in the formulation of domestic preparedness policies and with the development of OSLDPS programs to enhance state and local first responder capabilities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* The data collection being proposed is a one-time effort incorporating three main components: A terrorist threat and risk assessment, a public health capabilities assessment, and an equipment needs and capabilities assessment. Information will be collected by approximately 9,000 local law enforcement, public health, and emergency management agencies. In addition, a state administrative agency in each state will roll-up the local data and submit this information to OJP/OSLDPS. Collection and tabulation of the raw data at the local level may take up to one month. Jurisdictions using the OJP data collection tool designed for this exercise may experience burdens ranging from 4–8 hours to collect, tabulate and input data. In addition, roll-up of the data at the state level and electronic submission to OJP may take up to 4 hours.

(6) *An Estimate of the Total Public Burden (in hours) Associated With the Collection:* The total public burden associated with this one-time data collection will be approximately 66,200 hours.

If additional information is required, contact: Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place Building, 1331 Pennsylvania Avenue, NW., Washington, DC 20530.

Dated: December 27, 2000.

Brenda E. Dyer,

Department Deputy Clearance Officer, Department of Justice.

[FR Doc. 01–232 Filed 1–3–01; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 27, 2000.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact Karin Kurz ((202) 693–4127 or by E-mail to Kurz-Karin@dol.gov). To obtain documentation for ESA, MSHA, OSHA, and VETS contact Darrin King ((202) 693–4129 or by E-mail to King-Darrin@dol.gov).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), on or before February 5, 2001.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Type of Review: Extension of a currently approved collection.

Agency: Occupational Safety and Health Administration (OSHA).

Title: Asbestos in Construction.

OMB Number: 1218–0134.

Affected Public: Business or other for-profit; Federal Government; and State, Local or Tribal Government.

Frequency: On occasion.

Number of Respondents: 286,821.

Number of Annual Responses: 52,828,437.

Estimated Time Per Response: Varies from 5 minutes to maintain records to 17.3 hours for training a competent person.

Total Burden Hours: 5,569,659.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $30,730,200.

Description: 29 CFR 1926.1101 requires employers to train employees about hazards of asbestos exposure, to provide medical surveillance, and maintain accurate records of employee exposure to asbestos. These records will be used by employers, employees, and the Federal government to ensure that employees are not harmed by occupational exposure to asbestos.

Type of Review: Extension of a currently approved collection.

Agency: Occupational Safety and Health Administration (OSHA).

Title: Asbestos in Shipyards.

OMB Number: 1218–0195.

Affected Public: Business or other for-profit; Federal Government; and State, Local, or Tribal Government.

Frequency: On occasion.

Number of Respondents: 80.

Number of Annual Responses: 2,470.

Estimated Time Per Response: Varies from 5 minutes to maintain records to 17.3 hours for training a competent person.

Total Burden Hours: 1,483.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $34,147.

Description: 29 CFR 1915.1001 requires employers to train employees about hazards of asbestos exposure, to provide medical surveillance, and maintain accurate records of employee exposure to asbestos. These records will be used by employers, employees, and the Federal government to ensure that employees are not harmed by occupational exposure to asbestos.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 01–224 Filed 1–3–01; 8:45 am]

BILLING CODE 4510–26–M

NUCLEAR REGULATORY COMMISSION

[Docket No.: 030–14784]

U.S. Army Chemical School, Fort McClellan, Alabama; Notice of Intent To Amend Byproduct Materials License for the Former U.S. Army Chemical School Facilities in Fort McClellan, Alabama, Environmental Assessment, Finding of No Significant Impact, and Opportunity for Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of intent.

SUMMARY: The U.S. Nuclear Regulatory Commission (hereafter referred to as NRC staff) is considering issuance of a license amendment to Nuclear Materials License No. 01–02861–05, issued to the Department of the Army's Chemical School, to authorize decommissioning of a radioactive waste burial mound located at the Pelham Range at Fort McClellan, Alabama.

This amendment would involve the approval of the Remediation (Decommissioning) Plan for the Department of the Army's Fort McClellan Pelham Range Burial Mound, Fort McClellan, Alabama, dated September 9, 1999. The Army is obligated to remediate the Fort McClellan site to meet the release criteria in 10 CFR 20, Subpart E (NRC, 1997).

Based on our evaluation of the Army's Fort McClellan Remediation (Decommissioning) Plan, NRC staff has determined that the proposed plan complies with NRC's public and occupational dose and effluent limits, and that authorizing the proposed activities would not be a major Federal action significantly affecting the quality of the human environment. NRC staff concludes that a Finding of No Significant Impact is justified and appropriate, and that an environmental impact statement is not required.

Introduction

On July 23, 1998, the Army's Material License No. 01–02861–05 was amended to include cesium 137 (Cs–137) and cobalt 60 (Co–60) waste contained in a burial mound located at Rideout Field, Pelham Range, Area 24C at Fort McClellan, Alabama. The Army requested this amendment based on a characterization study completed in January 1996. The study consisted of walkover surface scans, hole logging and sample analysis. The Army obtained 571 systematic random and biased samples and analyzed them for radiological parameters by gamma spectroscopy. The analysis supported the conclusion that the mound was contaminated with Cs–137 and Co–60 waste from previously licensed activities at the base.

The Co–60 concentration varied between 1.6 and 187 pCi/g for the surface samples and from 0 to 330 pCi/g for sub-surface samples. The Cs–137 samples varied from 0.2 to 179 pCi/g for the surface samples and from 0 to 12 pCi/g for the sub-surface samples. One sample contained an individual Co–60 spec with a mass of 0.0043 grams and an activity of 243,000 pCi.

Pelham Range consists of approximately 22,000 acres of land west of the main post, which is located adjacent to Anniston, Alabama. One of the uses of the Pelham Range was as a radiological training area for simulated large area radioactive contamination (fallout) from the surface detonation of a small yield nuclear weapon. The training concept involved the raising and lowering of sealed radioactive sources. Students would then perform ground and aerial surveys to map the fallout pattern. This training occurred from the mid 1950s through May of 1973. The Army used locally fabricated Co–60 sources and higher activity commercially produced Cs–137 sources. A number of leaking locally fabricated Co–60 sources contributed to the formation of the burial mound.

The Army Base Closure and Realignment Committee has identified Fort McClellan as an installation for closure. The remediation of the burial mound is one of several radiological issues that must be resolved prior to the termination of the materials license and final base closure.

Proposed Action

The Army is proposing to collect the radiologically contaminated materials from the Pelham Range burial mound. The Army intends to remediate the site to the NRC criteria for unrestricted use delineated in 10 CFR 20, Subpart E, that

being 25 mrem/year TEDE to the critical group. For the Pelham Range site, this was modeled for a residential family (*i.e.,* the critical group) which occupies the land and operates it as a self-sustaining farm.

The Army modeled the future residential farm scenario using site specific environmental parameters to determine acceptable clean up levels using the Residual Radioactivity (RESRAD) computer code. The model calculated acceptable cleanup levels of 2.3 pCi/g of Co–60 and 9.2 pCi/g of Cs–137. These represent the maximum average acceptable contaminant levels that will meet the NRC's release criteria. In addition, the Army will operate under the concept of As Low As Reasonable Achievable (ALARA). After reviewing the site characterization data and considering the sensitivity of available field instrumentation, by applying ALARA, the predicted average concentrations after decommissioning will be approximately 0.1 pCi/g of Co–60 and approximately 0.1 pCi/g of Cs–137.

The general decommissioning outline is as follows:

1. Clear all brush from the burial mound area.
2. Reestablish the survey grid system.
3. Identify the contaminated areas within the remediation parameters.
4. Remove the soil/sand which contains the radioactivity.
5. Survey the area to ensure remediation was successful.
6. Remove any residual activity discovered after excavation.
7. Package and prepare radioactive material for shipment.
8. Complete the final survey of the remediated mound for release.
9. Ship radioactive material for disposal.

During the remediation process, the Army will obtain sufficient water samples to characterize the groundwater in the area to ensure that no contamination is present in the groundwater.

The Army plans to package and ship the radiologically contaminated material offsite to the Envirocare facility in Clive, UT. Envirocare is a licensed low-level waste disposal site. The Army will perform a 100-percent surface survey of the remaining soil in and around the Pelham Range burial mound.

The Army expects to generate approximately 392 cubic meters (498 cubic yards) of low-level radioactive waste that they will ship offsite for disposal. Roll-on, roll-off containers with hard covers and six mil plastic liners will be used for shipment to the disposal site. As each container is filled it will be readied for shipment. Each container will be covered and sealed before it leaves the site after the exterior surfaces are surveyed and found to be free of loose contamination.

The Army plans to transport the sealed containers by truck to the nearby rail spur. At the rail spur, the Army plans to load the containers onto railcars for transport to the Envirocare disposal facility, in Clive, Utah. The Army is committed to shipments complying with NRC and DOT package and shipping requirements.

The Army estimates that the maximum expected exposure rate on the exterior surface of the waste shipping containers will be 0.5 milliroentgen/hour (mR/hr); the maximum dose to the onsite worker from this proposed activity will be 0.03 millisieverts (mSv) [3 millirem (mrem)] and the maximum dose to a member of the public from the transportation of this material will be less than 0.01 mSv (1 mrem).

The Need for the Proposed Action

Fort McClellan is being closed under Base Relocation and Closure (BRAC) and will be turned over to the State of Alabama for unrestricted use. The proposed action is necessary to reduce residual contamination at the site to meet NRC's unrestricted release criteria.

Alternative to Proposed Action

The alternatives to the proposed action are releasing the area under a restricted release condition or taking no action.

The restricted release option under NRC guidelines would require the Army to implement institutional controls to limit the future land use for the decommissioned grounds. The intended future land use (and current use) is for training of Army National Guard troops. This training does and will include the use of tanks, which can disturb the contaminated area and lead to the spread of the contamination. The Army has decided that decommissioning the grounds to unrestricted release conditions would be a better and more cost effective approach.

Taking no action conflicts with NRC's requirement, in 10 CFR 40.42, of timely remediation at sites that have ceased NRC licensed operations. Although there is no immediate threat to the public health and safety from this site, not undertaking remediation, at this time, does not resolve the regulatory and potential long-term health and safety problems involved in storing this waste. No action now would delay remediation until some time in the future, when costs could be much higher than they are today. It is even possible that no disposal option will be available in the future if the current low-level radioactive waste disposal facilities are closed and no new ones are opened.

Environmental Impacts of Proposed Action

There are limited potential short-term environmental impacts associated with the proposed decommissioning activities. These include the potential release to the environment of airborne and liquid effluents, which may contain low levels of radioactive contamination during certain activities such as excavation, packaging, and waste transportation. NRC regulation 10 CFR Part 20 specifies the maximum allowable amounts of radioactive materials that a licensee can release from a site in the form of either airborne or liquid effluents.

The NRC will require the Army to comply with these regulations. The Army has established action levels that will ensure that effluent releases during decommissioning activities are below the levels allowed by Part 20.

The Army has committed to implementing a contamination monitoring and control program to detect and minimize the spread of contamination. Contamination monitoring will be accomplished by: (1) Performing all site remediation work under a Radiation Work Permit system, (2) conducting routine radioactivity surveys, (3) use of access controls to prevent inadvertent personnel access to contaminated areas, (4) use of personal protection, (5) surveying and decontaminating all personnel, equipment and vehicles before they leave the work site, and (6) employee training.

The Army will minimize the potential for airborne effluent releases by having a water truck available to suppress dust during activities that could generate significant quantities of dust. Activities that could generate significant quantities of dust include the excavation of the waste, processing and packaging of the waste, as well as during conveyor system screening and sampling operations. The Army will implement an environmental air monitoring program. Specifically, they will collect air samples in the breathing zone of workers during work that may produce airborne contamination, and they will position low volume air samplers downwind of the work area.

If airborne activities exceed 50-percent of the Derived Airborne Concentration (DAC) from Appendix B of the Code of Federal Regulations (CFR) Title 10, Part 20, the Army will:

(a) Implement dust-control measures;
(b) Cease all work activities;
(c) Investigate the cause for the airborne activity;
(d) Document all findings and measurements;
(e) Implement corrective actions before proceeding with decommissioning activities.

There are no expected adverse impacts to air quality as a result of planned decommissioning activities. There will a slight increase in dust emissions during the removal of the contaminated sand/soil; however, the burial mound is in a remote area of the installation and will not have an adverse impact on the ambient air quality. There is little likelihood that airborne radioactive material will be a problem on the range during any operation conducted for the remediation. The maximum general area dose rate for the Pelham Range Burial Mound is 11.7 uR/hour at 1-meter above ground. All Army site workers will wear personnel dosimetry devices. Based on the Army's calculations, the highest expected dose to an onsite worker is 30 mSv (3 mrem) (*i.e.,* 11.7 uR/hour x 250 worker-hours). The Army has determined that no immediate threat to public health and safety exists. The Army will monitor all potential exposure pathways, and exposure from each pathway will be kept as low as is reasonably achievable, during decommissioning activities.

Pelham Range workers not expected to receive an occupational dose as defined by 10 CFR 20.1502 and members of the public are expected to receive less than 10 mSv (1 mrem) from all exposure pathways as a result of decommissioning activities.

The proposed decommissioning action will have a positive environmental impact on the water quality in the area since low-level radioactive contamination will be removed from the soil above the aquifer. The Pelham Range Burial Mound is not located in the flood plain of any stream or river. There are no wetlands located in the project area. There will be no water bodies diverted in order to decontaminate the burial mound.

This action will not have an adverse impact on future land use. Ft. McClellan has used the Pelham Range Burial Mound to store the radioactive contamination for several years. The removal of the radioactive contaminated soil will be a beneficial environmental impact.

The radioactive material will be packaged, handled and stored according to the appropriate health and safety procedures. Packaging contaminated soil shall conform to Department of Transportation (DOT) regulations and the disposal site requirements. The Army will ship the waste in accordance with all DOT, State and Low Level Radioactive Waste Compact Commission regulations.

There will be no significant/prolonged periods of increased noise levels. The decommissioning activities will generate some elevated sound levels for a 6–8 week period. The elevated noise will come from the operation of heavy machinery and electrical generators. The noise from these activities is not expected to significantly impact the wildlife or the general public.

There is no adverse impact expected on cultural resources. The project will consist of the sampling and removal of radiologically contaminated materials that the Army placed in the mound within the past few decades. The likelihood of encountering any artifacts in the area is remote.

NRC staff conducted an evaluation of the potential for environmental justice issues due to low income populations. Based on the staff's evaluation, it is concluded that the Pelham Range site does not have an environmental justice potential because of its isolated location, there are no disproportionately high minority or low-income populations.

Agencies and Individuals Consulted

This environmental assessment was prepared by NRC staff and coordinated with the following agencies: the State of Alabama Department of Public Health, the U.S. Fish and Wildlife Service, and the Alabama Historical Commission. These agencies had no objection with the proposed action. No other sources were used beyond those referenced in this environmental assessment.

Conclusions

Decommissioning of the site to the cleanup levels proposed for this action will result in reduced residual contamination levels in the burial mound, enabling release of the area for unrestricted use and termination of the radioactive materials license. No radiologically contaminated effluents are expected during the decommissioning. Occupational doses to decommissioning workers are expected to be low and well within the limits of 10 CFR Part 20. No radiation exposure to any member of the public is expected, and public exposure will therefore also be less than the applicable public exposure limits of 10 CFR Part 20. Therefore, the environmental impacts from the proposed action are expected to be insignificant.

References

NRC, ''Radiological Criteria for License Termination'', 10 CFR Part 20, Subpart E, 62 FR 139, July 21, 1997
NRC, ''Multi-Agency Radiation Survey and Site Investigation Manual, (MARSSIM), NUREG–1575, December 1997
NRC, Draft ''Manual for Conducting Radiological Surveys in Support of License Termination'', NUREG/CR–5849, June 1992
NRC, ''Guidelines for Decommissioning of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for By-product, Source or Special Nuclear Material'', May 3, 1973
NRC, ''NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees'' March 1997
U.S. Army, Phase II, Burial Mound Decommissioning Plan, February 1999
U.S. Army, Draft Environmental Assessment For The Proposed Decommissioning of The Ft. McClellan Pelham Range Burial Mound, October 8, 1999

Finding of No Significant Impact

Pursuant to 10 CFR Part 51, NRC has prepared this EA in support of the proposed amendment related to the approval of the Army's Fort McClellan Pelham Range Burial Mound Remediation (Decommissioning) Plan. On the basis of the EA, the Commission has concluded that this licensing action will not significantly affect the quality of the human environment and has determined not to prepare an Environmental Impact Statement.

Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

The documents related to this proposed action are publicly available.

Opportunity for a Hearing

The NRC hereby provides notice that this is a proceeding on an application for amendment of a license falling within the scope of Subpart L ''Informal Hearing Procedures for Adjudication in Materials Licensing Proceedings,'' of NRC's rules and practices for domestic licensing proceedings in 10 CFR Part 2. Pursuant to § 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing in accordance with § 2.1205(a). A request for hearing must be filed within thirty (30) days of the date of publication of this **Federal Register** notice.

The request for a hearing must be filed with the Office of the Secretary either:

1. By delivery to the Docketing and Service Branch of the Secretary at One

White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738; or

2. By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Docketing and Service Branch.

In addition to meeting other applicable requirements of 10 CFR Part 2 of the NRC's regulations, a request for a hearing filed by a person other than the applicant must describe in detail:

1. The interest of the requester in the proceeding;

2. How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(g); and

3. The requester's areas of concern about the licensing activity that is the subject matter of the proceeding; and

4. The circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(c).

In accordance with 10 CFR 2.1205(e) each request for a hearing must also be served, by delivering it personally or by mail, to:

1. The applicant, U.S. Army Chemical School, Attn: ATSN–CM, 401 Engineer Loop, Ft. Leonard Wood, MO 65473–8928, Attention: Commandant; and

2. The NRC staff, by delivery to the Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or by mail, addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

For further details with respect to this action, the site decommissioning plan will be available for review on the NRC's Public Electronic Reading Room.

Dated at Atlanta, Georgia, this 18th day of December 2000.

For the Nuclear Regulatory Commission.

Douglas M. Collins,

Director, Division of Nuclear Materials Safety.

[FR Doc. 01–228 Filed 1–3–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATES: Weeks of January 1, 8, 15, 22, 29 and February 5, 2001.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of January 1, 2001

There are no meetings scheduled for the Week of January 1, 2001.

Week of January 8, 2001—Tentative

Tuesday, January 9, 2001

9:30 a.m.
Briefing on EEO Program (Public Meeting) (Contact: Irene Little, 301–415–7380)

Wednesday, January 10, 2001

9:25 a.m.
Affirmation Session (Public Meeting) (If needed)
9:30 a.m.
Briefing on Status of Nuclear Materials Safety (Public Meeting) (Contact: Claudia Seelig, 301–415–7243)
This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*.

Week of January 15, 2001—Tentative

Wednesday, January 17, 2001

9:25 a.m.
Affirmation Session (Public Meeting) (If needed)
9:30 a.m.
Briefing on Status of Nuclear Reactor Safety (Public Meeting) (Contact: Mike Case, 301–415–1134)
This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*.

Week of January 22—Tentative

There are no meetings scheduled for the Week of January 22.

Week of January 29—Tentative

Tuesday, January 30, 2001

9:30 a.m.
Briefing on Status of Nuclear Materials Safety (Public Meeting) (Contact: Claudia Seelig, 301–415–7243)
This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*.

Wednesday, January 31, 2001

9:25 a.m.
Affirmation Session (Public Meeting) (If needed)
9:30 a.m.
Briefing on Status of OCIO Programs, Performance, and Plans (Public Meeting) (Contact: Donnie Grimsley, 301–415–8702)
This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*.

Thursday, February 1, 2001

9:30 a.m.
Briefing on Status of OCFO Programs, Performance, and Plans (Public Meeting) (Contact: Lars Solander, 301–415–6080)
This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*.

Week of February 5, 2001—Tentative

There are no meetings scheduled for the Week of February 5, 2001.

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Bill Hill (301) 415–1661.

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/SECY/smj/schedule.htm*

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

Dated: December 29, 2000.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 01–350 Filed 1–2–01; 1:57 pm]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

The National Partnership Council, Notice of Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

TIME AND DATE: 1:30 p.m., January 11, 2001.

PLACE: OPM Conference Center, Room 1350, U.S. Office of Personnel Management, Theodore Roosevelt Building, 1900 E Street, NW., Washington, DC. The conference center is located on the first floor.

STATUS: This meeting will be open to the public. Seating will be available on a first-come, first-serve basis. Individuals with special access needs wishing to attend should contact OPM at the number shown below to obtain appropriate accommodations.

MATTERS TO BE CONSIDERED: Dr. Marick Masters, University of Pittsburgh, will present the findings of the NPC Research Project.

CONTACT PERSON FOR MORE INFORMATION: Jeff Sumberg, Director, Office of Labor and Employee Relations, Office of Personnel Management, Theodore Roosevelt Building, 1900 E Street, NW., Room 7H28, Washington, DC 20415–2000, (202) 606–2930.

Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 01–174 Filed 1–3–01; 8:45 am]

BILLING CODE 6325–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 24805; 812–12310]

Scudder Weisel Capital Entrepreneurs Fund and Scudder Weisel Capital LLC; Notice of Application

December 27, 2000.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 18(c) and 18(i) of the Act, under sections 6(c) and 23(c)(3) of the Act for an exemption from rule 23c–3 under the Act, and pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based distribution fees and early withdrawal charges.

APPLICANTS: Scudder Weisel Capital Entrepreneurs Fund (the ''Fund'') and Scudder Weisel Capital LLC (''Scudder Weisel'').

FILING DATES: The application was filed on October 24, 2000 and amended on December 26, 2000.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on January 18, 2001, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants, 88 Kearny Street, San Francisco, California, 94108.

FOR FURTHER INFORMATION CONTACT: Sara P. Crovitz, Senior Counsel, at (202) 942–0667, or Michael W. Mundt, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0101, (202) 942–8090.

Applicants' Representations

1. The Fund is a closed-end management investment company registered under the Act and organized as a Delaware business trust. Scudder Weisel is registered as an investment adviser under the Investment Advisers Act of 1940 and will serve as investment adviser to the Fund. Scudder Weisel also is registered as a broker-dealer under the Securities Exchange Act of 1934 and will distribute the Fund's shares. Applicants request that the order also apply to any other registered closed-end management investment company established in the future for which Scudder Weisel, or any entity controlling, controlled by, or under common control with Scudder Weisel acts as principal underwriter or investment adviser.[1]

2. The Fund's investment objective is to provide investors with long-term capital appreciation. The Fund seeks its objective by investing primarily in public and private equity securities of U.S. and non-U.S. companies.

3. The Fund intends to continuously offer its shares to the public at net asset value, plus any applicable sales charges. The Fund's shares will not be offered or traded in the secondary market and will not be listed on any exchange or quoted on any quotation medium. The Fund intends to operate as an ''interval fund'' pursuant to rule 23c–3 under the Act and to make quarterly repurchase offers to its shareholders.

4. The Fund currently intends to offer one class of shares, Class A shares, that will be sold with a front-end sales charge and will be subject to a shareholder services fee. Class A shares will not be subject to an early withdrawal charge (''EWC''). The Fund seeks the flexibility to be structured as a multiple-class fund and may in the future offer other classes of shares with different distribution structures, including shares with no front-end sales charge but with an EWC. Future classes of shares of the Fund may also be subject to an asset-based distribution fee. Applicants represent that shareholder services fees and asset-based distribution fees will comply with the provisions of rule 2830(d) of the Conduct Rules of the National Association of Securities Dealers, Inc. (''NASD Sales Charge Rule''). Applicants also represent that the Fund will disclose in its prospectus, the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multi-class funds under Form N–1A.

5. All expenses incurred by the Fund will be allocated among the various classes of shares based on the net assets of the Fund attributable to each class, except that the net asset value and expenses of each class will reflect distribution fees, service fees, and any other incremental expenses of that class. Expenses of the Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. The Fund may create additional classes of shares in the future that may have different terms from Class A shares. Applicants state that the Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

6. The Fund may waive the EWC for certain categories of shareholders or transactions to be established from time to time. With respect to any waiver of, scheduled variation in, or elimination of the EWC, the Fund will comply with rule 22d–1 under the Act as if the Fund were an open-end investment company.

7. The Fund may offer its shareholders an exchange feature under which shareholders of the Fund may, during the Fund's quarterly repurchase periods, exchange their shares for shares of the same class of other registered open-end investment companies or registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, and that are in the Scudder Weisel group of investment companies. Fund shares so exchanged will be counted as part of the

[1] Any registered closed-end investment company relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each investment company presently intending to rely on the requested relief is listed as an applicant.

repurchase offer amount as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act as if the Fund were an open-end investment company subject to that rule. In complying with rule 11a–3, the Fund will treat the EWC as if it were a contingent deferred sales charge (''CDSC'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Fund may be prohibited by section 18(c).

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Fund may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Fund to issue multiple classes of shares.

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit the Fund to facilitate the distribution of its securities and provide investors with a broader choice of shareholder services. Applicants assert that their proposal does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that the Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

5. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company will purchase securities of which it is the issuer, except: (i) on a securities exchange or other open market; (ii) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (iii) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

6. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shared at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act provides that an interval fund may deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is reasonably intended to compensate the fund for expenses directly related to the repurchase.

7. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased. As noted above, section 6(c) provides that the Commission may exempt any person, security or transaction from any provision of the Act, if and to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request relief under sections 6(c) and 23(c) from rule 23c–3 to permit them to impose EWCs on shares submitted for repurchase that have been held for less than a specified period.

8. Applicants believe that the requested relief meets the standards of sections 6(c) and 23(c)(3). Rule 6c–10 under the Act permits open-end investment companies to impose CDSCs, subject to certain conditions. Applicants state that EWCs are functionally similar to CDSCs imposed by open-end investment companies under rule 6c–10. Applicants state that EWCs may be necessary for Scudder Weisel to recover distribution costs. Applicants will comply with rule 6c–10 as if that rule applied to closed-end investment companies. The Fund also will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSCs. Applicants further state that the Fund will apply the EWC (and any waivers or scheduled variations of the EWC) uniformly to all shareholders in a given class and consistent with the requirements of rule 22d–1 under the Act.

Asset-based Distribution Fees

9. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitting under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

10. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to permit the Fund to impose asset-based distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of rules 6c–10, 11a–3, 12b–1, 17d–3, 18f–3, and 22d–1 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the NASD Sales Charge Rule, as amended from time to time.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–150 Filed 1–3–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–24806; 812–11374]

Nike Securities L.P., et al.; Notice of Application

December 28, 2000.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from section 26(a)(2)(D) of the Act.

SUMMARY OF APPLICATION: Applicants seek an order to permit certain unit investment trusts (''UITs'') to deposit trust assets in the custody of foreign banks and securities depositories.

APPLICANTS: Nike Securities L.P. (the ''Sponsor'') and FT Series (the ''Trust'').

FILING DATES: The application was filed on October 28, 1998 and amended on November 17, 2000.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 22, 2001, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, 1001 Warrenville Road, Lisle, IL 60532.

FOR FURTHER INFORMATION CONTACT: Sara P. Crovitz, Senior Counsel, at (202) 942–0667 or Nadya B. Roytblat, Assistant Director, at (202) 942–0693 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee at the SEC's Public Reference Branch, 450 5th Street, NW., Washington, DC 20549 (telephone (202) 942–8090).

Applicants' Representations

1. The Sponsor is a broker-dealer registered under the Securities Exchange Act of 1934. The Trust is registered under the Act and consists of several UITs registered or to be registered under the Securities Act of 1933 (the ''Trust Series''). Each Trust Series is created under the laws of the U.S. pursuant to a trust agreement that will contain information specific to that Trust Series and which will incorporate by reference a master trust indenture (the ''Indenture'') among the Sponsor, a bank (as defined in section 2(a)(5) of the Act), an evaluator, and a supervisor. Applicants request that any order granted pursuant to the application extend to any future UIT sponsored by the Sponsor or an entity controlling, controlled by, or under common control with the Sponsor (together with the Trust, the ''Trusts'' and their series, ''Trust Series'') and any bank which acts as trustee (a ''Trustee'') for any Trust Series.

2. Several Trust Series have investment objectives that specify the investment of assets in non-United States securities. To date, the existing Trust Series that invest in foreign securities have been able to deposit those securities in the custody of a foreign branch of a U.S. bank or with the securities clearance and depository facilities operated by Morgan Guaranty Trust Company of New York, in its capacity as operator of the Euroclear System (''Euroclear''), or with Central de Livraison de Valeurs Mobilieres, S.A. (''Cedel''), under an exemptive order granted to The Chase Manhattan Bank.[1] Future Trust Series may invest in foreign securities traded in countries (such as Australia, France, and New Zealand) that either are not eligible for settlement through Euroclear or Cedel or for which those depositories are not used in the ordinary course of settling transactions. Applicants therefore request an order to permit the Trust Series to deposit investments, including foreign currencies, for which the primary market is outside the United States and such cash and cash equivalents as reasonably necessary to effect the Trust Series' transactions in those investments (collectively, ''Foreign Investments''), with any foreign bank or securities depository subject to the requirements described below.

Applicants' Legal Analysis

1. Under sections 2(a)(5) and 26(a)(1) of the Act, the trustee of a UIT must be a bank that is subject to regulation by the U.S. government or one of the states. Section 26(a)(2)(D) also requires that the trust indenture provide that the trustee ''shall have possession of all securities and other property in which the funds of the trust are invested * * * and shall segregate and hold the same in trust * * * until distribution thereof to the security holders of the trust.'' Under these provisions, the only foreign entity that qualifies as a UIT custodian is an overseas branch of a U.S. bank.

2. Section 6(c) provides that the SEC may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of the Act or any rule or regulation under the Act if, and to the extent that, the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

3. Rules 17f–5 and 17f–7 under the Act govern the custody of assets of registered management investment companies overseas. Applicants seek an order under section 6(c) exempting them and any U.S. bank that acts as Trustee for any Trust Series from section 26(a)(2)(D) of the Act to the extent necessary to permit a Trustee to deposit Foreign Investments with an eligible foreign custodian as that term is defined in rule 17f–5 under the Act (''Eligible Foreign Custodian''), or eligible securities depository, as that term is defined in rule 17f–7 under the Act (''Eligible Securities Depository'').[2]

4. Under the proposed arrangements, a Trust Series would comply with all of the requirements of rule 17f–5, as amended on June 12, 2000, except that the Trustee would perform the duties that rule 17f–5 requires to be performed by the foreign custody manager, as that term is defined in rule 17f–5 (''Foreign Custody Manager''). Applicants state that the Trustee can fulfill the duties of a Foreign Custody Manager under rule 17f–5 to select an Eligible Foreign Custodian and monitor the foreign custody arrangements. Applicants also assert that the Trustee will have the necessary expertise and generally be in the best position to make the determinations required by rule 17f–5. Under the proposed arrangements, a Trust Series also would comply with all of the requirements of rule 17f–7, with the Trustee providing the risk analysis to the Sponsor, monitoring the custody risks associated with maintaining

[1] Investment Company Act Release Nos. 22000 (May 31, 1996) (notice) and 23186 (May 14, 1998) (order) and 21673 (Jan. 16, 1996) (notice) and 21751 (Feb. 16, 1996) (order).

[2] Applicants state that, although the compliance date for rule 17f–5, as last amended, and rule 17f–7 is July 2, 2001, they will comply with amended rule 17f–5 and rule 17f–7 upon the issuance of the requested order.

Foreign Investments with an Eligible Securities Depository on a continuing basis, and promptly notifying the Sponsor of any material change in these risks. Applicants also state that the Sponsor will be required to take appropriate action in response to a notification by the Trustee.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. The Indenture will contain provisions under which the Trustee agrees to indemnify the Trust Series against the risk of loss of Trust Series' Foreign Investments held with an Eligible Foreign Custodian in accordance with the foreign custody contract.

2. The Indenture will contain provisions under which the Trustee agrees to exercise reasonable care, prudence, and diligence such as a person having responsibility for the safekeeping of Trust Series assets would exercise, and to be liable to the Trust Series for any loss occurring as a result of the Trustee's failure to do so.

3. The Indenture will contain provisions under which the Trustee agrees to perform all the duties assigned by rule 17f–5, as now in effect or as it may be amended in the future, to a Foreign Custody Manager. A Trustees' duties under this condition will not be delegated.

4. The Indenture will contain provisions under which the Trustee agrees that it (or the Trustee's agent) will (i) provide the Sponsor with an analysis of the custody risks associated with maintaining assets with an Eligible Securities Depository; (ii) monitor the custody risks associated with maintaining assets with the Eligible Securities Depository on a continuing basis and promptly notify the Sponsor of any material change in these risks; and (iii) exercise reasonable care, prudence and diligence in performing the foregoing duties.

5. The Sponsor will be required to take appropriate action in response to a notification by the Trustee provided pursuant to condition 4 above.

6. The Trust Series' prospectuses will contain such disclosure regarding foreign securities and foreign custody as is required for management investment companies by Forms N–1A and N–2. The prospectus also will contain disclosure concerning the Sponsor's responsibilities pursuant to condition 5 above.

7. The Trustee will maintain and keep current written records regarding the basis for the choice or continued use of each foreign custodian. These records will be preserved for a period of not less than six years from the end of the fiscal year in which the Trust Series was terminated, the first two years in an easily accessible place. The records will be available for inspection at the Trustee's main office during the Trustee's usual business hours, by unitholders and by the Commission or its staff.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–215 Filed 1–3–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43775; International Series Release No. 1241; File No. 601–01]

Self-Regulatory Organizations; Morgan Guaranty Trust Company, Brussels Office, as Operator of the Euroclear System and Euroclear Bank, S.A.; Order Approving Application to Modify an Existing Exemption from Clearing Agency Registration

December 28, 2000.

I. Introduction

On September 21, 2000, Morgan Guaranty Trust Company of New York, Brussels office (''MGT-Brussels''), as operator of the Euroclear System,[1] and Euroclear Bank, S.A., (''Euroclear Bank'') filed with the Securities and Exchange Commission (''Commission'') an application on Form CA–1 [2] to modify an existing exemption from clearing agency registration (''Modification Application'') pursuant to section 17A of the Securities Exchange Act of 1934 (''Exchange Act'') [3] and Rule 17Ab2–1 thereunder.[4] The existing exemption enables MGT-Brussels as operator of the Euroclear System to perform the functions of a clearing agency with respect to transactions involving U.S. government agency securities for its U.S. participants subject to certain limitations without registering as a clearing agency.[5] The Modification Application substitutes Euroclear Bank for MGT-Brussels as operator of the Euroclear System. Notice of the application was published in the **Federal Register** on December 1, 2000.[6] No comment letters were received in response to the notice of filing of the Modification Application. This order grants the Modification Application.

II. Description

On February 11, 1998, the Commission approved an application by MGT-Brussels as operator of the Euroclear System for an exemption from registration as a clearing agency under section 17A (the ''1998 Exemption Order''). The 1998 Exemption Order granted MGT-Brussels as operator of the Euroclear System the authority to provide clearance, settlement, and collateral management services for its U.S. participants' transactions in: (i) Fedwire-eligible U.S. Government securities; (ii) mortgage-backed pass through securities that are guaranteed by the Government National Mortgage Association (''GNMAs''); and (iii) any collateralized mortgage obligation whose underlying securities are Fedwire-eligible U.S. Government securities or GNMA guaranteed mortgage-backed pass through securities and that are depository eligible securities collectively (collectively ''Eligible U.S. Government Securities'').

On January 1, 2000, the owners and operators [7] decided that MGT-Brussels would be replaced by Euroclear Bank as operator of the Euroclear System. In May 2000, Euroclear Bank was created. On July 27, 2000 the Belgian Banking and Finance Commission (''BFC'') granted Euroclear Bank a Belgian Banking license. MGT-Brussels will continue to operate the Euroclear System until the changeover, which is scheduled to occur on December 31, 2000. At the Changeover, the business and related assets and liabilities of the Euroclear System will vest in and

[1] MGT-Brussels presently operates the Euroclear System pursuant to an operating agreement with Euroclear Bank. The Euroclear System functions as a clearance and settlement system for internationally traded securities. Securities settlement through the Euroclear System can occur with other participants in the Euroclear System, with members of Clearstream, formerly Cedel Bank, societe anonyme, Luxembourg (''Clearstream''), or with counterparties in certain local markets that are not members of either the Euroclear System or Clearstream.

[2] Copies of the application for exemption are available for inspection and copying at the Commission's Public Reference Room.

[3] 15 U.S.C. 78q–1.

[4] 17 CFR 240.17Ab2–1.

[5] Securities Exchange Act Release No. 39643 (February 11, 1998), 63 FR 8232.

[6] Securities Exchange Act Release No 43592 (November 17, 2000), 65 FR 75324 (December 1, 2000).

[7] Copies of the application for amendment to exemption from registration as a clearing agency are available for inspection and copying at the Commission's Public Reference Room. See volume 2 of 9, exhibit S of the application for amendment to exemption for a description of the change in ownership structure of the Euroclear System.

virtually all of the MGT-Brussels staff will be transferred to Euroclear Bank.

As a result of the changeover, Euroclear Clearance System Public Limited Company (''Euroclear PLC''), a limited liability company organized under the laws of the United Kingdom, will own 58.5% of Euroclear Bank. Calar Investments, a wholly-owned subsidiary of Euroclear PLC, will own 35.5% of Euroclear Bank. The remaining five percent of Euroclear Bank will be owned by the former members of Euroclear Clearance System Societe Cooperative (the ''Cooperative''), the predecessor of Euroclear Bank.

III. Comment Letters

The Commission received no comment letters in response to the notice of filing of the Modification Application.

IV. Discussion

A. Statutory Standards

Under section 17A(b)(1) of the Exchange Act, the Commission may conditionally or unconditionally exempt any clearing agency or security or any class of clearing agencies or securities from any provisions of section 17A or the rules or regulations thereunder, if the Commission finds that such exemption is consistent with the public interest, the protection of investors, and the purposes of section 17A, including the prompt and accurate clearance and settlement of securities transactions and the safeguarding of securities and funds.[8]

In granting the 1998 Exemption Order, the Commission required the Euroclear System to be substantial compliance with section 17A and the rules and regulations.[9] Therefore, to approve the Modification Application, Euroclear Bank must demonstrate that the Euroclear System will continue to be in substantial compliance with Section 17A.

B. Evaluation of the Modification Application

Euroclear Bank will operate the Euroclear System in the manner currently operated by MGT-Brussels and employing the same personnel, operating systems, risk management and operating procedures as MGT-Brussels.

1. Safety and Soundness Protections

a. Financial Condition. Section 17A(b)(3) and (F) of the Exchange Act require a clearing agency to be organized and its rules be designed to facilitate the prompt and accurate clearance and settlement of securities transactions for which it is responsible and to safeguard securities and funds in its custody or control or for which it is responsible.[10] The Commission believes that the Euroclear System as operated by Euroclear Bank will substantially satisfy this standard.

Euroclear Bank's senior debt is expected to be rated at least AA by Fitch IBCA Limited and AA by S&P. Euroclear Bank's and Euroclear PLC's annual statements of financial condition will be made available to all shareholders and participants on a timely basis in accordance with local custom. The financial condition of each of the securities intermediaries through which it holds its positions in U.S. government and agency securities is similarly strong. Euroclear Bank's depositary bank in the United States is currently Chase Manhattan Bank. Its Tier 1 capital ratio was 8.5% as of March 31, 2000. S&P rated Chase's most recent offering of Class A Notes AAA and its offering of Class B Notes A−.

b. Operational Safeguards. A clearing agency must be organized in a manner that has established effective operational and audit controls while fostering director independence.[11] Euroclear Bank's personnel, systems, and procedures will essentially be the same as those of MGT-Brussels. Approximately 1300 MGT-Brussels personnel, representing all but 11 people in the entire MGT-Brussels workforce currently working at the Euroclear Operations Centre are expected to continue to be employed by the Euroclear Bank.

Further Euroclear Bank will continue the following operational safeguards:

(1) Euroclear Bank will have an audit committee comprised entirely of three to four outside directors. There will be a direct reporting line from the internal audit division to the audit committee as recommended by the Basel Committee.

(2) Euroclear Bank will have a separate audit division that will be responsible for the internal audit process.[12]

(3) PricewaterhouseCoopers has agreed to continue to act as the independent auditors of Euroclear Bank and, as such, will conduct an audit of Euroclear Bank's annual report and perform an annual review of Euroclear Bank's internal controls, policies and procedures in accordance with SAS–70 guidelines.

(4) Euroclear Bank will take over MGT-Brussels' data centers and contingency recovery facilities.

c. Regulatory Oversight. Euroclear Bank will be subject to the comprehensive supervision on a consolidated basis by the BFC. The BFC is primary regulator of credit institutions in Belgium. It is responsible for ensuring that credit institutions satisfy the authorization requirements and operating criteria of Belgium banking laws and regulations. Any credit institution wishing to operate in Belgium must be licensed by the BFC. In addition, any depositary bank through which U.S. government and agency securities would be held by Euroclear Bank would similarly be subject to the comprehensive supervision of the Federal Reserve Board or some other U.S. Federal bank regulatory agency.

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[8] 15 U.S.C. 78q–1(b)(1).

[9] Section 17A(b)(3) of the Exchange Act requires that the Commission make a number of determinations with respect to the clearing agency's organization, capacity, and rules. 15 U.S.C. 78q–1(b)(3). See also Section 19 of the Exchange Act, 15 U.S.C. 78s, and Rule 19b–4, 17 CFR 240.19b–4, setting forth procedural requirements for registration and continuing Commission oversight of clearing agencies and other self-regulatory organizations. The Commission has published the standards applied by its Division of Market Regulation in evaluating applications for clearing agency registration. Securities Exchange Act Release No. 16900 (June 17, 1980), 45 FR 41920 (Standards Release). These requirements are designed to assure the safety and soundness of the clearance and settlement system.

The 1998 Exemption Order provided that the Commission could modify the terms, scope, or conditions of the exemption from registration if the Commission determines that the modification is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act.

[10] In the 1998 Exemptive Order the Commission relied on MGT-Brussels' representations that its financial condition, operational safeguards, and the extent to which it is already subject to substantial U.S. regulatory oversight because Morgan Guaranty Trust Company of New York, the entity which is ultimately fiscally responsible for MGT-Brussels' operations, was a U.S. bank that was ''well capitalized'' and ''well managed'' as those terms are defined under applicable U.S. Federal Banking regulations. 1998 Exemptive Application at 26837 and 26838.

[11] Standards Release, supra note 9 at 45 FR 41925–26. As described in the 1998 Exemptive Order, the Commission was satisfied that MGT-Brussels' organizational and processing capacity substantially satisfied the Exchange Act requirements because MGT-Brussels' internal organizational structure, including its system of internal and external audit, is reasonably designed to provide the necessary flow of information to Morgan Guaranty Trust Company of New York's board of directors.

[12] The internal audit process of Euroclear Bank will, like that of MGT-Brussels, be based on a risk assessment methodology. Review of the participant, product, market and service dimensions of the Euroclear business, including technology infrastructure, will continue to be considered in this risk driven approach. Internal audit procedures will include tests, which are designed to independently assess the strengths and weaknesses of Euroclear Bank's control environment. The audit division will determine the scope of its audits independently of management and will report directly to the Managing Director and General Manager. Periodic reports will also be made to the audit committee.

d. Financial Risk Management. The Standards Release states that a clearing agency should establish a clearing fund and promulgate rules to assure an appropriate level of contributions in accordance with, among other things, the risks to which the clearing agency is subject for the protection of clearing agency participants and for the national system for clearance and settlement. Euroclear Bank will not have a clearing fund, but will have a separate risk management department that is responsible for identifying and controlling the risks of operating a multicurrency, cross-border clearance and settlement system.[13] The risk management department reports to the Chief Financial Officer. Euroclear Bank expects to maintain insurance coverage similar to that of MGT-Brussels with respect to securities at rest or in transit against risk of physical loss or damage, including securities held on the premises of its depositories, as well as fraudulent securities. It is also anticipated that Euroclear Bank will add new insurance coverage for operational errors. Euroclear Bank will take over MGT-Brussels' information technology division, with the same systems and the same personnel as MGT-Brussels, which will be in charge of the development and maintenance of its information technology infrastructure.

2. Fair Representation

Section 17A(b)(3)(C) of the Exchange Act requires that the rules of a clearing agency provide for fair representation of the clearing agency's shareholders or members and participants in the selection of the clearing agency's directors and administration of the clearing agency's affairs. This section contemplates that users of a clearing agency have a significant voice in the direction of the affairs of the clearing agency.[14]

The conversion of the Cooperative into Euroclear Bank did not change the participation rights of the Cooperative's 1,248 participant institutions. However, since the change of corporate form, Euroclear Bank participants will not automatically become shareholders. To become a shareholder, a new participant will have to purchase shares from current shareholders in Euroclear Bank or in PLC. Euroclear participants will be represented on the boards of Euroclear Bank and Euroclear PLC. Board members will be nominated from Euroclear participant organizations representing various financial sectors and geographical regions.

E. Participation Standards

Section 17A(b)(3)(B) of the Exchange Act enumerates certain categories of persons that a clearing agency's rules must authorize as potentially eligible for access to clearing agency membership and services. Section 17A(b)(4)(B) of the Exchange Act contemplates that a registered clearing agency have financial responsibility, operational capability, experience, and competency standards that are used to accept, deny, or condition participation of any participant or any category of participants enumerated in section 17A(b)(3)(B), but that these criteria may not be used to unfairly discriminate among applicants or participants. In addition, the Exchange Act recognizes that a clearing agency may discriminate among persons in the admission to or the use of the clearing agency if such discrimination is based on standards of financial responsibility, operational capability, experience, and competence.[15]

Euroclear Bank's standards for the admission of participants will be similar to those applied in the past. Consistent with section 17A(b)(4), any broker-dealer, clearing agency, investment company, bank, insurance company or other professional investor that demonstrates it meets certain financial and operational criteria may become a Euroclear participant. The applicant also must demonstrate the ability to maintain these financial and operational standards on an on-going basis. They must demonstrate that they have both the personnel and technological infrastructure to meet the operational requirements of the Euroclear System. They must show that they expect to derive material benefit from direct access to Euroclear and that they are reputable firms.

IV. Scope of Modification Application

This order modifies the 1998 Exemption Order by replacing MGT-Brussels with Euroclear Bank as operator of the Euroclear System.

1. Volume Limits

The volume limitations in the 1998 Exemption Order are unchanged. Specifically, the average daily volume of eligible U.S. government securities processed through Euroclear Bank as operator of the Euroclear System may not exceed five percent of the total average daily dollar value of the aggregate volume in eligible U.S. government securities.

2. Commission Access to Information

To continue to facilitate the Commission's monitoring of the operation of the Euroclear System's under the 1998 Exemption Order, Euroclear Bank will continue to provide the Commission with quarterly reports, calculated on a twelve-month rolling basis, of (1) the average daily volume of transactions in eligible U.S. government securities for U.S.participants that are subject to the volume limit as described in Section IV.C.2 of the 1998 Exemption Order and (2) the average daily volume of transactions in eligible government securities for all Euroclear System participants, whether or not subject to the volume limit as described in Section IV.C.2 of the 1998 Exemption Order.[16]

The Commission will require the execution of a satisfactory Memorandum of Understanding (''MOU'') with the BFC, Belgium banking and securities regulatory, to facilitate the provision of information by Euroclear Bank to the Commission. In addition, the Commission will monitor Euroclear Bank through review of information provided by to the BFC by Euroclear Bank and its external auditors.[17]

[13] The Euroclear System as operated by MGT-Brussels does not maintain a clearing fund. However, MGT-Brussels employed various financial and operational risk management mechanisms. In the 1998 Exemption Order, the Commission found that MGT-Brussels' rules and procedures and the methods substantially satisfied the requirements of the Exchange Act.

[14] Participants of the Euroclear System operated by MGT-Brussels did not have the right to appoint the directors of Morgan Guaranty Trust Company of New York. However, they could become members of the Cooperative and could use this membership to influence the range of MGT-Brussels services and the level of fees charged by MGT-Brussels. The board of directors of the Cooperative consisted of 23 members that were nominated from Euroclear's participant organizations representing various financial sectors and geographic regions. In the 1998 Exemption Order, the Commission found that the method in which the Cooperative's directors are selected and interact with Euroclear's management adequately addresses the requirements of Fair Representation under section 17A(b)(3)(C) of the Exchange Act.

[15] Because each of the enumerated categories of participants was eligible for Euroclear system membership and because Euroclear has accepted a wide range of participants based upon its standards of financial responsibility, operational capability, experience and competence, the Commission was satisfied that MGT-Brussels' participants standards adequately address the requirements of Section 17A of the Exchange Act.

[16] Euroclear Bank also continues to agree to provide information to the Commission as described in the 1998 Exemption Order.

[17] As described in the 1998 Exemption Order, MGT-Brussels is a division of the foreign branch of a U.S. bank and accordingly is subject to the comprehensive supervision and regulation of the Federal Reserve Bank of New York. Because there will be no similar U.S. regulation of Euroclear Bank, the Modification Application is contingent upon the execution of a satisfactory MOU with the BFC to facilitate the provision of information by Euroclear Bank to the Commission.

3. Modification of Order

The Commission may modify by order the terms, scope, or conditions of Euroclear's exemption from registration as a clearing agency granted to Euroclear Bank as operator of the Euroclear System if the Commission determines that such modification is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act.[18] Furthermore, the Commission may limit, suspend, or revoke this exemption if the Commission finds that Euroclear Bank has violated or is unable to comply with any of the provisions set forth in this order if such aciton is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act for the protection of investors and the public interest.

V. Conclusion

The Commission finds that the application by MGT-Brussels and Euroclear Bank to modify the exemption from registration as a clearing agency for Euroclear Bank as operator of the Euroclear System meets the standards and requirements deemed appropriate for such an exemption.

It is Therefore Ordered, pursuant to section 19(a)(1) of the Exchange Act, that the Modification Application to modify the exemption from registration as a clearing agency filed by MGT-Brussels and Euroclear Bank (File No. 601–01) be, and hereby is, approved subject to the conditions contained in this order.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–216 Filed 1–3–01; 8:45 am]

BILLING CODE 8010–01–M

[18] The exemption provided by this order is based upon representations by Euroclear Bank, its officers and attorneys, facts contained in Euroclear Bank's Modification Application, and other information known to the Commission regarding the substantive aspects of Euroclear Bank's proposal (collectively, ''representations and facts''). In addition, as described in the 1998 Exemption Order, Euroclear Bank, like MGT-Brussels, will be required to file with the Commission amendments to its application for exemption on Form CA–1 if it makes any fundamental change affecting its clearance and settlement business with respect to eligible U.S. government securities. Any changes in the representations or facts as represented to the Commission may require a modification of this order. Responsibility for compliance with all applicable U.S. securities laws rests with Euroclear Bank and its U.S. participants, as appropriate. Euroclear Bank also is advised that this order does not exempt Euroclear Bank from the anti-fraud or anti-manipulation provisions of the Exchange Act or any of the rules promulgated thereunder.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43766; File No. SR–BSE–00–13]

Self-Regulatory Organizations; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval to Amendments No. 2 and 3 to the Proposed Rule Change by the Boston Stock Exchange, Inc. to Issue Electronic Trading Permits for BEACON Remote Units

December 22, 2000.

I. Introduction

On September 21, 2000, the Boston Stock Exchange, Inc. (''BSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') 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 that would add rules regarding the issuance of Electronic Trading Permits (''ETPs'') to specialists and registered floor clerks of Exchange members for remote specialist operations. The ETPs will allow Exchange members access to the BEACON trading system from remote locations using authorized terminals and related equipment. The proposed rule change was published for comment in the **Federal Register** on October 12, 2000.[3] No comments were received on the proposal.

The Exchange filed Amendment No. 2 to the proposed rule on December 4, 2000 and on December 21, 2000, the Exchange filed Amendment No. 3. This order approves the proposed rule change and grants accelerated approval to Amendments No. 2 and 3 of the proposed rule change. The Commission is also soliciting comments on Amendments No. 2 and 3.

II. Description of the Proposal

In August 2000,[4] the Commission approved the Exchange's remote specialist program that generally permitted Exchange specialists to conduct regular trading activities off the Exchange's trading floor using the BEACON trading system. The Exchange's pending filing supplements its remote specialists filing. As noted by the Exchange, it is proposing to issue ETPs primarily as a surveillance tool to monitor its remote specialists operations.[5]

The Exchange proposes to add paragraph (o) to Chapter XXXIII, Section 9, *BEACON Remote,* to require and establish guidelines for Electronic Trading Permits (''ETP'') for remote specialist operations. Each BEACON Remote terminal will be individually identified and associated with (an) authorized and qualified specialist(s) and/or registered clerk(s). The Exchange will specifically authorize and approve each ETP based on certain qualifications. Each ETP will provide remote access to the BEACON system from remote locations using authorized terminals and related equipment. The ETP is in addition to the membership requirements, and even a specialist who holds a membership will be required to hold an ETP. Each Beacon remote specialist operation still requires a membership in the Exchange notwithstanding the ETP requirements. According to the Exchange, the ETP's are non-transferable permits that will be primarily used for surveillance purposes.[6]

The Exchange states that remote specialists and associated registered clerks with ETPs, like current Exchange floor specialist units, will receive orders, commitments over the Intermarket Trading system (''ITS'') and administrative messages through the BEACON system. The existing Exchange systems and rules will support remote specialists as they currently support the physical trading floor. As noted above, the BSE has also adopted specific rules applicable to remote specialist operations. All executions occurring within BEACON, whether conducted on the floor or electronically from remote locations, will be considered to be executions occurring on the Exchange.

The proposal, among other things, requires that all registered specialists and clerks complete a floor-training program, unless waived as discussed below, as well as successfully complete a BSE floor examination and the Series 63 (NASAA Uniform State Law Exam).[7]

[1] 15 U.S.C. 78s(b)(1). This notice incorporated typographical changes made by the Exchange in letter Amendment No. 1 filed September 29, 2000.

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 43394 (September 29, 2000), 65 FR 60705.

[4] Securities Exchange Act Release No. 43127 (August 14, 2000), 65 FR 49617.

[5] The approval order was conditioned on the Exchange putting into place specific information barrier policies and surveillance policies that are consistent with the Exchange's existing rules and that are acceptable to the Commission's Office of Compliance Inspections and Examinations (''OCIE''). *Id.* at 49620. Nothing herein is intended to change the requirement that the Exchange get its surveillance plan approved by OCIE.

[6] See Letter from John A. Boese, Assistant Vice President, to Madge Hamilton, Division of Market Regulation, Commission, dated December 1, 2000 (''Amendment No. 2'').

[7] The proposal originally allowed the floor examination to be waived. Amendment No. 3

Amendment No. 2 clarified when the two week on-floor training requirement could be waived for ETP applicants. Training would be waived for current floor specialists and registered clerks who transfer to remote specialist operations. The two week on-site floor training period could also be waived for other people in exceptional circumstances, if other arrangements are made with and approved by the Exchange. In such exceptional circumstances, a waiver will only be permitted if the Exchange is assured that the person requesting the waiver has made other arrangements that ensure that the person meet all of the training requirements listed in the BSE proposal.[8] However, the two week on-site floor training period could not be waived for easily remedied reasons such as geographical location or inconvenience. Furthermore, Amendment No. 2 clarified that a registered clerk in a remote specialist operation, who qualified for an ETP, would be operating under the direct supervision of a registered specialist, just as a registered clerk is supervised in the on-floor environment.

III. Discussion

The Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act[9] and section 11A of the Act.[10] Section 6(b)(5) of the Act[11] requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Section 11A of the Act promotes, among other things, the development of a national market system for securities to assure economically efficient execution of securities transactions and fair competition among brokers and dealers, among exchange markets and markets other than exchange markets.[12]

After having carefully reviewed the proposal, the Commission finds that the proposed rule is designed to protect investors and the public interest by permitting the Exchange to better surveil the activities of specialists and registered clerks that utilize the BEACON remote access system.[13] The Commission also finds for the same reasons that the proposed rule is designed to promote just and equitable principles of trade.

Each BEACON Remote terminal will be specifically identified and associated, by the use of the ETP, with an authorized and qualified specialist or registered clerk.[14] Any activity taking place on each terminal will be directly attributable to an individual specialist or registered clerk. According to the Exchange, the ETP is a necessary device which should assist it in attempting to replicate the visual surveillance of user terminals on the Exchange floor.

Although BEACON Remote registered clerks will be required to obtain an ETP, there is nothing in the ETP which will grant them any more rights or privileges than a current on-floor registered clerk possesses. Registered clerks will be under the direct physical supervision of a specialist at all times. It should also be noted that if an ETP registered clerk were to leave a firm a new ETP application would be required for a new clerk.

Under the Exchange's proposal, ETPs must be approved by the Exchange. In addition, each specialist unit must have a registered seat assigned to it and meet certain other requirements to issue an ETP, such as completion of the required floor training program; successful completion of the Exchange floor examination within 90 days of application; successful completion of the Series 63 (NASAA Uniform State Law Exam) and registrations with the Commonwealth of Massachusetts; and submission of fingerprint records to the Exchange. The Commission generally believes that the ETPs should provide the BSE with an adequate monitoring tool for remote operations. In addition, the training and examination requirements should help to ensure that remote specialists are adequately trained to operate from a remote location.

The proposed rule requires all specialists to complete a floor training program.[15] Under the Exchange's rule, there is a mandatory two-week training period required of all ETP applicants. This two week training period would be waived for current on floor specialists and registered clerks who transfer to remote specialist operations. The Commission believes this waiver is reasonable because these on-floor specialists and registered clerks already have had the required training.

The rule also allows for a waiver of the floor training requirement in exceptional circumstances if other arrangements are made with and approved by the Exchange. The BSE may only grant the waiver if it is assured that the person requesting the waiver has made other arrangements that ensure the person meets all of the specific training requirements designated in the BSE rule. The rule also states that the on-floor training period will not be waived for easily remedied reasons such as geographical location or inconvenience. The BSE stated, however, that there may be other situations whereby the Exchange may deem it appropriate to accept an alternative training venue or program. In justification for this waiver the Exchange has stated that it does not want to limit itself from considering other circumstances which may arise in the future, which could delay or prevent a firm from commencing or conducting business.

While the Commission would be extremely concerned about waivers of appropriate training, it appears that the Exchange has drafted its rule narrowly to only deal with exceptional circumstances. Further, the rule specifically requires anyone receiving a waiver to be appropriately trained and

deletes the provision that permitted this waiver. BSE notes that this deletion will ensure the remote specialist examination requirements are consistent with the floor examination requirements for on-floor specialists and registered clerks. These requirements currently do not permit waivers.

[8] The on-site floor training includes, among other things: communication procedures with Floor Brokers, Front Desk Operations, Surveillance, Systems Support, and ITS coordination with the Floor; Competing Specialist Initiative and Unlisted Trading Privilege applications and procedures, stock allocation procedures; trading halt procedures; and books and records/reports available.

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78k(a)(1)(B).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78k–1.

[13] In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[14] The Commission notes that the Exchange's ETPs are separate and distinct from other trading permits that the Commission has previously reviewed. The Exchange's ETP will be a non-transferable permit which will be used primarily for surveillance purposes, by allowing the BSE to identify each BEACON terminal with an individual specialist or registered clerk. Each BEACON Remote Specialist operation requires a membership in the Exchange. Therefore, only specialists and registered clerks who work for a member can be issued an ETP. The ETP is in addition to the membership requirement of the Exchange. The Exchange notes that the ETP does not constitute membership on the Exchange, nor does it carry with it any of the benefits or responsibilities of membership. Accordingly, the ETPs do not raise the same fair representation issue that have been at issue with other trading permits that confer certain membership rights to non-members.

[15] This requirement is in concert with the two-week training program mandated in BEACON Remote rule for specialists specifically (see Chapter XXXIII, BEACON, Section 9, BEACON Remote, Commentary).

meet all the training requirements.[16] Accordingly, the Commission has decided to approve this portion of the Exchange's proposal. The Commission, however, requests the Exchange to carefully monitor the use of exceptional waivers to ensure they are only used in accordance with the standards in the rule.

The Commission also finds that the proposed rule should assist the Exchange in promoting economically efficient execution of securities transactions and fair competition consistent with section 11A of the Act.[17] The proposed rule is designed to support remote access of the BEACON trading system. Each specialist unit identified by the member firm will be assigned an account (''give up'') and will be evaluated under the Exchange's Specialist Performance Evaluation Program, which currently measures performance in several separate categories comprising a relative overall performance ranking. This provision, along with other provisions of the proposed rule, should assist the Exchange in efficient and effective market operations.

In summary, the Commission believes that the issuance of ETPs under the requirements outlined above should aid and support the development of the Exchange's remote specialists operation. All of the requirements in the remote specialists rules will remain in place and must be followed. As noted above, the ETPs are not intended to transfer any specialist membership or trading rights but are primarily a surveillance tool. In addition, remote specialists and registered clerks are not permitted to do anything different from Exchange specialist units operating on the floor. Based on the above, the Commission believes the proposal should be approved consistent with the Act.

The Commission finds good cause for approving Amendments No. 2 and 3 prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. Amendment No. 2 clarifies when BSE may waive the required two week on-floor training for ETP applicants. In addition, Amendment No. 2, clarifies that a registered clerk in a remote specialist operation, who has qualified for an ETP, will be operating under the direct supervision of a registered specialist, just as a registered clerk is supervised on the floor of the Exchange. Amendment No. 3 deletes the privison that permitted BSE to waive the floor examination requirement for BEACON Remote specialists. Both Amendments clarify and strengthen BSE's proposal. In addition, the Amendments modify the proposal to make it consistent with other BSE rules. Those Amendments did not change the underlying nature of the original proposal that was noticed for comment, and for which no comments were received. Based on the above the Commission believes that good cause exists, consistent with section 6(b)(5) [18] and 19(b)(2) [19] of the Act, to accelerate approval of Amendments No. 2 and 3.

III Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendments No. 2 and 3, including whether it is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 at the Commission's Public Reference Room. 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 file number SR–BSE–00–13 and should be submitted by January 25, 2001.

V. Conclusion

It is Therefore Ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change SR–BSE–00–13, including Amendments, No. 1, No. 2 and No. 3, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[20]

Jonathan G. Katz,

Secretary.

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BILLING CODE 8010–01–M

[16] *See supra* note 8.

[17] 15 U.S.C. 78k–1.

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43768; File No. SR–NASD–00–74]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval on a Temporary Basis Until January 31, 2001 of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to EWN II Fees for Subscribers Who Are Not NASD Members

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 14, 2000, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of Terms of Substances of the Proposed Rule Change

The National Association of Securities Dealers, Inc. (''NASD''), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq'') is herewith filing a proposed rule change to increase the fees associated with the Enterprise Wide Network II (''EWN II'') to pass on costs related to increasing its capacity. The proposed rule change is intended to amend the current fee schedule for subscribers who are not members of the NASD. Nasdaq is filing a parallel rule filing to effect the same amendments to the EWN II fee structure to apply to NASD members. Below is the text of the proposed rule change. Proposed new language is underlined; proposed deletions are in brackets.

NASD Rule 7010. System Services

(a)–(e) No Change

(f) Nasdaq Workstation Service

(1) No Change

(2) The following charges shall apply to the receipt of Level 2 or Level 3 Nasdaq Service via equipment and communications linkages prescribed for the Nasdaq Workstation II Service:

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Service Charge: [$1,500]*$1,875/*month per service delivery platform (''SDP'') *from December 1, 2000 through February 28, 2001*; *$2,035/month per SDP beginning March, 1, 2001.*

Display Charge: $525/month per presentation device (''PD'').

Additional Circuit/SDP Charge: [$2,700] *$3,075/*month *from December 1, 2000 through February 28, 2001, and $3,235/month beginning March 1, 2001.**

A subscriber that accesses Nasdaq Workstation II Service via an application programming interface (''API'') shall be assessed the Service Charge for each of the subscriber's SDPs and shall be assessed the Display Charge for each of the subscriber's API linkages, including an NWII substitute or quote-update facility. API subscribers also shall be subject to the Additional Circuit/SDP Charge.

*No change to footnotes

* * * * *

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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange 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

1. Purpose

The purpose of this filing is to amend the subscriber fees applicable to subscribers to Nasdaq Workstation II (''NWII'') who are not NASD members.

In 1994, Nasdaq rolled out the NWII service, which provided many enhancements to the then-existing Nasdaq Workstation service.[3] As part of the NWII rollout, Nasdaq installed a network, known as the Enterprise Wide Network (''EWN I''), to delivery NWII functionality. To access NWII service, each subscriber location has at least one service delivery platform (''SDP'') or server, that resides on the network and connects to Nasdaq by a dedicated circuit. The SDP functions as the subscribers gateway from the NWII to the enterprise wide network. Each SDP currently is permitted to support up to eight presentation devices (''PD''), or Nasdaq Workstation IIs, although a firm may elect to have fewer than eight PDs on a single SDPl In addition, a subscriber may obtain NWII service through an application programming interface (''API''), which essentially allows a firm to obtain NWII Service using the firm's own hardware (*e.g.,* personal computer) and software systems to access, display, interface with, and operate NWII service.

Due to the ongoing growth in the Nasdaq market and increases in daily share volume after EWN I was installed,[4] Nasdaq became concerned in 1997 that its existing enterprise wide network capacity was rapidly approaching maximization. Specifically, the network's bandwith—the amount of data that can be transmitted through a given communications circuit in a fixed amount of time—could only handle one one-half billion shares per day. EWN I was expected to reach maximum circuit capacity during the second quarter of 1999.[5] To avoid the potential for any disruption to the Nasdaq market, Nasdaq contracted in late 1997 with MCI Communications Corporation (''MCI'') to build a new network—EWN II—to accommodate increased usage and provide increased circuit capacity.

According to Nasdaq, EWN II is a significant improvement over EWN I. Among other things, the system is fully scaleable and twice as fast as EWN I. The network was originally built with a 128 kilobit (''kb'') data stream feed speed scaleable up to T1 speed (1544 kilobits) levels. Nasdaq began converting subscribers to EWN II in 1998 and completed the conversion in 1999. In conjunction with the conversion, the Nasdaq filed fee increases which became effective in 1998, relating to EWN II.[6]

Since that time, Nasdaq share volume has continued to increase dramatically. The highest average daily share volume for a month in 2000 was just over 2 billion shares, compared to less than 1.5 billion in 1999, and less than 1 billion in 1998. The highest peak share volume day in 2000 was just under 3 billion shares, compared to under 2 billion in 1999, and just over 1 billion in 1998. The highest actual cumulative share volume for a month occurred twice in 2000 at over 40 billion shares, compared to over 30 billion in 1999, and almost 20 billion in 1998. In March 2000, share volume increased by over 103% compared to March 1999. In April 2000, the peak share volume increased by over 103% compared to April 1999.

To accommodate these increases, Nasdaq expanded the EWN II bandwidth from 128 kb to 192 kb in October 2000. The expanded bandwidth also gives Nasdaq the ability to support new products as they are introduced and future trading applications that will be developed. As a result of expansion to a 192 kb bandwidth, the fees that WorldCom[7] charges Nasdaq have increased by $375 per month per circuit. Nasdaq proposes on these costs to subscribers for the billing period covered by December 1, 2000 through February 28, 2001.

In order to accommodate additional increases in volume expected to accompany decimalization, Nasdaq will expand EWN II bandwidth to 256kb, and consequently, the fees that WorldCom changes Nasdaq will increase by an additional $160 per month per circuit. As of December 2000, Nasdaq projects that decimalization in penny increments will significantly increase the number of quote updates, such that on high volume days, a 192 kb bandwidth would be inadequate to support quote traffic. Therefore, Nasdaq proposes to pass on the costs associated with the increase to a 256 kb bandwidth effective March 1, 2001.

Under the proposal, the fee charges to a subscriber for an SDP would increase from $1,500 per month for each server to $1,875 per month for December 1, 2000 through February 29, 2001, and then to $2,035 per month, beginning March 1, 2001. The charge for an additional circuit would increase from $2,700 per month to $3,075 per month from December 1, 2000 through February 28, 2001, and then increase again on March 1, 2001 to $3,235 per month.[8]

[3] NWII provides a windows-based environment and several data management facilities not previously available in Nasdaq's former (pre-1994) workstation service.

[4] When Nasdaq installed EWN I, Nasdaq's average daily share volume (for 1994) was 295 million and projections showed that the average daily share volume for 1997 would be 520 million. In 1997, however, average daily share volume was 650 million.

[5] Similar to any other private network, EWN I was designed to have a maximum circuit capacity (*i.e,* 2, 100 circuits).

[6] *See* Securities Exchange Act Rel. Nos. 40434 (Sep. 11, 1998), 63 FR 49937, and 40716 (Dec. 2, 1998), 63 FR 66619.

[7] MCI and WorldCom merged in September 1998.

[8] As noted above, a T1 circuit supports up to six SDPs, and an SDP supports up to eight PDs. A subscriber will be subject to the additional circuit charge when the subscriber has not maximized capacity on its SDPs by placing eight PDs and/or API servers on an SDP; in such case, the NASD/Nasdaq will charge the additional circuit charge for those ''underutilized'' SDPs (the difference between the number of SDPs a subscriber has and the number of SDPs the subscriber would need to support its PDs and/or API servers, assuming an

Continued

Although NASD Rule 7010(f)(2) generally applies to both members and non-member subscribers to NWII service, this filing will only effect a change to the fees charged to subscribers who are not NASD members. Nasdaq is filing a separate but virtually identical rule change to impose the proposed new fees on NASD members.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A(b)(5) of the Act,[9] which requires that the rules of the NASD provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. The proposed fees, which will only apply to those who utilize NWII service, simply pass on the costs associated with increasing the capacity of EWN II to keep pace with volume increases. Ensuring adequate capacity is absolutely essential to protecting the integrity of the Nasdaq market, maintaining the confidence of the investing public, and preparing for decimalization.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Member, Participants or Others

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–NASD–00–74 and should be submitted by January 25, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission has reviewed the Nasdaq's proposed rule change and finds, for the reasons set forth below, that the proposal is consistent with the requirements of section 15A of the Act[10] and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission believes the proposal is consistent with sections 15A(b)(5) of the Act.[11] Section 15A(b)(5) requires that the rules of a registered securities association provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the association operates or controls. The above fee increases proposed by Nasdaq pass on the costs associated with increasing the capacity of EWN II to users of the NWII service. The Commission believes that such a fee increase, necessitated by recent system volume increases is a reasonable means by which Nasdaq intends to ensuring adequate capacity of its EWN II system.

Nasdaq has requested that the Commission approve this proposed rule change on an accelerated basis. Nasdaq believes that accelerated approval of this proposal is necessary to ensure that the costs associated with the expansion of its network are allocated uniformly among all NWII subscribers, regardless of whether they are members or non-members. The Commission finds good cause for approving the proposed rule change (SR–NASD–00–74) prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**.

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NASD–00–74) is hereby approved on an accelerated basis. The rule change has become effective as of December 1, 2000 and will remain in effect until January 31, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Jonathan G. Katz,

Secretary.

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BILLING CODE 8010–01–M

eight-to-one ratio). A subscriber also will be subject to the additional circuit charge when the subscriber has not maximized capacity on its T1 circuits by placing six SDPs on a T1 circuit. This pricing structure encourages subscribers to maximize circuit capacity and is aimed at preventing the premature exhaustion of such capacity.

[9] 15 U.S.C. 78o–3(b)(5).

[10] 15 U.S.C. 78o–3.

[11] 15 U.S.C. 78o–3(b)(5).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43769; File No. SR–NASD–00–73]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to EWN II Fees for NASD Members

December 22, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2000, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its wholly-owned subsidiary the Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Nasdaq has designated his proposal as one establishing or changing a due, fee or other charge imposed by the self-regulatory organization under section 19(b)(3)(A)(ii) of the Act, which renders the rule effective upon Commission receipt of this filing. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The National Association of Securities Dealers, Inc. (''NASD''), through its wholly-owned subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq'') is herewith filing a proposed rule change to increase the fees associated with the Enterprise Wide Network II (''EWN II'') to pass on costs associated with increasing its capacity. Nasdaq has designated this proposal as one establishing or changing a due, fee or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

other charge imposed by the self-regulatory organization under section 19(b)(3)(A)(ii) of the Act, which renders the rule effective upon Commission receipt of this filing. Below is the text of the proposed rule change. Proposed new language is underlined; proposed deletions are in brackets.

NASD Rule 7010. System Services

(a)–(e) No Change

(f) Nasdaq Workstation Service

(1) No Change

(2) The following charges shall apply to the receipt of Level 2 or Level 3 Nasdaq Service via equipment and communications linkages prescribed for the Nasdaq Workstation II Service:

Service Charge: [$1,500]*$1,875*/month per service delivery platform (''SDP'') *from December 13, 2000 through February 28, 2001*; *$2,035/month per SDP beginning March 1, 2001.*

Display Charge: $525/month per presentation device (''PD'').

Additional Circuit/SDP Charge: [$2,700]*$3,075/*month *from December 13, 2000 through February 28, 2001, and $3,235/month beginning March 1, 2001.**

A subscriber that accesses Nasdaq Workstation II Service via an application programming interface (''API'') shall be assessed the Service Charge for each of the subscriber's SDPs and shall be assessed the Display Charge for each of the subscriber' API linkages, including an NWII substitute or quote-update facility. API subscribers also shall be subject to the Additional Circuit/SDP Charge.

*No change to footnotes.

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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 Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Nasdaq 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

1. Purpose

The purpose of this filing is to amend the subscriber fees applicable to NASD members that use the Nasdaq Workstation II (''NWII'').

In 1994, Nasdaq rolled out the NWII service, which provided many enhancements to the then-existing Nasdaq Workstation service.[3] As part of the NWII rollout, Nasdaq installed a network, known as the Enterprise Wide Network (''EWN I''), to deliver NWII functionality. To access NWII service, each subscriber location has at least one service delivery platform (''SDP''), or server, that resides on the network and connects to Nasdaq by a dedicated circuit. The SDP functions as the subscriber's gateway from the NWII to the enterprise wide network. Each SDP currently is permitted to support up to eight presentation devices (''PD''), or Nasdaq Workstation IIs, although a firm may elect to have fewer than eight PDs on a single SDP. In addition, a subscriber may obtain NWII service through an application programming interface (''API''), which essentially allows a firm to obtain NWII Service using the firm's own hardware (*e.g.,* personal computer) and software systems to access, display, interface with, and operate NWII service.

Due to the ongoing growth in the Nasdaq market and increases in daily share volume after EWN I was installed,[4] Nasdaq became concerned in 1997 that its existing enterprise wide network capacity was rapidly approaching maximization. Specifically, the network's bandwidth—the amount of data that can be transmitted through a given communications circuit in a fixed amount of time—could only handle one and one-half billion shares per day. EWN I was expected to reach maximum circuit capacity during the second quarter of 1999.[5] To avoid the potential for any disruption to the Nasdaq market, Nasdaq contracted in late 1997 with MCI Communications Corporation (''MCI'') to build a new network—EWN II—to accommodate increased usage and provide increased circuit capacity.

EWN II is a significant improvement over EWN I. Among other things, the system is fully scaleable and twice as fast as EWN I. The network was originally built with a 128 kilobit (''kb'') data stream feed speed scaleable up to T1 speed (1544 kilobits) levels. Nasdaq began converting subscribers to EWN II in 1998 and completed the conversion in 1999. In conjunction with the conversion, the Nasdaq filed fee increases which became effective in 1998 relating to EWN II.[6]

Since that time, Nasdaq share volume has continued to increased dramatically. The highest average daily share volume for a month in 2000 was just over 2 billion shares, compared to less than 1.5 billion in 1999, and less than 1 billion in 1998. The highest peak share volume day in 2000 was just under 3 billion shares, compared to under 2 billion in 1999, and just over 1 billion in 1998. The highest actual cumulative share volume for a month occurred twice in 2000 at over 40 billion shares, compared to over 30 billion in 1999, and almost 20 billion in 1998. In March 2000, share volume increased by over 103% compared to March 1999. In April 2000, the peak share volume increased by over 103% compared to April 1999.

To accommodate these increases, Nasdaq expanded the EWN II bandwidth from 128 kb to 192 kb in October 2000. The expanded bandwidth also gives Nasdaq the ability to support new products as they are introduced and future trading applications that will be developed. As a result of expansion to a 192 kb bandwidth, the fees that WorldCom[7] charges Nasdaq have increased by $375 per month per circuit. Nasdaq proposes to pass on these costs to subscribers for the billing period covered by December 13, 2000 through February 28, 2001.[8]

In order to accommodate additional increases in volume expected to accompany decimalization, Nasdaq will expand EWN II bandwidth to 256kb, and consequently, the fees that WorldCom charges Nasdaq will increase by an additional $160 per month per circuit. As of December 2000, Nasdaq projects that decimalization in penny increments will significantly increase the number of quote updates, such that on high volume days, a 192 kb

[3] NWII provides a windows-based environment and several data management facilities not previously available in Nasdaq's former (pre-1994) workstation service.

[4] When Nasdaq installed EWNI, Nasdaq's average daily share volume (for 1994) was 295 million and projections showed that the average daily share volume for 1997 would be 520 million. In 1997, however, average daily share volume was 650 million.

[5] Similar to any other private network, EWN I was designed to have a maximum circuit capacity (*i.e.,* 2,100 circuits).

[6] *See* Securities Exchange Act Rel. Nos. 40434 (Sep. 11, 1998), 63 FR 49937, and 40716 (Dec. 2, 1998), 63 FR 66619.

[7] MCI and WorldCom merged in September 1998.

[8] The Commission notes the effective date for this proposed fee increase is December 13, 2000, the date this filing was received by the Commission. Nasdaq has amended its filing to change its stated effective date from December 1, 2000 to December 13, 2000, and has indicated that it intends to submit a separate filing pursuant to Section 19b-2 proposing to recover its fees for the period of December 1–12, 2000. *See* Letter from Edward S. Knight, Executive Vice President and General Counsel, Nasdaq, to Katherine England, Assistant Director, Division of Market Regulation, SEC, dated December 21, 2000.

bandwidth would be inadequate to support quote traffic. Therefore, Nasdaq proposes to pass on the costs associated with the increase to a 256 kb bandwidth effective March 1, 2001.

Under the proposal, the fee charged to a subscriber for an SDP would increase from $1,500 per month for each server to $1,875 per month from December 13, 2000 through February 28, 2001, and then to $2,035 per month, beginning March 1, 2001.[9] The charge for an additional circuit would increase from $2,700 per month to $3,075 per month from December 13, 2000 through February 28, 2001, and then increase again on March 1, 2001 to $3,235 per month.[10]

Although NASD Rule 7010(f)(2) generally applies to both members and non-member subscribers to NWII service, this filing will only effect a change to the fees charged to NASD members. Nasdaq is filing a separate but virtually identical rule change to impose the proposed new fees on non-member subscribers.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A(b)(5) of the Act,[11] which requires that the rules of the NASD provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. The proposed fees, which will only apply to those who utilize NWII service, simply pass on the costs associated with increasing the capacity of EWN II to keep pace with volume increases. Ensuring adequate capacity is absolutely essential to protecting the integrity of the Nasdaq market, maintaining the confidence of the investing public, and preparing for decimalization.

[9] *See Id.*

[10] As noted above, a T1 circuit supports up to six SDPs, and an SDP supports up to eight PDs. A subscriber will be subject to the additional circuit charge when the subscriber has not maximized capacity on its SDPs by placing eight PDs and/or API servers on an SDP; in such case, the NASD/Nasdaq will charge the additional circuit charge for those ''underutilized'' SDPs (the difference between the number of SDPs a subscriber has and the number of SDPs the subscriber would need to support its PDs and/or API servers, assuming an eight-to-one ratio). A subscriber also will be subject to the additional circuit charge when the subscriber has not maximized capacity on its T1 circuits by placing six

[11] 15 U.S.C. 78o–3(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee, or other charge imposed by the Exchange, it has become effective pursuant to section 19(b)(3)(A)(ii) [12] of the Act and subparagraph (f)(2) of Rule 19b-4 thereunder.[13] At any time within 60days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to the File No. SR–NASD–00–73 and should be submitted by January 25, 2001.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–152 Filed 1–3–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43770; File No. SR–NASD–00–71]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc., Relating to the Assessment of Fees for Automated Confirmation Transaction Service

December 22, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 5, 2000, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its wholly owned subsidiary The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Nasdaq has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the Association under section 19(b)(3)(A)(ii) of the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to: (1) Reduce the fee charged for Automated Give-Up (''AGU'') transactions [4] processed by the Automated Confirmation and Transaction Services (''ACT''); and (2) establish a separate fee for the correction of transactions already

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] The AGU transaction is currently charged the ''Comparison'' fee of $0.0144/side. Nasdaq is proposing to carve-out the AGU transaction from this existing ''Comparison'' category and to reduce to $0.01 the fee that Nasdaq assesses for these transactions. Telephone conversation between Jeffrey S. Davis, Assistant General Counsel, Nasdaq, and Joseph P. Morra, Special Counsel, SEC, December 21, 2000.

processed by ACT. The text of the proposed rule change is below. Proposed new language is in italics. Proposed deletions are in brackets.

* * * * *

Rule 7010. System Services.

(a) through (f) No Change.

(g) Automated Confirmation Transaction Service.

The following charges shall be paid by the participant for use of the Automated Confirmation Transaction Service (ACT):

Transaction Related Charges:

Comparison	$0.0144/side per 100 shares (minimum 400 shares; maximum 7,500 shares).
Automated Give-Up	*$0.01/side per 100 shares (minimum 400 shares; maximum 7,500 shares).*
Late Report—T+N	$0.288/side.
Browse/query	$0.288/query.
Terminal fee	$57.00/month (ACT only terminals).
CTCI fee	$575.00/month.
Service desk	$57.00/month*.
Trade Reporting	$.029/side (applicable only to reportable transaction not subject to trade comparison through ACT).
Risk Management Charges:	$0.35/side and $17.50/month per correspondent firm.
Corrective Transaction Charge:	*$0.25/Cancel, Error, Inhibit, Kill, or 'No' portion of No/Was transaction, paid by reporting side;* *$0.25/Break, Decline transaction, paid by each party;.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq 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

1. Purpose

Nasdaq has set forth below a brief description of the ACT system, followed by discussion of the fees that Nasdaq proposes to change as well as the functionality for which those fees are assessed. The two proposed changes are intended to adhere to the principle that system users should pay fees based upon the functionality they demand and the system usage required by that functionality.

Background. ACT is an automated trade reporting and reconciliation service that speeds the post-execution steps of price and volume reporting, comparison, and clearing of pre-negotiated trades completed in Nasdaq, OTC Bulletin Board, and other over-the-county securities. ACT handles transactions negotiated over the phone or executed through any of Nasdaq's automated trading services. It also manages post-execution procedures for transactions in exchange-listed securities that are traded off-board in the Third Market. Participation in Act is mandatory for NASD members that are members of a clearing agency registered with the SEC, that have a clearing arrangement with such a member, or that participate in any of Nasdaq's trading services.

Nasdaq market particpants—Market Makers and Order Entry firms— have specified obligations for the use of ACT when entering, accepting, or correcting trade details into ACT. Market Makers are obligated to report trades within 90 seconds of execution and to enter trade details of all clearable and internalized transactions through, among other means, the ACT Trade Report function of the Nasdaq Workstation II (''NWII'') and Computer to Computer Interface (''CTCI''). Order Entry firms are required to enter a version of the trade within 20 minutes of execution through, among other means, the ACT Trade Report function of the NWII and CTCI or to accept the trade within 20 minutes using the ACT Trade Scan function.

ACT accepts three different entries, each accomplishing a different objective and each using different levels of system resources: Trade Report Only; Clearing Only; and Trade Report and Clearing. The Clearing Only and the Trade Report and Clearing transactions are entered for trade comparison and clearing. This means that when these transactions are entered into ACT they will trigger the system to go through the comparison process to find the contra side's matching entry. If the contra side's entry is found then the two records are matched and will be considered a locked-in trade and can no longer be canceled. If no match is found, the transaction remains open and may be canceled by the entering firm. Whenever any new open transactions are entered into ACT it will search through all existing open transactions to find a match. The Trade Report Only transactions is designed solely to meet the NASD's trade reporting rule obligation. They do not go through the comparison process in ACT, and they may be canceled by a user.

Automated Give-Up Fee Reduction (''AGU''). In a ''give up'' arrangement, a member who reports or accepts a trade in ACT on behalf of another member would identify in the ACT screen give-up box the member on whose behalf the trade was being reported or accepted. Where the executing broker accepts a trade that has been reported by another member, the reporting member would have to report the trade with the executing broker as the contra side and identify the prime brokerage customer as the contra side give-up. The executing broker may then accept the trade as presented. This would avoid a second trade report and ensure that the prime brokerage customer is identified to the NASD.

The ACT Give-Up Automatic Lock-in function allows an introducing broker to enter and lock-in a trade when it is responsible for both sides of the trade. This occurs when two of its ''Give-Ups'' trade with each other or the introducing broker trades with one of its own Give-Up firms. In the non-automated Give-Up, the introducing broker submits a market-maker entry for one side and either accepts the trade or submits an order-entry firm entry to match the trade. In the automated system, by specifying the Give-Up Lock-In feature, the introducing broker avoids the need to accept the trade or submit the order-entry side. In other words, the lock-in feature will allow the introducing broker to submit just one entry, not two.

Use of the AGU substantially reduces the use of Nasdaq system resources. To process a non-automated give-up transaction, the ACT system must route

between six and twelve input and output messages. The use of the AGU reduces that number by as much as 50 percent. Based upon this reduction in system usage and the increased benefits to market participants, Nasdaq proposes to reduce the ''Comparison'' fee associated with AGU transactions from $.0144 per 100 share block to $.01 per 100 share block for trades of between 400 and 7,500 shares.[5] This represents a substantial savings to market participants and to investors.

ACT Corrective Transactions Fee. Market participants are required to correct trade reports that are inaccurate using one of five ACT functions; Cancel, Error, Inhibit, Kill, No/Was, Decline, or Break (collectively, ''Corrective Transactions''). Corrective Transactions utilize the comparison functionality of ACT, in that the system is required to identify a particular trade and perform an operation that matches the conduct of the contra parties to the transaction. In fact, these transactions consume system capacity and staff resources disproportionate to those required for standard reporting transactions, and disproportionate to the fee imposed for standard comparison functions. Currently, Nasdaq assesses the standard comparison fee to such transactions.

Along with the rapid growth of Nasdaq daily trading volume, the number of Corrective Transactions is increasing rapidly, unbalancing the proper allocation of system costs to users of system functionality. Accordingly, Nasdaq proposes implementing a $0.25 fee charged to the reporting party for Cancel, Error, Inhibit, Kill, and the ''No'' portion of ''No/Was'' trades, as well as a $0.25 fee per side for Break and Decline transactions. The fee is designed to cover a portion of the costs of processing Corrective Transactions that have not previously been charged to market participants. The proposed fee would discourage the unnecessary entry of Corrective Transactions, such as the practice of canceling a number of individual trades and re-entering a single bunched trade to avoid ACt fees. Nasdaq notes that numerous self-regulatory organizations already impose comparable fees for corrective transactions, such as Nasdaq is proposing here.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[6] which requires, among other things, that the Association's rules be designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Nasdaq believes that the proposed rule change is wholly consistent with the purposes of the Act in that it will provide a cost effective and efficient mechanism to report trades, and therefore facilitates clearance and settlement. Additionally, Nasdaq believes the proposed rule change will enhance the process by which members engage in the comparison and clearing of securities transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change was effective upon filing with the Commission pursuant to section 19(b)(3)(A)(ii) of the Act[7] and subparagraph (f)(2) of Rule 19b–4 thereunder,[8] because it establishes or changes a due, fee, or other charge imposed by the Association. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–00–71 and should be submitted by January 25, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–153 Filed 1–3–01; 8:45 am]

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[5] The AGU transaction is currently charged the ACT ''Comparison'' fee because it uses the ACT Comparison functionality. *See* footnote 4, *supra.*

[6] 15 U.S.C. 78o–3(b)(6).

[7] 15 U.S.C. 78s(b)(3)(A)(ii).

[8] 17 CFR 240.19b–4(f)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43765; File No. SR–NASD–99–46]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc., Requiring Registration of Chief Compliance Officers

December 21, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 20, 1999, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its wholly-owned subsidiary, NASD Regulation, Inc. (''NASD Regulation''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD Regulation. NASD Regulation filed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Amendment Nos. 1 [3] and 2 [4] to the proposed rule change on December 11, 2000 and December 6, 2000, respectively. 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

NASD Regulation is proposing to amend NASD Rule 1022(a) to require chief compliance officers to register with the NASD as general securities principals. Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

1022. Categories of Principal Registration

(a) General Securities Principal

Each person associated with a member who is included within the definition of principal in Rule 1021, *and each person designated as a Chief Compliance Officer on Schedule A of Form BD,* shall be required to register with the Association as a General Securities Principal and shall pass an appropriate qualification examination before such registration may become effective unless [his] *such person's* activities are so limited as to qualify [him] *such person* for one or more of the limited categories of principal registration specified hereafter. A person whose activities in the investment banking or securities business are so limited is not, however, precluded from attempting to become qualified for registration as a General Securities Principal, and if qualified, may become so registered. Each person seeking to register and qualify as a General Securities Principal must, prior to or concurrent with such registration, become registered, pursuant to the Rule 1030 Series, either as a General Securities Representative or as a Limited Representative-Corporate Securities. *A person who has been designated as a Chief Compliance Officer on Schedule A of Form BD for at least two years immediately prior to [insert effective date of proposed rule change] and who has not been subject within the last ten years to any statutory disqualification as defined in Section 3(a)(39) of the Act; a suspension; or the imposition of a fine of $5,000 or more for violation of any provision of any securities law or regulation, or any agreement with or rule or standard of conduct of any securities governmental agency, securities self-regulation organization, or as imposed by any such regulatory or self-regulatory organization in connection with a disciplinary proceeding shall be required to register as a General Securities Principal, but shall be exempt from the requirement to pass the appropriate Qualification Examination. If such person has acted as a Chief Compliance Officer for a member whose business is limited to the activities described in Rule 1022(d)(1)(A) or Rule 1022(e)(2), he or she shall be exempt from the requirement to pass the appropriate Qualification Examination only if he or she registers as a Limited Principal pursuant to Rules 1022(d) or Rule 1022(e), as the case may be, and restricts his or her activities as required by such registration category. A Chief Compliance Officer who is subject to the Qualification Examination requirement shall be allowed a period of 90 calendar days following [insert effective date of proposed rule change] within which to pass the appropriate Qualification Examination for Principals.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD Regulation included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASD Regulation 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

1. Purpose

The purpose of the proposed rule change is to require the chief compliance officer designated on Schedule A of a member's Form BD to be registered as a principal. Some chief compliance officers may already be registered as a principal due to other NASD rule requirements. For example, NASD Rule 3010(a)(8) requires each member to designate and specifically identify to the NASD one or more principals who are required to review the member's supervisory system, procedures, and inspections implemented by the member and take appropriate action reasonably designed to achieve the member's compliance with applicable securities laws and regulations. For some members, the chief compliance officer is one of these designated principals. For other members, the chief compliance officer may already be registered as a principal because he or she is an officer of the member or otherwise engaged in the member's investment banking or securities business in a manner that requires principal registration under NASD Rule 1021.

For other members, however, chief compliance officers may not be registered. Rule 1021(a), which sets forth the requirements for principal registration, states that a member ''may'' make or maintain an application for principal registration for certain personnel, including compliance personnel. The negative implication of this provision is that compliance personnel are not required to be registered, but that a member may choose whether to register an individual with compliance responsibilities. Some members have chosen not to register any compliance personnel.

NASD Regulation believes that the chief compliance officer of a member, as designated on Schedule A of the Form BD, should be registered as a principal. Chief compliance officers generally advise registered representatives and other principals on compliance issues and devise compliance systems and procedures for the firm as a whole. As such, a chief compliance officer should be able to demonstrate his or her knowledge through a qualifications

[3] *See* Letter dated October 28, 1999, from Alden S. Adkins, Senior Vice President and General Counsel, NASD Regulation, to Katherine A. England, Assistant Director, Division of Market Regulation (''Division''), Commission (''Amendment No. 1''). Amendment No. 1 clarifies that if a person becomes a chief compliance officer for the first time after the effective date of the proposed rule change for a dual New York Stock Exchange and NASD member, that person may elect to take the New York Stock Exchange Series 14 exam, and would not be required to take NASD Series 24 exam.

[4] *See* Letter dated December 1, 2000, from Alden S. Adkins, Senior Vice President and General Counsel, NASD Regulation, to Jack Drogin, Assistant Director, Division, Commission (''Amendment No. 2''). Amendment No. 2 limits the grandfathering provision of the proposed rule change to individuals who have been designated as chief compliance officers on Schedule A of Form BD for at least two years immediately prior to the effective date of the proposed rule change and who have not been subject within the previous ten years to: (1) Any statutory disqualification as defined in Section 3(a)(39) of the Act; (2) a suspension; or (3) the imposition of a fine of $5,000 or more for a violation of any provision of any securities law or regulation, or any agreement with or rule or standard of conduct of any securities governmental agency, securities self-regulatory organization, or as imposed by any such regulatory or self-regulatory organization in connection with a disciplinary proceeding.

examination and be subject to continuing education requirements.

Under the proposed rule change, the chief compliance officer must be registered as a Series 24 General Securities Principal, unless the member's activities are limited to particular areas of the investment banking or securities business. In that case, the individual may apply for a limited principal registration. For example, if a member sells only mutual funds, the chief compliance officer of that member may apply for registration as either a Series 26 Limited Principal—Investment Company and Variable Contracts Products or a Series 24 General Securities Principal. Acceptable limited principal categories for a chief compliance officer are the Series 4 (Registered Options Principal), 26 (Limited Principal Investment Company and Variable Contracts Products), 39 (Limited Principal Direct Participation Programs), and 73 (Government Securities Principal), if the activities of the chief compliance officer's firm are limited to these areas.

By requiring chief compliance officers to be registered, NASD Regulation is not creating a presumption that they are supervising the member's securities or investment banking business or otherwise are control persons. Some chief compliance officers are completely segregated from a member's supervisory structure. As in the past, NASD Regulation will determine whether a person is acting as a supervisor or control person by looking at the responsibilities and functions he performs for the member, not simply his title.

To avoid imposing duplicative examination requirements on dual NASD/New York Stock Exchange (''NYSE'') members, NASD Regulation has determined that for purposes of chief compliance officer registration, it will accept the NYSE's Series 14 Compliance Official examination in lieu of any of the NASD principal examinations noted above. For example, if a person had passed the NYSE Series 14, and after the effective date of the rule, accepted a chief compliance officer position with an NASD member, then the person would not be required to take the Series 24 examination. In addition, if a person becomes a chief compliance officer for the first time after the effective date of the proposed rule change for a dual NASD/NYSE member, that person may elect to take just the NYSE Series 14 exam, and would not be required to take NASD Series 24 exam.[5]

NASD Regulation currently proposes to make the rule change effective on July 1, 2001. A person who has been designated as a chief compliance officer on Schedule A of Form BD for at least two years immediately prior to the effective date of proposed rule change and who has not been subject within the last ten years to the disciplinary procedures described in proposed Rule 1022(a) will not have to pass the appropriate qualification examination. All chief compliance officers ''grandfathered'' will be subject to continuing education requirements. If the chief compliance officer is registered as a Limited Principal, he or she will be exempt from the requirement to pass the appropriate qualification examination if he or she restricts his or her activities as required by such registration category. A chief compliance officer who is subject to the qualification examination requirement must pass the appropriate exam within 90 calendar days of the effective date of proposed rule change.[6]

If a person grandfathered under this provision wishes to serve as a principal for any other function, he must be appropriately qualified and registered. The grandfather provision applies only to the chief compliance officer function. Any person who is listed as the chief compliance officer on the Form BD for the first time on or after July 1, 2001, will be required to apply for registration, pass the required examinations, and participate in continuing education.

Finally, NASD Regulation wishes to clarify an interpretive position related to the new chief compliance officer registration requirement. In Notice to Members 99–49, NASD Regulation stated that a general counsel of a member is not required to be registered unless he sits on the member's board of directors or otherwise participates in the management of the member's securities or investment banking business.[7] NASD Regulation has determined that this interpretation will continue to apply after the effective date of the rule even if a registered chief compliance officer reports directly to the general counsel (*i.e.,* the general counsel has the power to hire and fire and direct the activities of the chief compliance officer). NASD Regulation does not believe that it is necessary at this time to impose a general registration requirement on general counsels, or to require them to be registered simply because registered persons may report to them.

2. Statutory Basis

NASD Regulation believes that the proposed rule change, as amended, is consistent with the provisions of section 15A(b)(6) of the Act,[8] which requires, among other things, that the Association's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade and, in general, to protect investors and the public interest. NASD Regulation believes that adding this registration requirement will help protect investors and the public interest by ensuring that chief compliance officers can demonstrate their knowledge about compliance matters and stay up-to-date with industry requirements through continuing education.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD Regulation does not believe that the proposed rule change, as amended, will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The proposed rule change was published for comment in NASD Notice to Members 99–51. NASD Regulation received sixty-one comments in response to the Notice. Thirty-seven commenters favored registration of chief compliance officers[9] and 15 were

[5] *See* Amendment No. 1, *supra* note 3.

[6] *See* Amendment No. 2, *supra* note 4.

[7] The Notice to Members further explained that an employee of a member who sits on its board of directors is generally presumed to be involved in the day-to-day management of the member's business and therefore is required to be registered as a principal. If the general counsel or corporate secretary is not a director but has management-level responsibilities for supervising any aspect of the member's investment banking or securities business, he would have to be registered as a principal. Management responsibilities in this context would include serving as a voting member of the firm's executive, management, or operations committees. A general counsel may participate in such committees' activities without triggering a registration requirement if he only provides counsel to the committee and does not vote.

[8] 15 U.S.C. 78*o*–3(b)(6).

[9] Letters from A.G. Edwards & Sons, Inc. (''A.G. Edwards''); American Equity Capital, Inc. (''American Equity''); Atlantic Capital Management, LLC (Atlantic); BMS International (''BMS''); Burke, Christensen & Lewis Securities, Inc. (''Burke, Christensen''); California Association of Independent Broker-Dealers (''CAIBD''); Centennial Securities Co. (''Centennial''); Consolidated Financial Investments, Inc. (''Consolidated Financial''); Corporate Network Brokerage Services, Inc. (''Corporate Network''); Melissa Crockett (''Crockett''); Davenport & Company, LLC (''Davenport''); Dreyfus Brokerage Services (''Dreyfus''); Robert A. Eder, Sr. (''Eder''); FAS Wealth Management Services, Inc. (''FAS Wealth Management''); Fulcrum Financial Advisors, Inc.

opposed.[10] Nine commenters did not take a specific position on requiring chief compliance officer registration.[11] Some of the commenters who opposed the proposed rule change stated that it is not necessary for chief compliance officers to demonstrate their knowledge through examinations because they could not obtain the position unless they were competent and/or that the expenses associated with registration would be burdensome.[12] One commenter stated that continuing education programs are already available to compliance personnel.[13] Another commenter stated that the rule would create a presumption that the chief compliance officer is a control person.[14]

NASD Regulation does not believe that the incremental effort required for a chief compliance officer to pass examinations to demonstrate his knowledge would be burdensome. As noted above, some chief compliance officers already are registered as principals, so no additional requirement is being imposed on them. Also, NASD Regulation does not believe that the cost associated with registering at most one more person for each member is unduly burdensome. Furthermore, required annual continuing education programs will assist the chief compliance officer in staying current with regulatory requirements and developments. Finally, as stated above, NASD Regulation will not presume that a chief compliance officer is a supervisor or control person just by virtue of his title.

Twenty-six commenters favored using the Series 24 General Securities Principal registration category (or a limited principal category as appropriate);[15] four commenters were opposed.[16] Only nine commenters favored the creation of a new examination,[17] while 14 commenters opposed it.[18] NASD Regulation determined not to create a new examination because it believes that the Series 24 is suitable for testing knowledge of compliance matters, some chief compliance officers have already taken and passed it, and the development costs associated with a new examination would have to be passed along to members.

Nine commenters favored accepting the NYSE Series in lieu of the Series 24.[19] NASD Regulation agrees with these commenters and will accept the NYSE examination for purposes of chief compliance officer registration.

Most commenters did not address the issue of whether a general counsel who supervises a registered chief compliance officer should be registered. However, nine commenters specifically favored requiring such a general counsel to be registered,[20] while eight were opposed.[21] Only one of the commenters in favor of general counsel registration offered a rationale for its position, stating that a law degree does not ensure knowledge of securities laws and that a general counsel who supervises a chief compliance officer is in effect the chief compliance officer himself.[22] While NASD Regulation agrees with the first reason, it disagrees with the second. The fact that a chief compliance officer reports to another officer such as the general counsel does not make that officer the ''effective'' chief compliance officer. Commenters opposed to requiring a general counsel to register stated that a registration requirement could lead firms to restructure reporting lines, undermine the independence of the general counsel, and improperly interfere with the practice of law.[23] NASD Regulation does not believe that a compelling reason has been offered at this time to impose a general registration requirement on general counsels who supervise chief compliance officers.

Six commenters opposed grandfathering current chief compliance officers (*i.e.,* applying the proposed rule change prospectively only).[24] NASD Regulation disagrees with these commenters. As noted previously, the NASD rules to date have not explicitly required chief compliance officer registration, and it would be unnecessarily burdensome to apply the new requirement immediately to all persons currently serving in this position. Therefore, NASD Regulation determined to impose the requirement only on persons who have not acted as chief compliance officers for at least two years immediately prior to the effective date of the proposed rule change and who have not been subject within the last ten years to the disciplinary procedures described in proposed Rule 1022(a).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of 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 NASD Regulation consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

(''Fulcrum''); H.C. Wainwright & Co., Inc. (''Wainwright''); Jackson Securities, Inc. (''Jackson''); John Hancock Mutual Life Insurance Company (''John Hancock''); Lynn Junkin (''Junkin''); Betty Kabanek; Don Katz (''Katz''); Keystone Brokerage, Inc. (''Keystone''); Andrew J. Lenza (''Lenza''); Liberty Funds Distributor, Inc. (''Liberty Funds''); Lincoln Investment Planning, Inc. (''Lincoln Investment''); Larry Lowman (''Lowman''); Mid-Florida Equities, Inc. (''Mid-Florida Equities''); MidSouth Capital Incorporated (''MidSouth Capital''); mlmcarthurlafon@dstsystems.com; MML Investors Services, Inc. (''MML''); Nalico Equity; Linda K. Parker (''Parker''); Regions Investment Company, Inc. (''Regions''); Althea Roberts (''Roberts''); SIA Self-Regulation and Supervisory Practices Committee (''SIA Committee''); Tradition, Inc. (''Tradition''); and Unified Management Corporation (''Unified Management'').

[10] Letters from Branch Cabell & Co., Inc. (''Branch Cabell''); Charles Schwab & Co., Inc. (''Schwab''); Mark Geregach (''Geregach); George T. Goldman; Mark Horin (''Horin''); Knight Securities, L.P. (''Knight Securities''); Eric D. Koval (''Koval''); lizakahn@aol.com; Joel Martin McTague (''McTague''); Orrick, Herrington & Sutcliffe, LLP; Princeton Equity Securities, Inc.; St. Bernard Financial Services, Inc.; Syndicated Capital; John Tubman; and Robert Woeber (''Woeber'').

[11] Letters from DMA Management and Regulatory Consulting; Donald W. Gendron (''Gendron''); Investment Company Institute (''ICI''); Eileen Miotke; Bill Mullally; NBC Capital Markets Group, Inc.; Nationwide Life Insurance Company; Lisa Roth; and The Securities Center, Inc. (''TSC''). For example, some commenters stated that small firms should be exempted from the requirement of chief compliance officer registration. *See* Letters from Gendron and TSC.

[12] *See* Letters from Branch Cabell; Horin; Koval; Schwab; and Woeber.

[13] *See* Letter from Geregach.

[14] *See* Letter from Knight Securities.

[15] *See* Letters from A.G. Edwards; Atlantic; BMS; Consolidated Financial; Corporate Network; Crockett; Eder; FAS Wealth Management; Fulcrum; Jackson; John Hancock; Junkin; Keystone; Lenza; Liberty Funds; Lincoln Investment; Lowman; Mid-Florida Equities; MidSouth Capital; mlmcarthurlafon@dstsystems.com; MML; Parker; Regions; SIA Committee; Tradition; and Unified Management.

[16] *See* Letters from American Equity; Burke, Christensen; and CAIBD.

[17] *See* Letters from A.G. Edwards; Burke, Christensen; CAIBD; Centennial; Fulcrum; Lenza; Mid-Florida Equities; and Lisa Roth.

[18] *See* Letters from American Equity; Corporate Network; Eder; Wainwright; John Hancock; Katz; Liberty Funds; Lowman; MidSouth Capital; mlmcarthurlafon@dstsystems.com; MML; Parker; Regions; and SIA Committee.

[19] *See* Letters from A.G. Edwards; Corporate Network; Davenport; Dreyfus; H.C. Wainwright; John Hancock; Roberts; Schwab; and SIA Committee.

[20] *See* Letters from A.G. Edwards; Crockett; Davenport; Eder; Keystone; MidSouth Capital; MML; NBC Capital Markets Group, Inc.; and Tradition.

[21] *See* Letters from ICI; John Hancock; Knight Securities; Lenza; Liberty Funds; McTague; Nationwide Life Insurance Company; Syndicated Capital.

[22] *See* Letter from Davenport.

[23] *See* Letters from ICI and Knight Securities.

[24] *See* Letters from A.G. Edwards; Crockett; Fulcrum; MidSouth Capital; Parker; and SIA Committee.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. 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 Room. Copies of the filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the File No. SR–NASD–99–46 and should be submitted by January 25, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[25]

Johnathan G. Katz,

Secretary.

[FR Doc. 01–154 Filed 1–3–01; 8:45 am]

BILLING CODE 8010–10–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43767; File No. SR–NYSE–00–18]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change and Notice of Filing and Order Accelerating Approval of Amendment Nos. 1 and 2, on a Pilot Basis Ending on December 21, 2001, Relating to NYSe Direct+, the Exchange's Automatic Execution Facility for Certain Limit Orders of 1099 Shares or Less

December 22, 2000.

I. Introduction

On May 1, 2000, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), 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 implementing NYSe Direct+, an automatic execution facility for certain limit orders of 1099 shares or less. The proposed rule change was published for public comment in the **Federal Register** on June 15, 2000.[3] The Commission received one comment letter regarding the proposed rule change.[4] The Exchange submitted Amendment Nos. 1 and 2 to the proposed rule change on August 21, 2000[5] and December 21, 2000,[6] respectively. This order approves the proposed rule change on a pilot basis ending on December 21, 2001 and grants accelerated approval to Amendment Nos. 1 and 2. The Commission is also soliciting comment on Amendment Nos. 1 and 2 to the proposed rule change.

II. Description of the Proposed Rule Change

The proposed rule change establishes a new trading platform, NYSe Direct+, for the automatic execution of certain limit orders of 1099 shares or less (''auto ex'' orders) against trading interest reflected in the Exchange's published quotation. Limit orders priced at or above the Exchange's published offer price (in the case of an auto ex order to buy), and limit orders priced at or below the Exchange's published bid price (in the case of an auto ex order to sell) are eligible for automatic execution via NYSe Direct+. The contra side of the auto ex order would be the trading interest reflected in the Exchange's bid or offer, in accordance with the Exchange's auction market principles of priority and parity codified in Exchange Rule 72. Auto ex orders would receive automatic executions without being exposed to the auction market.[7] However, if the automatic execution feature is not available,[8] the auto ex order would be entered for execution in the Exchange's auction market. Auto ex transactions would be identified on the Consolidated Tape with a unique identifier, and the Exchange's published bid or offer would be automatically decremented to the extent of the size of the auto ex order to reflect the automatic execution.

It would not be mandatory that all eligible limit orders of 1099 shares be entered as auto ex orders NYSe Direct+. Member organizations (or their customers if enabled by the member organization) can choose to use NYSe Direct+ when the speed and certainty of an execution at the Exchange's published bid or offer price is in the customer's best interest. If a customer's interest would best be served by affording the customer's order the opportunity for price improvement, the member (or customer) may enter a limit or market order by means of the SuperDOT system for representation in the auction market, rather than an auto ex order.

The Exchange's proposal would be implemented in proposed Rules 1000 through 1005.[9] Rule 1000 species the types of orders eligible for entry as auto ex orders. In addition, the Rule lists six instances where the automatic execution feature would not be available due to, for example, particular market situations, lack of depth in the published quotation, or inappropriate

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[25] 17 CFR 2000.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 42913 (June 8, 2000), 64 FR 55514.

[4] Letter from Craig S. Tyle, General Counsel, Investment Company Institute (''ICI'') to Jonathan G. Katz, Secretary, Commission, dated July 6, 2000 (''ICI Letter'').

[5] Letter from Daniel Parker Odell, Assistant Secretary, Exchange, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated August 17, 2000 (''Amendment No. 1''). Amendment No. 1 clarifies several items relating to Rule 1000, 1004, and 1005. With respect to Rule 1000, Amendment No. 1 clarifies that orders that are not automatically executed will be entered in the auction market, and an order entered into the auction market is treated the same as any other limit order entered on the Exchange through the SuperDOT system. Amendment No. 1 also clarifies that proposed Rules 1000(ii) and (v) are, in effect, examples of proposed Rule 1000(iv) because both relate to situations where the Exchange's published bid or offer is 100 shares. The Exchange further explained that to ''gap'' a quotation involves setting the bid and asked prices at a spread wider than normal in a stock in order to alert market participants that a special situation exists. With respect to Rule 1004, Amendment No. 1 clarifies that executions of orders entered in NYSe Direct+ (or ''auto ex orders'') shall elect stop limit orders as well as stop orders and percentage orders electable at the price of such executions. With respect to Rule 1005, Amendment No. 1 clarifies the prohibition on the entry of auto ex orders within 30 seconds for the same customer applies on a per stock basis. Finally, Amendment No. 1 states that the Exchange intends to choose the stocks eligible for participation in the pilot program for NYSe Direct+ based on a number of criteria, including volume, trading characteristics and floor location.

[6] Letter from James E. Buck, Secretary and Senior Vice President, Exchange, to Jack Drogin, Assistant Director, Division, Commission, dated December 20, 2000 (''Amendment No. 2''). Amendment No. 2 replaces the phrase ''is being completed'' with ''has been agreed upon'' in proposed Rule 1003. Amendment No. 2 also deletes the prohibition in proposed Rule 1005 against orders larger than 1,099 shares being broken up in smaller amounts for the purpose of receiving an automatic execution.

[7] To be exposed or entered in the Exchange's auction market means that the order would be treated like orders received from the SuperDOT system. *See* Amendment No. 1, *supra* note 5.

[8] *See* proposed Rule 1000.

[9] The Exchange file a separate proposed rule change to implement Rule 1006, which provides for the automatic execution of coupled orders of 1099 shares or less at a price that is at or within the Exchange's published quotation. Securities Exchange Act Release No. 43110 (August 2, 2000), 65 FR 48776 (August 9, 2000).

pricing of the auto ex order.[10] Rule 1001 sets forth the execution parameters for orders entered in NYSe Direct+, including the contra side interest reflected in the Exchange's published quotation. Rule 1001(a)(iv) provides that the specialist shall be the contra party to any automatic execution of an auto ex order where interest reflected in the published quotation against which the auto ex order was executed is no longer available.[11] Rule 1002 addresses when the system is available for automatic execution each trading day. Rule 1003 governs the application of tick tests to auction market transactions when an auto ex order is reported at a different price after an auction market transaction has been agreed upon, but before the market transaction is reported.[12] This rule provides that any tick test applicable to the auction market transaction will be based on the last reported auction market sale.[13] Rule 1004 provides that auto ex orders may elect stop orders and percentage orders electable at the price of such executions.[14] Rule 1005 prohibits the entry of auto ex orders in intervals of less than 30 seconds on a per stock basis.[15] The Exchange also proposes to amend Exchange Rule 13 to add the definition of auto ex orders and to amend Exchange Rule 476A to add Rules 1000–1005 to the list of rules subject to summary fine procedures.

Interpretive Issues

The Exchange also requested that the Commission approve interpretations of Exchange Rules 123A.40, 91, and 104. These interpretations arise in situations under proposed Rule 1001(a)(iv) where the specialist is required to take the contra side of an auto ex execution against the published quotation, as discussed above. In short, the interpretations provided by the Exchange state that when the specialist is required to take the contra side of an auto ex order pursuant to Rule 1001(a)(iv), the specialist may not be required to fill any stop orders elected by an auto ex execution at the price of the electing sale pursuant to Rule 123A.40; that the transaction confirmation requirements of Rule 91 do not apply; and that in any instance in which the specialist is effecting a direct tick transactions only because he or she has been required to assume the contra side of an auto ex execution, the transaction shall be deemed a ''neutral'' transaction for purposes of Exchange Rule 104.

Commission Rule 10a–1.

As stated in the notice for this proposed rule change, Commission Rule 10a–1 and Exchange Rule 440B do not permit short sales to be effected on a minus or zero minus tick. However, the Exchange proposed that under Rule 1001(a)(iv), the specialist should be permitted to sell short on a minus or zero minus tick when he or she takes the contra side of an auto ex execution because either: (1) the published quotation reflects interest that has received an execution, but the quotation has not been updated to reflect this fact; or (2) the published quotation reflects this fact. The Exchange believes that the specialist should be exempted from Commission Rule 10a–1 under these circumstances because the specialist is required to trade at a price set by other market participants.

In addition, as also set forth in the notice for this proposed rule change, the Exchange has requested an exemption from Commission Rule 10a–1 for Rule 1003. Rule 1003 provides that if a transaction has been agreed upon [16] in the auction market, and an execution involving auto ex orders is reported at a different price before the auction market transaction is reported, any tick test applicable to the auction market transaction will be based on the last reported trade prior to the reporting of the auto ex transaction.

III. Comments

The Commission received one comment letter from the Investment Company Institute (''ICI'').[17] The ICI questioned the purpose and necessity of the 30-second delay between entry of auto ex orders. Specifically, the ICI stated that the delay would ''defeat the purpose of providing investors with a facility to automatically execute limit orders without intervention of a dealer.'' The ICI also strongly supported the idea of increasing the maximum number of shares that can be entered into NYSe Direct+ for automatic execution, and recommended that the pilot program include ''securities representing a substantial portion of the NYSE market, *e.g.,* the top 100 NYSE listed securities, with the remainder chosen from quintiles of NYSE securities.'' In response to the ICI's comments on these particular issues, the Exchange noted that the proposed parameters are appropriate for the initial launch of the pilot program.[18] The Exchange also noted that a primary purpose of the pilot program is to allow the Exchange, NYSe Direct + participants, and the Commission to examine the operation of the system on a controlled basis. Thus, the Exchange believes that the parameters regarding each of the issues noted above are appropriate at this pilot stage.

The ICI also questioned the prohibition on breaking up orders for entry into NYSe Direct+. The ICI noted that it is unclear what type of ''order'' the proposed rules are referring to, and requested clarification whether a broker for an institution asked to ''work'' a large order could utilize NYSe Direct+ to execute all or part of the institution's order. In response, the Exchange has deleted this prohibition from the proposed rule change although it has retained the 30-second interval between orders on a per share basis.[19] The Exchange noted, moreover, that a broker ''working'' an institutional client's order by simply breaking the order up for entry into NYSe Direct+ may not be executing the order consistent with the broker's duty of best execution.[20]

Finally, the ICI recommended that strict price/time priority be applied to the execution of NYSe Direct+ orders, rather than executed in accordance with Exchange Rule 72, which provides for executions pursuant to principles of priority and precedence. Specifically, the ICI noted that applying strict price/time priority would ''rectify, for example, a situation where a market

[10] The Exchange notes that Rules 1000(ii) and (v) are, in effect, examples of proposed Rule 1000(iv). *See* Amendment No. 1, *supra* note 5.

[11] For purposes of Rule 1001(a)(iv), the only circumstances under which interest reflected in the published quotation ''is no longer available'' are either: (1) The published quotation reflects interest that has received an execution, but the quotation has not been updated to reflect this fact; or (2) the published quotation reflects interest that has been cancelled, but the quotation has not been updated to reflect this fact. *See* Letter regarding NYSe Direct+ (December 21, 2000) (''Exemption Letter''). rule 1001(a)(iv) is the subject of an exemption issued by the Commission to the Exchange granting certain relief from Commission Rule 10a–1. *Id.*

[12] *See* Amendment No. 2, *supra* note 6. Rule 1003 is also the subject of an exemption issued by the Commission to the Exchange granting certain relief from Commission Rule 10a–1. *See* Exemption Letter.

[13] *See* Amendment No. 1, *supra* note 5.

[14] Amendment No. 1 clarifies that executions of auto ex order shall elect stop limit orders as well as stop orders and percentage orders electable at the price of such executions. *See* Amendment No. 1, *supra* note 5.

[15] Amendment No. 1 clarifies that the prohibition on entering orders within 30-seconds applies on a per stock basis. *See* Amendment No. 1, *supra* note 5.

[16] *See* Amendment No. 2, *supra* note 6.

[17] *See supra* note 4.

[18] The Exchange responded to these concerns in a phone call between Brian McNamara, Vice President, Market Surveillance, NYSE, Donald Siemer, Director, Market Surveillance, NYSE, Rebekah Liu, Special Counsel, Division, Commission, and Sonia Patton, Attorney, Division, Commission (August 31, 2000).

[19] *See* Amendment No. 2, *supra* note 6.

[20] *Id.*

participant would be able to participate on the contra side of an automatic execution even though another participant may have placed an order in the NYSE earlier in time.'' In response, the Exchange stated that it believes that all orders, including orders entered in NYSe Direct+, executed on the Exchange should be subject to the same execution principles of priority and precedence, as set forth in Exchange Rule 72.[21]

IV. Discussion

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. In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act[22] which requires an Exchange to have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change is also consistent with section 11A(a)(1) of the Act[23] which states that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure economically efficient execution of securities transactions and the practicability of brokers executing investor orders in the best market, and to provide an opportunity for investors' orders to be executed without the participation of a dealer.[24]

The Commission finds that by allowing the automatic execution of limit orders against the interest reflected in the Exchange's published quotation, NYSe Direct+ helps to perfect the mechanism of a free and open market by providing a trading venue for customers who value the speed and certainty of automatic execution more than the opportunity for price improvement offered by the Exchange's agency-auction trading floor. NYSe Direct+ also facilitates securities transactions to the benefit of investors by allowing direct access by a member organization, or its customer, to the trading interest reflected in the Exchange's published quotation. The Commission notes that this direct access, in turn, may attract more order flow and increase the depth and liquidity of the Exchange's market to the benefit of investors and the public interest.

The Commission further finds that NYSe Direct+ provides an opportunity for a customer's order to be executed with limited broker participation, consistent with the goals of the Act. Although a member firm must still act as the gateway for any customer wishing to utilize NYSe Direct+, the direct and automatic matching of customer limit orders against the interest reflected in the Exchange's quotation minimizes the involvement of the member firm. The Commission also believes that NYSe Direct+ may have the potential to lower transaction costs, another potential benefit to Exchange customers.

The Commission also finds that operation of NYSe Direct+ is consistent with the protection of investors and the public interest and should help to maintain a fair and orderly market. The proposed rules specifically outline the terms under which a customer's order would be handled by the NYSe Direct+ system, and they provide for the handling of those orders if there is no contra-side interest in the Exchange's published quotation.

The Commission finds that the Exchange has addressed the most significant concerns raised by the ICI Letter.[25] The Commission agrees that the proposed parameters are appropriate for the initial launch of the pilot program. A primary purpose of the pilot program is to allow the Exchange, NYSe Direct+ participants, and the Commission to examine the operation of the system on a controlled basis. Thus, the Commission finds that the proposed parameters by the Exchange for NYSe Direct+ are appropriate at this pilot stage. The Commission notes that it will expect the Exchange to choose stocks eligible for the pilot program based on a number of appropriate criteria, including volume, trading characteristics and floor location.[26]

With respect to the ICI's request for further clarification on the prohibition of breaking up orders of greater than 1099 shares into smaller amounts, the Commission notes that the Exchange amended the proposed rule change to delete the explicit prohibition against breaking up orders for the purpose of receiving an automatic execution. The Commission believes that amended Rule 1005 provides an appropriate mechanism to discourage brokers from breaking up large orders solely to obtain an automatic execution, while allowing brokers acting on behalf of institutions to use NYSe Direct+ to ''work'' large orders, consistent with their duty of best execution. The Commission also finds that for purposes of consistency and uniformity, all bids or offers executed on the Exchange should be subject to the execution principles set forth in Exchange Rule 72.

Interpretative Issues

The Commission also approves the Exchange's interpretation of Exchange Rules 123A.40, 91, and 104.[27] These interpretations all concern a situation where, pursuant to proposed Rule 1001(a)(iv), the specialist is required to take the contra side of an auto ex execution against the published quotation, even though the specialist's interest was not part of the published quotation. In addition, the Commission has granted the Exchange exemptive relief from Commission Rule 10a–1 for purposes of proposed Rule 1001(a)(iv).[28] The Commission therefore finds the requested interpretations are appropriate and necessary for the proper functioning of the NYSe Direct+ trading platform.

Commission Rule 10a–1

Commission Rule 10a–1 and Exchange Rule 440B did not permit short sales to be effected on a minus or zero minus tick. As discussed above, the Exchange has requested an exemption from Rule 10a–1 when a specialist is required to take the contra side of an auto ex execution pursuant to Exchange Rule 1001(a)(iv). In addition, the Exchange has requested an exemption to

[21] *Id.*

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78k–1(a)(1).

[24] In approving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[25] *See supra* Section II and note 4.

[26] This is consistent with the Exchange's representations in Amendment No. 1, *supra* note 5.

[27] The interpretations of these Rules are as follows:

Exchange Rule 123A.40. The specialist shall not be required to fill any stop orders elected by an auto ex execution at the price of the electing sale in any instance where the specialist was required by Rule 1001(a)(iv) to take the contra side of an auto ex execution.

Exchange Rule 91. As the specialist does not accept an auto ex order for execution or act as agent for such order, the transaction confirmation requirements of Rule 91 will not apply in any instance where the specialist is the contra party to an auto ex execution.

Exchange Rule 104. Exchange Rule 104 contains the specialist's affirmative and negative obligations, and restricts the specialists' ability to purchase stock on direct plus ticks, and sell stock on direct minus ticks. The Exchange is proposing that any instance in which the specialist is effecting such a direct tick transaction only because he or she has been required to assume the contra side of an auto ex execution as described above shall be deemed to be a ''neutral'' tranaction for purposes of Rule 104, and shall be deemed not to be in violation of the rule. The Exchange believes that this interpretation is appropriate because the specialist is not setting the price, but is simply being required to trade at a price set by other market participants.

[28] *See* Exemption Letter.

permit floor brokers to effect short sales in the auction market based upon the last reported transaction at the time of the agreement to the auction market trade, and irrespective of auto ex trades that are reported while the transaction is being completed, as contemplated by Rule 1003. In a letter dated December 21, 2000, the Commission granted to the Exchange certain exemptive relief from Commission Rule 10a–1 regarding these Exchange rules for the duration of the pilot, subject to the conditions described in the letter.[29] Consequently, the Commission finds that in light of the relief granted from Rule 10a–1, Rule 10a–1 does not prohibit implementation of NYSe Direct+ as discussed in this order, during the pilot program. If the Exchange decides to continue the program, the Exchange would be required to submit a proposed rule change extending, or requesting permanent approval of, the pilot, and another request for relief from Commission Rule 10a–1.

Accelerated Approval for Amendment No. 1

The Commission finds good cause for accelerating approval of Amendments Nos. 1 and 2 to the proposed rule change prior to the thirtieth day after publication in the **Federal Register**. The Commission notes that these Amendments provide useful clarifications to the proposed rules. Accordingly, the Commission finds that good cause exists, consistent with sections 6(b)(5) of the Act,[30] and section 19(b) of the Act [31] to accelerate approval of Amendments Nos. 1 and 2 to the proposed rule change.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendments Nos. 1 and 2, including whether the amendments are consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW, Washington, DC 20549–0609. 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 Commissions 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to the File No. SR–NYSE–00–18 and should be submitted by January 25, 2001.

VI. Conclusion

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act,[32] that the proposed rule change (SR–NYSE–00–18), as amended, is approved on a pilot basis until December 21, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[33]

Jonathan G. Katz,

Secretary.

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[29] *See* Exemption Letter. The exemption granted with respect to proposed rule 1001(a)(iv) is limited to situations where the specialist is required to take the contra side of an auto ex execution against the published quotation, even though the specialist's interest was not part of the published quotation, because: (1) The published quotation reflects interest that has received an execution, but the quotation has not been updated to reflect this fact: or (2) the published quotation reflects interest that had been cancelled, but the quotation has not been updated to reflect this fact. The no-action relief with respect to proposed Rule 1003 is subject to certain limitations. First, when an auto ex trade is reported between the time that the auction market short sale is agreed upon and when it is reported, and the auto ex trade report is at a price that would result in the auction market trade being reported as a minus or zero-minus tick, the auction market short sale must be presented to an NYSE floor official. In addition, the NYSE floor official must: (a) Find that the short sale was presented for reporting immediately after agreement to the trade; (b) find that the short sale was priced in compliance with Rule 10a–1 at the time that the floor brokers agreed to the trade; (c) find that the short sale price is not lower than the best bid displayed in the auction market at the time the transaction is reported; and (d) direct that the trade be reported as a ''sold sale.'' Finally, the NYSE must keep records of all floor brokers' transactions relying upon this exemption, and present this information upon request to the Division.

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78s(b).

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43771; File No. SR–NYSE–00–33]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc., Amending NYSE Rule 15A Relating to the Intermarket Trading System

December 22, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 18, 2000, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On November 30, 2000, the Exchange filed an amendment to the proposed rule change.[3] As amended, the proposal is effective upon filing with the Commission, pursuant to section 19(b)(3)(A) of the Act,[4] and Rule 19b–4(f)(6) thereunder.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Rule 15A with respect to the definition of ''ITS/CAES Market Maker.'' Below is the text of the proposed rule change. Additions are italicized and deletions are in brackets.
NYSE Rule 15A(a)(6)

''ITS/CAES Market Maker'', as that term is used in the Rule, means a NASD member that is registered as a market maker with the NASD for the purposes of the Applications with respect to one or more specified *System securities* [''ITS/CAES securities'' as more fully described in the ITS Plan].

II. Self-Regulatory Organization's Statement of the Purposes of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* November 30, 2000 letter from James E. Buck, Corporate Secretary, NYSE, to Joseph P. Morra, Special Counsel, Division of Market Regulation, Commission (''Amendment No. 1''). In Amendment No. 1, the NYSE asked the Commission to consider the proposal pursuant to Section 19(b)(3)(A) of Act and Rule 19b–4(f)(6) thereunder. 15 U.S.C. 78s(b)(3)(A), 17 CFR 240.19b–4(f)(6). The Commission has agreed to accept the original proposal as satisfying the 5-day pre-filing requirement pursuant to Rule 19b–4(f)(6). 17 CFR 240.19b–4(f)(6).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6). For purposes of calculating the 60-day abrogation period, the Commission considers the period to begin as of the date the Exchange filed Amendment No. 1, November 30, 2000.

Exchange 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

1. Purpose

According to the Exchange, the purpose of the proposed rule change is to amend the definition of ''ITS/CAES Market Maker'' to eliminate the current reference to ''ITS/CAES securities.'' Since 1982, the National Association of Securities Dealers' participation in the ITS Plan had been limited to securities subject to SEC Rule 19c–3 (''ITS/CAES Securities'').[6] On December 9, 1999, the Commission adopted amendments to the ITS Plan to expand the ITS/CAES linkage to all listed securities, thus rendering unnecessary the term ''ITS/CAES securities.'' [7]

2. Statutory Basis

The Exchange believes that the proposed amendment to NYSE Rule 15A is consistent with section 6(b)(5) of the Act [8] as it is designed to promote just and equitable principles of trade. The Exchange also believes the amendment is consistent with section 11A(a)(1)(D) of the Act,[9] which calls for the linking of markets for qualified securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited not received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549–0609. 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange.

All submissions should refer to File No. SR–NYSE–00–33 and should be submitted by January 25, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

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[6] 17 CFR 240.19c–3.

[7] *See* Securities Exchange Act Release No. 42212 (December 9, 1999), 64 FR 70297 (December 16, 1999).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78k–1(a)(1)(D).

[10] U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43773; File No. SR–Phlx–00–31]

Self Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendments No. 1 and No. 2 by the Philadelphia Stock Exchange, Inc., Relating to the Listing of Trust Issued Receipts

December 27, 2000.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2000, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. On December 13, 2000, the Phlx filed Amendment No. 1 to the proposed rule change.[3] On December 18, 2000, the Phlx filed Amendment No. 2 to the proposed rule change.[4] The Commission is publishing this notice to solicit comments on the proposed rule change and Amendments No. 1 and No. 2 from interested persons and to approve the proposal and Amendments No. 1 and No. 2 on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend its rules to create listing criteria and additional trading halt criteria to allow the Exchange to list and trade trust issued receipts, and to trade Holding Company

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from John Dayton, Assistant Secretary and Counsel, Phlx, to Nancy J. Sanow Assistant Director, Division of Market Regulation (''Division''), Commission, dated December 12, 2000 (''Amendment No. 1''). In Amendment No. 1, the Phlx corrected technical errors in the rule text and the language of the rule text. The Phlx also deleted proposed Phlx Rule 803(j)(4) because the 4:00 p.m. deadline until which trust issued receipts can trade is already addressed in current Phlx Rule 101, Supplementary Material .02. The Phlx determined to reserve Phlx Rule 803(j)(4) for future use.

[4] *See* Letter from John Dayton, Assistant Secretary and Counsel, Phlx, to Nancy J. Sanow Assistant Director, Division, Commission, dated December 15, 2000 (''Amendment No. 2''). In Amendment No. 2, the Phlx renumbered proposed Phlx Rule 133, Supplementary Material .05 as proposed Phlx Rule 136(b). Phlx Rule 136 was created in a separate Phlx filing and relates to trading halts in certain exchange traded funds. *See* Securities Exchange Act Release No. 43717 (December 13, 2000) (Phlx–00–54). The Phlx also clarified certain changes to the rule text made in Amendment No. 1.

Depositary Receipts (''HOLDRs''),[5] a type of trust issued receipt, pursuant to unlisted trading privileges (''UTP'').

Below is the text of the proposed rule change. Proposed new language is in *italics*.

* * * * *

Rule 136. Trading Halts in Certain Exchange Traded Funds

(a) Rule 1047A(c) shall apply to the trading of Trust Shares listed pursuant to the terms of Rule 803(i). The term ''option'' as used therein shall be deemed for the purposes of this rule only to include a Trust Share.

(b) Rule 1047A(c) shall apply to the trading of Trust Issued Receipts listed pursuant to the terms of Rule 803(j). The term ''option'' as used therein shall be deemed for the purposes of this rule only to include a Trust Issued Receipt. The term ''index'' as used therein shall be deemed for the purposes of this rule only to mean ''basket''.

* * * * *

Criteria for Listing—Tier I

Rule 803

(j) Trust Issued Receipts

(1) Applicability, Rule 803(j) is applicable only to Trust Issued Receipts. Except to the extent inconsistent with Rule 803(j) or unless the context otherwise requires, the provisions of the By-laws and all other rules and policies of the Board of Governors shall be applicable to the trading on the Exchange of such securities. Trust Issued Receipts are included within the definition of ''security'' or ''securities'' as such terms are used in the By-laws and Rules of the Exchange.

(2) Definitions. The following terms as used in the Rules shall, unless the context otherwise requires, have the meanings herein specified:

(A) Trust Issued Receipts. The term ''Trust Issued Receipt'' means a security

(i) that is issued by a trust (''Trust'') which holds specified securities deposited with the Trust;

(ii) that, when aggregated in some specified minimum number, may be surrendered to the Trust by the beneficial owner to receive the securities; and

(iii) that pays beneficial owners dividends and other distributions on the deposited securities, if any are declared and paid to the trustee by an issuer of the deposited securities.

(B) Reporting Authority. The term ''Reporting Authority'' in respect of a particular series of Trust Issued Receipts means the Exchange, a wholly-owned subsidiary of the Exchange, an institution (including the Trustee for that series of Trust Issued Receipts), or a reporting service designated by the Exchange or its subsidiary or by the exchange that lists a particular series of Trust Issued Receipts (if the Exchange is trading the particular series of Trust Issued Receipts pursuant to unlisted trading privileges) as the official source for calculating and reporting information relating to such series of Trust Issued Receipts, including, but not limited to, any current basket or portfolio value; the current value of the basket or portfolio of securities required to be deposited to the Trust in connection with issuance of that series of Trust Issued Receipts; the amount of any dividend equivalent payment or cash distribution to holders of that series of Trust Issued Receipts, net asset value, or other information relating to the creation, redemption or trading of that series of Trust Issued Receipts.

(3) Prospectus. Members and member organizations shall provide to all purchasers of newly issued Trust Issued Receipts a prospectus for the series of Trust Issued Receipts.

(4) Reserved.

(5) Designation. The Exchange may list and trade Trust Issued Receipts based on one or more securities. The Trust Issued Receipts based on particular securities shall be designated as a separate series and shall be identified by a unique symbol. The securities that are included in a series of Trust Issued Receipts shall be selected by the Exchange or its agent, a wholly-owned subsidiary of the Exchange, or by such other person as shall have a proprietary interest in such Trust Issued Receipts.

(6) Initial and Continued Listing. Trust Issued Receipts will be listed and traded on the Exchange subject to application of the following criteria:

(A) Initial Listing. For each Trust, the Exchange will establish a minimum number of Trust Issued Receipts required to be outstanding at the time of commencement of trading on the Exchange.

(B) Continued Listing. Following the initial twelve month period after formation of a Trust and commencement of trading on the Exchange, the Exchange will consider the suspension of trading in or removal from listing of a Trust upon which a series of Trust Issued Receipts is based under any of the following circumstances:

(i) if the Trust has more than 60 days remaining until termination and there are fewer than 50 record and/or beneficial holders of Trust Issued Receipts for 30 or more consecutive trading days;

(ii) if the Trust has fewer than 50,000 receipts issued and outstanding;

(iii) if the market value of all receipts issued and outstanding is less than $1,000,000; or

(iv) if such other event shall occur or condition exists which in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

(C) Upon termination of a Trust, the Exchange requires that Trust Issued Receipts issued in connection with such Trust be removed from Exchange listing. A Trust may terminate in accordance with the provisions of the Trust prospectus, which may provide for termination if the value of securities in the Trust falls below a specified amount.

(7) Term. The stated term of the Trust shall be as stated in the Trust prospectus. However, a Trust may be terminated under such earlier circumstances as may be specified in the Trust prospectus.

(8) Trustee. The Trustee must be a trust company or banking institution having substantial capital and surplus and the experience and facilities for handling corporate trust business. In cases where, for any reason, an individual has been appointed as trustee, a qualified trust company or banking institution must be appointed co-trustee.

(9) Voting. Voting rights shall be as set forth in the Trust prospectus.

(10) Limitation of Liability. Neither the Exchange, the Reporting Authority nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current basket or portfolio value, the current value of the portfolio of securities required to be deposited to the Trust; the amount of any dividend equivalent payment or cash distribution to holders of Trust Issued Receipts; net asset value; or other information relating to the creation, redemption or trading of Trust Issued Receipts, resulting from any negligent act or omission by the Exchange, or the Reporting Authority, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange or its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in

[5] ''HOLDRs'' and ''Holding Company Depositary Receipts'' are service marks of Merrill Lynch & Co.

one or more underlying securities. The Exchange makes no warranty, express or implied, as to results to be obtained by any person or entity from the use of Trust Issued Receipts or any underlying basket or portfolio of securities or data included therein and the Exchange makes no express or implied warranties, and disclaims all warranties of merchantability or fitness for a particular purpose with respect to Trust Issued Receipts or any underlying basket or portfolio of securities or data included therein. This limitation of liability shall be in addition to any other limitation contained in the Exchange's Articles of Incorporation or By-laws or elsewhere in the Rules.

(11) Listing Fees and Other Rules. The Exchange may, in its discretion, waive listing fees for any issuer of Trust Issued Receipts listed on the Exchange pursuant to Rule 803(j). The provisions of Rules 847, 849, 850 and 851 do not apply to trusts issuing Trust Issued Receipts listed on the Exchange pursuant to Rule 803(j), or to the trustees or the sponsors thereof. In addition, consideration of the suspension of trading in or removal from listing of any Trust Issued Receipts pursuant to Rule 810 will be made pursuant to the criteria set forth in section 6(B) of this Rule 802(j) rather than the specific criteria set forth in subsections (1) through (5) of Rule 810(a).

* * * * *

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 Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange 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

1. Purpose

The Exchange is proposing listing criteria and additional trading half criteria to allow the Exchange to list trust issued receipts, and to trade currently issued HOLDRs,[6] a series of trust issued receipts, pursuant to UTP. The Exchange represents that trust issued receipts provide investors with a flexible, cost-effective way to purchase, hold and transfer the securities of one or more specified companies.

a. *Trust Issued Receipts Generally. Description.* Trust issued receipts are negotiable receipts which are issued by a trust representing securities of issuers that have been deposited and are held on behalf of the holders of the trust issued receipts. Trust issued receipts allow investors to hold securities investments from a variety of companies throughout a particular industry in a single, exchange-listed and traded instrument that represents their beneficial ownership of each of the deposited securities. Holders of trust issued receipts maintain beneficial ownership of each of the deposited securities evidence by trust issued receipts. Holders may cancel their trust issued receipts at any time to receive the deposited securities.

Beneficial owners of the receipts have the same rights, privileges and obligations as they would have if they beneficially owned the deposited securities outside of the trust issued receipt program. For example, holders of the receipts have the right to instruct the trustee to vote the deposited securities evidenced by the receipts; receive reports, proxies and other information distributed by the issuers of the deposited securities to their security holders; and receive dividends and other distributions if any are declared and paid by the issuers of the deposited securities to the trustee.

Creation of a Trust. Trust issued receipts will be issued by a trust created pursuant to a depository trust agreement. After the initial offering, the trust may issue additional receipts on a continuous basis when an investor deposits the requisite securities with the trust. An investor in trust issued receipts will be permitted to withdraw his or her deposited securities upon delivery to the trustee of one or more round-lots of 100 trust issued receipts and to deposit such securities to receive trust issued receipts.

b. *Criteria for Initial and Continued Listing.* The Exchange believes that the listing criteria proposed in its new rule are generally consistent with the ''Other Securities'' criteria currently found Phlx Rule 803(f) as well as the trust issued receipt listing criteria currently used by the Amex,[7] the Chicago Stock Exchange, Inc. (''CHX''),[8] and the Boston Stock Exchange, Inc. (''BSE'').[9]

Under the proposal rule, if trust issued receipts are to be listed on the Exchange, the Exchange will establish a minimum number of trust issued receipts required to be outstanding at the time trading commences on the Exchange and will include that number in any required submission to the Commission.

With respect to continued listing, the proposed rule provides that the Exchange will consider the suspension of trading in, or removal from listing of, a trust upon which a series of trust issued receipts is based in certain circumstances. More specifically, following the initial twelve month period after formation of a trust and commencement of trading on the Exchange, the Exchange will consider the suspension of trading in or removal from listing of a trust upon which a series of trust issued receipts is based if: (1) The trust has more than sixty days remaining until termination and there are fewer than fifty record and/or beneficial holders of trust issued receipts for thirty or more consecutive trading days; (2) the trust has fewer than 50,000 receipts issued and outstanding; (3) the market value of all receipts issued and outstanding is less than $1,000,000; or (4) such other event shall occur or condition exists which in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

These criteria are designed to eliminate less liquid products while maintaining the flexibility to avoid delisting trust issued receipts (leading to a possible termination of the trust) because of relatively brief fluctuations in market conditions that may cause the number of holders to vary.

The Exchange will not, however, be required to suspend or delist from trading, based on the proposed rule, any trust issued receipts for a period of one

[6] Currently-issued, HOLDRs includes Biotech, Broadband, Business to Business, Internet, Internet Architecture, Internet Infrastructure, Market 2000+, Pharmaceutical, Regional Bank, Semiconductor, Software, Telecom and Utilities HOLDRs, all of which are listed on the American Stock Exchange LLP (''Amex''). Within the next few weeks, the Exchange will file an amendment to the proposed listing standards to accommodate a change in the HOLDRs product related to the composition of the portfolio. The prospectus for Market 2000+ HOLDRs describes this change. Telephone conversation between John Dayton, Assistant Secretary and Counsel, Phlx, and Heather Traeger, Attorney, Division, Commission, on December 21, 2000.

[7] *See* Securities Exchange Act Release No. 41892 (September 21, 1999), 64 FR 52559 (September 29, 1999) (SR–Emex–99–20).

[8] *See* Securities Exchange Act Release No. 42056 (October 22, 1999), 64 FR 58870 (November 1, 1999) (SR–CHX–99–22).

[9] *See* Securities Exchange Act Release No. 42347 (January 13, 2000), 64 FR 4451 (January 27, 2000) (SR–BSE–99–15).

year after the initial listing of such trust issued receipts for trading on the Exchange. Notwithstanding, in the first year and thereafter, if the number of companies represented by the deposited securities drops to less than nine, and each time thereafter the number of companies is reduced, the Exchange will consult with the Commission to confirm the appropriateness of continued listing of the trust issued receipts.

c. *Exchange Rules Applicable to the Trading of Trust Issued. Receipts.* Trust issued receipts are considered ''securities'' under the Rules of the Exchange and are subject to all applicable trading rules, including the provisions of Phlx 2001A, ITS Trade-Throughs and Locked Markets, which addresses trade-throughs for ITS securities, as well as rules governing priority, parity and precedence of orders, market volatility-related trading halt provisions and responsibilities of the assigned specialist firm.[10] Exchange equity margin rules will apply.

Trust issued receipts will trade in the appropriate minimum variation, pursuant to Phlx Rule 125. If the trust issued receipts are also traded on the Amex, those receipts will trade at a minimum variation of 1/16 of $1.00 for trust issued receipts selling at or above $.25 and 1/32 of $1.00 for those selling below $.25. If the trust issued receipts are traded on any other exchange or are exclusively listed on the Phlx, different minimum variations may apply. In addition, the Exchange notes that due to industry-wide changes in minimum price variations, trading in trust issued receipts are expected to be converted from fractions to decimals.[11]

The Exchange's surveillance procedures for trust issued receipt will be similar to the procedures used for Trust Shares and will incorporate and rely upon existing Phlx surveillance systems.

Prior to the commencement of trading of each new trust issued receipt, the Exchange will distribute a circular to its members and member organizations alerting them to the unique characteristics of trust issued receipts, including the fact that trust issued receipts are not individually redeemable. The circular will also confirm that trust issued receipts are subject to the Exchange's rule relating to trading halts in certain Exchange traded funds (Phlx Rule 136) and other criteria set forth in proposed Phlx Rule 136(b).[12] The circular will advise members that, in exercising the discretion described in proposed Phlx Rule 136(b), appropriate Exchange officials may consider a variety of factors, including the extent to which trading is not occurring in an underlying security and whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[13]

d. *Disclosure to Customers.* The Exchange will require its members to provide all purchasers of newly issued trust issued receipts with a prospectus for that series of trust issued receipts. Exchange members will be informed of this requirement through the informational circular on each HOLDRs product to be delivered prior to the commencement of trading. The Exchange believes that delivery of this information will apprise investors of the terms, characteristics, and risks of trading trust issued receipts.

e. *Trading of Currently-Issued HOLDRs.* As noted above, upon approval of the Exchange's listing standards for trust issued receipts, the Exchange intends to begin trading various series of trust issued receipts, specifically currently-issued HOLDRs, pursuant to UTP.[14] All currently issued HOLDRs are listed on the Amex.

The Exchange requests approval to trade currently-issued HOLDRs on a UTP basis when it determines it is advisable to do so. Currently-issued HOLDRs will be subject to all Exchange trading rules applicable to securities trading on a UTP basis with the following exceptions. Currently-issued HOLDRs may be acquired, held or transferred only in round-lot amounts (or round-lot multiples) of 100 receipts. Thus, upon implementation of the appropriate systems feature, orders for less than a round-lot will be rejected, while orders for greater than a round-lot, but not a round-lot multiple, will be executed to the extent of the largest round-lot multiple, rejecting the remaining odd-lot.[15] In addition, transactions in currently-issued HOLDRs have received an exemption from the short sale rule; therefore, they will not be subject to that restriction on the Exchange.[16] Transactions in trust issued receipts may be effected until 4:00 p.m.[17]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6 of the Act[18] in general, and in particular, with section 6(b)(5),[19] in that it is designed to promote just and equitable principle of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that trading of currently-issued HOLDRs on a UTP basis should add additional liquidity and provide investors with another choice of venue to conduct trading in these products.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange did not receive any written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change and Amendments No. 1 and No. 2 are consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission,

[10] If trust issued receipts are traded only in round lots (or round lot multiples), the Exchange's rules relating to odd lot executions will not apply.

[11] The Exchange notes that Semiconductor HOLDRs are participating in the Decimal Pilot Program and therefore, if traded on the Exchange, will trade in the appropriate minimal variation.

[12] The Phlx confirmed the Phlx Rule 133 should be changed to Phlx Rule 136, and that proposed Phlx Rule 133, Supplementary Material .05, should be changed to proposed Phlx Rule 136(b) in accordance with the changes made in Amendment No. 2, *supra* note 4. Telephone conversation between John Dayton, Assistant Secretary and Counsel, Phlx , and Sapna C. Patel, attorney, Division, Commission, December 14, 2000.

[13] *Id.*

[14] *See supra* note 6.

[15] For example, an order for 50 Trust Issued Receipts will be rejected, while an order for 1,050 Trust Issued Receipts will be executed in part (1,000) and rejected in part (50).

[16] The Exchange understands that the Commission has provided an exemption from the short sale rule, Rule 10a–1 under the act, for transactions in HOLDRs. *See* SEC Exemption Letter, 1999 WL 1038048 (S.E.C.). The Exchange will issue a notice to its members detailing the terms of the exemption prior to any trading in HOLDRs.

[17] *See* Amendment No. 1, *supra* note 3. Amendment No. 1 indicates the Phlx Rule 101, Supplementary Material .02 states that equities on the Exchange's Equity Floor trade until 4:00 p.m. unless otherwise announced by the Exchange. The Exchange has confirmed that it will make the appropriate filing with the Commission should it decide to change this time. Telephone conversation between John Dayton, Assistance Secretary and Counsel, Phlx, and Sapna C. Patel, Attorney, Division, Commission, December 14, 2000.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Phlx–00–31 and should be submitted by January 25, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

A. Generally

The Commission finds that the proposed rule change is consistent with the requirements of section (b)(5) of the Act [20] and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds, as it did in the Amex, the CHX, and the BSE orders approving the listing and trading of trust issued receipts and Internet HOLDRs,[21] that the proposed establishing listing standards for trust issued receipts and to trade Internet HOLDRs will provide investors with a convenient and less expensive way of participating in the securities market. The proposal should advance the public interest by providing investors with increased flexibility in satisfying their investment needs by allowing them to purchase and sell a single security replicating the performance of a broad portfolio of stocks at negotiated prices throughout the business day. Accordingly, the Commission finds that the proposal will facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[22]

As noted in the Amex approval order, the Commission believes that trust issued receipts will provide investors with an alternative to trading a broad range of securities on an individual basis, and will give investors the ability to trade trust issued receipts representing a portfolio of securities continuously throughout the business day in secondary market transactions at negotiated prices. Trust issued receipts will allow investors to: (1) Respond quickly to changes in the overall securities markets generally and for the industry represented by a particular trust; (2) trade, at a price disseminated on a continuous basis, a single representing a portfolio of securities that the investor owns beneficially; (3) engage in hedging strategies similar to those used by institutional investors; (4) reduce transaction costs for trading a portfolio of securities; and (5) retain beneficial ownership of the securities underlying the trust issued receipts.

Although trust issued receipts are not leveraged instruments, and, therefore, do not possess any of the attributes of stock index options, their prices will be derived and based upon the securities held in their respective trusts. Accordingly, the level of risk involved in the purchase or sale of trust issued receipts is similar to the risk involved in the purchase or sale of traditional common stock, with the exception that the pricing mechanism for trust issued receipts is based on a basket of securities.[23] Nevertheless, the Commission believes that the unique nature of trust issued receipts raises certain product design, disclosure, trading, and other issues.

B. Trading of Trust Issued Receipts—Listing and UTP

The Commission finds that the Phlx's proposal contains adequate rules and procedures to govern the trading of trust issued receipts whether by listing or pursuant to UTP. Trust issued receipts are equity securities that will be subject to the full panoply of Phlx rules governing the trading of equity securities on the Phlx, including, among others, rules governing the priority, parity and precedence of orders, responsibilities of the specialist, account opening and customer suitability requirements, and the election of a stop or limit order.[24]

In addition, the Phlx had developed specific listing and delisting criteria for trust issued receipts that will help to ensure that a minimum level of liquidity will exist for trust issued receipts to allow for the maintenance of fair and orderly markets. The delisting criteria also allows the Phlx to consider the suspension of trading and the delisting of a trust issued receipt if an event occurred that made further dealings in such securities inadvisable. This will give the Phlx flexibility to delist trust issued receipts if circumstances warrant such action. The Phlx's proposal also provides procedures to halt trading in trust issued receipts in certain enumerated circumstances.

Moreover, in approving this proposal, the Commission notes the Exchange's belief that trust issued receipts will not trade at a material discount or premium in relation to the overall value of the trusts' assets because of potential arbitrage opportunities. The Exchange represents that the potential for arbitrage should keep the market price of a trust issued receipt comparable to the overall value of the deposited securities.

Furthermore, the Commission believes that the Exchange's proposal to trade trust issued receipts in minimum fractional increments of 1/16 of $1.00 is consistent with the Act.[25] The Commission believes that such trading should enhance market liquidity, and should promote more accurate pricing, tighter quotations, and reduced price fluctuations. The Commission also believes that such trading should allow customers to receive the best possible execution of their transactions in trust issued receipts.

Finally, the Phlx will apply surveillance procedures for trust issued receipts that will be similar to the procedures used for Trust Shares and will incorporate and rely upon existing Phlx surveillance procedures governing equities. The Commission believes that these surveillance procedures are adequate to address concerns associated

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[20] *Id.*

[21] *See supra* note 9 (approving listing and trading of trust issued receipts and Internet HOLDRs on the BSE pursuant to UTP); *see supra* note 8 (approving listing and trading of trust issued receipts and Internet HOLDRs on the CHX pursuant to UTP); and *see supra* note 7 (approving listing and trading of trust issued receipts and Internet HOLDRs on the Amex).

[22] In approving this rule, the Commission notes that it has also considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[23] The Commission has concerns about continued trading of the trust issued receipts whether listed or pursuant to UTP, if the number of component securities falls to a level below nine securities, because the receipts may no longer adequately reflect a cross-section of the selected industry. Accordingly, the Phlx has agreed to consult the Commission concerning continued trading, once the trust has fewer than nine component securities, and for each subsequent loss of a security thereafter. Telephone conversion between John Dayton, Assistant Secretary and Counsel, Phlx, and Heather Traeger, Attorney, Division, Commission, November 29, 2000.

[24] Trading rules pertaining to the availability of odd-lot trading do not apply because trust issued receipts only can be traded in round-lots.

[25] The Exchange notes, however, that due to industry-wide changes in minimum price variations, trading in trust issued receipts are expected to be converted from fractions to decimals. More specifically, the Exchange notes that semiconductor HOLDRs are participating in the Decimal Pilot Program and therefore, if traded on the Exchange, will trade in the appropriate minimal variation.

with listing and trading trust issued receipts, including any concerns associated with purchasing and redeeming round-lots of 100 receipts. Accordingly, the Commission believes that the rules governing the trading of trust issued receipts provide adequate safeguards to prevent manipulative acts and practices and to protect investors and the public interest.

C. Disclosure and Dissemination of Information

The Commission believes that the Exchange's proposal will ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading trust issued receipts. The prospectus will address the special characteristics of a particular trust issued receipt basket, including a statement regarding its redeemability and method of creation. The Commission notes that all investors in trust issued receipts who purchase in the initial offering will receive a prospectus. In addition, anyone purchasing a trust issued receipt directly from the trust (by delivering the underlying securities to the trust) will also receive a prospectus. Finally, all Phlx member firms who purchase trust issued receipts from the trust for resale to customers must deliver a prospectus to such customers.

The Commission also notes that upon the initial listing of any trust issued receipts, the Exchange will issue a circular to its members explaining the unique characteristics and risks of this type of security. The circular also will note the Exchange members' prospectus delivery requirements, and highlight the characteristics of purchases in trust issued receipts. The circular also will inform members of Exchange policies regarding trading halts in issued receipts.

D. Accelerated Approval

The Phlx has requested that the Commission find good cause for approving the proposed rule change and Amendments No. 1 and No. 2 to the thirtieth day after the date of publication of notice in the **Federal Register**. The Commission believes that the Exchange's proposal to trade trust issued receipts, and specifically the existing series of HOLDRs [26] pursuant to UTP privileges, will provide investors with a convenient and less expensive way of participating in the securities markets. The Commission believes that the proposed rule change should produce added benefits to investors through the increased competition between other market centers trading the product. Specifically, the Commission believes that by increasing the availability of trust issued receipts, and in particular Internet HOLDRs, as an investment tool, the Phlx's proposal should help provide investors with increased flexibility in satisfying their investment needs, by allowing them to purchase and sell a single security replicating the performance of a broad portfolio of stocks at negotiated prices throughout the business day. The Commission notes, however, that notwithstanding approval of the listing standards for trust issued receipts, other similarly structured products, including trust issued receipts based on other industries, will require review by the Commission prior to being traded on the Exchange. Additional series cannot be listed by the Exchange prior to contacting Division staff. In addition, the Phlx may be required to submit a rule filing prior to trading a new issue or series on the Exchange.

As noted above, the Commission has approved the listing and trading of trust issued receipts, including various series of HOLDRs, at the Amex, the CHX, and the BSE, under rules that are substantially similar to Phlx Rule 803(j). The trading requirements of trust issued receipts at the Phlx will be substantially similar to the trading requirements of trust issued receipts at the Amex, the CHX, and the BSE. The Commission published those rules in the **Federal Register** for the full notice and comment period. No comments were received on the proposed rules, and the Commission found them consistent with the Act.[27] The Commission does not believe that trading of this product raises novel regulatory issues that were not addressed in the previous filing.

The Commission also finds good cause for approving Amendments No. 1 and No. 2 prior to the thirtieth day after notice of the Amendments is published in the **Federal Register** pursuant to section 19(b)(2) of the Act.[28] Amendment No. 1 makes technical changes to the proposed rule text, deletes proposed Phlx Rule 803(j)(4) because the 4:00 p.m. deadline until which trust issued receipts can trade is already mentioned in current Phlx Rule 101, Supplementary material .02, and indicates that the Phlx is reserving Phlx Rule 803(j)(4) for future use. Amendment No. 2 renumbers proposed Phlx Rule 133, Supplementary Material .05 as proposed Phlx Rule 136(b) to place this proposed rule in the appropriate section of the Phlx Rules. Phlx Rule 136 was created in a separate Phlx filing and relates to trading halts in certain exchange traded funds. In Amendment No. 2, the Phlx also clarifies certain changes to the rule text made in Amendment No. 1. The Commission finds that accelerated approval of Amendments No. 1 and No. 2 is appropriate in order to permit the Phlx to establish accurate and orderly rules regarding the listing and trading of trust issued receipts.

Accordingly, the Commission finds good cause for approving the proposed rule change and Amendments No. 1 and No. 2 prior to the thirtieth day after the date of publication of notice in the **Federal Register**.

It is Therefore Ordered, pursuant to section 19(b)(2) of the Act,[29] that the proposed rule change (SR–Phlx–00–31) and Amendments No. 1 and No. 2 are hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[30]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–157 Filed 1–3–01; 8:45 am]

BILLING CODE 8010–01–M

[26] *See supra* note 6.

[27] *See supra* note 21.

[28] 15 U.S.C. 78s(b)(2).

[29] *Id.*

[30] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

Office of Defense Trade Controls

[Public Notice 3531]

Notifications to the Congress of Proposed Commercial Export Licenses

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State has forwarded the attached Notifications of Proposed Export Licenses to the Congress on the dates shown on the attachments pursuant to sections 36(c) and 36(d) and in compliance with section 36(e) of the Arms Export Control Act (22 U.S.C. 2776).

EFFECTIVE DATE: As shown on each of the nine letters.

FOR FURTHER INFORMATION CONTACT: Mr. William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (202 663–2700).

SUPPLEMENTARY INFORMATION: Section 38(e) of the Arms Export Control Act mandates that notifications to the Congress pursuant to sections 36(c) and

36(d) must be published in the **Federal Register** when they are transmitted to Congress or as soon thereafter as practicable.

Dated: December 28, 2000.

William J. Lowell,

Director, Office of Defense Trade Controls, U.S. Department of State.

October 5, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c)(d) of the Arms Export Control Act, I am transmitting herewith certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount $50,000,000 or more.

The transaction contained in the attached certification involves the export of defense services and technical data to Germany and France, for the cooperative development and production of a Storable Upper Stage Rocket Engine (SUSE).

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 66–00.

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 11, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of six (6) Multi-Mission Surveillance Aircraft Systems to the Government of Algeria for use by the Algerian Ministry of Defense. It includes a technical assistance agreement for defense services to support these systems.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 095–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 2, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting herewith certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount $50,000,000 or more.

The transaction contained in the attached certification involves the export to Japan of the Imagery Management Support System to operate in association with the IKONOS commercial remote-sensing satellite.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 096–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

September 15, 2000.

Dear Mr. Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting herewith certification of a proposed Manufacturing License Agreement with Japan.

The transaction described in the attached certification involves the manufacture of image intensifier assemblies for return to the United States.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 98–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 5, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of technical data, information and services on communication satellites GE7, GE8, GE9, GE1A and GE2A to the underwriters from Australia, Belgium, Bermuda, Canada, France, Germany, Italy, Japan, Norway, Sweden and the United Kingdom in order to provide adequate insurance coverage during the operational life of the satellites.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 111–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 3, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting herewith certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the commercial lease of four (4) C-17 cargo aircraft to the United Kingdom Ministry of Defence.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin, Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 113–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 11, 2000

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting herewith certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export of the AsiaSat 4 commercial communications satellite to Hong Kong with launch scheduled from the United States.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 114–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 2, 2000.

Dear Mr. Speaker: Pursuant to Section 36(d) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed Manufacturing License Agreement with Italy.

The transaction described in the attached certification involves the transfer of technical data and defense services for the co-development of an Identification Friend or Foe (IFF) Digital Transponder, Traffic Collision Avoidance System and Ethernet interface.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 127–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

October 11, 2000.

Dear Mr. Speaker: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the export of defense articles or defense services sold commercially under a contract in the amount of $50,000,000 or more.

The transaction contained in the attached certification involves the export to Israel of technical information, defense articles and services necessary for the development of Switchable Eyesafe Laser Rangefinder/Designator (SELRD) systems for Comanche and Apache helicopters.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Barbara Larkin,

Assistant Secretary, Legislative Affairs, Department of State.

Enclosure: Transmittal No. DTC 141–00

The Honorable J. Dennis Hastert, Speaker of the House of Representatives.

[FR Doc. 01–225 Filed 1–3–01; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2000–8557; Notice 1]

Uniroyal Goodrich Tire Manufacturing, Receipt of Application for Decision of Inconsequential Noncompliance

Uniroyal Goodrich Tire Manufacturing (Uniroyal) has determined that a total of 284 P205/60R15 Regul Sport Challenger passenger car tires do not meet the labeling requirements mandated by Federal Motor Vehicle Safety Standard (FMVSS) No. 109, ''New Pneumatic Tires.''

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Uniroyal has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR Part 573, ''Defect and Noncompliance Reports.''

This notice of receipt of an application is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the application.

FMVSS No. 109 (S4.3(d)) requires that each tire shall have permanently molded the generic name of each cord material used in the plies (both sidewall and tread area) of the tire. (S4.3(e)) requires that each tire shall have permanently molded into or onto both sidewalls the actual number of plies in the sidewall, and the actual number of plies in the tread area if different.

The noncompliance with S4.3(d) and (e) relates to the mold number. The tires were marked: Tread Plies: 2 Polyester + 2 Steel + 1 Nylon, Sidewall Plies: 2 Polyester, instead of the required marking of: ''Tread Plies: 1 Polyester +2 Steel, Sidewall Plies: 1 Polyester.

Uniroyal states that of the total (284) tires produced, no more than 17 may have been delivered to their end users. The remaining tires have been isolated in their warehouses and are being scrapped. They do not believe that this marking error will impact motor vehicle safety because the tires meet all applicable Federal Motor Vehicle Safety performance standards.

Interested persons are invited to submit written data, views, and arguments on the application described above. Comments should refer to the docket number and be submitted to: U.S. Department of Transportation, Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested that two copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date, will also be filed and will be considered to the extent possible. When the application is granted or denied, the notice will be published in the **Federal Register** pursuant to the authority indicated below. Comment closing date: February 5, 2001.

Authority: (49 U.S.C. 301118, 301120; delegations of authority at 49 CFR 1.50 and 501.8).

Issued on: December 28, 2000.

Noble N. Bowie,

Acting Associate Administrator for Safety Performance Standards.

[FR Doc. 01–190 Filed 1–3–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Delays in Processing of Exemption Applications

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), RSPA is publishing the following list of exemption applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: J. Suzanne Hedgepeth, Director, Office of Hazardous Materials, Exemptions and Approvals, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001, (202) 366–4535.

Key to ''Reasons for Delay''

1. Awaiting additional information from applicant.

2. Extensive public comment under review.

3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis.

4. Staff review delayed by other priority issues or volume of exemption applications.

Meaning of Application Number Suffixes

N—New application.
M—Modification request.
PM—Party to application with modification request.

Issued in Washington, DC, on December 19, 2000.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials Exemptions and Approvals.

Application No.	Applicant	Reason for delay	Estimated date of completion
	New Exemption Applications		
11862–N	The BOC Group, Murray Hill, NJ	4	01/31/2001
11927–N	Alaska Marine Lines, Inc., Seattle, WA	4	01/31/2001
12142–N	Aristech Chemical Corp., Pittsburgh, PA	4	01/31/2001
12158–N	Hickson Corporation, Conley, GA	4	01/31/2001
12181–N	Aristech, Pittsburgh, PA	4	01/31/2001
12248–N	Ciba Specialty Chemicals Corp., High Point, NC	4	01/31/2001
12281–N	ABS Group, Inc., Houston, TX	4	01/31/2001
12290–N	Savage Industries, Inc., Pottstown, PA	4	01/31/2001
12307–N	Kern County Dept. of Weights & Measures, Bakersfield, CA.	4	01/31/2001
12332–N	Automotive Occupant Restraints Council, Lexington, KY.	4	01/31/2001
12339–N	BOC Gases, Murray Hill, NJ	4	01/31/2001
12353–N	Monson Companies, South Portland, ME	4	01/31/2001
12355–N	Union Tank Car Company, East Chicago, IN	4	01/31/2001
12368–N	Occidental Chemical Corp., Dallas, TX	4	01/31/2001
12381–N	Ideal Chemical & Supply Co., Memphis, TN	4	01/31/2001
12397–N	Astaris, LLC (formerly FMC Corp.), Philadelphia, PA	4	01/31/2001
12406–N	Occidental Chemical Corporation, Dallas, TX	4	01/31/2001
12412–N	Great Western Chemical Company, Portland, OR	4	01/31/2001
12422–N	Connecticut Yankee Atomic Power Co., East Hampton, CT.	1, 4	01/31/2001
12433–N	The Lighter Company, Inc., Miami, FL	4	01/31/2001
12434–N	Salmon Air, Salmon, ID	4	01/31/2001
12440–N	Luxfer Inc., Riverside, CA	4	02/28/2001
12443–N	ChemCentral/Charlotte, Charlotte, NC	4	02/28/2001
12444–N	ST Services, Dallas, TX	4	02/28/2001
12454–N	Ethyl Corp., Richmond, VA	4	02/28/2001
12455–N	United States Marine Safety Association, Philadelphia, PA.	4	02/28/2001
12456–N	Baker Hughes, Houston, TX	4	02/28/2001
12469–N	Department of Energy, Germantown, MD	4	01/31/2001
12473–N	Old Bridge Metals & Chemicals, Inc., Old Bridge, NJ	4	01/31/2001
12475–N	Chemetall GmbH Gesellschaft, Langlshiem, DE	4	02/28/2001
12476–N	Fisher-Rosemount Petroleum, Tulsa, OK	4	02/28/2001
12479–N	Luxfer Gas Cylinder, Riverside, CA	4	02/28/2001
12485–N	StanTrans Services, Dallas, TX	4	02/28/2001
12491–N	PPG Industries, Inc., Pittsburgh, PA	4	12/29/2000
12493–N	Caroline Power & Light Co., Southport, NC	4	02/28/2001
12495–N	South Carolina Electric & Gas Co., Jenkinsville, SC	4	02/28/2001
12497–N	Henderson International Technologies, Inc., Richardson, TX.	4	02/28/2001
12515–N	FIBA Technologies, Inc., Westboro, MA	4	02/28/2001
12517–N	Cytec Industries Inc., Willow Island, WV	4	02/28/2001
	Modifications to Exemptions		
4661–M	Chemetall Foote Corporation, Kings Mountain, NC	4	01/31/2001
6658–M	Mason & Hanger Corp. (USDOE/Pantex Plant), Amarillo, TX.	4	01/31/2001
8086–M	The Boeing Co (Mil Aircraft & Missiles Sys Group), Seattle, WA.	4	01/31/2001
8308–M	Tradewind Enterprises, Inc., Hillsboro, OR	4	01/31/2001
8554–M	Orica USA, Inc., Englewood, CO	4	01/31/2001
10656–M	Conf. of Radiation Control Program Directors, Inc., Frankfort, KY.	4	01/31/2001
10672–M	Burlington Packaging, Inc., Brooklyn, NY	4	01/31/2001
11296–M	Heritage Transport, LLC, Indianapolis, IN	4	01/31/2001
11316–M	TRW Automotive, Queen Creek, AZ	4	01/31/2001
11537–M	JCI Jones Chemicals, Inc., Milford, VA	4	01/31/2001
11769–M	Great Western Chemical Company, Portland, OR	4	01/31/2001
11769–M	Great Western Chemical Company, Portland, OR	4	01/31/2001

Application No.	Applicant	Reason for delay	Estimated date of completion
11769–M	Hydrite Chemical Company, Brookfield, WI	4	01/31/2001
11798–M	Air Products and Chemicals, Inc., Allentown, PA	4	01/31/2001
11798–M	Anderson Development Company, Adrian, MI	4	01/31/2001
11911–M	Transfer Flow, Inc., Chico, CA	4	02/28/2001
11916–M	CP Industries, Inc., McKeesport, PA	4	02/28/2001
11967–M	Savage Industries Incorporated, Pottstown, PA	4	02/28/2001
12074–M	Van Hool NV, B–2500 Lier Koningshooikt, BG	1	02/28/2001
12130–M	FIBA Technologies, Inc., Westboro, MA	4	02/28/2001
12178–M	STC Technologies, Inc., Bethlehem, PA	1	02/28/2001
12301–M	Steptoe & Johnson, LLP, Washington, DC	4	02/28/2001

[FR Doc. 01–238 Filed 1–3–01; 8:45 am]
BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Docket No. RSPA–00–7283; Notice No. 01–03]

Hazardous Materials Safety: Public Meeting Related to Customer Service and Regulatory Review

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of public meeting.

SUMMARY: RSPA will hold a public meeting to seek information from the public on improving safety, reducing costs (especially to small businesses) and increasing customer service through RSPA's management of the national hazardous materials transportation safety program. This meeting is being held in conjunction with a Hazardous Materials Multimodal Training Seminar sponsored by RSPA on February 6 and 7, 2001.

ADDRESSES: The public meeting will be held at the Westin Long Beach Hotel, 333 East Ocean Blvd., Long Beach, CA 90802 (562–436–3000). For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact Michael Johnsen at the address or phone number listed under **FOR FURTHER INFORMATION CONTACT** as soon as possible.

DATES: The public meeting will be held on Wednesday, February 7, 2001, 1:00 p.m. to 5:00 p.m.; however, the meeting may end prior to 5:00 p.m., dependent upon public interest.

FOR FURTHER INFORMATION CONTACT: Michael Johnsen, Office of Hazardous Materials Standards, RSPA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. Phone (202) 366–8553.

SUPPLEMENTARY INFORMATION:

Focus on Issues of Interest to Affected Parties

RSPA (''we'' and ''our'') is interested in soliciting comments on the kind and quality of services our customers want and their level of satisfaction with the services we currently provide to promote understanding and compliance with the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). These services include the following:

(1) *Hazardous Materials Information Center (HMIC).* A staff of three persons is available Monday to Friday (except Federal holidays) between 9:00 am and 5:00 pm (Eastern time) to address telephonic inquiries from shippers, carriers, packaging manufacturers and other persons concerning requirements in the HMR for the safe transportation of hazardous materials. In 2000, the HMIC handled more than 33,000 calls. The toll-free number is 1–800–HMR–4922.

(2) *Internet access.* Our site on the worldwide web (*http://hazmat.dot.gov*) provides information concerning hazardous materials rulemakings, exemptions, letters of clarification, international activities, incident data, the 2000 Emergency Response Guidebook and much more.

(3) *Fax on demand.* For persons who do not have access to the internet, we operate an automated fax-back system that allows callers access to more than 600 pages of informational materials, including letters of clarification and recently published rulemakings, through their own fax machines. A facsimile copy of the catalog of available documents may be obtained by accessing the fax-on-demand feature through our HMIC number 1–800–HMR–4922.

(4) *Training.* To promote compliance with the HMR, we distribute brochures, charts, publications, training materials, videotapes, and other safety-related information to hazmat employers and hazmat employees in the private and government sectors, as well as to the general public. Hazardous materials training is provided to Federal, State and local enforcement agencies, industry, and emergency response personnel. In addition, we provide personal computer based self-study programs through a CD–ROM modular training series.

(5) *Government-Industry partnerships.* To the extent permitted through our limited resources, we participate in meetings, conferences, training workshops, and the like sponsored by public sector, industry, and international organizations having an interest in the safe transportation of hazardous materials.

Regulations and Administrative Procedures

On December 20, 1999, we published a notice of regulatory review (Docket No. RSPA–99–5143, 64 FR 71098) requesting comments on the economic impact of the regulations on small entities. This year we are analyzing rules in 49 CFR parts 174 and 177, Carriage by Rail and Carriage by Public Highway, respectively. Meeting participants are invited to take this opportunity to suggest whether specific rules in these parts should be revised or revoked to lessen the impact on small entities.

We are interested, also, in receiving comments on the quality of our processing of written requests for information, applications for exemptions and approvals, registration statements, and other administrative actions. Meeting participants are encouraged to provide suggestions on how we may improve our performance in processing these administrative actions.

We welcome all comments on ways to improve understanding and compliance with the HMR, including removal of obsolete requirements, revisions to conflicting or confusing requirements, and the use of plain language in regulations. We will address inquiries concerning new or proposed requirements, including recently

published rulemaking actions concerning:

- RSPA's registration and fee assessment program (Docket No. RSPA–00–8439; 65 FR 76890, December 7, 2000); and
- Harmonization of requirements in the HMR pertaining to the transportation of hazardous materials with standards published by the United Nations Recommendations on the Transport of Dangerous Goods, the International Maritime Dangerous Goods Code, and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (Docket No. RSPA–2000–7702; 65 FR 63294, October 23, 2000).

Representatives from the United States Coast Guard, Federal Aviation Administration, Federal Railroad Administration and Federal Motor Carrier Safety Administration will participate with RSPA in this public meeting and address modal-specific issues.

Conduct of the Meeting

This is an informal meeting intended to produce a dialogue between agency personnel and persons affected by the hazardous materials transportation safety program. The presiding official may find it necessary to limit the time available to each person to ensure that all participants have an opportunity to speak. Conversely, this meeting may conclude early if all persons wishing to participate have been heard. While there will be no transcript of the meeting, RSPA will prepare a written summary of the meeting and post it in this notice's docket (RSPA–00–7283). Persons interested in participating in this public meeting need not be registered for the Hazardous Materials Multimodal Training Seminar.

Issued in Washington, D.C. on December 29, 2000.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 01–239 Filed 1–3–01; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration (RSPA), DOT

[Docket No. RSPA–00–7666; Notice 1 and RSPA–00–7408; Notice 1]

Pipeline Safety: Pipeline Integrity Management in High Consequence Areas (Natural Gas Pipelines) and Communications (Natural Gas and Hazardous Liquid Pipelines)

AGENCY: Office of Pipeline Safety, Research and Special Programs Administration, DOT.

ACTION: Notice of public meeting and request for comments.

SUMMARY: This notice announces a three-day public meeting. Day 1 will feature reports on the status of industry and government activities on how to improve the integrity of natural gas pipelines. On Day 2, the Integrity Management Communications Work Group will report its status and presentations from members of the public and will further explore communication needs and options. On Day 3, meeting attendees are invited to participate in in-depth discussions on the integrity of natural gas pipelines. This meeting is a continuation of the integrity project begun at a November 18, 1999, public meeting held in Herndon, VA. Since that meeting, OPS has initiated rulemakings requiring hazardous liquid pipeline operators to assess the integrity of pipeline segments that, in the event of a leak or failure, could affect high consequence areas. In anticipation of similar rulemakings applying to natural gas pipelines, OPS has been meeting with representatives of the natural gas pipeline industry, research institutions, and State pipeline safety agencies to understand how integrity management principles can best be applied to improve safety in the gas pipeline industry. OPS has also been exploring communication requirements for all pipeline operators to share information with community and State officials and the public about risks from pipelines, how pipeline risks can be managed and controlled, and how we know the pipelines are being operated safely. This three-day public meeting will present, to the widest possible audience, the results of all analyses and discussions to date, identify issues, and obtain public comment.

DATES: The public meeting will be on February 12, 2001, from 9 a.m. to 4 p.m., February 13, 2001, from 9 a.m. to 4 p.m., and February 14, 2001, from 9 a.m. to 12 noon, at the Crystal City Marriott.

ADDRESSES: (1) *Meeting Address:* Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA, 22202, 703–413–5500. Rooms may be reserved within a block identified as ''Department of Transportation Integrity Management Meetings''. (2) *Address for Written Comments:* OPS requests that comments relating to the public meeting be submitted on or before January 29, 2001, so they can be considered as the meeting agenda is being developed. Submit written comments by mail or delivery to the Dockets Facility, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. You also may submit written comments to the docket electronically. To do so, log on to the dms.dot.gov. Click on ''Help & Information'' for instructions on how to file a document electronically. Written comments should identify the appropriate docket RSPA–00–7666 for integrity management for gas pipelines and RSPA–00–7408 for communications. Anyone desiring confirmation of mailed comments must include a self-addressed stamped postcard. The Dockets Facility is located on the plaza level, Room PL–401, of the US Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. It is open from 10 a.m. to 5 p.m., Monday through Friday, except federal holidays.

If you want to make an oral presentation at the meeting, please notify Jenny Donohue no later than January 29, 2001, by phone (202–366–4046) or by Internet e-mail (jenny.donohue@rspa.dot.gov).

FOR FURTHER INFORMATION CONTACT: Beth Callsen (tel: 202–366–4572; E-mail: beth.callsen@rspa.dot.gov). You can read comments and other material in the docket on the Internet at: http://dms.dot.gov.

SUPPLEMENTAL INFORMATION:

1. Background

OPS's integrity management and communication initiatives are the culmination of experience gained from pipeline inspections, accident investigations and risk management and system integrity initiatives. These initiatives are intended to improve safety and environmental protection and to provide better assurance to the public about the safety of pipelines. They are also intended to comprehensively address National Transportation Safety Board (NTSB) recommendations, Congressional mandates and pipeline safety and environmental issues raised over the years.

OPS is issuing integrity management program requirements in several steps. Because natural gas and hazardous liquids have different physical properties, pose different risks, and the configuration of the systems differ, and because OPS already possessed sufficient information about integrity management practices on hazardous liquid pipelines, OPS began the series of rules by issuing requirements pertaining to hazardous liquid operators. A final rule applying to hazardous liquid operators with 500 or more miles of pipeline was issued November 3, 2000, (65 FR 75378). This rule applies to pipelines that can affect high consequence areas (HCAs), which include populated areas defined by the Census Bureau as urbanized areas or places, unusually sensitive environmental areas, and commercially navigable waterways. A notice of proposed rulemaking applying to hazardous liquid operators with fewer than 500 miles of pipeline will be issued soon.

Day 1: Integrity Management Concepts for Gas Pipelines

OPS has been meeting with representatives of the gas pipeline industry, research institutions, and State pipeline safety agencies to gather the information needed for rulemakings pertaining to gas operators. Since January 2000, there have been nine meetings with State agencies, representatives of the Interstate Natural Gas Association of America (INGAA), the American Gas Association (AGA), Battelle Memorial Institute, the Gas Technology Institute (GTI), Hartford Steam Boiler Inspection and Insurance Company, and operators covered under 49 CFR part 192. (See DOT Docket #7666 for summaries of the meetings.) The purpose of these meetings was to develop integrity management concepts that could most effectively be applied to gas transmission pipelines. At the meetings, industry representatives presented their perspectives on a number of issues relating to integrity management. Presentations on each of these subject areas will be included in the public meeting agenda. They include:

- Considerations for defining HCAs affected by gas pipelines
- Evaluation of design factors currently used for gas transmission pipelines
- Evaluation of performance history and experience with the impact zone in gas transmission failures
- Integrity management best practices and relationship between incident causes and industry practices
- Options for various forms of direct assessment of the integrity of gas pipelines; their costs and effectiveness
- Basis for establishing test intervals
- Appropriateness of distinguishing between pipelines on basis of pressure
- Status of research activities
- Status of development of new national consensus standards

Day 2: Communications With the Public

Because communications with the public is an important part of a pipeline integrity management program, OPS is examining the need for standards for how operators are to communicate with State and local officials and the public about results of risk assessment processes and measures to prevent and mitigate damage to pipelines in case of a failure. OPS seeks comment on how State and local officials and the public could use and benefit from risk assessment information, how the consequences of potential pipeline failures should be characterized, how risk control actions should be described, and what operational information would be meaningful. To provide OPS input on both the content and optimal delivery of pipeline information, OPS formed the Integrity Management Communications Work Group. This nine-member group includes balanced representation of government, industry, and public interest stakeholders. At the public meeting, the Work Group will report the status of its discussions on the following topics:

- Proposed information to be communicated
- Expected utility of that information to the end user
- Feasibility of collecting/reporting that information
- Summary of any issues or debates concerning public access to that information

Presentations from members of the public will further explore communication needs and options.

Day 3: In-Depth Integrity Management Discussions

To ensure full consideration of all issues relating to gas pipeline integrity, attendees are invited to participate in a more in-depth and interactive treatment of topics raised on Day 1. These unstructured discussions will utilize an informal roundtable format.

Issued in Washington, DC, on December 28, 2000.

John Hess,

Acting Associate Administrator for Pipeline Safety.

[FR Doc. 01–237 Filed 1–3–01; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33975]

Gulf & Ohio Railways, Inc., d/b/a Mississippi Delta Railroad—Lease and Operation Exemption—Lines of the County of Coahoma, Mississippi

Gulf & Ohio Railways, Inc., d/b/a Mississippi Delta Railroad (MSD), a Class III rail carrier, has filed a notice of exemption under 49 CFR 1150.41 to lease and operate approximately 18.6 miles of rail line owned by the County of Coahoma, Mississippi (Coahoma), from milepost 55.40 at or near Lula, MS, to milepost 74.00 at or near Lyon, MS (the Lula line). MSD also seeks to lease from Coahoma the lines extending from milepost 74.00 at or near Lyon, to milepost 79.00 at or near Clarksdale, Coahoma County, MS, and from milepost 76.54 at or near Clarksdale to milepost 104.00 at or near Swan Lake, Tallahatchie County, MS. In addition, Coahoma will assign MSD its rights to operate over 1.39 miles of incidental trackage rights extending from milepost 104.00 to milepost 105.39 at or near Swan Lake.[1] MSD originally acquired or leased the above lines from Illinois Central Railroad Company.[2] MSD certifies that its projected revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier.

This transaction is related to a simultaneously filed notice of exemption in STB Finance Docket No. 33977, *County of Coahoma, Mississippi—Acquisition Exemption—Line of Gulf & Ohio Railways, Inc., d/b/a Mississippi Delta Railroad,* wherein Coahoma seeks to acquire the Lula line from MSD.

MSD states that it has agreed to operate the above-described rail lines through June 30, 2001, in order to provide Coahoma time to locate a long-term operator. *See* STB Finance Docket No. 33977.

The transaction was scheduled to be consummated on or shortly after December 20, 2000.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of

[1] *See County of Coahoma, Mississippi—Acquisition Exemption—line of Illinois Central Railroad Company,* STB Finance Docket No. 33953 (STB served Dec. 7, 2000).

[2] *See Gulf & Ohio Railways, Inc.—Exemption From 49 U.S.C. 11301, 10901 and 11322,* Finance Docket No. 30683 (ICC served Nov. 6, 1985).

a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33975, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Rose-Michele Weinryb, Esq., Weiner, Brodsky, Sidman & Kider, P.C., 1300 19th Street, NW., Fifth Floor, Washington, DC 20036–1609.

Board decisions and notices are available on our website at http://WWW.STB.DOT.GOV.

Decided: December 28, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–209 Filed 1–3–01; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33977]

County of Coahoma, Mississippi—Acquisition Exemption—Line of Gulf & Ohio Railways, Inc., d/b/a Mississippi Delta Railroad

The County of Coahoma, Mississippi (Coahoma), a Class III rail carrier, has filed a notice of exemption under 49 CFR 1150.41 to acquire (by purchase) approximately 18.6 miles of rail line known as the Lula Line from the Gulf & Ohio Railways, Inc., d/b/a Mississippi Delta Railroad (MSD) extending from milepost 74.00 at Lyon, MS, to milepost 55.40 at Lula, MS.[1] According to Coahoma, it and MSD have negotiated and at the time of the filing of this notice were executing an Asset Purchase Agreement providing for Coahoma's acquisition of MSD's right, title and interest in the Lula line. Coahoma indicates that the Lula line connects at Lyon with another rail line, the Swan Lake line, previously owned by the Illinois Central Railroad Company (IC) and operated by MSD pursuant to a now-expired lease. *See* Finance Docket No. 30683. Coahoma has since acquired the Swan Lake line from IC which is also operated by MSD.[2] Coahoma certifies that its annual revenues will not exceed those that would qualify it as a Class III rail carrier and that its annual revenues are not projected to exceed $5 million.

This transaction is related to a simultaneously filed notice of exemption in STB Finance Docket No. 33975, *Gulf & Ohio Railways, Inc. d/b/a Mississippi Delta Railroad–Lease and Operation—Lines of the County of Coahoma, Mississippi,* wherein MSD seeks to lease and operate the line being acquired by Coahoma.

Coahoma states that, pursuant to an agreement, MSD has agreed to provide service on the Lula Line through June 30, 2001, or until the earlier of either Coahoma finding a long-term operator for the line or July 1, 2001, at which time MSD will cease its operations. Coahoma further states that MSD will seek the Board's approval for any authority needed in connection with its cessation of operations, or having in place Coahoma's long-term operator.

The transaction was expected to be consummated on or shortly after December 20, 2000.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33977, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on William C. Sippel, *Esq.*, Fletcher & Sippel LLC, Two Prudential Plaza, Suite 3125, 180 North Stetson Avenue, Chicago, IL 60601–6721.

Board decisions and notices are available on our website at *http://www.stb.dot.gov.*

Decided: December 28, 2000.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 01–210 Filed 1–3–01; 8:45 am]

BILLING CODE 4915–00–P

[1] *See Gulf & Ohio Railways, Inc.—Exemption From 49 U.S.C. 11301, 10901 and 11322,* Finance Docket No. 30683 (ICC served Nov. 6, 1985).

[2] *See County of Coahoma, Mississippi—Acquisition Exemption—Line of Illinois Central Railroad Company,* STB Finance Docket No. 33953 (STB served Dec. 7, 2000).

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 18, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0045.

Form Number: ATF F 5130.10.

Recordkeeping Requirement ID Number: ATF REC 5130/2.

Type of Review: Extension.

Title: Letterhead Applications and Notices Filed by Brewers.

Description: The Internal Revenue Code requires brewers to file a notice of intent to operate a brewery. ATF Form 5130.10 is similar to a permit; and, when approved by ATF, is a brewer's authorization to operate. Letterhead applications and notices are necessary to identify brewery activities so that ATF may insure that proposed operations do not jeopardize Federal revenues.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 1,750.

Estimated Burden Hours Per Respondent: ATF F 5310.10—3 hours; Notices and Applications—30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 9,625 hours.

OMB Number: 1512–0387.

Recordkeeping Requirement ID Number: ATF REC 7570/2 and ATF REC 7570/3.

Type of Review: Extension.

Title: Records of Acquisition and Disposition, Collectors or Firearms.

Description: These records are used by ATF in criminal investigations and compliance inspections in fulfilling the Bureau's mission to enforce the gun control laws.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 172,250.

Estimated Burden Hours Per Recordkeeper: 3 hours.

Estimated Total Recordkeeping Burden: 559,791 hours.

OMB Number: 1512–0474.

Recordkeeping Requirement ID Number: ATF REC 5130/5.

Type of Review: Extension.

Title: Principal Place of Business on Beer Labels.

Description: ATF regulations permit domestic brewers who operate more than one brewery to show as their address on labels and kegs of beer their ''principal place of business'' address. This label option may be used in lieu of showing the actual place of production on the label or of listing all of the brewer's locations on the label.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 1,200.

Estimated Burden Hours Per Respondent: 0.

Estimated Total Reporting Burden: 1 hour.

OMB Number: 1512–0510.

Form Number: None.

Type of Review: Extension.

Title: Letter Application to Obtain Authorization for the Assembly of a Nonsporting Rifle or Nonsporting Shotgun for the Purpose of Testing and Evaluation.

Description: This information collection is required by ATF to provide a means to obtain authorization for the assembly of a nonsporting rifle or nonsporting shotgun for the purpose of testing or evaluation.

Respondents: Business or other for-profit, Individuals or households.

Estimated Number of Respondents: 5.

Estimated Burden Hours Per Respondent: 30 minutes.

Estimated Total Reporting Burden: 3 hour.

Clearance Officer: Frank Bowers (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, NW., Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 01–144 Filed 1–3–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 27, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0024.

Form Number: ATF F 1 (5320.1).

Type of Review: Extension.

Title: Application to Make and Register a Firearm.

Description: This form is used by persons applying to make and register a firearms that falls within the purview of the National Firearms Act. The information supplied by the applicant on the form helps to establish the applicant's eligibility.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 1,071.

Estimated Burden Hours Per Respondent: 4 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 4,271 hours.

OMB Number: 1512–0042.

Form Number: ATF F 7 (5310.12).

Type of Review: Extension.

Title: Application for License under 18 U.S.C. Chapter 44, Firearms.

Description: This form is used by the public when applying for a Federal firearms license as a dealer, importer, or manufacturer. The information requested on the form establishes eligibility for the license. The form is also used when responsible persons are added to an existing license in item 20.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents: 10,000.

Estimated Burden Hours Per Respondent: 1 hour, 15 minutes.

Frequency of Response: Other (once).

Estimated Total Reporting Burden: 12,500 hours.

OMB Number: 1512–0130.

Form Number: ATF F 4473 (5300.9) Part II.

Type of Review: Extension.

Title: Firearms Transaction Record, Part II Non-Over-The-Counter.

Description: The form is used to determine the eligibility of a person to receive a firearm from a Federal firearms licensee. It is also used to establish the identity of the buyer. The form is also used in law enforcement investigations to trace firearms or to confirm criminal activity.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Recordkeepers: 20,900.

Estimated Burden Hours Per Respondent: 6 minutes.

Frequency of Response: On occasion.

Estimated Total Recordkeeping Burden: 9,057 hours.

OMB Number: 1512–0490.

Form Number: ATF F 4473 (5300.24) Part I (LV) and ATF F 4473 (5300.25) Part II (LV).

Recordkeeping Requirement ID Number: ATF REC 7570/2.

Type of Review: Extension.

Title: Firearms Transaction Record Part I—Low Volume—Over-the-Counter (ATF F 4473 (5300.24)); and Firearms Transaction Record Part II—Low Volume—Intra-State Non-Over-the-Counter (ATF F 4473 (5300.25)).

Description: ATF Form LV Parts I and II is for use only by Federal firearms licensees disposing of 50 or fewer firearms per 12-month period. It is kept, at the licensee's option, in lieu of ATF F 4473 and records of acquisition and disposition.

Respondents: Business or other for-profit, Individuals or households.

Estimated Number of Recordkeepers: 5,000.

Frequency of Response: On occasion.

Estimated Burden Hours Per Recordkeeper: 6 minutes.

Estimated Total Recordkeeping Burden: 1,042 hours.

OMB Number: 1512–0529.

Form Number: ATF F 1676 (5510.2).

Type of Review: Extension.

Title: Bond Covering Removal To and Use of Wine At Vinegar Plant.

Description: ATF F 1676 (5510.2) is a bond form which serves as a contact between the proprietor of a vinegar plant and a surety. The bond coverage stated on the form is an amount sufficient to cover the federal excise tax on wine in transit to and stored on the vinegar premises until the wine becomes vinegar.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 25.

Estimated Burden Hours Per Respondent: 1 hour.

Estimated Total Reporting Burden: 25 hours.

OMB Number: 1512–0534.

Form Number: ATF F 2103 (5220.5), ATF F 2104 (5200.15), ATF F 2105

(5000.7), ATF F 2490 (5620.10), and ATF F 3070 (5210.13).

Type of Review: Extension.

Title: Bond—Export Warehouse Proprietor (F 2103); Export Bond—Customs Bonded Cigar Manufacturing Warehouse (F 2104); Extension of Coverage of Bond (F 2105); Bond Under 26 U.S.C. 6423 (F 2490); and Bond—Manufacturer of Tobacco Products (F 3070).

Description: ATF F 2103 (5220.5), Bond—Export Warehouse Proprietor is used to establish the qualifications of an applicant for an export status has changed and must change the information already on file. The applicant certifies the intention to produce and/or store a specified amount of tobacco products and takes certain precautions to protect it from unauthorized use. The completed application and supporting data is a permanent record of the business and its qualifications to operate.

ATF F 2104 (5200.15), Export Bond—Customs Bonded Cigar Manufacturing Warehouse is used to establish the qualifications of an applicant who seeks authorization to manufacture cigars within a customs bonded warehouse for subsequent exportation, or by a current manufacturer of such cigars whose status has changed and must change the information already on file. The applicant certifies the intention to produce, store and export a specified quantity of cigars products and takes certain precautions to protect them from unauthorized use. The completed application and supporting data is a permanent record of business and its qualifications to operate.

ATF F 2105 (5000.7), Extension of Bond Coverage is used to determine compliance by payment on untaxpaid commodities.

ATF F 2490 (5620.10), Bond Under 26 U.S.C. 6423, and ATF F 3070 (5210.13), Bond—Manufacturer of Tobacco Products are tobacco products and cigarette papers and tubes bond forms used by the manufacturers or proprietor and a surety company as a contract to ensure tax payment.

Respondents: Business or other for-profit.

Estimated Number of Recordkeepers: 15.

Estimated Burden Hours Per Recordkeeper: 1 hour, 40 minutes.

Estimated Total Recordkeeping Burden: 25 hours.

Clearance Officer: Frank Bowers (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, NW., Washington, DC 20226.

OMB Reviewer: Alexander T. Hunt (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 01–145 Filed 1–3–01; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 15, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Financial Management Service (FMS)

OMB Number: 1510–0007.

Form Number: Standard Form 1199A.

Type of Review: Reinstatement.

Title: Direct Deposit Sign-Up Form.

Description: The Direct Deposit Sign-Up Form is used by recipients to authorize the deposit of Federal payments into their accounts at a financial institution. This information is used to route the Direct Deposit payment to the correct account at the correct financial institution. It identifies persons who have executed the form.

Respondents: Individuals or households, Business or other for-profit, Federal Government.

Estimated Number of Respondents/Recordkeepers: 604,000.

Estimated Burden Hours Per Respondent/Recordkeeper: 10 minutes.

Frequency of Response: Other (one-time).

Estimated Total Reporting/Recordkeeping Burden: 102,680 hours.

Clearance Officer: Juanita Holder, Financial Management Service, 3700 East West Highway, Room 144, PGP II, Hyattsville, MD 20782.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 01–146 Filed 1–3–01; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 27, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Financial Management Service (FMS)

OMB Number: 1510–0019.

Form Number: FMS 1133.

Type of Review: Extension.

Title: Claim Against the United States for the Proceeds of a Government Check.

Description: If a payee claims non-receipt of a Treasury check, the FMS–1133 claims form and a copy of the negotiated check are sent to the payee. If the payee wishes to submit a claim of nonreceipt, he or she answers the questions on the form, signs the form and returns it to the Financial Management Service for adjudication by a claims analyst. This may result in the issuance of a replacement check if the claim is valid.

Respondents: Individuals or households.

Estimated Number of Respondents: 53,895.

Estimated Burden Hours Per Respondent: 11 minutes.

Frequency of Response: Other (as needed).

Estimated Total Reporting Burden: 10,229 hours.

Clearance Officer: Juanita Holder, Financial Management Service, 3700 East West Highway, Room 144, PGP II, Hyattsville, MD 20782.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New

Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–147 Filed 1–3–01; 8:45 am]

BILLING CODE 4810–35–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 27, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1448.

Regulation Project Number: EE–81–88 Final.

Type of Review: Extension.

Title: Deductions for Transfers of Property.

Description: These regulations concern the Secretary's authority to require the filing of an information return under Code section 6041 and expand the requirement to furnish forms to certain corporate service providers.

Respondents: Business or other for-profit, Individuals or households, Not-for-profit institutions, Farms.

Estimated Number of Respondents: 1.

Estimated Burden Hours Per Respondent: 1 hour.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 1 hour.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–148 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 27, 2000.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 5, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1452.

Regulation Project Number: FI–43–94 Final.

Type of Review: Extension.

Title: Regulations Under Section 1258 of the Internal Revenue Code of 1986; Netting Rule for Certain Conversion Transactions.

Description: Section 1258 recharacterizes capital gains from conversion transactions as ordinary income to the extent of the time value element. This regulation provides that certain gains and losses may be netted for purposes of determining the amount of gain recharacterized.

Respondents: Business or other for-profit, Not-for-profit institutions.

Estimated Number of Recordkeepers: 50,000.

Estimated Burden Hours Per Recordkeeper: 6 minutes.

Estimated Total Recordkeeping Burden: 5,000 hours.

OMB Number: 1545–1706.

Revenue Procedure Number: Revenue Procedure 2000–42.

Type of Review: Extension.

Title: Section 1503(d) Closing Agreement Requests.

Description: Revenue Procedure 2000–42 informs taxpayers of the information they must submit to request a closing agreement under Reg. § 1.1503–2(g)(2)(iv)(B)(2)(I) to prevent the recapture of dual consolidated losses (DCLs) upon the occurrence of certain triggering events.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 20.

Estimated Burden Hours Per Respondent: 100 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 2,000 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW, Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 01–149 Filed 1–3–01; 8:45 am]

BILLING CODE 4830–01–P

UNITED STATES INSTITUTE OF PEACE

Sunshine Act Meeting

AGENCY: United States Institute of Peace.

DATE/TIME: Thursday, January 18, 2001, 9:00 a.m.–5:30 p.m.

LOCATION: 1200 17th Street, NW., Suite 200, Washington, DC 20036.

STATUS: Open Session—Portions may be closed pursuant to Subsection (c) of Section 552(b) of Title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Public Law 98–525.

AGENDA: January 2000 Board Meeting; Approval of Minutes by the Ninety-Seventh Meeting (November 16, 2000) of the Board of Directors; Chairman's Report; President's Report; Committee Reports; Review of Unsolicited Grant Applications; Other General Issues.

CONTACT: Dr. Sheryl Brown, Director, Office of Communications, Telephone: (202) 457–1700.

Dated: January 2, 2001.

Charles E. Nelson,

Vice President for Management and Finance, United States Institute of Peace.

[FR Doc. 01–327 Filed 1–2–01; 11:52 am]

BILLING CODE 6820–AR–M

Federal Register

Thursday,

January 4, 2001

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 411 and 424

Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411 and 424

[HCFA–1809–FC]

RIN 0938–AG80

Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with 90-day comment period (Phase I of this rulemaking) incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act (the Act). Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services (DHS) under the Medicare program, unless an exception applies. The following services are DHS: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

In addition, section 1877 of the Act provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for DHS furnished under a prohibited referral, nor may we make payment for a designated health service furnished under a prohibited referral.

Paragraph (a) of section 1877 of the Act includes the general prohibition. Paragraph (b) of the Act includes exceptions that pertain to both ownership and compensation relationships, including an in-office ancillary services exception. Paragraph (h) includes definitions that are used throughout section 1877 of the Act, including the group practice definition and the definitions for each of the DHS.

We intend to publish a second final rule with comment period (Phase II of this rulemaking) shortly addressing, to the extent necessary, the remaining sections of the Act. Phase II of this rulemaking will address comments concerning the ownership and investment exceptions in paragraphs (c) and (d) and the compensation exceptions in paragraph (e) of section 1877 of the Act. Phase II of this rulemaking will also address comments concerning the reporting requirements and sanctions provided by paragraphs (f) and (g) of the Act, respectively, and include further consideration of the general exception to the referral prohibition related to both ownership/investment and compensation for services furnished in an ambulatory surgical center (ASC), end-stage renal dialysis facility, or by a hospice in § 411.355(d) of the regulations (this exception presently is in force and effect as to clinical laboratory services). In addition, Phase II of this rulemaking will address section 1903(s) of the Act, which extends aspects of the referral prohibition to the Medicaid Program. Phase II will also address comments received in response to this rulemaking, as appropriate, and certain proposals for new exceptions to section 1877 of the Act not included in the 1998 proposed rulemaking, but suggested in the public comments.

DATES: *Effective date:* The regulations delineated in Phase I of this rulemaking are effective on January 4, 2002 except for § 424.22(d), which is effective on February 5, 2001.

Comment date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 4, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only: Health Care Financing Administration, Department of Health and Human Services, Attn: HCFA–1809–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Since comments must be *received* by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays. If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or C5–15–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments mailed to the two addresses provided in this paragraph may be delayed and received too late to be considered.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1809–FC.

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 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC 20201, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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we provide a document on our website, the document that we publish in the **Federal Register** is the official HCFA publication.

To help readers locate information in this final rule, we are providing the following Table of Contents:

I. Background
A. Legislative and Regulatory History
1. Section 1877 of the Act
2. Section 1903(s) of the Act
B. Regulations History
1. Regulations Published by HCFA and the Office of the Inspector General (OIG) Relating to Section 1877 of the Act
2. Details about Prior Related Regulations
II. Development of Phase I of this Final Rulemaking
A. Technical Explanation of Bifurcation of the Regulation
B. General Comments Regarding the January 1998 Proposed Rule and Responses
III. General Prohibition Under Section 1877 of the Act
A. When Is There a Financial Relationship Between the Physician and the Entity?
B. When Does a Physician Make a Referral?
1. ''Referral''
2. ''Consultation''
IV. Physician Compensation Under Section 1877 of the Act: An Overview
V. ''Volume or Value'' of Referrals and ''Other Business Generated'' Standards: An Overview
VI. Exceptions Applicable to Ownership and Compensation Arrangements (Section 1877(b) of the Act)
A. Physician Services (Section 1877(b)(1) of the Act)
B. In-office Ancillary Services (Section 1877(b)(2) of the Act)
1. Scope of Designated Health Services That Can Be In-office Ancillary Services
2. Direct Supervision
3. The Building Requirements
4. The Billing Requirement
C. Group Practice Definition (Section 1877(h)(4) of the Act)
1. General Comments
2. Single Legal Entity Requirement
3. Members of the Group
4. The ''Full Range of Services Test''
5. The ''Substantially All Test''
6. The ''Seventy-five Percent Physician-Patient Encounters Test''
7. The ''Unified Business Test''
8. Profit Shares and Productivity Bonuses
9. Group Practice Attestations
D. Prepaid Plans (Section 1877(b)(3) of the Act)
VII. New Regulatory Exceptions
A. Academic Medical Centers
B. Fair Market Value (§ 411.357(l))
C. Non-Monetary Compensation up to $300 (and Medical Staff Benefits) (§§ 411.357(k) and (m))
VIII. Definitions of the Designated Health Services
A. General Principles
B. General Comment: Professional Services as Designated Health Services
C. Clinical Laboratory Services
D. Physical Therapy Services
E. Occupational Therapy Services
F. Radiology and Certain Other Imaging Services
G. Radiation Therapy
H. Durable Medical Equipment (DME)
I. Parenteral and Enteral Nutrients, Equipment, and Supplies
J. Prosthetics, Orthotics, and Prosthetic Devices and Supplies
K. Home Health Services
L. Outpatient Prescription Drugs
M. Inpatient and Outpatient Hospital Services
N. Other Definitions
1. Consultation
2. Entity
3. Fair Market Value
4. Group Practice
5. Health Professional Shortage Areas
6. Employee
7. Immediate Family Members
8. Referral
9. Remuneration and the Exceptions in Section 1877(h)(1)(C) of the Act
IX. Collection of Information Requirements
X. Regulatory Impact Statement
A. Overall Impact
B. Anticipated Effects
1. Effects on Physicians
2. Effects on Other Providers
3. Effects on the Medicare and Medicaid Programs
4. Effects on Beneficiaries
C. Alternatives Considered
D. Conclusion
Regulations Text
Attachment

I. Background

A. Legislative and Regulatory History

1. Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act prohibited a physician from referring a patient to an entity for clinical laboratory services for which Medicare might otherwise pay, if the physician or the physician's immediate family member had a financial relationship with the entity. The statute defined ''financial relationship'' as an ownership or investment interest in the entity or a compensation arrangement between the physician (or the physician's immediate family member) and the entity. The statute provided for several exceptions to the prohibition. Some applied to ownership/investment interests and compensation arrangements; others applied only to ownership/investment interests or only to compensation arrangements.

The statute further prohibited an entity from presenting or causing to be presented a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under a prohibited referral. Additionally, the statute mandated refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposed reporting requirements and provided for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover 10 ''designated health services,'' in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103–432), enacted on October 31, 1994, amended the list of designated services, effective January 1, 1995, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

2. Section 1903(s) of the Act

Title XIX of the Act established the Medicaid program to provide medical assistance to individuals who meet certain income and resource requirements. The States operate Medicaid programs in accordance with Federal laws and regulations and with a State plan that we approve. Though States administer the Medicaid programs, the Federal and State governments jointly finance them. We call the Federal government's share of medical assistance expenditures ''Federal financial participation'' (FFP).

Until OBRA 1993, there were no statutory or regulatory requirements affecting a physician's referrals for services covered under the Medicaid program. Section 13624 of OBRA 1993, entitled ''Application of Medicare Rules Limiting Certain Physician Referrals,'' added a new paragraph (s) to section 1903 of the Act, that extends aspects of the Medicare prohibition on physician referrals to Medicaid. This provision

bars FFP in State expenditures for DHS furnished to an individual based on a physician referral that would result in a denial of payment for the services under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan. The statute also made certain reporting requirements in section 1877(f) of the Act and a civil monetary penalty provision in section 1877(g)(5) (related to the reporting requirements) applicable to providers of DHS for which payment may be made under Medicaid in the same manner as they apply to providers of such services for which payment may be made under Medicare. Section 1903(s) of the Act applies to a physician's referrals made on or after December 31, 1994.

B. Regulations History

1. Regulations Published by HCFA and the Office of the Inspector General (OIG) Relating to Section 1877 of the Act

The following is a summary of the series of regulations we have published in the **Federal Register** over the past several years to implement the provisions of section 1877 of the Act, as amended, and section 1903(s) of the Act:

- On December 3, 1991, we issued an interim final rule with comment period (54 FR 61374) to set forth the reporting requirements under section 1877(f) of the Act.
- On March 11, 1992, we issued a proposed rule (57 FR 8588) to implement the self-referral prohibition and exceptions related to referrals for clinical laboratory services established by section 1877 of the Act, and amended by OBRA 1990.
- On August 14, 1995, we issued a final rule with comment period (60 FR 41914) incorporating the provisions of OBRA 1993 and SSA 1994 that relate to referrals for clinical laboratory services under section 1877 of the Act, effective January 1, 1992, and revising the March 11, 1992 proposal based on the public comments we received.
- On January 9, 1998, we issued a proposed rule (63 FR 1659) to amend the provisions of the August 1995 final rule and to reflect other changes in section 1877 of the Act enacted by OBRA 1993 and SSA 1994 that were effective January 1, 1995. These include, among other changes, the expansion of the referral prohibition to the 10 additional DHS, and the Medicaid expansion.
- On January 9, 1998, we published a final rule with comment period (63 FR 1846) incorporating into our regulations the specific procedures we will use to issue advisory opinions, as required under section 1877(g)(6) of the Act. Section 1877(g)(6) of the Act requires that we issue written advisory opinions to outside parties concerning whether the referral of a Medicare patient by a physician for DHS (other than clinical laboratory services) is prohibited under section 1877 of the Act.

We also note that on October 20, 1993, the OIG published a proposed rule (58 FR 54096) to implement the civil money penalty provisions under sections 1877(g)(3) and (g)(4) of the Act. The OIG followed with publication of a final rule with comment period (60 FR 16580) on March 31, 1995.

2. Details About Prior Related Regulations

On August 14, 1995, we published in the **Federal Register** a final rule with comment period (60 FR 41914) that incorporated into regulations the provisions of section 1877 of the Act prohibiting physician referrals for clinical laboratory services under the Medicare program. That rule incorporated certain expansions and exceptions created by OBRA 1993, and the amendments in SSA 1994. It included only the expansions and other changes that related to prohibited referrals for clinical laboratory services that were retroactively effective to January 1, 1992, and interpreted the new provisions only in a few limited instances in which it was essential to implement the law. That rule also included our responses to the public comments we received on both the December 3, 1991 interim final rule with comment period (56 FR 61374) that established the reporting requirements under section 1877(f) of the Act, and the March 11, 1992 proposed rule (57 FR 8588) that covered section 1877 of the Act, as amended by OBRA 1990, and related to referrals for clinical laboratory services.

Because the August 1995 rule addressed only those changes made by OBRA 1993 and SSA 1994 that had a retroactive effective date of January 1, 1992, we explained our intent to later publish a proposed rule to fully implement the extensive revisions to section 1877 of the Act made by OBRA 1993 and SSA 1994, and to interpret those provisions when necessary. In the later proposed rule, we intended to include the revisions that relate to referrals for the additional DHS (including clinical laboratory services) that became effective January 1, 1995, and to implement the Medicaid expansion in section 1903(s) of the Act that became effective for referrals made on or after December 31, 1994.

As intended, on January 9, 1998, we published the proposed rule (63 FR 1659). The rule was organized as follows: In section I (63 FR 1661 through 1663), we summarized the problems associated with physician self-referrals and the relevant legislative and regulatory background. In section II (63 FR 1663 through 1673), part A, we summarized the provisions of our proposed rule and described how we proposed to alter the final regulation covering referrals for clinical laboratory services to apply it to the additional DHS and to reflect the statutory changes in section 1877 of the Act that were effective on January 1, 1995. In section II, part B, we described the changes we proposed to make to the Medicaid regulations to incorporate section 1903(s) of the Act. In section III (63 FR 1673 through 1705), we discussed in detail how we proposed to interpret any provisions in sections 1877 and 1903(s) of the Act that we believed were ambiguous, incomplete, or that provided us with discretion. We also discussed policy changes or clarifications we proposed to make to the August 1995 rule covering referrals for clinical laboratory services. Section IV (63 FR 1705 through 1715) of the proposed rule included our responses to some of the most common questions concerning physician referrals that we received from physicians, providers, and others in the health care community. We included our interpretations of how the law applies in the situations described to us. Section V (63 FR 1715 through 1719) included a Regulatory Impact Analysis, and section VI (63 FR 1719 through 1720) covered our policy on responding to comments. The proposed regulation text appeared at 63 FR 1720 through 1728.

In the January 1998 proposed rule, we proposed to incorporate the Medicaid expansion in section 1903(s) of the Act into § 435.1012(a) (Limitation to FFP related to prohibited referrals). Section 435.1012(a) stated that no FFP was available for a State's expenditures for certain DHS, as they are defined in proposed § 411.351, furnished to an individual under the State plan. No FFP is available if the services are those furnished on the basis of a physician referral that would, if Medicare provided for coverage of the services to the same extent and under the same terms and conditions as under the State plan, result in the denial of Medicare payment for the services under §§ 411.351 through 411.360. In § 435.1012(c), we included a cross reference to the procedures we

established for individuals or entities to request advisory opinions from us on whether a physician's referrals relating to DHS (other than clinical laboratory services) are prohibited under section 1877 of the Act. Although these advisory opinions were meant to reflect our interpretation of section 1877 of the Act, they can potentially affect FFP payments to States under the Medicaid program.

Section 1877(b)(3) of the Act excepts from the referral prohibition services furnished to enrollees of certain ''prepaid'' health plans; however, these exceptions extend only to services furnished to Medicare beneficiaries under Medicare contracts and demonstration projects. As a result, the exception for prepaid arrangements does not apply to physicians who wish to refer in the context of the Medicaid program. In order to give effect to this exception in the Medicaid context, we included, in the January 1998 proposed rule, in § 435.1012(b) an exception for DHS furnished by managed care entities analogous to the Medicare entities excepted under section 1877(b)(3) of the Act. The new exception was meant to cover entities that provide services to Medicaid-eligible enrollees under contract with State Medicaid agencies and under certain demonstration projects. (We discussed these analogous entities in detail in the proposed rule at 63 FR 1697.)

To accommodate the Congress's subsequent creation of the Medicare+Choice (M+C) Program in the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA 1997), we included an amendment to the physician referral regulations as part of the June 26, 1998 interim final rule with comment period (63 FR 35066) establishing the M+C Program. We amended the final physician self-referral regulations covering referrals for clinical laboratory services by adding an exception in § 411.355(c)(5) for services furnished to prepaid enrollees by a coordinated care plan. We defined a coordinated care plan as such a plan, within the meaning of section 1851(a)(2)(A) of the Act, offered by an organization in accordance with a contract with us under section 1857 of the Act and the M+C regulations. We are reprinting that provision in Phase I of this rulemaking.

II. Development of Phase I of This Final Rulemaking

A. Technical Explanation of Bifurcation of the Regulation

Phase I of this rulemaking implements subsections (a) and (b) of section 1877 of the Act, and related definitions, as applied to the Medicare program. We intend to issue Phase II of this rulemaking to cover the remainder of section 1877 of the Act, including its application to the Medicaid program, shortly.

Phase I of This Rulemaking

Given the importance of subsections (a) and (b), and the substantial changes we are making to the January 1998 proposed rule, we are proceeding with the issuance of Phase I of this rulemaking at this time. Further, we are issuing Phase I for comment and delaying its effective date for 1 year to allow individuals and entities engaged in business arrangements affected by Phase I time to restructure those arrangements to comply with the provisions of Phase I, except for § 424.22(d), which is effective February 5, 2001. The statutory provisions interpreted by Phase I remain in effect, as they have been since 1989 for clinical laboratory services and 1993 for all other DHS.

Phase I of this rulemaking differs substantially from the January 1998 proposed rule in several major respects, which include the following:

- Clarification of the definitions of DHS.
- Clarification of the concept of ''indirect financial relationship'' and creation of a new exception for indirect compensation arrangements.
- Substantial broadening of the in-office ancillary services exception by easing the criteria for qualifying as a group practice and conforming the supervision requirements to HCFA coverage and payment policies for the specific services.
- Expansion of the in-office ancillary services exception to cover certain DME provided in physicians' offices to patients to assist them in ambulating, and blood glucose monitors.
- Allowance of shared facilities in the same building where physicians routinely provide services that are in addition to Federal and private pay DHS.
- Exclusion of services personally performed by the referring physician from the definition of ''referral.''
- Creation of a new exception for compensation of faculty in academic medical centers.
- Addition of a new ''risk-sharing'' exception for commercial and employer-sponsored managed care plans.
- Interpretation of the ''volume or value'' standard for purposes of section 1877 of the Act as permitting unit of service or unit of time-based payments, so long as the unit of service or unit of time-based payment is fair market value and does not vary over time. (The details of these and other changes are explained at length in section VI of this preamble.)
- Creation of an exception where DHS are furnished by entities that did not know of or have reason to suspect the identity of the referring physician.

In developing Phase I of this rulemaking, we have carefully reconsidered the January 1998 proposed rule given both the history and structure of section 1877 of the Act and the extensive comments we received on the January 1998 proposed regulation. We believe that Phase I of this rulemaking addresses many of the industry's primary concerns, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs.

Our paramount concern is to implement section 1877 of the Act consistent with congressional intent. Prior to enactment of section 1877, there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships (some of these studies involved compensation as well). Increased utilization occurred whether the physician owned shares in a separate company that provided ancillary services or owned the equipment and provided the services as part of his or her medical practice. This correlation between financial ties and increased utilization was the impetus for section 1877 of the Act.

The approach chosen by the Congress in enacting section 1877 of the Act is preventive because it essentially prohibits many financial arrangements between physicians and entities providing DHS. Specifically, section 1877 of the Act imposes a blanket prohibition on the submission of Medicare claims (and payment to the States of FFP under the Medicaid program) for certain DHS when the service provider has a financial relationship with the referring physician, unless the financial relationship fits into one of several relatively specific exceptions. Significantly, no wrongful intent or culpable conduct is required. The primary remedy is simply nonpayment by the program, without penalties. In other words, the basic remedy is recoupment of overpayments by the program. (Of course, wrongful conduct, such as knowingly submitting a claim in violation of the prohibition, can be punished through recoupment of overpayments and imposition of

penalties, the False Claims Act, and other Federal statutory and common law remedies.)

The effect of this statutory scheme is that failure to comply with section 1877 of the Act can have a substantial financial result. For example, if a hospital has a $5,000 consulting contract with a surgeon and the contract does not fit in an exception, every claim submitted by the hospital for Medicare beneficiaries admitted or referred by that surgeon is not payable, since all inpatient and outpatient hospital services are DHS.

While the statutory scheme of the physician self-referral prohibition is, in large part, the key to its effectiveness, it obligates us to proceed carefully in determining the scope of activities that are prohibited. In Phase I of this rulemaking, we have attempted to minimize the impact of the rule on many common physician group governance and compensation arrangements.

The potential impact of the regulation was further confirmed by the voluminous comments we received from the public and health care community in response to the January 1998 proposed rule. In addition to specific complaints and objections about the January 1998 proposed rule, the commenters expressed several general concerns, which include the following:

- The rule inappropriately intruded into the organization and delivery of medical care within physicians' offices.
- The rule, in many respects, was counter to our other long-standing policies on coverage and similar issues.
- The rule was unclear in many areas and that given the potentially serious consequences (for example, payment denial), ''bright line'' rules were essential.
- Some aspects of the rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

With these overall considerations in mind, we have developed several criteria for evaluating our regulatory options. First, we have tried in Phase I of this rulemaking to interpret the prohibitions narrowly and the exceptions broadly, to the extent consistent with the statutory language and intent. As a practical matter, we believe that, while the statute must be implemented to achieve its intent, we should be cautious in interpreting its reach so broadly as to prohibit potentially beneficial financial arrangements. Accordingly, we have tried to focus the regulation on financial relationships that may result in overutilization, which we believe was the main abuse at which the statute was aimed. Some provisions of the January 1998 proposed rule did not appear to address overutilization so much as other potential abuses, such as unfair competition. At the same time, we do not believe the Congress intended us to review every possible designated health service to determine its potential for overutilization. The Congress has already made that determination, and we believe that compliance with the exceptions in Phase I of this rulemaking should not cause undue disruption of the health care delivery system.

Second, a corollary of the above interpretation is that the Congress only intended section 1877 of the Act to establish a minimum threshold for acceptable financial relationships, and that potentially abusive financial relationships that may be permitted under section 1877 of the Act could still be addressed through other statutes that address health care fraud and abuse, including the anti-kickback statute (section 1128B(b) of the Act). In some instances, financial relationships that are permitted by section 1877 of the Act might merit prosecution under section 1128B(b) of the Act. Conversely, conduct that may be proscribed by section 1877 of the Act may not violate the anti-kickback statute.

Third, we have attempted to ensure that Phase I of this rulemaking will not adversely impact the medical care of Federal health care beneficiaries or other patients. In those instances in which we have determined that the provisions of Phase I of this rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement so that patients could continue to receive the care in the same location. In almost all cases, we believe the provisions of Phase I of this rulemaking should not require substantial changes in delivery arrangements, although they may affect the referring physician's or group practice's ability to bill for the care. In other words, while the provisions of Phase I of this rulemaking may affect a physician's ability to profit financially from the provision of some services, there should be alternative providers available to provide the services in the same setting or alternative business structures that would permit the services to be provided (again, possibly without physician financial interest).

Fourth, we have revised the provisions of our January 1998 proposed rule to conform, as much as possible, to our other policies that affect the same or similar activity. For example, we are dropping the requirement that an in-office ancillary service be supervised under the strict ''direct supervision'' standards of the ''incident to'' billing rules in favor of requiring the level of supervision that is mandated under Medicare payment and coverage rules applicable to particular DHS.

Fifth, we have attempted, as much as possible, to establish ''bright line'' rules so that physicians and health care entities can ensure compliance and minimize administrative costs. We agree with the commenters that as a payment rule, the regulations implementing section 1877 of the Act should establish clear standards, and we have attempted to do so within the constraints of the statutory and regulatory scheme.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and, yet, is consistent with the statute. Given the breadth of the statute and the myriad of financial relationships to which it applies, it is impossible to satisfy all concerns in all instances. We have attempted to read the statute narrowly to avoid adversely impacting potentially beneficial arrangements. However, we will continue to monitor financial arrangements in the health care industry and will revisit particular regulatory decisions if we determine there is abuse or overutilization.

B. General Comments Regarding the January 1998 Proposed Rule and Responses

Comment: Many commenters echoed the general views expressed by a major physician trade association. The trade association noted that section 1877 of the Act significantly impacts the manner in which physicians deliver health care services and the manner in which they relate to one another and to other health care providers. The trade association urged us to give physicians and other providers clear direction on how to structure their financial arrangements, while providing sufficient flexibility for physicians and providers practicing in numerous and varying arrangements throughout the health care industry. The trade association and other commenters expressed concern that the January 1998 proposed rule failed to reflect the fundamental changes occurring in the health care marketplace—especially the consolidation and integration of physician practices, hospitals, and other health care entities. Indeed, the commenters perceived the proposed regulations as hostile to those changes.

The trade association and others believe that section 1877 of the Act and our regulations should focus on passive ownership and referral arrangements and not on partially and fully integrated practices demanded by the current competitive marketplace.

In addition, some commenters, including the trade association, thought that the provisions of the January 1998 proposed rule exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services, with no apparent public benefit. In their view, the provisions of the January 1998 proposed rule (1) micro-managed physician practices in situations that do not pose a real potential for abuse, (2) limited proper and reasonable management practices, and (3) inappropriately interfered with the practice of medicine. Finally, a number of commenters suggested that, instead of promulgating a set of regulations that micro-manage the business of medicine, we could better control overutilization of DHS by monitoring the medical necessity of such services and the competency of those providing them.

Response: In developing Phase I of this rulemaking, we have been mindful of the criticism that the provisions of the January 1998 proposed rule inappropriately micro-managed physician practices. Given the purpose, structure, and scope of section 1877 of the Act, some impact on physician practices is inevitable and, frankly, intended. In Phase I of this rulemaking, we have endeavored to create ''bright line'' rules that are easily applied, while providing the health care industry with as much flexibility as possible. Where possible, we have tried to simplify the requirements in Phase I of this rulemaking, consistent with the clear congressional mandate to prohibit certain physician referrals tainted by physician financial self-interest. We believe Phase I of this rulemaking offers adequate flexibility to physician practices as they integrate and consolidate. For example, the revised unified business test, in the group practice definition, no longer bars cost-center or location-based distribution of a group practice's revenues from services that are not DHS. Another example: the in-office ancillary services exception covers certain ancillary services provided in facilities shared by practitioners in the same building in which they practice.

The provisions of Phase I of this rulemaking do not prevent physicians from directly providing their patients with convenient, cost-effective DHS. Consistent with the purpose of the statute, however, the provisions of Phase I of this rulemaking do restrict the circumstances under which physicians can financially benefit from DHS they order that are provided by others. This distinction is important. Section 1877 of the Act regulates the financial relationship between referring physicians and the provider of the DHS. If a physician determines not to provide access to such services in the absence of personal profit, the decision is the physician's, not the statute's. Nothing in section 1877 of the Act restricts patient access to those services.

Finally, we cannot agree with the claim that medical necessity reviews are always an effective control on overutilization. Medical necessity reviews alone cannot control unnecessary utilization and contain health care costs. These reviews are costly and only effective in controlling the most aberrant behavior. Most importantly, the statute does not permit us—nor would we choose—to override the Congress' judgement by substituting medical necessity reviews for existing statutory standards.

Comment: Other commenters expressed concern that neither the statute nor the January 1998 proposed rule goes far enough in preventing abusive referral arrangements. Several commenters complained that allowing physicians to provide ancillary services competitively disadvantages independent ancillary services providers that are not owned or controlled by physicians. These commenters believe that an obvious referral-for-profit scheme occurs when a physician employs his or her own ancillary personnel. While most commenters who expressed this view were independent ancillary services providers, one physician also complained about fellow physicians who ''churn'' patients through CT/MRI machines in their offices, resulting in what the commenter termed, a ''cash spigot.'' The commenter expressed the view that such machines are not standard in a physician's office and are solely added to physicians' offices to generate profits. Commenters also expressed concern that, in some cases, physicians do not have appropriate oversight or credentialing for the ancillary services they provide. One commenter suggested that physicians should only be permitted to provide ancillary services if no other provider is available in the area.

Response: While we believe the commenters raised valid concerns about abuses in the health care system, the plain language of the statute makes clear that the Congress did not intend section 1877 of the Act to bar all physician-owned ancillary services facilities. To the contrary, these facilities are expressly allowed under certain specific circumstances (*see* sections 1877(b), (c), and (d) of the Act). Simply stated, the law is meant to prevent only the most egregious financial relationships; it does not address every potential act of fraud and abuse. As we caution throughout this preamble, section 1877 of the Act provides only a threshold check against fraud and abuse; many arrangements that are lawful under section 1877 of the Act may still violate other fraud and abuse laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Several commenters believe that section 1877 of the Act and implementing regulations would not permit patients to receive services, such as x-rays, physical therapy, or crutches, at a physician's office or in a long term care facility where the patient resides. The commenters observed that requiring patients to seek services related to their diagnoses or treatment at several different locations is an inconvenience to patients and may require them to travel long distances to obtain services, thus, discouraging elderly or disabled patients from seeking needed health care services.

Response: The commenters misunderstand section 1877 of the Act. Section 1877 of the Act regulates financial relationships; it does not regulate the delivery of services. Section 1877 of the Act does not bar the provision of ancillary services in a physician's office, in a long term care facility, or at nearby, convenient locations. The law only imposes restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider, such as an employment contract, an office space lease, or an ownership interest. Depending on the structure of the financial relationship, the physician may be able to profit from ordering ancillary services, thereby creating a risk that his or her orders may be motivated, in part, by personal financial considerations. Statutory and regulatory exceptions are designed to enable physicians to make ancillary services available on-site to their own patients, provided they meet the conditions set forth in the applicable exception. However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For example, a physician may arrange for a

diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills, provided that any rental arrangement meets the rental exception in § 411.357(b) and does not violate the anti-kickback statute. Section 1877 of the Act reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives. These regulations reflect that policy balance.

Comment: One commenter stated that we had not informed Medicare beneficiaries about the potential restrictions on their access to care under section 1877 of the Act and its regulations, or informed Medicare providers about the potential restrictions on their ability to provide ancillary services.

Response: Once both Phase I and Phase II of this rulemaking are published, we intend to educate providers further about the new regulations. Providers have been on notice as to section 1877 of the Act since 1989 with respect to clinical laboratory services and 1993 with respect to all other DHS. We intend to provide general information to beneficiaries as well. However, we do not believe beneficiaries will face the restrictions on access that the commenters contemplate. Indeed, these regulations do not restrict the provision of services to Medicare beneficiaries. If a physician chooses not to make services available to patients if he or she cannot personally benefit financially from services he or she orders, but which are provided by others, the physician is responsible for restricting access. Finally, Phase I of this rulemaking is being, and Phase II of this rulemaking will be, published in the **Federal Register** and noted on the Department's website, which serves as notice to the affected community. We believe most providers will also be informed through their trade press, trade associations, and other sources.

Comment: Two commenters expressed concern that section 1877 of the Act and associated regulations would criminalize common conduct in physicians' offices.

Response: Section 1877 of the Act is a civil, not a criminal, statute. A violation of section 1877 of the Act results in nonpayment of claims and monetary sanctions. Criminal penalties or deprivation of liberty are not authorized by section 1877 of the Act.

Comment: Given the alleged complexity of the physician self-referral law and regulations and their impact on physicians' traditional business practices, several commenters requested that the effective date of the regulation be delayed to allow a reasonable time for physicians to familiarize themselves with the law and that the regulations be applied prospectively only. One commenter asked that we issue compliance guidelines. Another commenter inquired about penalties if physicians ignore the physician self-referral law.

Response: We agree with the commenters that the health care providers engaged in business arrangements affected by Phase I of this rulemaking may need time to restructure those arrangements to comply with Phase I of this rulemaking where it proscribes conduct not previously prohibited. We are, therefore, delaying the effective date of Phase I of this rulemaking for 1 year, except for § 424.22(d), which is effective February 5, 2001. In the meantime, the statute, in its entirety, remains in full force and effect with respect to all DHS listed in section 1877(h)(6) of the Act. Until the effective date of these new final regulations, the August 1995 final rule covering referrals for clinical laboratory services remains in full force and effect with respect to clinical laboratory services referrals and claims for services. Any party or parties who do not comply with the provisions of the statute, the August 1995 final rule covering referrals for clinical laboratory services, or the provisions of Phase I of this rulemaking (when it becomes effective one year from the date of publication of this **Federal Register** notice) are subject to all applicable penalties and sanctions, including those that appear in section 1877(g) of the Act. (Section 1877(g)(3) and (g)(4) sanctions are covered in an OIG regulation that was published at 60 FR 16580 on March 31, 1995.)

Because of the significant changes we are making in Phase I of this rulemaking, we are publishing these regulations in final form with a 90-day comment period. We are interested in the industry's views as to the changes we have incorporated into these regulations. Any further changes we deem necessary based on comments will be addressed in Phase II of this rulemaking or shortly thereafter.

Regarding the issue of compliance guidelines, we often issue guidelines in the form of manual provisions or operational policy letters when we find that the statute and regulations do not address particular issues in sufficient detail.

Comment: A number of commenters objected to what they perceived as disparate treatment of solo and group practitioners. One commenter, for example, complained that under the proposed rule, a solo practitioner could provide, and keep the profits from, unlimited ancillary services provided to his or her patients, regardless of how much the physician self-refers in his or her own office, whereas a group practitioner could not.

Response: Certain disparities between the treatment of group and solo practitioners are inherent in the statutory language and structure. For example, the Congress expressly limited profit shares for group practice members to methodologies that do not directly take into account the member's DHS referrals. For obvious reasons, solo practitioners cannot be similarly limited. On the other hand, the statute allows group practices greater flexibility in terms of the locations where they can provide DHS to their patients and still come within the in-office ancillary services exception. To the extent possible, and consistent with the statute, we have tried in Phase I of this rulemaking to minimize the regulatory disparities between group and solo practitioners.

Comment: In noting that the January 1998 proposed regulation interpreted the statute to minimize any risk of fraud or abuse, several commenters stated that the marginal anti-fraud benefit of this approach is low because of additional post-1993 fraud and abuse legislation, the implementation of the anti-kickback statute, computer claims payment edits instituted by our carriers, and the creation of the National Practitioners Data Bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) increased funding for Medicare program safeguards such as increased coordination between Federal, State, and local authorities; investigations, audits, and inspections; and guidance to the industry. HIPAA also established the Medicare Integrity Program to encourage private entities to engage in anti-fraud activities. The BBA in 1997 also created more severe criminal penalties for health care fraud. The commenters stated that the January 1998 proposed regulation prohibits many otherwise appropriate relationships in order to deter a small proportion of inappropriate practices. The commenters asked that the final rule be more flexible and not overcompensate for potential risks because the commenters believe that post-1993 legislation and enforcement

efforts can address any inappropriate practices that may or may not be deterred by the physician self-referral law.

Response: As described above, the approach taken by the Congress in enacting section 1877 of the Act results in important differences between it and other anti-fraud and abuse measures, especially the criminal anti-kickback statute (section 1128B(b) of the Act). The laws are complementary and, although overlapping in some aspects, not redundant. We believe the Congress intended to create an array of fraud and abuse authorities to enable the government to protect the public fisc, beneficiaries of Federal programs, and honest health care providers from the corruption of the health care system by unscrupulous providers. We have revisited the January 1998 proposed rule in significant respects that minimize any unnecessary impact on providers.

Comment: A number of commenters objected to the inclusion in several of the proposed regulatory exceptions, such as the exception for fair market value transactions, of a requirement that the transaction be in compliance with the anti-kickback statute. According to the commenters, the two statutes are separate and, since the anti-kickback statute is intent-based, it would be impossible to determine with certainty whether a transaction meets the exceptions.

Response: We recognize that section 1877 of the Act and the anti-kickback statute, section 1128B(b) of the Act, are different statutes and compliance with one does not depend on compliance with the other in most situations. Notwithstanding, the Secretary's authority to create additional regulatory exceptions to section 1877 of the Act is limited by the requirement in section 1877(b)(4) that she determine that the excepted financial relationship ''does not pose a risk of program or patient abuse.'' Section 1877 of the Act sets a *minimum* standard for acceptable financial relationships; many relationships that may not merit blanket prohibition under section 1877 of the Act can, in some circumstances and given necessary intent, violate the anti-kickback statute. If the requirement that a financial relationship comply with the anti-kickback statute were dropped, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception created under section 1877(b)(4) of the Act. (By contrast, the statutory exceptions require no finding by the Secretary and, thus, carry no presumptive protection under the anti-kickback statute.) In addition, some arrangements may pose a risk of improper billing or claims submission.

As a practical matter, the statutory language authorizing exceptions leaves us two choices: (1) we can limit the exceptions to those situations that pose no risk of fraud or abuse—a very stringent standard that few, if any, of the proposed regulatory exceptions meet; or (2) we can protect arrangements that, in most situations, would not pose a risk, and rely on the anti-kickback statute or other fraud and abuse laws to address any residual risk. Given the commenters' expressed preference for flexibility, we have chosen the latter alternative. Moreover, since the parties should be in compliance with the anti-kickback statute, the additional regulatory burden is minimal. In the interest of simplification, we are considering an additional exception under section 1877 of the Act for any arrangement that fits squarely in an anti-kickback ''safe harbor'' (section 1001.952 (Exceptions)) and plan to address the matter further in Phase II of this rulemaking.

III. The General Prohibition Under Section 1877 of the Act

Section 1877(a) of the Act establishes the basic structure and elements of the statutory prohibition: A physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (3) if there is a financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations issued by the Secretary. (DHS are defined in § 411.351 and discussed at length in section VIII.A of this preamble.) In this section, we discuss our interpretations of what constitutes a financial relationship, especially an indirect financial relationship, and what constitutes a referral, including an indirect referral.

Existing Law: Subject to certain exceptions, section 1877(a)(1) of the Act prohibits a physician from making a referral to an entity for the furnishing of DHS for which Medicare would otherwise pay, if the physician (or an immediate family member) has a financial relationship with the DHS entity, and prohibits the DHS entity from billing Medicare or any individual (including, but not limited to, the beneficiary), third party payer, or other entity for those services. A financial relationship is (i) either an ownership or investment interest in the DHS entity (or in another entity that holds an ownership or investment interest in the entity) or (ii) a compensation arrangement with the DHS entity, either directly or indirectly. An ownership or investment interest may exist through equity, debt, or other means.

As defined by section 1877(h)(5) of the Act, a ''referral'' means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists.

Proposed Rule: In general, we proposed interpreting the concept of ''indirect financial relationship'' very broadly. In the January 1998 proposed rule, we proposed including within the reach of section 1877 of the Act any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed.

We similarly proposed a broad interpretation of the phrase ''referral to an entity.'' As defined in the statute, a referral is a ''request'' by a physician for a DHS. We proposed defining a ''request'' as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the DHS is necessary. Under this broad reading, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). We interpreted ''referrals'' to include DHS services subsequently performed by the referring physician.

The Final Rule: Given the significance of the general prohibition, we received many comments related to various aspects of the January 1998 proposed rule. In particular, commenters sought clarification of fundamental statutory concepts, including direct and indirect

compensation and ownership or investment arrangements. In addition, many commenters took issue with our interpretation of several of the key terms, including ''referral,'' ''consultation,'' and ''furnishing.''

We are making a number of significant changes to the general prohibition sections in Phase I of this rulemaking. These revisions include the following:

- Clarification as to what constitutes a ''direct'' versus an ''indirect'' financial arrangement, including the addition of a ''knowledge'' element for indirect financial relationships.
- Creation of a new exception for indirect compensation arrangements.
- Clarification that payment obligations that are secured, including those secured by a revenue stream, are among the relationships considered to be ownership or investment interests.
- Revision of the definition of ''referral'' to exclude services personally performed by the referring physician.
- Creation of an exception under section 1877 of the Act for entities submitting claims for DHS that did not know of and did not have reason to suspect the identity of the physician who made the DHS referral to the entity.

These changes are discussed in greater detail below. First, we address the definition of a ''financial relationship;'' second, we address the definition of ''referral.'' These two aspects of the general prohibition under section 1877 of the Act are analytically distinct and require separate analyses. In general, we believe a sensible approach is to ask two questions: (1) Is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS? (2) Is there a referral for DHS from the physician to the entity? If the answer to both questions is affirmative, section 1877 of the Act is violated, unless an exception applies.

A. When Is There a Financial Relationship Between the Physician and the Entity?

The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate for triggering the application of section 1877 of the Act. Section 1877(a)(2) defines a financial relationship as: (1) An ownership or investment interest of a referring physician (or immediate family member) in the entity furnishing DHS, or (2) a compensation arrangement between the referring physician (or an immediate family member) and the entity furnishing DHS. Any financial relationship between the referring physician and the DHS entity triggers application of the statute, even if the financial relationship is wholly unrelated to a designated health service payable by Medicare. In many instances, the financial relationship will not relate to DHS. Unless the financial relationship fits into a statutory or regulatory exception, however, referrals for DHS are prohibited.

The statute expressly contemplates that ''financial relationships'' include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements between referring physicians and DHS entities (sections 1877(a)(2) and 1877(h)(1) of the Act, respectively). We consider a ''direct'' financial relationship to be an arrangement between the entity furnishing DHS and a referring physician or immediate family member with no person or entity (other than agents) interposed between them. While some commenters inquired whether particular arrangements or relationships, such as stock options or vesting in retirement plans, could be characterized as ownership or compensation arrangements, there were no substantive comments as to the underlying definition of a direct financial relationship. The specific questions raised by the commenters are addressed in the comments and responses that follow.

With respect to ''indirect'' financial relationships, in the preamble to the January 1998 proposed rule, we proposed to include as an ''indirect'' financial relationship any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed. In short, we proposed very broad interpretations of indirect financial relationships.

We have generally adopted the overall interpretations of ''financial relationship'' in the January 1998 proposed rule, with the important exception of ''indirect'' financial relationships. Many commenters objected to the discussions in the preamble to the January 1998 proposed regulations relating to indirect financial relationships on the grounds that the discussions were confusing, inconsistent, administratively impracticable, or unfair. We have responded to the commenters by substantially revising the regulations pertaining to indirect financial relationships, especially indirect compensation arrangements. As described in the paragraphs that follow, we have added a knowledge element to the definitions of ''indirect'' financial relationships. We have also made other significant changes in the treatment of indirect compensation arrangements.

Knowledge Element for Establishing the Existence of an Indirect Financial Arrangement

We are amending the definitions of (i) ''indirect ownership or investment interest'' and (ii) ''indirect compensation arrangement'' in § 411.354 to include a knowledge element. Many commenters expressed concern that by extending liability for indirect financial relationships to relationships involving any number of intermediate persons or entities, the January 1998 proposed regulation imposed an unfair burden on entities furnishing DHS affirmatively to ferret out and discover potential indirect financial relationships or else risk submitting improper claims because of relationships they knew nothing about. While we believe that, in most circumstances, the referring physician (or his or her immediate family member) will only be one or two degrees of separation from the entity furnishing the DHS, we have nevertheless modified the January 1998 proposed regulation to add a ''knowledge'' element in cases of indirect financial relationships. This modification limits exposure under section 1877 of the Act to those circumstances in which the entity furnishing DHS has actual knowledge of an indirect financial relationship or acts in reckless disregard or deliberate ignorance as to the existence of an indirect financial relationship. (We sometimes refer to this ''actual knowledge or reckless disregard or deliberate ignorance'' standard in this preamble by the shorthand phrase ''knows or has reason to suspect.'') We define the ''knowledge'' element in a manner consistent with Federal law, as described below.

In order to satisfy this ''knowledge'' element in the case of an indirect ownership or investment interest, the DHS entity need only know or have reason to suspect that the referring physician (or immediate family member) has some ownership or investment interest in the entity furnishing the DHS (or in an entity that holds an ownership or investment interest in the DHS entity). Likewise, to satisfy this ''knowledge'' element in the case of an indirect compensation arrangement, the DHS entity need only

know or have reason to suspect that the referring physician (or immediate family member) is receiving some aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS. In other words, we are not requiring that the DHS entity have knowledge of every link in the chain of entities having financial relationships that connects the DHS entity to the referring physician (or immediate family member).

Specifically, we are providing that, in the case of indirect financial relationships, referrals will only be prohibited (and claims disallowed) if the DHS entity (i) has actual knowledge that the referring physician (or immediate family member) has an indirect financial relationship (that is, that the referring physician or immediate family member (a) has some ownership or investment interest in the DHS entity or (b) receives aggregate compensation that takes into account or otherwise reflects referrals or other business generated by the referring physician for the entity furnishing DHS), or (ii) acts in reckless disregard or deliberate ignorance of whether such an indirect financial relationship exists. Essentially, we are adopting a ''knowledge'' element comparable to the *scienter* standard in the Civil Monetary Penalty Law, section 1128A of the Act. This ''knowledge'' element generally imposes a duty of reasonable inquiry on providers. In the specific context of indirect financial relationships under section 1877 of the Act, we wish to make clear that, given the impracticability of investigating every possible indirect financial relationship involving a referring physician, the knowledge element does not impose an affirmative obligation to inquire as to indirect financial relationships. A duty of reasonable inquiry does require, however, that providers in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship take reasonable steps to determine whether such a financial relationship exists and, if so, whether that indirect financial relationship falls within an exception to the statute (such as the new exception for certain indirect compensation arrangements in § 411.354) or whether the DHS being furnished fall within an exception (such as the in-office ancillary services exception) *before* submitting a claim for the referred item or service or making a referral. The reasonable steps to be taken will depend on the circumstances. Reasonable steps may include the DHS entity obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician's or immediate family member's aggregate compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity, so as to qualify under the new exception for certain indirect financial relationships in § 411.354 (discussed below). A written assurance is not determinative, however, especially if the DHS entity has knowledge of, or reason to suspect, other, contradictory evidence or information.

The addition of a knowledge requirement as an element of an improper indirect financial relationship addresses the concerns expressed by many commenters that it would be impossible continuously to investigate and uncover indirect financial relationships of every referring physician and his or her immediate family members. While the ''knowing'' element we are adopting may allow more claims to be paid than a requirement that would interpret the statute to impose an absolute duty to investigate (and may impose a higher evidentiary burden on the government in an enforcement action), we believe that incorporating a knowledge element in the definition of indirect financial relationships more fairly balances the burden of compliance against the risk of abuse the statute was intended to prevent. We iterate that for purposes of section 1877 of the Act, the DHS entity has no affirmative duty to inquire or investigate whether an indirect financial relationship with a referring physician (or immediate family member) exists, absent some information that would put a reasonable person on alert, and that the duty that is imposed is one of reasonable inquiry in the circumstances.

Indirect Compensation Arrangements

We have substantially revised the January 1998 proposed regulations by restructuring our approach to indirect compensation arrangements. In the January 1998 proposed regulation, we had proposed to trace compensation paid by an entity furnishing DHS through any number of other persons or entities, regardless of how the compensation might be transformed. Many commenters complained that the examples provided in different parts of the preamble to the January 1988 proposed rule were inconsistent or unclear. Upon reviewing the comments and the preamble, we understand the commenters' confusion and have revised the provisions that apply to indirect compensation arrangements by:

- Defining ''indirect compensation arrangement'' to establish a ''bright line'' test, including the ''knowing'' element described above; and
- Creating a new exception under section 1877(b)(4) of the Act for certain indirect compensation arrangements that is generally consistent with the new ''fair market value'' exception for direct compensation arrangements.

This treatment of indirect compensation arrangements more clearly parallels the analysis and regulatory treatment of direct compensation arrangements by (i) defining the universe of financial relationships that potentially triggers disallowance of claims (that is, the definition of ''indirect compensation arrangement''); and (ii) creating an exception for the subset of ''indirect compensation arrangements'' that will not trigger disallowance. The standards in the new exception for indirect compensation arrangements are based in large part on the standards found in the various statutory and proposed regulatory exceptions for direct compensation arrangements, especially the fair market value exception proposed in the January 1998 proposed regulations, which was received favorably by the commenters and has been incorporated into the final regulations in § 411.354(d).

The definition of an ''indirect compensation arrangement'' and the new exception are discussed in detail below.

- *Definition of ''Indirect Compensation Arrangement.''* We have developed a simple test to identify whether an indirect compensation relationship exists. We are adopting in Phase I of this rulemaking, a definition of ''indirect compensation arrangement'' that has three elements: (1) There must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link); (2) the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the

referring physician for the entity furnishing DHS; and (3) the DHS entity must have actual knowledge that the aggregate compensation received by the referring physician (or immediate family member) from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or act in reckless disregard or deliberate ignorance of the existence of such relationship.

The first element of the indirect compensation arrangement definition is met if there is an unbroken chain of financial relationships from the DHS entity to the referring physician (or immediate family member), regardless of the form or purpose of the payments or their relationship to the DHS referrals. This element is relatively straightforward. The unbroken chain that creates an indirect compensation arrangement can consist of any combination of excepted or unexcepted financial relationships, whether ownership or investment interests or compensation arrangements.

One issue raised by several commenters was whether an ownership or investment interest could also create a compensation arrangement. An ownership or investment interest creates a direct compensation arrangement between the owner/investor and the owned/investment entity, since the ownership or investment establishes an arrangement for the distribution of any profits or other benefits (for example, tax benefits in the case of a pass-through entity) from the venture to the owners/investors. However, when the ownership or investment interest itself meets a specific statutory exception under section 1877 of the Act, any anticipated return on investment or other remuneration flowing from the ownership or investment is similarly excepted, provided the return or other remuneration is *bona fide* and not a sham (sham returns would include, for example, use of loan proceeds to make distributions in the absence of *bona fide* profits from the venture).

An excepted financial relationship may still constitute a link in a chain that establishes an indirect compensation arrangement between a referring physician and a DHS entity. For example, if a referring physician owns an interest in a hospital that meets the exception under section 1877(d)(3) of the Act (which allows a referring physician to own an interest in a hospital as a whole, but not in a subdivision of the hospital), and the hospital contracts for services with a clinical laboratory to which the physician refers, there would exist a chain of persons or entities having financial relationships between the referring physician and the DHS entity (referring physician → whole hospital → clinical laboratory), even though the financial relationship between the referring physician and the hospital fits in an exception. We address this issue further in the responses to comments that follow.

The second element of the definition of indirect compensation arrangement is that the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. For the purpose of the definition of indirect compensation arrangements, we are looking at whether aggregate compensation in the direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. Accordingly, for purposes of this element, any ''per service'' or ''per use'' payment arrangement between the physician and the person or entity with which the physician has the direct relationship that is based, in whole or in part, on referrals or other business generated for the DHS entity would satisfy this element. So too, any payment or other remuneration conditioned more generally on referrals or business generated for the DHS entity would satisfy this element of the definition of ''indirect compensation arrangement,'' except as described in § 411.354(d)(5) (describing limited circumstances when an entity may condition compensation on referrals). (For a discussion of § 411.354(d)(5), see section V of this preamble).

If the financial arrangement between the physician (or immediate family member) and the person or entity in the chain with which the physician has the direct financial relationship is an ownership or investment interest, we will look at the relationship between that person or entity (that is, the ''owned entity'') and the next person or entity in the chain with which the owned entity has a direct financial relationship (if that financial relationship is also an ownership or investment interest, we will look to the next direct financial relationship in the chain, and so forth, until we reach a compensation arrangement with an ''unowned'' entity with which there is a compensation arrangement—a chain consisting entirely of owned entities is an indirect ownership or investment interest, not an indirect compensation arrangement). The inquiry then becomes whether the aggregate compensation the owned entity receives varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

The third element in the definition of indirect compensation arrangement is that the entity furnishing DHS must know or have reason to suspect that the referring physician's (or immediate family member's) aggregate compensation varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS. As discussed above, reason to suspect a financial relationship will trigger a duty to make an inquiry into the relationship that is reasonable in the circumstances. In the context of indirect compensation arrangements, in most cases, the referring physician (or immediate family member) will have knowledge of the basis for his or her compensation and be in the best position to assure compliance with section 1877 of the Act. Thus, as noted above, reasonable inquiry by the DHS entity may include obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician's or immediate family member's aggregate compensation falls within the indirect compensation arrangement exception in § 411.354 (that is, the compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity). As discussed below, we are creating a new exception for indirect compensation arrangements, for which we believe most nonabusive indirect compensation arrangements can readily qualify.

• *Exception for Indirect Compensation Arrangements.* While the definition of an ''indirect compensation arrangement'' identifies the universe of potentially improper arrangements, we recognize that many of those indirect compensation arrangements may be substantially similar to direct compensation arrangements that fit in one of the existing statutory exceptions in section 1877 of the Act or one of the

regulatory exceptions we proposed in January 1998. However, many of these indirect compensation arrangements cannot fit in those direct compensation arrangement exceptions, because the arrangements are with persons or entities that are not the person or entity furnishing DHS. Accordingly, we are creating a new exception, using the Secretary's authority under section 1877(b)(4) of the Act, to provide an exception for certain indirect compensation arrangements. The new exception would protect an indirect compensation arrangement if the following conditions are satisfied:

- The compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;
- The compensation arrangement between the referring physician (or immediate family member) and the person or entity in the chain with which the physician (or immediate family member) has the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (in the case of a bona fide employment relationship, the arrangement need not be set out in a written contract, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer);
- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Where the financial relationship between the physician and the person or entity with whom he or she has a direct financial relationship is an ownership or investment interest, we will apply the requirements of this exception to the first compensation arrangement in the chain of relationships between the physician and the entity furnishing DHS.

For purposes of the new exception, in determining whether compensation takes into account the value or volume of referrals or other business generated by the referring physician for the DHS entity, we will apply the tests for ''volume or value of referrals'' and ''other business generated'' that are discussed in section V of this preamble and set forth in § 411.354(d) of these regulations. This is consistent with our determination to interpret those phrases uniformly in all exceptions in which they appear. Thus, ''per service'' or ''per use'' compensation arrangements can fit in the new exception for indirect compensation arrangements, provided the ''per use'' or ''per service'' payments are fair market value for the items or services provided (and do not include any additional amount that might be attributable to the volume or value of referrals or other business generated between the referring physician and the entity furnishing DHS) and the payments do not vary during the term of the compensation arrangement in any manner that takes into account referrals to the DHS entity.

Some of the statutory and regulatory exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act, when certain criteria are satisfied. In effect, services described in these exceptions are not DHS for purposes of the statute. These service-based exceptions include the physicians' services exception, in-office ancillary services exception, prepaid plans exception, and academic medical center exception, in § 411.355 of these regulations. Thus, even if there is an indirect compensation arrangement between a referring physician and an entity furnishing DHS, these exceptions may apply to referrals of the particular services described in the exception. Referrals of DHS that do not fit in a services-based exception would be prohibited unless the indirect compensation arrangement fits in the new exception for indirect compensation arrangements.

Finally, we are not adopting our interpretation in the January 1998 proposed rule with regard to common ownership or investment in the same entity (which is not the entity furnishing DHS) by the referring physician (or immediate family member) and the entity furnishing DHS. In the January 1998 proposed rule, we proposed that such common ownership would not create a compensation arrangement between the referring physician and the DHS entity. However, in the light of our modified and more limited definitions of indirect financial relationships, we have revisited the issue of common ownership. We believe that such relationships should be analyzed in the same manner as any indirect financial relationship.

We are also making the following changes in the general prohibition sections of the regulations:

- Clarification that an ownership or investment interest in a subsidiary corporation will not be considered a direct ownership or investment interest in the parent or a sibling corporation. However, an owner of a subsidiary corporation may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.
- Treatment of stock options as creating a compensation relationship and not an ownership interest until such time as the options are exercised.
- Clarification that payment obligations that are secured, including those that are secured by a revenue stream, are considered ownership or investment interests.

In the following paragraphs, we address the specific comments we received on the discussion and proposed interpretations of financial relationships set out in the January 1998 proposed rule and our responses to them.

Comment: A number of commenters objected to the concept of ''tracing'' compensation from, and ownership or investment interests in, an entity furnishing DHS through any number of intermediate entities to a referring physician. According to these commenters, the administrative burden of trying to comply would be costly and ultimately impossible. These commenters believe that our proposed interpretation would place the entities furnishing the services, as well as physicians making referrals, at risk for what was unknowable given potentially complex business arrangements. One commenter suggested that we keep the same definition of financial relationship as the August 1995 final rule, which the commenter stated was limited to direct ownership and compensation arrangements.

Response: The commenter who suggested that the August 1995 final rule was limited to direct financial relationships is mistaken. In the August 1995 final rule, we defined financial relationship to include indirect financial relationships. We did not, however, expand on how we would interpret and apply the term ''indirect.'' We believe that limiting the statutory prohibition to direct ownership and compensation arrangements would seriously weaken the statute. Unscrupulous physicians and entities furnishing DHS would simply interpose entities between themselves and funnel the money through them. Furthermore, as we stated in the preamble to the January 1998 proposed rule, the statute, by its terms, applies to indirect ownership and investment interests and compensation arrangements.

As discussed above, we have revised the treatment of indirect compensation arrangements. First, we are no longer

requiring any tracing of payments. The initial screen is simply whether there is an unbroken chain of persons or entities having financial relationships between the referring physician (or an immediate family member) and the entity furnishing DHS, regardless of the nature of the payments or financial relationships. Second, we have limited liability to instances in which the DHS entity knows or has reason to suspect that aggregate compensation received by the referring physician (or immediate family member) varies with, or otherwise reflects, the volume or value of referrals or other business generated for the DHS entity. Finally, we have made clear that absent information that would put a reasonable person on alert, a DHS entity has no affirmative duty to inquire or investigate such arrangements.

Comment: A major trade association representing physicians (and other commenters) claimed that our explanations of how we would treat several types of situations involving indirect financial relationships appeared inconsistent. Specifically, the association referred to the example of a hospital contracting with a group practice to furnish physician services and to staff the hospital, and the hospital paying the group practice for these services, and with the group practice, in turn, compensating the physicians through salaries that ''in some way'' reflect the hospital services. According to the January 1998 proposed rule, the physicians would have an indirect compensation relationship with the hospital that would require an exception. The commenter complained that this position is inconsistent with another example in the preamble in which we stated that, when a physician who owned a physical therapy (PT) company referred patients for treatment including PT to a skilled nursing facility (SNF) that contracted with the physician's PT company, we would equate the physician with the PT provider.

Response: We believe the new provisions for indirect compensation arrangements address the commenters' concerns.

In the example cited by the commenter involving the payments by a hospital to a group practice that, in turn, pays its employees a salary, we would not require evidence that the salary is ''in some way'' related to the hospital payment. It is enough that the hospital has a financial relationship (that is, a personal services contract) with the medical group, which, in turn, has a financial relationship with its employees. Since there is an unbroken chain of financial relationships between the referring physician and the DHS entity, the first element in the indirect compensation definition is satisfied.

The second element of the definition of an indirect compensation arrangement would be satisfied if the aggregate compensation to the referring physician from the medical group varied with, or otherwise reflected, the volume or value of referrals or other business generated by the referring physician for the DHS entity (that is, the hospital)—a fact that should be relatively easy to establish.

The final element in the definition of an indirect compensation relationship requires that the hospital (that is, the DHS entity) (i) have actual knowledge or reason to suspect that the referring physician is receiving compensation from the medical group (that is, the entity in the chain with which the referring physician has a direct financial relationship) that varies with, or otherwise reflects, the volume or value of referrals or other business generated for the hospital.

Indirect compensation arrangements that do not fit in the new exception for such arrangements can be restructured or abandoned. Arrangements under which a referring physician receives compensation tied to the volume or value of his or her referrals or other business generated for a DHS entity are the very arrangements at which section 1877 of the Act is targeted.

Commenters claimed that our discussion at 63 FR 1710 in the preamble of the January 1998 proposed rule was confusing because of the way we described a physician's referrals to a SNF, which, in turn, referred the patients to a PT company in which the referring physician had an ownership interest and which billed Medicare directly for services to SNF patients. In that example, the referring physician had a direct financial relationship (ownership) with the PT company. There was no indirect financial relationship involving the SNF. Rather, the referring physician had a referral arrangement with the SNF, but not a financial relationship, and the SNF had a referral arrangement with the PT provider, but not a financial relationship. We think the issue in the example is whether, by sending patients to the SNF, the physician is making referrals to the PT provider, with which the physician has a direct financial relationship. We discuss that issue in the following section on referrals.

However, we think it useful to reconsider the example in light of consolidated billing for SNFs. (We note that consolidated billing should not be confused with composite rate payments. Consolidated billing is a process for submitting claims while composite rate payment constitutes a distinct payment methodology.) Under consolidated billing, the SNF in the example will be billing the PT services directly to Medicare. In this situation, there would be an indirect compensation relationship between the SNF—which is now the DHS entity—and the referring physician. Since the SNF would be purchasing PT services from the PT company owned by the referring physician, a financial relationship would exist between the SNF and the PT company, and the physician's ownership interest in the PT company would complete the chain (SNF→ PT company→ referring physician). Thus, the first element of the definition of an indirect compensation arrangement would be satisfied. With respect to the second element, the financial relationship between the referring physician and the person or entity in the chain with which the referring physician has a direct financial relationship (that is, the PT company) is an investment interest. Accordingly, we look to the compensation paid by the SNF to the owned entity (that is, the PT company) in order to see if the second element is satisfied. Since the PT company is compensated on a per service basis that reflects referrals by the referring physician to the SNF, the second element is met. Assuming knowledge on the part of the SNF, there would be an indirect compensation arrangement, and the issue becomes whether the indirect compensation arrangement satisfies the new exception for indirect compensation arrangements in § 411.354.

Comment: Several commenters stated that when there is a chain of payments that begins with a payment by a provider of DHS to another entity controlled by it, the first payment outside the entities under common control should be the arrangement that has to meet an exception. For example, in looking at payments from a hospital to a physician group practice that is wholly owned by the hospital for hospital staffing and subsequent payments from the group to its employed physicians, the payments that would need to qualify for an exception are the payments to the employed physicians. One commenter proposed that when tracing indirect financial relationships, the inquiry should end any time a payment in the chain meets an exception.

Response: The first commenters' suggested approach is problematic because the ''volume or value'' standard

for the employed physician's compensation is measured based on referrals to the physician's employer, the medical group. Applying the commenters' proposed test to the example, the medical group could pay the physician employees based on the volume and value of referrals and business generated for the hospital and still comply with the employment exception. Phase I of this rulemaking would require that the compensation to the physicians *not* vary with or otherwise reflect either referrals to the group (to comply with the employee exception) or referrals to, or other business generated for, the hospital (so that it does not qualify as an indirect compensation relationship). To the extent that the compensation paid to the physicians did vary based on referrals or other business generated for the hospital, the arrangement would still be protected if it complied with the new indirect compensation arrangements exception in § 411.354.

We also considered, but ultimately rejected, the second commenter's proposal that the inquiry end any time a financial relationship fits in an exception. The fact that one financial arrangement meets an exception does not necessarily prevent the referring physician from receiving payments based on DHS referrals to a DHS entity. For example, if a person or entity owns both a group practice and a DHS entity, a compensation arrangement with a physician employee of the group practice could fit in an exception so long as it did not take into account referrals between the employee and the group practice. The exception would not, however, prevent the compensation arrangement from taking into account referrals or other business generated by the physician employee for the DHS entity.

Having considered the several views of the commenters, we believe that Phase I of this rulemaking strikes a balance that protects the Medicare program while limiting the reach of the regulation to abusive relationships. Under Phase I of this rulemaking, there would be an unbroken chain of financial relationships (the DHS entity → the owner → medical group → referring physician). However, unless the compensation received by the employed physician varies with or otherwise reflects his or her referrals to, or other business generated for, the DHS entity, and the DHS entity has the requisite knowledge, there would not be an indirect compensation arrangement. If there were, the arrangement would have to meet an applicable exception.

Comment: One commenter asked whether there would be an indirect compensation arrangement if an employed physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer.

Response: There may be an indirect compensation arrangement if a physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer, since the physician would be referring to a DHS entity that has a financial relationship (ownership or investment) with an entity that has a financial relationship (compensation) with the physician. If the referring physician's compensation from his or her employer reflected DHS referrals or other business generated by the referring physician for the entity providing the DHS, and the DHS entity had actual knowledge or reason to suspect that the physician's aggregate compensation reflected the volume or value of referrals or other business for the DHS entity, there would be an indirect compensation arrangement. Unless the arrangement fit in the new indirect compensation arrangements or another exception, referrals to the entity would be prohibited.

Comment: Another commenter asked whether a physician's referrals would be prohibited in a situation involving a physician practice management company (PPMC). Specifically, the commenter asked about a referring physician who has an ownership or investment interest in a PPMC, which, in turn, controls a captive professional corporation (PC) through a web of legal agreements, including a long-term management contract. The physician refers patients for DHS to the captive professional corporation.

Response: In the scenario described by the commenter, there is very likely an indirect compensation arrangement, since the captive PC has a financial relationship with the PPMC (the management contract), which has a financial relationship (ownership or investment) with the referring physician. Since the financial relationship between the physician and the entity in the chain of financial relationships with which the physician has a direct financial relationship (that is, the PPMC) is an ownership or investment interest, we look to the compensation arrangement between the owned entity (that is, the PPMC) and the next entity in the chain, in this case, the captive PC, to determine whether the second element of the test for an indirect compensation arrangement is met. Accordingly, if the entity furnishing the DHS (the captive PC in this example) knows or has reason to suspect that the PPMC's compensation from the captive PC varies with, or otherwise reflects, the value or volume of the captive PC's business (and consequently varies, in the aggregate, based on the referring physician's DHS referrals to the captive PC), there would be an indirect financial relationship between the captive PC and the referring physician. Unless the indirect compensation arrangement fits in the new indirect compensation arrangements or another exception, the physician could not refer DHS to the captive PC, and the captive PC could not submit claims for those DHS referrals.

Comment: Several commenters objected to our proposal that a physician can receive indirect compensation through a nonprofit enterprise if the enterprise is controlled by an individual who is in a position to ''influence'' the physician's referrals. The example was the owner of a clinical laboratory who is also the director of research at a nonprofit research facility that could provide physician research grants in exchange for referrals to the laboratory.

Response: The issue is whether there is a prohibited indirect financial relationship between the DHS entity (the clinical laboratory) and the referring physician. Assuming there is a financial relationship between the owner of the clinical laboratory and the nonprofit research facility, there would be a chain of persons or entities with financial relationships (clinical laboratory → research director → not-for-profit → referring physician), and the issues become (i) whether the aggregate amount of the research grants to the referring physician varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the clinical laboratory, (ii) whether the clinical laboratory knows of or has reason to suspect that the referring physician's aggregate compensation under the research grants varies with, or otherwise reflects, the volume or value of referrals or other business generated for the clinical laboratory, and (iii) if there is an indirect financial relationship, whether an exception applies. Of course, even if there is no financial relationship between the clinical laboratory and the nonprofit research facility, there could be a violation of the anti-kickback statute, section 1128B(b) of the Act, in the situation described in the comment.

Comment: Several commenters stated that compensation derived from an

ownership or investment interest (for example, a return on an investment interest or a dividend) should not give rise to indirect compensation. To support this position, they referred to discussions in the preamble to the January 1998 proposed rule and in the preamble to the August 1995 final regulations, in which we stated that compensation derived from, or ancillary to, an investment interest that qualified for an investment exception under sections 1877 (b) through (d) of the Act would not also have to meet a compensation exception.

Response: We agree with the commenters that dividends or profit distributions from an ownership or investment interest that qualifies for an ownership or investment interest exception under sections 1877(b) through (d) of the Act do not also have to meet a separate compensation exception. In other words, the ownership and investment exceptions in the statute protect the ownership or investment interest and any corresponding return on the excepted investment. Our discussion in the preamble to the January 1998 proposed rule specifically referenced and clarified the August 1995 final rule preamble discussion, which was limited to the issue of whether distributions from an excepted investment interest (that is, an ownership or investment interest protected under sections 1877(b) through (d) of the Act) had to meet an additional exception for compensation arrangements. Nothing in either preamble discussion was intended to be interpreted as saying that any other ownership or investment interests (that is, ownership or investment interests that are not specifically excepted) are not compensation arrangements. We believe that an ownership or investment interest (including distributions from the interest) creates a compensation arrangement, as defined in section 1877(h)(1)(A) of the Act, between the owner/investor and the owned/investment entity and can be part of a chain of persons or entities having financial relationships that create an indirect compensation arrangement.

Without this interpretation, unscrupulous physicians could evade section 1877 of the Act by simply interposing a shell entity, which they own, between themselves and the DHS entity (which they do not own) and taking out the compensation as dividends. In short, they would simply launder the compensation through the shell investment entity.

Comment: Another commenter suggested that a loan and any interest payments should be treated as either ownership or compensation, but not both.

Response: We agree with the commenter. If a loan qualifies as a protected ownership or investment interest, the interest payments do not create a separate compensation arrangement. Accordingly, the interest payments need not satisfy a separate compensation exception.

Comment: A number of commenters asked that we clarify that an investment in a subsidiary that does not furnish DHS is not necessarily an ownership interest in the parent or a sibling corporation.

Response: An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. However, an owner of a subsidiary company may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.

Comment: One commenter objected to the suggestion in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest. Another commenter stated that an unsecured loan that was subordinated to an entity's credit facility should not be treated as an ownership or investment interest.

Response: We are persuaded by the logic of the commenter and, accordingly, we withdraw the statement in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act. We will consider contributions (including employer contributions) to retirement plans to be part of an employee's overall compensation arrangement with his or her employer. We also agree that an unsecured loan that is subordinated to a credit facility is a compensation arrangement and not an ownership or investment interest for purposes of section 1877 of the Act.

Comment: Another commenter stated that secured debt given by a not-for-profit hospital, as part of its acquisition of medical practices, should not be treated as an ownership or investment interest in the hospital, but as compensation.

Response: Section 1877(a)(2) of the Act provides that ''an ownership or investment interest * * * may be through equity, debt or other means.'' Accordingly, we believe that loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion thereof, constitute investment interests within the meaning of section 1877 of the Act. In addition, a contrary reading would result in disparate treatment of entities based on their organizational status.

Comment: One commenter asserted that stock options should be treated as either ownership or investment interests or compensation arrangements, but not both. Another commenter stated that stock options should be treated as compensation and not ownership since they do not carry voting rights or the right to dividends and must be sold upon conversion.

Response: In Phase I of this rulemaking, we are revising the rule to treat stock options as compensation at the time they are awarded. At the time they are exercised or converted, they create an ownership or investment interest and must meet an appropriate exception. Any dividends or profit distributions derived from an excepted stock ownership or investment interest would not have to meet a separate compensation exception.

Comment: Another commenter stated that stock options could be structured to discourage referrals for DHS.

Response: The fact that a particular financial arrangement might be structured to discourage referrals does not provide a basis for creating an exception. The statute is intended to remove incentives to overutilize by prohibiting certain financial relationships. If application of the statute required a case-by-case examination to determine the effect of the financial relationship, the statute's efficacy would be undermined.

Comment: One commenter suggested that the determination of whether a convertible security is a compensation arrangement or an ownership or investment interest should depend on which party has the right to convert the security. According to the commenter, if the DHS entity has the right to convert the security, the interest should be treated as compensation until conversion.

Response: We are applying the same approach to convertible securities as we are applying to stock options, and we will classify them as compensation until they are converted into equity. However, many convertible securities are bonds that can be converted into stock. Since bonds are typically secured debt, bonds will be treated as an ownership or investment interest.

B. When Does a Physician Make a Referral?

As defined by section 1877(h)(5) of the Act, a ''referral'' means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists. In the January 1998 proposed rule, we interpreted ''referral'' to mean any request by a physician for a service, including services subsequently performed by the physician. We proposed defining a ''request'' as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the service is necessary. Under this broad definition, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). As a general principle, we proposed that a physician may ''cause'' a referral to be made if he or she has the ability to control or influence the individual who selects the entity that furnishes the DHS.

In response to the public comments, we are making several significant changes to the definition of ''referral'' in Phase I of this rulemaking. These changes include the following:

- Revision of the definition of ''referral'' to exclude services performed personally by the referring physician. Simply stated, we are persuaded that a physician cannot make a ''request'' of himself or herself for services he or she *personally* performs. However, a physician can make a ''request'' of others, including, without limitation, his or her employees, co-workers, or independent contractors. These requests are ''referrals'' under section 1877 of the Act (although many of them will fit in an exception). We continue to believe that a referral can occur in a wide variety of formats, written, oral, or electronic, depending on the particular service.
- Adding an exception using our regulatory authority under section 1877(b)(4) of the Act for certain referrals of DHS to an entity with which the referring physician has a prohibited financial relationship that are ''indirect'' referrals (for example, when a physician has caused a referral to be made by someone else or has directed or routed a referral through an intermediary) or are oral referrals (that is, no written request or other documentation that would identify the referring physician is required). A claim by the entity furnishing the DHS may be paid for purposes of section 1877 of the Act if the entity did not know or have reason to suspect the identity of the referring physician. In these circumstances, there is minimal risk of patient or program abuse by the entity submitting the claim (provided that the claim is otherwise valid).
- Clarification of the definition of a ''consultation.'' In light of the clarifications relating to indirect and oral referrals described above, the practical significance of the definition of a ''consultation'' is substantially reduced.

We believe that these changes address many of the concerns expressed by commenters. In particular, we have endeavored to respond to the perceived harshness of section 1877 of the Act by creating a narrow exception under our section 1877(b)(4) authority. If the entity furnishing DHS knows of or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral, the DHS entity may not submit a claim for the services. If the physician who prescribes or orders a DHS is someone with whom the DHS entity has a prohibited financial relationship, we think a reasonable DHS entity should suspect that the physician referred the patient to the entity, absent some credible evidence to the contrary.

In the following paragraphs, we discuss and respond to the comments we received on the proposed interpretations of ''referral'' and ''consultation'' as published in the January 1998 proposed rule.

1. ''Referral''

Comment: Many commenters objected to our interpretation in the January 1998 proposed rule that a service ordered and personally performed by a physician is a referral within the meaning of section 1877 of the Act. Commenters asked us to clarify that there is no referral if the referring physician personally performs the service. Similarly, some commenters sought clarification that there is no referral if the services are ''incident to'' services personally performed by the referring physician.

Response: We are persuaded by the commenters that a physician does not make a ''request,'' in the ordinary sense of that term, if he or she personally performs a designated health service. We agree it does not make sense to consider work that a referring physician initiates and personally performs as a referral *to* an entity. Thus, we are amending our definition of ''referral'' to exclude services that are personally performed by the referring physician (that is, the referring physician physically performs the service), and we are revising our definition of ''entity'' to clarify that the referring physician himself or herself is not an entity for purposes of section 1877 of the Act (although the physician's practice is an entity). All other Medicare-covered DHS performed at the request of a referring physician are ''referrals'' for purposes of section 1877 of the Act. A service performed by a hospital for which the hospital bills the technical or facility component of the charge would be a referred service. In such circumstances, however, the physician's service performed at the hospital for which the physician would bill Part B would not be a referred service.

With respect to services performed by others, including a physician's employees, we think the issue is more complicated. Services performed by others are reasonably considered to be performed as a result of a ''request.'' Moreover, the statutory language in section 1877(h)(4)(B)(i) of the Act indicates that the Congress considered there to be a difference between personally performed services and services performed by others. On balance, we have chosen to include services performed by others, including a physician's employees, in the definition of referral. We are concerned that a blanket rule exempting services performed by a physician's employees from the definition of ''referral'' could, in some circumstances, undermine the intent of section 1877 of the Act. For example, by stationing employees in off-site DHS facilities, a physician practice could circumvent the statutory ''building'' requirements of the in-office ancillary services exception.

Even the more limited suggestion made by some commenters that there should be no ''referral'' if an employee's services are properly billable as ''incident to'' a physician's personally performed services could result in circumvention of the ''building'' requirements in some cases.

However, we believe the definition of ''referral'' we are adopting here—in conjunction with the in-office ancillary services exception—strikes an appropriate balance. Under the final rule, services performed by anyone other than the referring physician (whether an employee, a staff member, or a member of the physician's group practice) is a ''referral'' for purposes of section 1877 of the Act. Thus, services performed by a physician's employees will be considered ''referrals''. However, in most cases, such referrals will be permitted under the in-office ancillary services exception, which is substantially broader in this final rule than in the 1998 proposed rule. Services performed by employees that do not meet the ''same building'' or ''centralized building'' tests (as applicable, depending on whether the physician is a solo or group practitioner) will be prohibited unless another exception applies.

We recognize that, in many cases, services performed by a physician's employees are, for practical purposes, tantamount to services performed by the physician (for example, a physician's assistant applying a neck brace ordered by a physician for an individual who has been in an auto accident, when the face-to-face encounter with the patient, including the physical examination by the physician, indicates the need for a properly adjusted neck brace.) While such services are included in the definition of ''referral'' under this final rule, given the significance of this issue, we are soliciting comments as to whether, and under what conditions, services performed by a physician's employees could be treated as the physician's personally performed services under section 1877 of the Act.

Comment: A commenter asked that we clarify that a plan of care that includes the provision of DHS by the physician establishing the plan of care is not a referral. If not clarified as suggested, the commenter believes that the physician would effectively be barred from treating his or her own patients.

Response: If the DHS are personally performed by the physician who established the plan of care, there would be no referral as to those personally performed services.

Comment: Some commenters objected to our proposed presumption that a physician has referred his or her patient to an entity for the furnishing of DHS if the patient obtains the services from the entity with which the physician has a financial relationship. One commenter described the following scenario: A physician orally tells a patient or another person that the patient needs a designated health service. The patient obtains the service from an entity with which the physician has a prohibited financial relationship. The entity does not know (and cannot know) that the physician orally told the patient (or other person) that the service was needed. The commenter sought clarification as to the application of section 1877 of the Act in these circumstances.

Response: We are establishing an exception for indirect and oral referrals. When there is no written order or other documentation of the referral, the issue is whether the DHS provider knows or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral.

Comment: Several commenters sought clarification that a physician's ordering, dispensing, or prescribing of drugs does not constitute a referral to the manufacturer of the drugs. The commenters noted that the manufacturers are not entities that furnish DHS (that is, outpatient prescription drugs) to patients. Rather, furnishing of DHS is performed by physicians, pharmacies, hospitals, and clinics.

Response: We agree that, in most cases, drug manufacturers are not entities that furnish DHS to patients for purposes of section 1877 of the Act, and, therefore, the ordering, dispensing, or prescribing of drugs would not constitute a referral to the manufacturer of the drugs. However, manufacturer-owned or -affiliated retail pharmacy operations, or other health care providers may be entities for purposes of section 1877 of the Act, if they furnish DHS to patients.

Comment: A commenter recommended that activities that a solo practitioner performs as a customary and integral part of patient treatment should not be considered a ''referral.''

Response: We find the commenter's proposed language too vague to be used in creating a standard. We believe our revised definition of ''referral'' that excludes personally performed services and our changes to the in-office ancillary services exception (see section VII.B.1 of this preamble) adequately address the commenter's concerns.

Comment: A commenter stated that referrals for DHS by a nonphysician professional employee of a group practice, such as a nurse practitioner or a physician assistant, should not be imputed to a physician member of the group practice, when the nonphysician is authorized and licensed to prescribe treatment on his or her own and can make independent decisions regarding referrals. For example, if a nurse practitioner, staffing a group practice office without a physician member present, orders and performs a plain x-ray, the referral for the x-ray should not be imputed to a physician member of the group practice. If the referral is imputed, the service may not qualify under the in-office ancillary services exception, because it is not personally performed by the referring physician, another physician in the group practice, or a person who is directly supervised by the referring physician or another group practice physician. Alternatively, the commenter suggested that we modify the ''direct supervision'' standard to mirror our payment and coverage requirements to enable ''imputed'' referrals by a nurse practitioner and a physician assistant to fit in the in-office ancillary services exception.

Response: As previously stated, we are revising the ''direct supervision'' standard in the in-office ancillary services exception to mirror our payment and coverage requirements. (See discussion in section VI.B.2 of this preamble.) This change should address the concern identified by the commenter.

We believe that the question of whether a referral by a nurse practitioner or a physician assistant should be imputed to an employer physician will depend on the facts and circumstances of the referral. The inquiry is whether the physician controls or influences the nonphysician's referral. The Congress and HHS have recognized that many nurse practitioners and physician assistants are independent providers authorized and licensed to prescribe treatment and make independent decisions regarding referrals. However, these practitioners do not always act independently of their employers. For example, sometimes services of a nonphysician practitioner are billed ''incident to'' a physician service rather than directly under the nonphysician's independent billing number. In short, we are concerned that physicians could attempt to circumvent section 1877 of the Act by funneling referrals through nonphysician practitioners. We believe the change in the supervision requirement affords sufficient protection for legitimate arrangements.

Comment: Several commenters were confused by our discussion in the preamble to the January 1998 proposed rule at 63 FR 1710 of a situation in which a physician who owned a physical therapy (PT) company referred patients for treatment, including PT, to a skilled nursing facility (SNF) that

contracted with the physician's PT company. In the preamble, we indicated that we would analyze the arrangement as an indirect compensation arrangement and equate the physician with the PT provider.

Response: In the preamble of the January 1998 proposed rule, we suggested that the critical factor would be the degree of control the physician had over the PT provider and the extent of the PT provider's relationship with the SNF. We are abandoning that analysis. We think the proper focus is whether the physician is making a referral to the PT provider within the meaning of section 1877 of the Act. In other words, we believe that a physician can make a referral of DHS ''to an entity'' even though the referral is first directed or routed through another person or entity, provided the physician has reason to know the identity of the actual provider of the service. In the SNF/PT provider example, the relevant inquiry is whether the physician has made a referral, directly or indirectly, to the entity furnishing DHS, in other words, whether he or she is referring ''to'' that entity. Accordingly, if the physician referring the patient to the SNF knows that the PT company in which he or she has an investment interest will furnish DHS to the patient or could reasonably be expected to know that the PT company will actually furnish DHS to the patient, the referral is a referral ''to the entity'' and is prohibited, unless an exception applies. Similarly, where the PT company knows or has reason to suspect that the referral for DHS came from a referring physician with whom the PT company has a prohibited financial relationship, the PT company cannot submit the claim for the DHS. The PT/SNF example will be affected by the advent of full consolidated billing for SNFs, as described above in the responses to comments on indirect compensation arrangements.

To trigger section 1877 of the Act, the direction or steering of a patient ''to an entity'' does not need to be in writing, nor does it have to be absolute; it need only be reasonably intended to result in the patient receiving the service from the entity. Thus, for example, when a physician provides an order or prescription for a DHS to a patient that ostensibly can be filled by any of a number of entities and then suggests or informs the patient that the order can be serviced by a particular entity, there would be a referral ''to'' that entity. Given the administrative burden on entities presenting claims, in the context of an indirect financial relationship, we believe a claim for DHS should be subject to nonpayment unless the entity does not know that, and does not have reason to suspect that, the referring physician had directed the patient to the entity.

2. Consultation

The Existing Law: Section 1877(h)(5)(C) of the Act excepts from the definition of a ''referral'' by a ''referring physician'' a request by a pathologist for clinical laboratory tests or pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if the services are furnished by, or under the supervision of, the specialist, pursuant to a consultation requested by another physician. Section 1877(h)(5)(C) creates a narrow exception from the definition of ''referral'' for a small subset of services provided or ordered by certain specialists pursuant to a consultation requested by another physician (the referring physician).

The Proposed Rule: In the preamble to the 1998 proposed rule, we referred to the interpretation of consultation that appeared in the March 1992 proposed rule for clinical laboratory services (57 FR 8595). There, we interpreted a consultation to be:

> A professional service furnished to a patient by a physician (the consultant) at the request of the patient's attending physician. A consultation includes the history and examination of the patient as well as a written report that is transmitted to the attending physician for inclusion in the patient's permanent record. If, in the course of that consultation, the consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring [attending] physician has a financial interest. Other referrals, such as sending a patient to a specialist who assumes responsibility for furnishing the appropriate treatment, or providing a list of referrals for a second opinion, are not ''consultations'' or ''referrals'' that would trigger the [physician referral provision].

We did not add anything to this definition in the August 1995 final rule concerning referrals for clinical laboratory services.

Commenters to the 1998 proposed rule took issue with this interpretation for several reasons, including the requirement that the consulting physician examine and take a history of the patient, and the interpretation's failure to demarcate clearly when a consultant takes over treatment of the patient.

The Final Rule: The final rule adopts a very broad interpretation of a consultation. We want to make clear that this definition is only for the very limited purpose of determining when a pathologist's, diagnostic radiologist's, or radiation oncologist's ordering of DHS from a facility with which he or she has an otherwise prohibited financial relationship will not prohibit submission of a claim to Medicare. *Most importantly, this definition is not intended to, and has no bearing on, coverage or payment rules relating to consultations.* Coverage and payment rules related to consultations raise many issues that are irrelevant for the very limited application of the term in section 1877 of the Act. Simply put, while there may be many difficult issues in determining when certain specialty services are consultations, as opposed to routine treatment, such difficulties are relatively rare in the context of the three exceptions in section 1877(h)(5)(C) of the Act (namely, a request by a pathologist for clinical laboratory services or pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy).

As a preliminary matter, we think it important to recognize that section 1877 of the Act defines referrals very broadly. Section 1877(h)(5) specifically includes referrals or requests for services made by the referring physician, as well as any DHS provided pursuant to a consultation with another physician, including DHS provided by the consulting physician or any DHS ordered by the consulting physician.

Section 1877(h)(5)(A) of the Act having established that a referral includes all DHS ordered by a consulting physician, section 1877(h)(5)(C) then carves out: (i) A request by a pathologist for clinical laboratory services or pathological examination services, (ii) a request by a radiologist for diagnostic radiology services, and (iii) a request by a radiation oncologist for radiation therapy, if the services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician.

The final rule adopts the following criteria to identify a consultation for purposes of section 1877:

(1) A consultation is provided by a physician whose opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation is documented in the patient's medical record.

(3) After the consultation is provided, the consulting physician prepares a

written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Finally, we want to make clear that the exception in section 1877(h)(5)(C) of the Act only protects the referral of DHS from the pathologist, diagnostic radiologist, or radiation oncologist to the DHS provider. If the DHS provider—(1) knows or has reason to suspect that the referral originated from the referring physician, and (2) has a direct or indirect financial relationship with the referring physician, the DHS provider cannot submit a claim to Medicare for the DHS unless the financial relationship fits into an exception. Moreover, the referring physician may not make the referral to the consultant if he or she knows or has reason to suspect that the consultant will order DHS from an entity with which the referring physician has a direct or indirect financial relationship to which no exception applies.

Comment: A commenter suggested that the ''diagnostic radiology'' exception should be expanded to include other DHS performed or supervised by nonradiologist physicians to assure quality of care and access to a broad variety of services. The commenter asked that we broaden the consultation exception to include all DHS used to diagnose disease that are ordered pursuant to a consultation initiated by another physician.

Response: We agree that section 1877(h)(5)(C) of the Act creates an exception for the referrals of some specialists and not others. However, the Congress specifically excepted the requests of radiologists for diagnostic radiology services if the services are furnished by, or under the supervision of, the radiologist, pursuant to a consultation requested by another physician. It is our view that the Congress regarded most radiologists in this situation and the other excepted specialists as physicians who were not instigating a referral for services, but merely implementing the request of another physician who has already determined that the patient is likely to need radiology services. The Congress believes that, in general, a radiologist in this situation would not be likely to overutilize services.

We do not believe that we have the authority to extend this exception to other specialists, some of whom provide separate physician services to patients and would be in a position to instigate the referral for radiology.

Comment: One commenter was concerned about our willingness to exempt pathologists, radiologists, and radiation oncologists, yet require other arrangements and physicians to alter their referral methods. The commenter asserted that pathologists will order further stains or studies on specimens to aid in a diagnosis. Radiologists, not infrequently, recommend further studies as part of their interpretation, again to help make a diagnosis. The commenter stated that given the current medico-legal atmosphere, it is rare that he does not follow the suggestions of these consultants. In addition, the commenter stated that he has seen cancer patients with new or progressive diseases who are being treated by radiation oncologists without any direct input from attending or primary care physicians. In the commenter's view, these examples are standard medical practice and self-serving. Since radiologists often have an ownership interest in the diagnostic facility and pathologists in a laboratory facility, they are doubly benefitted by the referral.

Response: The statute clearly establishes special rules for diagnostic radiologists, pathologists, and radiation oncologists.

Comment: A number of commenters explained their problems with distinguishing a consultation from a referral based on their particular speciality area. For example, one commenter stated that during an active phase of an oncologic, hematologic, or pneumatologic illness, the care of the patient specific to that illness may be managed by the subspecialist and the overall care of the patient may be managed by the referring physician using the information obtained from the consultation. This commenter believes that a referral would occur only if the total care of the patient were transferred.

Another commenter asserted that rarely does a treating physician completely give up the care of a patient to another physician, and rarely does the treating physician completely retain responsibility for the care of the patient. Rather, a physician will send a patient to a specialist for testing, diagnosis, and initial treatment, and then the originating physician will take over the care of the patient.

Representing specialists who frequently perform consultations and assume the neurological care of patients at the request of referring physicians, one commenter asserted that it is appropriate to bill for a consultation when care is transferred, rather than a lower-paying evaluation and management visit, because of the extra work for the consulting physician involved in preparing a report for the attending physician.

Response: We agree with the commenters that it can be difficult to determine whether a first physician initiating a visit to a second physician should constitute a referral to another physician or the request for a consultation with that physician. However, as discussed above, in the three specific instances identified in the statute, we think there will be little disagreement in determining when there is a consultation. In any event, for purposes of section 1877(h)(5)(C) of the Act, we are adopting a broader interpretation of a consultation than is in the coverage rules. Finally, payment and coverage for consultations are not addressed or affected by this rule.

Comment: One commenter, representing an association of radiologists, discussed the case of what happens when a patient is sent to a radiation oncologist for treatment of a tumor. The commenter stated that radiation oncology treatment occurs over a period of weeks or months, and is provided within a continuum of care involving the radiation oncologist, the referring physician, and even other physicians.

Response: We agree with the commenter and have clarified the definition to recognize that radiation therapy may extend over a prolonged period of time and still be considered to be pursuant to a consultation, provided the radiation oncologist regularly communicates with the referring physician as to the patient's care.

Comment: Commenters stated that when a referring physician sends a patient to a radiation oncologist for radiation therapy, the referring physician may not see the patient for some time. The radiation oncologist may decide during this time that the patient needs services other than radiation therapy services. The commenter asked whether the radiation oncologist's referrals for nonradiation therapy services falls within the scope of the consultation exception.

Response: Under section 1877(h)(5)(C) of the Act, for radiation oncology, only a request for radiation therapy by a radiation oncologist is not considered to be a referral. We understand that in some situations when a patient is undergoing radiation therapy, the patient's care is not supervised by a physician other than the radiation

oncologist. However, the radiation oncologist cannot send the patient for DHS other than radiation therapy services to an entity with which the radiation oncologist has a financial relationship without meeting an appropriate exception.

Comment: Section 1877(h)(5)(C) of the Act excepts DHS provided by consulting pathologists, diagnostic radiologists, and radiation oncologists if the services are furnished by, or under the supervision of, the consulting physician. A commenter inquired whether the required supervision could be delegated to a member of the consulting physician's group practice.

Response: The plain language of section 1877(h)(5)(C) of the Act does not allow for supervision by anyone other than the consulting physician. However, we are broadly interpreting the supervision requirement in this section to be consistent with the supervision requirements elsewhere in these regulations. Thus, the level of supervision required is whatever level is required under the applicable Medicare payment and coverage requirements. Furthermore, the in-office ancillary services exception may be available for services supervised by a physician in the consulting physician's group practice.

Comment: A commenter stated that neither diagnostic radiologists nor pathologists perform physical examinations on patients. An association representing certain specialists stated that the definition of a consultation should be modified so as *not to require* a patient history and physical examination except when appropriate; for example, diagnostic radiologists and nuclear medicine physicians generally do not take a patient's history or perform a medical examination. However, a nuclear medicine physician would perform a history and physical examination when a patient is referred for therapy. In addition, an association representing clinical laboratories declared that it is unlikely that a pathologist would ever see a patient or take a history from a patient. An association representing radiologists asserted that diagnostic radiologists generally do not take a patient's history or conduct a medical examination; therefore, we should clarify that a history and examination of the patient is not required as part of a radiologic consultation.

Response: For purposes of section 1877 of the Act, we agree that a consultation does not necessarily include either taking the history of a patient or performing a physical examination. Certainly, pathologists would rarely see a patient. We do expect that, on occasion, a consulting physician, such as a radiologist, might interview a patient to gain additional information about the patient's condition, but this might not amount to a full scale history. Similarly, the radiologist might examine a patient, but focus only on a particular area of concern. We are amending our description of a ''consultation'' to clarify that there is no requirement that these steps be performed.

Comment: A commenter asked whether the prohibition under section 1877 of the Act is triggered when a physician, who has no financial relationship with a diagnostic imaging center, initiates a referral to the imaging center rather than to a particular radiologist.

Response: We understand the commenter to be asking whether the consultation exception set forth in section 1877(h)(5)(C) of the Act applies if the request for the consultation is made to the entity that employs or contracts with a consulting radiologist rather than to the consulting radiologist. The commenter's main concern seemed to be whether a subsequent request by the employed or contractor radiologist for diagnostic radiology services furnished by the imaging center would be protected under section 1877(h)(5)(C) of the Act. We believe that under section 1877(h)(5)(C) of the Act, the request for a consultation can be made to either a particular radiologist or an entity. Also, if the referring physician does not have a financial relationship with the diagnostic imaging center, the referral to the center is not prohibited under the general prohibition in section 1877(a) of the Act.

IV. Physician Compensation Under Section 1877 of the Act: An Overview

Many public comments addressed physician compensation issues. The statute touches on physician compensation in several places: the definition of group practice, the employee exception, and the personal services exception. The interplay of section 1877 of the Act and physician compensation is one of the most significant aspects of the self-referral law.

Obviously, the issue of physician compensation is of critical importance to the physician community. As a starting point, we do not believe that the Congress intended section 1877 of the Act to regulate physician compensation practices, except as necessary to minimize financial incentives to refer DHS to entities with which the physicians have financial relationships. Having carefully studied the public comments and having reconsidered the statutory provisions, the legislative history, and our January 1998 regulatory proposals, we believe the following general principles govern the application of the statute to the manner in which physicians are paid:

- First, as explained in section III.B of this preamble, for purposes of section 1877 of the Act, the term ''referral'' does not include DHS that are personally performed by the physician. As a practical matter, the statutory language and structure indicate Congressional recognition that physicians are commonly compensated based on productivity with respect to services they personally perform.
- Second, with respect to group practices, the Congress intended to confer group practice status on *bona fide* group practices and not on loose confederations of physicians who come together as a ''group'' substantially in order to capture the profits of DHS under the in-office ancillary services exception to section 1877 of the Act. To that end, we proposed adding a ''unified business'' standard to the group practice definition, using the statutory authority the Congress conferred on the Secretary to impose additional standards on group practices. However, in response to comments, we have reconsidered the test for a ''unified business''; the final regulations under Phase I of this rulemaking adopt a considerably more flexible approach to the same end. Under Phase I of this rulemaking, one of several characteristics of a ''unified business'' is that the group's physician compensation methodologies are established by the centralized management of the group practice. For the limited purposes of establishing that a group practice is a unified business, we think it is appropriate to look at physician compensation derived from all sources, not just from DHS. However, location- and specialty-based compensation practices are expressly permitted with respect to the distribution of revenues derived from services that are not DHS. Such practices may also be allowed for DHS, depending on the circumstances. (See the discussion of the group practice definition in section VI.C of this preamble.)
- Third, except for the limited purpose of determining whether a group practice is a unified business, the physician compensation provisions for group practices under section 1877 of the Act only affect the distribution of revenues derived from DHS. In general, these revenues are likely to comprise a relatively small portion of the total

revenues of most group practices. As we indicated in 1998, section 1877 of the Act does not affect the distribution of monies earned from other services. From a practical business standpoint, however, some group practices may find it impractical to segregate DHS revenues. These parties may find it more expedient to allocate compensation in accordance with the methods permitted for DHS revenues under section 1877 of the Act.

- Fourth, the statute implicitly recognizes that solo practitioners will keep all the profits from DHS that fit in the in-office ancillary services exception, whether performed personally or by others.
- Fifth, section 1877 of the Act contemplates that physicians—whether group practice members, independent contractors, or employees—can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS. In other words, ''productivity,'' as used in the statute, refers to the quantity and intensity of a physician's own work, but does not include the physician's fruitfulness in generating DHS performed by others (that is, the fruits of passive activity). ''Incident to'' services are not included in productivity bonuses under the statute unless the services are incident to services personally performed by a referring physician who is in a *bona fide* group practice. (''Incident to'' services must meet the requirements of section 1861(s)(2)(A) of the Act and section 2050, ''Services and Supplies,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process.) In the case of independent contractors under the personal service arrangements exception and employees under the *bona fide* employment exception, the amount of compensation for personal productivity is limited to fair market value for the services they personally perform. The fair market value standard in these exceptions acts as an additional check against inappropriate financial incentives. (The personal service arrangements exception, as well as several other exceptions, contains additional restrictions on compensation that varies based on the volume or value of referrals. The volume or value standard is discussed in section V of this preamble.)
- Sixth, the Congress recognized that in the case of group practices, revenues derived from DHS must be distributed to the group practice members in some fashion, even though the members generate the DHS revenue. However, the Congress wished to minimize the economic incentives to generate unnecessary referrals of DHS. Accordingly, the Congress permitted group practice members (and independent contractors who qualify as ''physicians in the group practice'') to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of referrals generated by the member or ''physician in the group practice'' for DHS performed by someone else. In addition, the Congress permitted groups to pay their physicians productivity bonuses based directly on personal productivity (including services incident to personally performed services), but precluded groups from paying group practice physicians any productivity bonus based *directly* on referrals of DHS performed by someone else. As detailed below, we are establishing under Phase I of this rulemaking certain methodologies that describe compensation practices that will be deemed to be *indirectly* related to the volume or value of DHS referrals for purposes of section 1877(h)(4)(B)(i) of the Act and therefore allowable under section 1877 of the Act. Groups are free to develop their own indirect methodologies, but such methodologies are subject to case-by-case review.

V. ''Volume or Value'' of Referrals and ''Other Business Generated'' Standards: An Overview

Many of the exceptions in section 1877 of the Act covering specific kinds of compensation arrangements include as one element of the exception a requirement that the compensation not take into account the volume or value of any referrals and, in some of the exceptions, the further requirement that the compensation not take into account other business generated between the parties.

In the preamble to the January 1998 proposed regulation, we had interpreted this volume or value standard as follows:

- Compensation could be based on units of service (for example, ''per use'' equipment rentals) so long as the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per procedure basis, except for lithotripsies for patients referred by the physician-owner; payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals.
- The language ''or other business generated between the parties'' meant that the payment in an arrangement had to be fair market value for the services expressly covered by the arrangement and could not include any payment for services not covered by the arrangement.
- Physician compensation arrangements that were fixed in amount but conditioned either expressly or implicitly on the physicians referring patients to a particular provider or supplier took into account the value or volume of referrals within the meaning of the statute.

After reviewing the comments received, we are substantially revising the regulation with respect to the scope of the volume or value standard. Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. In the case of those exceptions that include the additional restriction that the payment not take into account ''other business generated between the parties,'' the per unit payment also may not take into account any other business, including non-Federal health care business, generated by the referring physician. We are interpreting the phrase ''generated between the parties'' to mean business generated by the referring physician for purposes of section 1877 of the Act.

Applying Phase I of this rulemaking to the lithotripter example noted above, the ''per use'' rental payments would be protected, even for lithotripsies performed on patients referred by the physician-owner, provided that the ''per use'' rental payment was at fair market value, did not vary over the lease term, and met the other requirements of the rental exception. In other words, if the ''per use'' payment is fair market value, we will not require a separate payment arrangement for use of the equipment on patients referred by the physician-owner. In determining whether the initial ''per use'' payment is at ''fair market value,'' we will generally look to the price a hospital would pay to rent the equipment from a company that did not have any physician ownership or investment (and thus was not in a position to generate referrals or other business—*DHS or otherwise*—for the hospital) in an arm's-length transaction. In some cases, all the available

comparables or market values may involve transactions between entities that are in a position to refer or generate other business. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors. (The definition of fair market value is discussed in more detail in section VII.B of this preamble.)

In the light of our interpretation of the volume or value standard as permitting unit of service or unit of time-based payments, we have determined that the additional limiting phrase ''not taking into account * * * other business generated between the parties'' means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid DHS or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

In order to establish a ''bright line'' rule, we are applying this interpretation of the volume or value standard uniformly to all provisions under section 1877 of the Act and part 411 where the language appears (for example, the employee, personal service arrangements, rental of office space/equipment, fair market value, non-monetary compensation under $300, hospital medical staff benefits, academic medical center exceptions, indirect compensation arrangements, and the group practice definition). The ''other business generated'' restriction applies only to those exceptions in which it expressly appears.

Consistent with this interpretation, we have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the anticipated or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires referrals to certain providers will not vitiate the exception. Any such contract, however, must expressly provide exceptions (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is not in the best medical interest of the patient in the physician's judgment. We caution that these mandatory arrangements could still implicate the anti-kickback statute, depending on the facts and circumstances.

Finally, we want to clarify that ownership or investment interests that are not protected under sections 1877(b) through (d) of the Act (and are therefore compensation arrangements under section 1877(h)(1)(A) of the Act) are deemed to take into account the value or volume of referrals. We believe this view is consistent with the general prohibition on investment and ownership interests in the statute.

Our responses to comments follow below:

Comment: One commenter asked us to clarify the statement in the preamble of the January 1998 proposed rule at 63 FR 1780 that the volume or value standard that is in the compensation and other exceptions is uniformly meant to cover (and thus exclude from an exception) other business generated between the parties. Another commenter asked us to clarify that the requirement that the compensation not take into account the volume or value of referrals or other business generated between the parties refers only to referrals of DHS.

Response: The discussion of the phrase ''other business generated between the parties'' in the preamble to the January 1998 proposed rule caused confusion. Based on our review of the legislative history, we believe that the Congress intended the language to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of DHS business. Simply stated, in the provisions in which the phrase appears, affected payments cannot be based or adjusted in any way on referrals of DHS or on any other business referred by the physician, including other Federal and private pay business.

Comment: One commenter urged us to amend the language of the regulation to correspond to the extensive discussion of the volume or value standard in the preamble.

Response: We are modifying the regulation to clarify the meaning of the volume or value standard.

Comment: One commenter asked us to clarify that a valuation of a physician's practice could include the value of self-generated DHS in the purchase price as long as the purchase agreement was not contingent on future referrals.

Response: For purposes of section 1877 of the Act, the valuation of a physician practice could include the value of DHS in the purchase price if the DHS provided by the selling physician fit into an exception, such as the in-office ancillary services exception, and the purchase agreement (and purchase price) is not contingent on future referrals. Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the anti-kickback statute.

Comment: Several commenters asked us to clarify that the language requiring that the payment be fixed in advance and not be determined in a manner that takes into account the value or volume of referrals or other business generated between the parties does not require that the aggregate compensation be established in advance, but only that the methodology (for example, a rental per use, or payment per service) be fixed in advance.

Response: We are modifying the regulation to make it clear that the aggregate payment need not be specified in advance. However, if the aggregate amount is not specified, the amount of the payment on a ''per use,'' ''per service,'' or ''per time period'' basis must be fixed in advance. For example, a contract could include a fee schedule for services, provided the fee schedule is uniformly applied to all services provided to the contracting party. In addition, the payment must be fair market value compensation not taking into account the volume or value of referrals or other business generated by the referring physician either at inception or during the term of the agreement.

Comment: Commenters also wished us to clarify whether the following arrangements take into account the volume or value of referrals or other business generated between the parties: (1) Payments based on a percentage of gross revenues; (2) payments based on a percentage of collections; (3) payments based on a percentage of expenses; and (4) payments based on a percentage of a fee schedule.

Response: A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the

arrangement in any manner that takes into account referrals or other business generated. The first three arrangements described by the commenters are neither aggregate fixed compensation amounts, nor fixed ''per service,'' ''per use,'' or ''per time period'' payment amounts. Percentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections, or expenses, is not fixed in advance. Accordingly, the first three arrangements do not meet the requirement that compensation be fixed in advance. Whether the fourth arrangement mentioned by the commenters—a percentage of a fee schedule—is fixed in advance compensation depends on the circumstances. If the percentage payments are based on a single fee schedule, such that there is, in effect, a single fixed fee for each service, the arrangement meets the requirement that the compensation be fixed in advance. However, a percentage of fee schedule arrangement that bases payments on multiple fee schedules, such that there may be different fees for a particular service depending on the ultimate payer, is not fixed in advance. Thus, for example, if a physician has a contract for services with a hospital that has a chargemaster for all services, the physician can be paid a fixed percentage of that chargemaster fee schedule for each service. However, when the hospital accepts different payment amounts from different payers for a service, the physician cannot be paid a percentage of those varying amounts.

Comment: Several commenters requested that the final rule make clear that payments based on ''per use'' or ''per service'' meet the volume or value standard in the exceptions so long as the payments are at fair market value and the ''per use'' or ''per service'' amount does not change over the term of the contract based on the value or volume of referrals of DHS. The commenters stated that their position was consistent with the intent of the Congress and supported their position with language from the Conference Committee report.

Response: As described above, we are modifying the regulation to reflect the Conference Committee report, H. Rep. No. 213, 103rd Cong., 1st Sess. 814 (1993). The ''per use,'' ''per service,'' or ''per time period'' amount must reflect fair market value at inception not taking into account the volume or value of referrals and must not change over the term of the contract based on the volume or value of DHS referrals, or, when applicable, other business (that is, other Federal or private pay business) generated by the referring physician.

Comment: One commenter specifically objected to our proposed interpretation that a ''per use'' payment was acceptable except when the payment was for a referral from a physician with an ownership or investment interest in the equipment. According to the commenter, the physician's ownership or investment interest should not matter so long as the physician does not have a controlling interest.

Response: We believe equipment rental arrangements are subject to abuse whether the payment received is only a small portion of the rental or the entire amount. Control is irrelevant; it is the financial incentive that has been shown repeatedly to result in overutilization. Despite the obvious potential for abuse, given the clearly expressed congressional intent in the legislative history, we are permitting ''per use'' payments even when the physician is generating the referrals. We wish to make clear that these arrangements may violate the anti-kickback statute.

Comment: A commenter asked that we clarify that a hospital can lease equipment on a ''per use'' basis to a physician for use in the physician's practice.

Response: A hospital can lease equipment to a physician for use in the physician's practice on a ''per use'' basis, provided the lease arrangement otherwise fits in the rental exception. As noted above, these arrangements may violate the anti-kickback statute.

Comment: Many commenters objected to our proposed interpretation in the preamble that fixed payments to a physician could be determined to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer DHS to a given entity, such as an employer or an affiliated entity. A number of commenters stated that we did not have statutory authority for our proposed interpretation. Some commenters said these arrangements were necessary to develop integrated networks and ensure quality control. Another commenter stated that the proposal would interfere with exclusive hospital-based physician relationships. One commenter argued that the proposed interpretation was inconsistent with the employee exception, while yet another stated the position was inconsistent with the common law duty of loyalty owed by an employee to his or her employer and the employer's right to set the terms and conditions of employment. Another commenter stated that the proposed interpretation would adversely impact managed care arrangements by, in effect, requiring all managed care arrangements to meet the physician incentive plan regulations. Finally, a commenter proposed that we allow entities to require physicians to refer to a particular provider as part of a contract, except (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is against the physician's judgment.

Response: While we believe that payments tied to referral requirements can be abused, we agree that the proposed interpretation potentially would have had far-reaching effects, especially for managed care arrangements and group practices. We are adopting in modified form the one commenter's suggestion for appropriate conditions listed in the last sentence of the comment. We believe the suggested conditions will not impose a significant burden, since they are likely to be required anyway under existing laws, professional codes, and most contracts. Thus, so long as the referral requirement does not apply if a patient expresses a different choice, the patient's insurer determines the provider, or the referral is not in the best medical interest of the patient in the physician's judgment *and* the payment to the physician is fixed in advance at fair market value for the services actually rendered and does not vary based on referrals or, when applicable, other business generated by the physician, the fact that referrals may be required to be made to specific providers will not nullify an exception.

Comment: One commenter stated that the final rule should not prohibit primary care case management arrangements.

Response: As discussed in the preceding comment, we are no longer viewing these arrangements as violating the volume or value standard simply because referrals may be required to be made to certain providers. The arrangement would have to meet the other provisions of an exception.

Comment: According to two commenters, many covenants not to compete could be called into question by the proposed interpretation that fixed payments tied to referral requirements can violate the volume or value standard, a component of many of the exceptions. The commenters argued that these covenants are necessary adjuncts to many business acquisitions and personal services or management arrangements and urged us to affirm their legitimacy.

Response: The commenters were unclear as to how the proposed

interpretation would have adversely impacted covenants not to compete. A requirement to refer to a specific provider is different from an agreement not to establish a competing business. In other words, a covenant not to compete might prevent a physician from setting up a private practice or offering services that compete with the entity that purchased his or her practice. If an agreement also included the requirement that the physician refer business to the purchaser, the agreement would be suspect under the anti-kickback statute.

Comment: One commenter asked us to clarify that the discussion in the preamble about the volume or value standard applies not only to its interpretation in the context of the compensation exceptions, but also to its interpretation in the other exceptions in which the same language appears.

Response: The meaning of the volume or value standard as set forth in the preamble and regulations text under Phase I of this rulemaking applies to the standard wherever it appears in the statute and regulations.

Comment: One commenter stated that the interpretation of the volume or value standard in the January 1998 proposed rule at 63 FR 1701 would permit hospitals to pressure physicians to refer to network and other providers that the hospitals own or control.

Response: It is not clear from the comment what aspect of the proposed rule would lead the commenter to believe that this kind of coercion would occur. Nonetheless, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that a particular arrangement is not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive; it simply means that a referral and submission of a claim for DHS is not prohibited under section 1877 of the Act.

VI. Exceptions Applicable to Ownership and Compensation Arrangements (Section 1877(b) of the Act)

A. Physician Services (Section 1877(b)(1) of the Act)

The Existing Law: Section 1877(b)(1) of the Act specifies that the general prohibition under section 1877 of the Act does not apply to services furnished on a referral basis, if the services are physician services, as defined in section 1861(q) of the Act, and are furnished (1) personally by another physician in the same group practice as the referring physician or (2) under the personal supervision of another physician in the same group practice as the referring physician. Section 1861(q) defines ''physicians' services'' as ''professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6) [certain intern and resident services]).'' A physician is defined in the Act as a duly licensed and authorized doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or chiropractor who meets certain qualifications specified in the Act. (See section 1861(r) of the Act.)

The August 1995 final rule incorporated this provision in § 411.355 (General exceptions to the referral prohibition related to both ownership/investment and compensation), paragraph (a) (Physician services), covering physician services as defined in § 410.20 (Physicians' services), paragraph (a) (Included services). The definition of a physician service in § 410.20(a) generally parallels the definition in section 1861(r) of the Act, with the addition of diagnosis and therapy services. Under the August 1995 final rule, physician services need not be performed in any specific location.

The Proposed Rule: The January 1998 proposed rule retained § 411.355(a) as set forth in the August 1995 final rule. In the preamble to the January 1998 proposed rule, we noted that the exception would apply to physician services that constitute DHS under section 1877 of the Act and regulations and that the exception in the Medicare context would not apply to services performed by nonphysicians, even though furnished under a physician's supervision, such as ancillary or ''incident to'' services. We interpreted ''personal supervision'' to mean that the group practice physician must be legally responsible for monitoring the results of any test or other designated health service and must be available to assist the individual who is furnishing the service, even though the group practice physician need not be present while the service is being furnished.

The Final Rule: In general, we believe that the physician services exception is of limited application. However, the physician services exception does afford protection for referrals of the narrow class of physician services that are included in the definitions of DHS, especially in the area of radiology. (See discussion in section VIII.A of this preamble.) The physician services exception enables physicians in group practices to make referrals for physician services that are DHS within their group practices. In addition, the in-office ancillary services exception may also apply, depending on the circumstances. We are interpreting the physician services exception to apply to referrals to (or referral services supervised by) a member of the group practice or an independent contractor who qualifies as a ''physician in the group'' as defined in § 411.351 (Definitions).

In particular, we are incorporating the physician services exception in § 411.355(a) as proposed in our January 1998 proposed rule, with the following modifications:

First, we are interpreting ''personal supervision'' to correspond with our revised interpretation of ''direct supervision'' in the context of the in-office ancillary services exception. (See discussion in section VI.B.2 of this preamble.) We can discern no compelling reason to have separate and potentially inconsistent supervision standards in the exceptions under section 1877 of the Act. Accordingly, the level of supervision required under the physician services exception is the level of supervision required under the payment and coverage rules applicable to the particular physician service at issue.

Second, as noted above, we are expressly interpreting the exception to apply to referrals to (or physician's services supervised by) a member of the group practice or an independent contractor who qualifies as a ''physician in the group'' as defined in § 411.351.

Finally, as many have pointed out, the physician services exception (unlike the in-office ancillary services exception) does not cover referred services that are performed by the referring physician. We believe this narrower scope of the physician services exception is evidence that personally performed physician services fall outside the scope of section 1877 of the Act. For this and other reasons expressed elsewhere in this preamble, in § 411.351 of Phase I of this rulemaking, we are defining a ''referral'' for purposes of section 1877 of the Act to exclude referrals for work personally performed by the referring physician, and we have made clear that a referring physician is not himself or herself an entity to which he or she makes referrals.

Comment: A commenter asked that the regulations include a clear provision for providing compensation for professional reading fees within an outpatient group practice for diagnostic procedures such as EKG, pulmonary function testing, EEG, etc.

Response: To the extent that the professional reading fees mentioned by

the commenter are DHS (see § 411.351), the rules set forth in these regulations apply. (We note, however, that pulmonary function testing and EKGs and ECGs typically will not be DHS unless furnished in a hospital setting.) First, if the professional reading is performed personally by the referring physician, no referral occurs for purposes of section 1877 of the Act (though there may still be a referral of the technical component). Second, if the professional reading is performed by a physician other than the referring physician, the physician services and in-office ancillary services exceptions are available. In the case of a group practice, physician compensation will be governed by the rules in § 411.352 (Group practice). Subject to those rules, the physician performing the professional reading may be paid directly based on his or her personal performance of professional services.

Comment: A commenter expressed the view that all physician services are excluded from the scope of section 1877 of the Act. The commenter asserted that no evidence exists that the Congress intended to include in section 1877 of the Act physician services within the meaning of section 1861(s)(1) of the Act. The commenter, therefore, concluded that including professional components of services is beyond the scope of section 1877 and our regulatory authority.

Response: We disagree. A number of the DHS enumerated by the Congress in section 1877(h)(6) of the Act include substantial physician services components, and the Congress provided no exclusion or carve out. Indeed, we believe the physician services exception itself clearly evidences the Congress's recognition that the DHS categories set forth in section 1877(h)(6) of the Act include some physician services. At the very least, the Congress anticipated that there might be situations in which it would be difficult to demarcate clearly professional and technical components of the DHS. For those situations, the Congress provided an exception that makes clear that group practice physicians may refer physician services within their group practices when the conditions of the exception are satisfied.

Comment: A commenter inquired whether the physician services exception applies to services performed by a nonphysician. In the commenter's view, if the exception does not apply to these services, the exception would conflict directly with our other rules on the practice parameters applicable to nonphysician practitioners.

Response: We are cognizant of the expanding and evolving role of nonphysician practitioners in the health care delivery system for Medicare beneficiaries. Notwithstanding, we are not persuaded that an expansion of the physicians' services exception is appropriate or, in the light of other interpretations set forth in these regulations, necessary to accommodate the commenter's concerns.

Section 1877(b)(1) expressly applies only to physicians' services as defined in section 1861(q) of the Act. Section 1861(q) of the Act provides that physician services are ''professional services performed by physicians.'' The Act provides for Medicare coverage for certain services that would be physicians' services if furnished by a physician when such services are performed by a physician assistant (under the supervision of a physician) or a nurse practitioner or clinical nurse specialist (working in collaboration with a physician) (see sections 1861(s)(K)(i) and (s)(K)(ii) of the Act.) However, while such services may be identical to physicians' services, they are not physicians' services under section 1861(q) of the Act. Congress has provided for separate treatment of such services under the payment rules. To define nonphysician services as physician services for purposes of section 1877(b)(1) of the Act would distort Medicare's overall payment and coverage scheme.

We are also concerned that expanding the physicians' services exception, which has no building or billing requirements, to include nonphysician practitioners' services would permit group practices to circumvent the requirements of the in-office ancillary services exception.

However, while we are not including nonphysician services under section 1877(b)(1) of the Act, we have made other changes in the regulations that address the commenter's concerns. Specifically, we have interpreted the direct supervision requirement of the in-office ancillary services exception as requiring the level of supervision mandated under the relevant Medicare payment and coverage rules. See section VII.B.2 of this preamble. In other words, in the case of nonphysician practitioners, the supervision requirement of the in-office ancillary services exception corresponds to the supervision requirements applicable to such practitioners. Thus, the in-office ancillary services exception will cover most referral DHS provided by nonphysician practitioners in a group practice setting (provided the exception's building and billing requirements are also satisfied), without imposing additional supervision requirements on such practitioners.

Moreover, referrals made by nonphysician practitioners generally do not implicate section 1877 of the Act, which focuses exclusively on referrals by physicians. However, if a referral made by a physician assistant or nurse practitioner (or other nonphysician) is directed or controlled by a physician, we are treating the referral as an indirect referral made by the directing or controlling physician, who is, in fact, the ''referring physician.'' This interpretation is necessary to prevent the use of nonphysician practitioners to circumvent section 1877 of the Act.

We believe these interpretations adequately address the commenter's concerns and are consistent with the statutory language and structure. However, we invite public comments as to the need for a further exception for referred DHS performed by nonphysician practitioners in a group practice setting.

Comment: A commenter sought clarification as to the treatment of ''incident to'' services under the physicians' services exception. The commenter believed that unless ''incident to'' services are included in the exception, the exception would conflict with other payment and coverage rules.

Response: We are interpreting the physicians' services exception to apply only to ''incident to'' services (as defined in § 411.351) that are physician services under section 1861(q). All other ''incident to'' services would need to qualify under the in-office ancillary services or another exception.

Comment: A commenter suggested that the term ''physician'' should be defined in the regulations.

Response: The Act defines ''physician'' in section 1861(r). We agree that it would be helpful to incorporate this definition into these regulations and are doing so.

B. In-office Ancillary Services (Section 1877(b)(2) of the Act)

The Existing Law: We have divided our discussion of the in-office ancillary services exception into four subsections that correspond with the statutory structure: DHS included in the in-office ancillary services exception, supervision, building requirements, and billing requirements. The relevant provisions of the existing law are described in each subsection below.

The Proposed Rule: The relevant provisions of the proposed rule are described in each subsection below.

The Final Rule: Many commenters were highly critical of the January 1998

proposed rule's interpretation of the exception for in-office ancillary services, contending that the rule was arbitrary, inconsistent with our existing policies, and inefficient. We have revisited the premises of the January 1998 proposed rule, reexamined the statutory language and legislative history, and restructured the exception. The in-office ancillary services exception in Phase I of this rulemaking is consistent with the language of section 1877 of the Act and the organization and operation of many modern physicians' offices. While in most respects the exception is broader and administratively simpler than the proposed exception, we have substantially limited the ability of group practices to use part-time arrangements to provide DHS in buildings or facilities in which they do not routinely provide a wide range of services other than Federal or private pay DHS.

In revising the exception, we were cognizant of several key considerations. First, the Congress clearly was concerned with regulating physicians' ordering of DHS, even in the context of their own practices; otherwise, a detailed exception would not have been necessary. Second, the Congress intended to protect some in-office ancillary services provided they were truly ancillary to the medical services being provided by the physician or group; otherwise, the Congress would not have created the exception. Finally, we believe the boundaries of the exception as intended by the Congress are best expressed in the building requirement in section 1877(b)(2)(A)(ii) of the Act, which permits DHS to be provided in the same building where the physicians provide their regular medical services, or, in the case of a group practice, in a central DHS building.

Based on those considerations, we have revised the in-office ancillary services exception to permit the provision of DHS in the same building in which a group or a physician routinely provides the full range of the group's or physician's medical services with a minimum of restrictions. In general, the final exception will protect shared DHS facilities, so long as the physicians or groups that share the facility also routinely provide their full range of services in the same building. Moreover, in certain circumstances, part-time practitioners would be permitted to share the DHS facility, as long as they are also providing medical services they routinely provide that are not DHS (whether Federal or private pay). Coupled with a relaxation of the proposed supervision requirement described below, we believe the final exception captures what the Congress intended to protect.

What will not be protected by Phase I of this rulemaking are a number of part-time, intermittent arrangements that functionally are nothing more than shared off-site facilities. Many of these part-time, off-site ancillary services arrangements are inconvenient for patients both as to location and time, and are created by physicians principally to capture revenue rather than to enhance patient care. To preclude such arrangements, and as a counter-balance to allowing certain shared facilities, we have interpreted the same building requirement as including a ''full range of services'' condition, and the centralized building requirement as requiring exclusivity. These interpretations are consistent with the statutory language and structure. To the extent the January 1998 proposed rule would have permitted these arrangements, it is no longer operative. To qualify under the ''centralized building'' standard, Phase I of this rulemaking will require, among other things, the group practice to own or lease and use the space exclusively on a full-time basis.

In addition to the changes to the ''building'' requirements, the exception for in-office ancillary services under Phase I of this rulemaking contains a number of other significant changes (all described in more detail in the relevant comments and responses sections that follow):

- Significantly expanding the scope of services potentially included in the in-office ancillary services exception by—(1) making clear that outpatient prescription drugs may be ''furnished'' in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of durable medical equipment (DME) furnished in a physician's office for the convenience of the physician's patients.
- Substantially modifying the ''direct supervision'' requirement to conform it to relevant Medicare and Medicaid payment and coverage rules for the specific service, in keeping with our premise that the Congress did not intend to revamp radically the provision of ancillary services in physicians' offices.
- Allowing independent contractors to provide the requisite supervision, provided they are ''physicians in the group practice,'' meaning that they have contracted with the group practice to treat group practice patients on group premises and have reassigned their claims to the group under § 424.80 of these regulations (as further explained in section 3060, ''Reassignment,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process).

Additional revisions and modifications to the rule are addressed in the discussion below. The discussion is divided into four subparts: the scope of DHS, supervision, building requirements, and billing requirements. The discussion of each subpart contains summaries of public comments and our responses to them.

1. Scope of Designated Health Services That Can Be In-Office Ancillary Services

The Existing Law: As a threshold matter, the DHS that are potentially protected by the in-office ancillary services exception are any of the DHS enumerated in section 1877(h)(6) of the Act, *except* DHS specifically excluded from the exception under section 1877(b)(2) of the Act. Excluded are all parenteral and enteral nutrients, equipment, and supplies (PEN) and DME (except for infusion pumps, which remain eligible for the exception). Referrals—in-office or otherwise—for services that are not DHS need not fit in the exception, since they do not implicate the statute. The scope of services that are considered to be DHS is discussed in section VIII.A of this preamble.

The Proposed Rule: We proposed that DHS would be considered furnished in the location where the service was actually performed or where a patient receives and begins using an item. We also proposed expanding the category of DHS included in the in-office ancillary services exception to include crutches, provided the physician does not mark up the cost of the crutches.

The Final Rule: First, we are revising the rule to provide that services will be considered ''furnished'' for purposes of the exception (1) in the location where the service is actually performed upon a patient or (2) when an item is dispensed to a patient in a manner that is sufficient to meet Medicare billing and coverage rules. This change will make application of the rule clearer in the case of outpatient prescription drugs and ambulatory infusion pumps that are DME. Second, in the interests of patient convenience, we are using our

regulatory authority under section 1877(b)(4) of the Act to expand the exception to include certain DME, including crutches, canes, walkers, and folding manual wheelchairs, that meet conditions set forth in the regulations. (Braces and collars are orthotics and, thus, may already qualify under the statute for the in-office ancillary services exception.) These conditions generally will require that—(1) the items are DME, such as canes, crutches, walkers, and folding wheelchairs, that a patient uses to ambulate in order to leave the physician's office; (2) the items are furnished in a building that meets the ''same building'' requirements of section 1877(b)(2) of the Act and § 411.355(b)(2)(i) as part of the treatment for the specific condition for which the physician-patient encounter occurred; (3) the items must be furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice; (4) the physician who furnishes the DME must meet all DME supplier standards; (5) the arrangement does not violate the anti-kickback statute; (6) the billing and claims submission for the DME complies with all applicable laws and regulations; and (7) all other requirements of the in-office ancillary services exception are satisfied. We are similarly excepting blood glucose monitors.

We are withdrawing our proposal that physicians not mark up these items when provided in-office to their patients; we believe the current DME Regional Carrier (DMERC) reimbursement provisions provide sufficient cost containment controls. We believe these limited modifications to the DME exclusion will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, with respect to infusion pumps (other than pumps that are PEN equipment or supplies), we are including, under Phase I of this rulemaking, the furnishing of external ambulatory infusion pumps as in-office ancillary services covered by the exception (which uses the generic term ''infusion pumps''), provided all other conditions of the exception are satisfied. Because they are specifically included in the statutory exception, external ambulatory infusion pumps need not meet the added requirements for DME outlined in the preceding paragraph.

Comment: A hospital-based pathologist in a hospital with a full-service laboratory urged that the in-office ancillary services exception should not protect laboratories based in physicians' offices. The pathologist asserted that these laboratories are merely enterprises that enable physicians to profit from referrals for laboratory tests and create unfair competition for pathology laboratories that are not owned by physicians. The pathologist expressed skepticism about the justification proffered by many physicians that in-office laboratories exist for the convenience of patients, noting that, in his case, his hospital laboratory is located directly across the street from the offices of physicians with in-office laboratories.

Response: Despite the fact that physician-owned or controlled laboratories and other DHS facilities may competitively disadvantage entities that do not have physician ownership or control, the Congress made a policy determination not to apply the prohibition under section 1877 of the Act to DHS referrals that occur within the parameters of a physician's or group practices' own medical practice, provided these referrals fit squarely in an exception under section 1877 of the Act.

Comment: The in-office ancillary services exception applies to DHS that are ''furnished'' in accordance with certain statutory conditions. A number of commenters objected to our interpretation that the term ''furnished'' excluded items provided to a patient (or delivered to a patient's home) that are meant to be used at home rather than in the physician's office. The commenters observed that such a rule does not make sense in the case of outpatient prescription drugs, which are commonly dispensed to patients for later consumption at home.

Response: In general, we believe the Congress intended to exclude from the reach of the statute only items and services provided (or used, as the case may be) in the physician's office. However, we believe that our definition of those circumstances can be simplified to accommodate the provision of outpatient prescription drugs, as well as ambulatory infusion pumps that are DME. Accordingly, we are revising the rule to provide that services will be considered ''furnished,'' for purposes of the exception, in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the Medicare billing and coverage rules.

Comment: One commenter suggested that we should make clear that so long as the in-office ancillary services exception is met, discounts on drugs do not need to be passed on to Medicare.

Response: Nothing in section 1877 of the Act or these regulations is intended to require physicians to pass discounts on to the Medicare program. Whether a discount must be passed on to the program by physicians or others remains the subject of other statutory and regulatory provisions.

Comment: Commenters requested clarification that the furnishing of chemotherapy drugs can meet the in-office ancillary services exception. Commenters also sought clarification with respect to chemotherapy-related laboratory tests, x-rays, and prescription drugs that are secondary to the provision of chemotherapy.

Response: Chemotherapy infusion drugs and ancillary laboratory tests, x-rays, and prescription drugs are DHS for purposes of section 1877 of the Act that may be provided by physicians as in-office ancillary services if all of the conditions of the exception are satisfied. In light of the changes we are making in Phase I of this rulemaking—including revisions to the definition of ''furnish'' and to the supervision requirement in § 411.355(b)(5)—we believe the exception is sufficiently broad to accommodate virtually all existing arrangements for the provision of chemotherapy drugs and related services to patients in physicians' offices. Under Phase I of this rulemaking, referrals for chemotherapy infusion drugs may be protected by the in-office ancillary services exception if they are administered or dispensed to patients in the referring physician's office (or through the referring physician's group practice) in accordance with the supervision requirements already imposed by the Medicare program. We anticipate no appreciable disruption of chemotherapy services to Medicare or other patients as a result of Phase I of this rulemaking.

Comment: A commenter sought clarification whether the furnishing of allergen treatment sets would be protected under the in-office ancillary services exception.

Response: The provision of allergen treatment sets is protected by the in-office ancillary services exception so long as all of the conditions of the exception are satisfied. We believe that the changes in Phase I of this rulemaking to the definition of ''furnish'' in § 411.355(b)(5) and the supervision requirements make clear that allergen treatment sets may be furnished to patients under the in-office ancillary services exception.

Comment: A number of commenters questioned the scope of our proposed extension of the in-office ancillary services exception to include the

furnishing of crutches (DME being otherwise excluded by statute). The proposed extension would permit physicians to provide crutches if they make no profit on them and otherwise meet certain criteria. We proposed that the physician could bill only for the cost of acquiring and supplying the crutches. Commenters were confused as to how these costs would be determined and found the proposal to be unnecessarily restrictive. In addition, commenters wondered why crutches were included, but not canes, walkers, collars, splints, and the like. Other commenters variously sought inclusion of other DME, including DME for rheumatological conditions, orthopedic DME, and blood glucose monitors. Commenters suggested various measures for determining when DME should be permitted as an in-office ancillary service. One commenter proposed that whatever test we adopt should take into account the following: (1) the intended use of the item (that is, whether the item is an integral element in the customary continuum of patient care); (2) the cost of the item (that is, fair market value or a dollar cap); (3) the life-expectancy of the item (that is, whether items are limited to one-time prescriptions for 5 or 6 weeks); and (4) physician instruction (that is, whether some physician instruction in the use of the item is required). Other commenters proposed dollar caps as a means of excluding from the exception physician-directed sales of expensive wheelchairs, beds, and other pieces of equipment on which markups are significant.

Response: In the interest of patient convenience, we are using our regulatory authority under section 1877(b)(4) of the Act to expand the in-office ancillary services exception to include certain DME, including crutches, canes, walkers, and folding wheelchairs, that meet conditions set forth in the regulation (in our January 1998 proposed rule, we proposed a more limited exception for crutches only). (Braces and collars are classified as orthotics and already potentially qualify under the statute for the in-office ancillary services exception; splints are covered under section 1861(s)(5) of the Act and are not included in any category of DHS.) In doing so, we are concerned primarily with enabling the patient to depart from the physician's office. The narrow scope of this expansion and the fact that the need for ambulation equipment is objectively verifiable mitigate the potential for overutilization.

For somewhat different reasons, we are also creating an exception to permit blood glucose monitors (and one starter set of testing strips and lancets, consisting of no more than 100 of each; this number is at least one month's supply) to be provided under the in-office ancillary services exception (under the authority granted in section 1877(b)(4) of the Act). In light of section 4105 of the BBA 1997, which added a Medicare benefit for diabetes self-management training services, we do not believe that the Congress intended the physician self-referral law to interfere with a physician's efforts to provide blood glucose monitors to patients. Therefore, the in-office ancillary services exception may be used by a physician or group practice to furnish a blood glucose monitor and a starter set of strips and lancets if the physician or group furnishes outpatient diabetes self-management training to patients for whom the blood glucose monitors are furnished.

While commenters sought the inclusion in this exception of various other items of DME, we decline to extend the in-office ancillary services exception further. To do so would, in essence, vitiate the congressional determination to exclude DME from the in-office ancillary services exception. We do not find—and we believe that the Congress did not find—that the in-office furnishing of other DME would pose no risk of fraud or abuse, as required under section 1877(b)(4) of the Act.

Having considered the various suggestions made by the commenters, we are adopting the following conditions for DME provided as an in-office ancillary service (these conditions being in addition to all other conditions of the exception):

- The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets).
- The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the physician-patient encounter occurred.
- The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.
- A physician or group practice that furnishes the DME meets all DME supplier standards located in paragraph (c) of § 424.57 (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).
- The arrangement does not violate the anti-kickback statute or any law or regulation governing billing and claims submission. (This condition is necessary to meet the ''no risk of fraud or abuse'' standard in 1877(b)(4) of the Act.)
- All other requirements of the in-office ancillary services exception are satisfied.

We agree with the commenters that our proposal with respect to not marking up costs was confusing and unnecessarily restrictive, and we are not adopting it. While we find the commenters' suggestions for dollar caps on DME items attractive, we have concluded that it is not feasible to devise dollar caps that would appropriately include low-value DME and exclude high-value DME in all cases (for example, a $150 limit might be high for some types of DME and low for others). Upon further reflection, we believe the current DMERC reimbursement provisions provide sufficient cost containment controls, with respect to these items of DME we are including in the exception. We believe the modifications to the DME exclusion that we are making will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, we note with respect to DME furnished in physicians' offices that these arrangements remain subject to our conditions of participation for DME suppliers and other applicable payment and coverage rules.

Comment: A commenter asked that the final rule address whether the use of consignment closets as a means of providing DME in a physician's office implicates section 1877 of the Act. For example, a surgeon enters into an arrangement for a DME supplier to rent space (for example, a closet) in the surgeon's office at fair market value under a lease that meets the rental exception. The technician who measures for braces or DME supplies is a shared employee of the surgeon's practice and the supplier, with the supplier paying for the time the technician spends measuring the braces and supplying DME. The billing is done by the supplier. The commenter asserted that in this example, there is no financial relationship because the surgeon does not bill Medicare.

Response: If the lease fits squarely in the rental exception and the arrangement for the personal services of the technician fits squarely in the personal service arrangements exception, the ''consignment closet'' arrangement described in the preceding comment may not create a prohibited financial relationship under section

1877 of the Act. We wish to clarify that this result does not depend on whether the physician bills Medicare. To the contrary, the essential prohibition under section 1877 of the Act is on physicians making referrals to entities with which they have prohibited financial relationships and on those entities billing Medicare. Nothing in this rule is intended to, or should be interpreted as, legitimizing consignment closet arrangements. These arrangements raise significant questions under other legal authorities, including the anti-kickback statute and our supplier standards. Physicians and suppliers who are considering ''consignment closet'' arrangements would be well-advised to read the OIG's Special Fraud Alert on the Rental of Physician Office Space by Persons or Entities to Which They Refer published in the **Federal Register** on February 24, 2000 (65 FR 9274).

Comment: One commenter expressed concern about the interaction of section 1877 of the Act and the proposed surety bond rule that would exempt physicians from the surety bond requirement if they provide DME incident to patient care. Specifically, the commenter asked whether we believe that physicians are allowed to disburse DME, orthotics, and prosthetics incident to patient care without violating the provisions of section 1877 of the Act and whether these provisions are applicable if a physician has a surety bond.

Response: Section 1877 requirements under the exception exist wholly apart from other requirements of law that may apply. In addition, the commenter is mistaken in asserting that we proposed to exempt physicians who furnish DME in their offices from the proposed surety bond requirements that would apply to all suppliers. We assume that the commenter is referring to our proposed rule concerning supplier standards that was published on January 20, 1998 (63 FR 2926). Such an exception is not included in the proposed rule.

Comment: Oncologists complained that the proposed regulations—which interpreted the in-office ancillary services exception as applying only to infusion pumps that are implanted in a physician's office—would prohibit them from furnishing external ambulatory infusion pumps to their patients, contravening clear congressional intent and causing substantial inconvenience to patients. External ambulatory infusion pumps are used to administer chemotherapy agents and pain medication to cancer patients. The pumps are typically filled in the oncologist's office, and the drug flow is ordinarily initiated before the patient leaves the office. The statutory in-office ancillary services exception excludes DME (which typically is used by patients in their homes), but includes ''infusion pumps.'' Thus, the commenters asserted that the plain language of the exception indicates clear congressional intent to authorize physicians to furnish a certain category of DME—infusion pumps—to patients, even though those pumps will be used at home.

Response: We agree. The statute uses the general term ''infusion pumps.'' We are revising the regulation in § 411.355(b) to make clear that the in-office ancillary services exception protects external ambulatory infusion pumps (other than pumps that are PEN equipment or supplies) that are filled or serviced in the physician's office, even though the patient uses them at home. However, the in-office ancillary services exception does not protect an infusion pump that is used to deliver PEN because that pump is not classified as DME, but is considered PEN. PEN is categorically excluded from the exception under section 1877(b)(2) of the Act. The statutory language addressing infusion pumps in the in-office ancillary services exception applies only to DME.

Comment: Two commenters requested clarification as to the application of the in-office ancillary services exception to home care physicians who primarily treat patients in their homes. These commenters asserted that home care physicians play an important role in the delivery of cost-effective, quality care to patients and provide services that, in some cases, preclude the need for more expensive hospitalizations. These commenters believe that section 1877 of the Act should not apply to home visits. In the alternative, these commenters requested clarification of the following issues:

- Are DHS performed in a patient's home concurrently with the performance of a physician service included in the in-office ancillary services exception (for example, a physician uses a hand-held portable laboratory during a physician visit in the home)? Can a technician accompanying the physician perform the DHS during the home visit?
- What is the application of section 1877 of the Act to group practices that own home health agencies that in turn provide DHS to group patients?
- Are referrals from medical directors of home health agencies protected by the employee or another exception?

Response: We find nothing in the statute that excludes referrals for DHS by home care physicians from the reach of the statute. To the contrary, the Congress expressly included home health services as a designated health service. That said, we generally agree with the commenters that the provision of DHS in a patient's home should be protected by the in-office ancillary services exception, provided that all of the conditions of the exception are satisfied. However, in many cases, services provided by home care physicians will not fit neatly into the in-office ancillary services exception. For example, under the ''same building'' requirements, we are requiring that physicians provide substantial physician services unrelated to DHS in the building and that the services provided there be the full range of the physicians' services. We believe that a home care physician meets these ''same building'' tests if his or her principal medical practice consists of treating patients in their private homes (for purposes of determining whether a physician is principally a home care physician, private homes do not include nursing, long term care, or other facilities), and the physician (or a staff member accompanying him or her) provides a designated health service in a private home contemporaneously with a physician service (provided by the referring physician) that is not a designated health service and the other exception requirements are met. (DHS provided in facilities, such as nursing homes, by home care or other physicians may qualify under the in-office ancillary services exception if all conditions of the exception are satisfied.) We have concluded that it may be appropriate to develop additional rules for home care physicians under the in-office ancillary services exception. We are expressly soliciting comments on this issue and will consider it further in Phase II of this rulemaking.

As to the commenter's second question, section 1877 of the Act applies to a group practice's ownership of a home health agency in the same manner it applies to the ownership by a group practice of any DHS entity. Referrals to the entity by the group practice or by members of the group must qualify under an ownership exception, such as the in-office ancillary services exception. In general, we do not believe that the furnishing of most home health services will meet the requirements of the in-office ancillary services exception. Unless a physician in the group personally conducts the home visit and provides a physician service unrelated to the furnishing of DHS, the ''same building'' requirements will not be satisfied (we see no plausible way for

home health services to qualify under the ''centralized building'' option under section 1877(b)(2)(A)(ii)(II) of the Act). In some cases, the ''rural provider'' exception may apply (that exception will be discussed in the Phase II rulemaking).

Finally, with respect to referrals from medical directors of home health agencies, these referrals may be protected by the employee exception or the personal service arrangements exception, depending on the facts and circumstances of the medical director's relationship with the home health agency. However, if the medical director is an owner of a group practice that owns the home health agency, an ownership exception would still need to apply.

Comment: A commenter sought clarification as to whether a referral to a physician spouse in another group practice, who subsequently orders a designated health service for the referred patient, could come within the in-office ancillary services exception. The commenter observed that there are many two-physician marriages in the health care industry and that many spouses engage in different specialities and practice in different group practices. The commenter argued that the referrals between physician spouses to each other's group practices should not constitute prohibited referrals, so long as either the referring physician or the physician spouse accepting the referral complies with an exception. In our January 1998 proposed rule, we took the position that a physician in one group practice will be prohibited from referring to his or her physician spouse in another group practice because the referring physician cannot meet the in-office ancillary services exception. The commenter found this interpretation overly restrictive and narrow. In the commenter's view, if the physician receiving the referral meets the in-office ancillary services exception, he or she should be able to accept the referral, because the accepting spouse and not the referring spouse is ordering the designated health service.

Response: On reconsideration, we generally agree with the commenter, with one important distinction. We believe that the referral to a spouse should be allowed, if the referral is for a physician service unrelated to the furnishing of a designated health service (that is, a designated health service is not the reason for the referral) and any subsequent DHS referrals by the spouse fit within the in-office ancillary services exception with respect to the spouse receiving the referral. We recognize that there may be some circumstances, particularly in underserved areas, where a spouse may be the *only* qualified provider of a particular DHS. We are considering whether a limited additional exception is warranted and will address the issue further in Phase II of this rulemaking. We invite comments on this issue.

2. Direct Supervision

The Existing Law: Section 1877(b)(2) of the Act provides an exception for in-office ancillary services. To qualify as in-office ancillary services, the services must, among other things, be furnished personally by a referring physician or another physician member in the same group practice, or be furnished by individuals who are ''directly supervised'' by the referring physician or another physician in the group practice. The August 1995 final rule covering referrals for clinical laboratory services defined ''direct supervision'' in § 411.351 as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

The Proposed Rule: The January 1998 proposed rule retained this definition, with several clarifications and changes. In the preamble to the January 1998 proposed regulation, we expressed our view that the Congress intended the in-office ancillary services exception to apply to services that are closely attached to the activities of the referring physician. Consistent with this interpretation, we used the definition of ''direct supervision'' that appears in section 2050, ''Services and Supplies,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process, which describes services that are incident to a physician's professional services under section 1861(s)(2)(A) of the Act. Under this rule, supervision must be provided by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and who is immediately available to provide assistance and direction. The definition in the proposed rule also clarified the meaning of the term ''present in the office suite'' to mean that the physician is actually physically present. However, we would still have considered the physician ''present'' during brief unexpected absences, as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision.

The Final Rule: Our interpretation of the ''direct supervision'' standard produced the largest number of public comments about the in-office ancillary services exception, virtually all suggesting that our proposal would be overly burdensome, result in enigmatic technical rules, and require wasteful and inefficient practices.

We have revisited the direct supervision requirement and are now interpreting ''directly supervised'' in the statute to mean that the supervision meets the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for the specific services at issue. Upon further review and consideration, we concluded that the Congress did not use the phrase ''directly supervised'' in any technical sense. Rather, the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly ''ancillary'' to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history for section 1877 of the Act indicating that the Congress did not intend to require physicians to be present at all times that ancillary services were being performed. (*See* Conference Report for OBRA 1993, H. Rep. No. 213, 103d Congress 810 (1993).) Instead, we believe a sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.)

In our January 1998 proposed rule with respect to the group practice definition, we proposed eliminating independent contractors as members of the group practice. This created the prospect that independent contractors would not be able to provide the supervision required under the in-office ancillary services exception. The statute provides that physicians ''in the group practice'' may supervise the furnishing of ancillary services to patients of a referring physician who is a member of the group practice. Under Phase I of this rulemaking, physicians ''in the group practice'' include owners of the group practice, employees of the group practice, and independent contractors who are ''in the group practice.'' Owners and employees may also be

members of the group; independent contractors may not. We will consider an independent contractor physician to be ''in the group practice'' if he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities and the independent contractor's arrangement with the group complies with the reassignment rules in § 424.80(b)(3) of these regulations and in section 3060.3, ''Payment to Health Care Delivery System,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process. Independent contractors who qualify as physicians ''in the group practice'' may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations, and may provide the supervision required under the in-office ancillary services exception.

Comment: Many commenters raised concerns about the level of supervision required under the in-office ancillary services exception. Many commenters objected to our proposed interpretation of the direct supervision requirement, which would have adopted the supervision requirement applicable to ''incident to'' services in section 2050, ''Services and Supplies,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process, including a ''present in the office suite'' requirement, with an exception for brief absences by the physician. These commenters variously found the ''presence'' requirement overly burdensome, impractical, confusing, and unclear. Commenters believe that a general requirement of a physician's physical presence for all ancillary services would create unnecessary inefficiencies in the delivery of health care services, drive up costs, and inconvenience patients. For example, some commenters noted that tests are often scheduled in the mornings when physicians are making rounds or attending hospital meetings, with the physicians interpreting the tests when they arrive later at the office. Some commenters observed that they could discern no obvious connection between direct supervision and curtailing fraud and abuse. Others noted that a strict direct supervision requirement does not guarantee that DHS are medically appropriate and are not simply being performed for financial gain.

Commenters suggested various alternative standards, including ''appropriate supervision,'' ''professional responsibility,'' ''general supervision,'' and ''employee status.'' The vast majority of commenters, however, urged that the in-office ancillary services exception ''direct supervision'' requirement be interpreted to comport with the applicable supervision requirements under our other payment and coverage rules. These commenters stressed that these rules adequately take into account quality concerns and the health and safety of patients and that there is no justification for imposing an additional layer of supervision requirements.

Response: Upon further review and consideration of the statute, the legislative history, and the public comments, we have concluded that the Congress did not use the phrase ''directly supervised'' in any technical sense in the statute. Rather, we believe the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly ''ancillary'' to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history indicating that the Congress did not intend in the context of section 1877 of the Act to require physicians to be present at all times that ancillary services were being performed (''The conferees intend that the requirement for direct supervision by a physician would be met if the lab is in the physician's office which is personally supervised by a lab director, or a physician, even if the physician is not always on site'' (H. Rep. No. 213, 103d Cong. 810 (1993)). We are persuaded that a more sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.) Thus, the in-office ancillary services exception supervision requirements will be satisfied if the level of supervision provided meets all applicable Medicare or Medicaid payment and coverage requirements.

Comment: One commenter viewed the strict ''direct supervision'' standard established in the August 1995 final rule as an important check on inappropriate referrals and objected to any liberalization of the requirement, arguing that it would allow the connection between a physician's activities and DHS to ''grow too thin.'' The commenter believes it is appropriate for us to impose higher standards of care to protect patients who are referred for DHS, because these services have been determined to present a particularly high risk of inappropriate referrals. The commenter further noted that as the health and safety rationale for supervision declines (supervision being less necessary for certain low-risk services), the risk of unnecessary referrals and overutilization increases. The commenter recommended that we retain the ''incident to'' direct supervision standard. In the alternative, the commenter proposed a ''sphere of service'' test under which a physician would be allowed to refer a patient for services only if that physician, and not another licensed practitioner, normally would perform the services. According to the commenter, this approach would eliminate physician incentives to establish ''backroom'' practices to provide services that could be provided more efficiently elsewhere.

Response: We share this commenter's concerns about inappropriate financial incentives driving the provision of DHS. We are concerned that heightened downward pressure on physician incomes will generate increased upward pressure to expand in-office ancillary services as a means of offsetting income losses. However, we believe the Congress clearly articulated a policy determination to allow in-office ancillary services that meet certain statutory criteria. While the stricter ''incident to'' supervision standard might serve to reduce the risk of overutilization somewhat, on balance, we believe that using section 1877 of the Act to superimpose a separate supervision requirement on existing regulatory structures governing appropriate levels of supervision would be overly burdensome, inefficient, and inconsistent with the overall design of the statute. We note, however, that physicians wishing to bill DHS ''incident to'' (and group practice physicians wishing to obtain productivity bonuses for services incident to their personally performed physician services) must comply with the ''incident to'' supervision requirements, including the ''present and available'' requirement and the employee requirement, as set forth in section 2050, ''Services and Supplies,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process.

Comment: One commenter asked whether technicians must be directly supervised if a group practice provides technician services to a hospital. If so, the commenter requested that we clarify whether the group practice must follow self-referral supervision standards or hospital supervision standards.

Response: If a hospital is billing for the services, as this commenter implied,

the in-office ancillary services exception does not apply (along with its supervision requirement). Any hospital standards would always apply, since any requirement for supervision under section 1877 of the Act is separate and distinct from other supervision requirements under the Medicare and Medicaid statute and regulations.

Comment: While many commenters approved of our proposal to exclude independent contractors as members of a group practice for purposes of complying with the definitional tests for a group practice (making it easier for many groups, especially smaller groups, to qualify as a group practice for purposes of section 1877 of the Act), many commenters also urged that independent contractors be included as members of a group practice for purposes of the direct supervision requirement of the in-office ancillary services exception. Many commenters expressed concern that our bar on direct supervision by independent contractors would undercut the ability of group practices to deliver necessary health care services in situations in which employment of the physician is not possible or desirable. To support their claim that the statute does not require that the direct supervision be provided by a ''member'' of the group, commenters observed that section 1877(b)(2)(A)(i) of the Act only requires supervision ''by the [referring] physician or by another physician *in the group*.'' One commenter noted that this language is consistent with section 3060.3, ''Payment to the Health Care Delivery System,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process, which treats independent contractors as ''in the group'' for reassignment purposes. Another commenter suggested that an independent contractor could properly be considered ''in the group'' if the physician provides services to the group practice's patients in the group practice's facility under a contract with the group, and the services are billed by the group.

Response: Having reviewed the comments and reconsidered the statutory language, we are persuaded that independent contractors may be physicians ''in the group'' for purposes of the in-office ancillary services exception. We are considering an independent contractor physician to be ''in the group practice'' if (1) he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities, (2) the contract contains compensation terms that are the same as those that apply to group members under section 1877(h)(4)(iv) of the Act or the contract fits in the personal services exception, and (3) the contract complies with the reassignment rules at § 424.80(b)(3) of these regulations and in section 3060.3, ''Payment to the Health Care Delivery System,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process, so that his or her services are billed by the group practice. We are codifying this new test in § 411.351 of the regulations. This latter requirement presents a technical problem under the plain language of the statute, which we address as follows. The billing requirements under section 1877(b)(2)(B) of the Act do not provide for billing by the group practice when a supervising physician is ''a physician in the group practice,'' rather than a member of the group. Given the statutory structure and language, particularly the language of the direct supervision requirement under section 1877(b)(2)(A)(i)of the Act, we are interpreting the billing requirements to extend to billing by the group practice when the supervising physician is ''in the group practice'' in order to effectuate the direct supervision requirement. Independent contractors who qualify as ''physicians in the group practice'' may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations. As discussed in section VI.C.3 of this preamble, independent contractors are not ''members'' of the group.

Comment: Several commenters sought clarification with respect to the application of the in-office ancillary services exception to referrals for DHS from an independent contractor to the group practice with which he or she contracts (for example, referrals from an independent contractor to the group's in-office laboratory).

Response: Independent contractor physicians will have compensation relationships with the group practices with which they contract. In order for an independent contractor to refer DHS to the group practice, an exception must apply. Possible exceptions, depending on the circumstances, include the in-office ancillary services exception for independent contractors who are ''physicians in the group'', the physicians'' services exception, the personal service arrangements exception, or the risk-sharing exception for services provided to certain managed care enrollees. We note that under the in-office ancillary services exception, the furnishing of DHS would have to take place in a ''same building'' location under section 1877(b)(2)(A)(ii)(I) of the Act, as the ''centralized building'' provision (section 1877(b)(2)(A)(ii)(II) of the Act) only applies to referring physicians who are group members.

Comment: Several practitioners of ultrasonography commented that a direct supervision requirement that mandates physician presence for in-office ancillaries unfairly benefits radiologists, who are generally available on-site because they do not have ''patients'' to see or other responsibilities, while disadvantaging vascular laboratories that operate without physicians on-site. The commenters suggested that the rule require that ultrasound examinations and interpretations be performed in accordance with standards set by independent professional associations. However, another commenter—radiologist—urged us to retain the direct supervision requirement in the interest of patient health and safety.

Response: As noted above, we are modifying the direct supervision requirement under the in-office ancillary services exception to apply the requisite supervision requirements under Medicare and Medicaid payment and coverage rules.

3. The Building Requirements

The Existing Law: Under section 1877(b)(2)(A)(ii) of the Act, in-office ancillary services must be furnished in a building in which the referring physician, or another physician who is a member of the same group practice, furnishes physician services unrelated to the furnishing of DHS. Alternatively, in the case of a referring physician who is a member of a group practice, the in-office ancillary services can be furnished in another building that is used by the group practice for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's DHS (other than clinical laboratory services). (The existing regulations address the same and other building requirements only with respect to clinical laboratory services.)

The Proposed Rule: In our January 1998 proposed rule, we proposed defining the ''same building'' in § 411.355(b)(2)(i) as the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.

The Final Rule: The building requirements are designed to ensure that the DHS qualifying for the exception are truly ''in-office'' (that is, part of the physician's routine medical office practice) and not provided as part of a separate business enterprise. The location requirements do not pertain to

the furnishing of DHS that are not payable by Medicare or Medicaid; these services may be furnished anywhere, subject to any restrictions in other applicable Federal, State, or local laws.

In general, the structure of the statutory language suggests that the Congress had two main objectives: permitting the provision of in-office ancillary services for the convenience of patients during their patient visits and, in the group practice context, permitting the provision of in-office ancillary services in a dedicated building used for these services (for example, a central clinical laboratory). By contrast, we believe the Congress did not intend to protect part-time rentals of ancillary services facilities under this exception.

Upon further consideration, we believe that the Congress did not intend the application of the in-office ancillary services exception to turn on the nuances of architectural design. Thus, for purposes of Phase I of this rulemaking, a ''building'' is defined as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. For purposes of this rule, the ''same building'' does not include exterior spaces, such as courtyards, lawns, driveways, or parking lots, or interior parking garages. The building could include a SNF or other facility or a patient's home, provided all other conditions of the exception are satisfied. A mobile van or trailer is not a building or a part of a building.

The statute implements congressional intent by offering two location options: the ''same building'' option, available to solo practitioners and group practices, and the ''centralized building'' option, available only to groups. (See section 1877(b)(2)(A)(ii)(I) and (b)(2)(A)(ii)(II) of the Act.)

''Same Building''

Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished ''in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services.'' We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical services are routinely delivered. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services that are not related to the furnishing of DHS (that is, only token physician services that are not Federal or private pay DHS). Simply stated, the DHS should be ancillary to physician services that are not DHS, and not the other way around. The exception was intended as an accommodation to physicians' customary practice of medicine and not as a loophole for physicians and group practices to operate DHS enterprises that are unconnected—or only marginally connected—to their medical practices. In addition, the significant easing of the ''direct supervision'' requirement described above necessitates a somewhat stricter interpretation of the location standards than we proposed in our January 1998 proposed rule, in order to ensure an adequate nexus between in-office ancillary DHS and the physician's core medical practice. Thus, we are making the following changes (except where noted) in the ''same building'' requirements:

- In our January 1998 proposed rule, we proposed interpreting the rule as allowing any quantity of services unrelated to DHS to be furnished in the same building. We are revising the rule to require that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building *substantial* physician services unrelated to the furnishing of Federal or private pay DHS. We are defining the phrase ''services unrelated to the furnishing of designated health services'' to mean physician services that are neither Federal nor private pay DHS, even if the physician service leads to the ordering of DHS. In addition, to preclude single-service DHS enterprises from the in-office ancillary services exception, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).
- We are adding a requirement that the DHS furnished in the building be furnished to patients whose primary nexus with the referring physician (or his or her group practice) is the receipt of physician services unrelated to the furnishing of DHS. Simply stated, obtaining DHS should not be the main reason the patient has contact with the referring physician (or his or her group practice). Again, this standard will ensure that self-referred DHS are ancillary and not primary services for the patients who receive them. Thus, for example, a physician who provides physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide DHS under the in-office ancillary services exception.
- The space in the building in which the DHS are provided need not be adjacent to the space in which services that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules).
- Shared facilities in the same building are permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not, however, creating a broader shared-facility exception.
- We believe that a home care physician whose principal medical practice consists of treating patients in their private homes meets the ''same building'' requirements if the physician (or a staff member accompanying the physician) provides a designated health service contemporaneously with a physician service (provided by the referring physician) that is not a designated health service in the patient's private home and the other exception requirements are met. Because the location requirements of the in-office ancillary services exception may disadvantage home care physicians, we are considering whether special rules should be developed under the ''same building'' requirements for physicians who primarily practice as home care physicians. We are soliciting comments on that issue and intend to address it further in Phase II of this rulemaking.

''Centralized Building''

Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished ''in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services).'' We believe that this statutory provision—which allows group practices to have ''off-site'' DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes. However, in permitting group practices to provide centralized DHS, the Congress did not intend to

eviscerate the ''in-office'' element of the exception. We are therefore interpreting the ''centralized building'' standard as follows:

• The space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice's clinical laboratory services or centralized DHS qualifies for the exception only if it is used *exclusively* by the group, that is, it is wholly owned by the group practice or leased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week). To preclude part-time arrangements in the form of one-day rentals, we are requiring that the centralized building be owned or leased exclusively by the group practice for at least 6 months. This rule precludes facilities shared by group practices in off-site buildings.

• Part-time ''centralized'' DHS arrangements are precluded. For example, a group practice may not rent a magnetic resonance imaging (MRI) facility 1 day per week and treat that facility as a ''centralized'' building under section 1877(b)(2)(A)(ii)(II) of the Act.

• Under the authority granted to the Secretary in the unnumbered paragraph that follows section 1877(b)(2)(A)(ii)(II)(bb) of the Act (that allows the Secretary to determine other terms and conditions related to section 1877(b)(2)(A)(ii)(II)(bb) under which the provision of DHS does not present a risk of program or patient abuse), we are determining that a mobile facility (for example, an x-ray van) owned and used *exclusively* by a group practice (24 hours per day, 7 days per week, for at least six months) will be considered to meet the ''centralized building'' standard, even though a mobile facility is not a building.

• Group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis, but DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the ''same building'' requirements are met.

• Referrals for ancillary services from other physicians or group practices that are not affiliated with the group practice providing the DHS do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

These building rules are designed to give physicians and group practices a meaningful opportunity to provide *bona fide* in-office ancillary DHS to their patients, while preventing group practices from using the in-office ancillary services exception to operate enterprises that are functionally nothing more than self-referred DHS enterprises, providing minimal services that are not DHS so as to comply nominally with the exception and capture DHS profits. We believe the Congress did not intend the exception to include these operations. Far from promoting patient convenience and quality of care, these arrangements pose a significant risk of overutilization of services and shuttling of patients to DHS locations for the economic betterment of the physicians, without regard to the patient's best interests.

Comment: Many commenters found the proposed regulations and interpretations of the ''building'' requirements to be confusing, over broad, potentially contradictory, and, in the words of one commenter, ''metaphysical.'' With respect to our proposed ''physical structure'' requirements, many commenters urged us not to place the agency or physicians into surveying real estate to determine whether a structure is one building. Commenters variously observed that while some walkways or tunnels between commercial medical office buildings may be sidewalks between distinct and separate buildings, other walkways or tunnels are part of the modern architecture of these buildings or are required to comply with zoning, land use, open space, or other real estate laws or to surmount natural barriers present on the site of the building.

There were a number of suggestions for revising the requirement. One group of commenters urged us to adopt a mailing address rule stating that a building would be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of suite number. Under this rule, suites operated by the same group practice or solo physician in buildings that use separate street addresses would be treated as separate buildings for the purposes of the in-office ancillary services exception. Other commenters objected to a street address test, noting that physicians have no control over the manner in which their buildings are assigned street addresses and that the parameters for assigning street addresses may vary by State and locality. One commenter expressed concern about buildings located on corner lots that might have two street addresses.

A second approach proposed by one commenter was to revise the regulations to allow connected buildings or portions of buildings that are owned or controlled by the same group practice. Still other commenters claimed that the emphasis should be on the proximity of the supervising physician to the patient during the performance of DHS. Under this view, the location requirement of the in-office ancillary services exception should focus on whether the physician is ''immediately available'' to the support personnel and not on an artificially imposed physical design constraint. Along these lines, several commenters proposed that services be considered in the ''same building'' if the physician is within a certain number of minutes (for example, 10 minutes) from the patient or if the physician is ''close at hand.''

Response: We regard the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress's attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are ''in-office'' services that are being supervised from some remote place.

Notwithstanding, we realize that our proposed definition of a ''building''—which attempted to define a building in architectural terms—could cause practical problems for some physicians and that a clearer, ''bright line'' rule would be preferable. Accordingly, having considered the various alternatives suggested by the commenters, we have concluded that for purposes of Phase I of this rulemaking, we are defining a ''building'' as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building will be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number. Under this rule, suites used by the same group practice or solo physician in buildings with separate street addresses will be treated as separate buildings for the purposes of the in-office ancillary services exception. While we recognize that this mailing address rule may result in an occasional anomaly, we are persuaded that it creates a ''bright line'' rule that will be easy to apply and will produce fair results in the vast majority of cases. Questionable cases may be appropriate candidates for an advisory opinion.

The space in the building in which the DHS are provided need not be adjacent to the space in which services

that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are permitted under section 1877 of the Act to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not creating a broader shared facility exception.

Because of the increased risk of abuse, we do not intend to protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances described in section VI.B.3 of this preamble. Thus, we wish to make clear that for purposes of this rule, a ''building'' does not include exterior spaces, such as courtyards or parking lots, nor does it include interior parking garages. For purposes of the in-office ancillary services exception, a building consists of usable professional office space and common areas such as lobbies, corridors, elevator banks, and restrooms.

In light of the changes we are making in the supervision standard, we believe it is necessary to revisit the building standards in order to effectuate congressional intent to limit the scope of the in-office ancillary services exception to services that are truly ancillary to physician services and are not a primary business of the practice. Thus, we are revising the ''same building'' requirements to more definitively tie in-office ancillary services to the referring physician's core medical practice. Simply stated, we want to ensure that services covered by the exception are, in fact, furnished ''in office.'' Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished ''in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services.'' We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical practice occurs. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services unrelated to the furnishing of DHS. Thus, we are interpreting the ''same building'' requirements as follows:

- The referring physician (or another physician who is a member of the same group practice) must furnish in the same building *substantial* physician services unrelated to the furnishing of DHS. In addition, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice). Independent contractors are not members of a group practice for purposes of section 1877 of the Act; thus, their activities do not count for purposes of compliance with the substantial physician services test or the full range of services test under the ''same building'' requirements, unless they are the referring physician. (See discussion in section VI.B.3 of this preamble.)
- For purposes of this exception, we are defining the phrase ''services unrelated to the furnishing of designated health services'' to mean physician services that are neither Federal nor private pay DHS, even if the services might generate orders or referrals of DHS. Thus, for example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS. On the other hand, a cardiologist who reads the results of a diagnostic radiology test (such as, for example, a transthoracic echocardiography for congenital cardiac anomalies, CPT code 93303) (whether for a Federal or private pay patient) has performed a service that is related to the furnishing of DHS.
- The DHS furnished in the building are furnished to patients whose primary nexus with the referring physician (or the group practice of which the referring physician is a member) is the receipt of physician services unrelated to the furnishing of DHS. Thus, for example, a physician who provides physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide those services under the in-office ancillary services exception.

Comment: One commenter believes that our proposed interpretation of the ''same building'' requirements contradicts the purpose of section 1877(b)(2)(A)(ii) of the Act. The commenter focused on the part of this provision that requires that ancillary services be furnished in a building ''in which the referring physician * * * furnishes physicians' services unrelated to the furnishing of designated health services.'' The proposed rule regarded a physician's examination and diagnosis of a patient that leads to the physician requesting a designated health service as acts that are ''unrelated to the furnishing of designated health services.'' The commenter is concerned that this interpretation would allow a physician's office to be a single specialty ''mill'' in which the physician could quickly generate a large quantity of referrals for profit. In other words, the exception could apply to a physician who does little more than conduct cursory evaluations and refer patients for a particular designated health service (for example, physical therapy). The commenter believes that, instead, the physician's office is meant to be a location in which the physician provides *bona fide* diagnostic and curative services to individuals presenting a variety of conditions.

Response: We share the commenter's general concern about inappropriate DHS arrangements, although we believe that the statute does not require us to include in the in-office ancillary services exception only services referred by physicians who treat a variety of conditions. The focus of the exception, in our view, is the requirement that the services be provided or performed in conjunction with a physician's own professional activities or as adjuncts to physician services, in a location in which the physician (or a member of his or her group practice) practices. If we were to limit this exception as the commenter suggested, some physician specialists might be prohibited from referring within their own practices. On the other hand, we agree that some restriction in the definition is appropriate to preclude physicians from providing virtually nothing more than referrals for DHS. Thus, as discussed above, in Phase I of this rulemaking, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).

Comment: Several commenters believe that our proposal to have our regional carriers determine whether the building requirements are satisfied was unworkable and impractical and would result in inequitable application of the law. Commenters noted that local carriers are often reluctant to express opinions on these issues and disinclined to provide written opinions. If the proposal survives, one commenter urged us, at a minimum, to give carriers

explicit authority and direction to issue these written opinions.

Response: We have endeavored to develop regulations that provide sufficiently clear rules so that parties can determine compliance without resorting to a regional carrier's determination.

Comment: A commenter expressed concern about DHS performed by physicians who travel to see patients. The commenter is a physician in a group practice of six physiatrists who perform electromyography and nerve conduction studies in a midwestern State. The group travels to rural counties in the State in which it practices to evaluate patients for musculoskeletal and neurologic problems. The patients often need nerve testing, and the group's physiatrists are often the only health care professionals in the county able to perform this testing. The commenter expressed concern that the regulations would prohibit the physiatrists from providing needed medical assessment and care to patients in these circumstances.

Response: Electromyography and nerve conduction studies are not physical therapy services under our definition in § 411.351; therefore, referrals for these services do not implicate section 1877 of the Act. Nonetheless, we wish to address the commenter's underlying question regarding traveling practitioners. Assuming that the physiatrist group meets the definition of a group practice under section 1877(h)(4) of the Act and the DHS are performed in the same building where the physiatrist (or a member of the group) also performs substantial physician services unrelated to the furnishing of Federal or private pay DHS, we believe the in-office ancillary services exception may apply in the situation described by the commenter. As noted elsewhere, we are soliciting comments on problems faced by physicians who principally practice in patients' homes and may be disadvantaged by the location requirements of the in-office ancillary services exception. We note also that the rural provider exception (to be addressed in Phase II of this rulemaking) may apply in the situation described by the commenter.

Comment: A commenter asked that we make clear that if a solo practitioner provides a designated health service for his or her own patients in the solo practitioner's own office, then the solo practitioner is not in violation of section 1877 of the Act.

Response: In the vast majority of situations we can envision, if a solo practitioner provides a designated health service for his or her own patients in the solo practitioner's own office, then the solo practitioner will not violate section 1877 of the Act. First, we are revising the definition of a ''referral'' for purposes of section 1877 of the Act to exclude DHS personally performed by the referring physician. Second, with respect to DHS performed by employees of the solo practitioner (including ''incident to'' services), we believe the Congress intended for the in-office ancillary services exception to apply to solo practitioners as well as group practices. Thus, so long as a solo practitioner's provision of DHS meets the in-office ancillary services exception, section 1877 of the Act would not be violated.

Comment: Commenters were divided about the provision of ancillary services through mobile units. Some believe that the use of mobile units and equipment leads to abusive arrangements. Other commenters supported the use of mobile units as cost-efficient means of sharing expensive DHS resources, particularly in rural areas. One commenter noted that State certificate of necessity (CON) volume requirements would be nearly impossible to meet without mobile units. The same commenter argued that sharing equipment is a critical part of cost containment, because idle equipment may lead to overutilization. One commenter pointed out that Federal antitrust agencies approve joint ownership of high technology equipment and that Blue Cross/Blue Shield has many policy provisions requiring joint ownership. These commenters generally advocated that mobile units be permitted and that mobile units qualify as a centralized location for the provision of DHS. A commenter observed that under the January 1998 proposed rule, a group practice could move any piece of equipment from office to office and, applying the ''same building'' requirements, use that piece of equipment for the provision of DHS. In light of this, the commenter questioned whether it made sense for the group practice to be prohibited from transporting the piece of equipment in a mobile vehicle to the various practice sites and using the equipment in the vehicle, if the mobile unit were exclusively used by the group practice and is not leased to any other health care provider. The commenter requested clarification that in these circumstances, the mobile unit would meet either the ''same building'' requirements or ''centralized building'' standard. Other commenters urged a broader exception for mobile units, for example, including them if they are parked in the parking lot of a physician's medical office building or treating the units themselves as buildings.

Response: The treatment of mobile units presents difficult questions under section 1877 of the Act. On the one hand, we have serious concerns about the potential for fraud and abuse when services are provided with mobile units. These are the same concerns we have (and believe the Congress shares) about all shared physician-owned or controlled ancillary services facilities. We believe that section 1877 of the Act is aimed at arrangements that enable physicians to profit from referrals to free-standing, money-making services ventures that are not central to their medical practices. On the other hand, we agree that the statute clearly permits services provided by mobile units that qualify under the ''same building'' requirements. Thus, we agree with the commenter that a group practice can move any piece of equipment from office to office and use that ''in-office'' piece of equipment for the provision of DHS in a location that meets the ''same building'' requirements. Because we are defining ''building'' narrowly to exclude parking lots and interior parking garages, services provided in mobile vans or trailers will not comply with the ''same building'' requirements. We believe it reasonable to conclude that these services are not ''in-office'' when a van circulates among various physicians' offices and is rented serially by each. These arrangements would seem to be calculated to enhance physician revenues, rather than patient convenience, since patients would likely be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services.

That said, we believe that mobile services can constitute an important part of the health care delivery system for many patients. Nothing in the statute or these regulations precludes a physician or group practice from arranging for a mobile provider to treat the physician's patients at his or her office location, so long as the financial arrangement, if any, between the physician or group practice and the ancillary services provider fits in an exception under section 1877 of the Act. In addition, in rural areas, the ''rural provider'' exception (to be addressed in Phase II of this rulemaking) may apply to protect some physician-owned mobile service providers. Finally, we are persuaded that the risk is low if a group practice exclusively owns and uses its own mobile van or trailer that

circulates among its group practice locations. In that limited circumstance, we are treating the mobile unit as akin to a ''centralized'' building under section 1877(b)(2)(A)(ii)(II) of the Act.

Comment: Several commenters sought clarification in the regulations text that group practices can have more than one centralized location for the provision of DHS. However, one commenter offered a contrary view. This commenter expressed the view that the Congress intended that the in-office ancillary services exception be interpreted narrowly with respect to centralized, free-standing locations. Specifically, the commenter cites the Conference Report for OBRA 1993 in H. Rep. No. 213, 1st Sess., 810 (1993), which states: ''The conference agreement includes an exception for clinical laboratory services provided by a group practice with multiple office locations. For all other DHS the exception for group practices applies only if the services are provided in *a* centralized location'' (emphasis added). Based on this language, the commenter believes that the Congress intended to permit group practices to have *a* single centralized location to provide DHS, but not to permit group practices to establish multiple wholly owned locations or franchises for DHS.

Response: Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished ''in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services).'' Neither the statute nor the legislative history for this provision specifically requires one *single* centralized location for a group to provide DHS. In addition, we see no compelling reason to impose such a requirement. We are interpreting the word ''centralized'' to apply when a group practice has established a separate facility for furnishing DHS to patients, without the requirement that it service all of the practice's offices or provide all of the practice's DHS. We are incorporating this interpretation into the regulations text.

If we were to require only one centralized facility for DHS, a group practice could be in the position of having to send patients from some offices to inconvenient locations or to house a variety of different kinds of ancillary services in one location, such as combining all physical therapy, laboratory services, and x-rays in one building. It may be entirely impractical for a group practice to house the equipment and staff for such diverse services in one location. We believe the Congress meant to allow groups to use this kind of ''central'' or dedicated location in situations in which the facility is convenient to some of the different offices, but as a result may not be physically attached to any one of them. Thus, the facility is ''central'' to multiple offices, rather than attached to just one.

Comment: Several commenters sought clarification that a group practice with a single office location for the delivery of services that are not DHS can have a separate, centralized building for the delivery of DHS.

Response: While we believe that the ''centralized building'' provision—which allows group practices to have ''off-site'' DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes, we can discern nothing in the statute or legislative history that would prevent a group practice with only one office location from using a centralized building for the provision of DHS.

However, we are concerned that allowing single and multi-office group practices to have multiple off-site locations for DHS would effectively gut the in-office ancillary services exception without additional controls. Accordingly, we are modifying the ''centralized building'' standard to ensure that DHS referrals protected by the in-office ancillary services exception are truly part of the group practice's medical practice. First, we are requiring that the centralized office space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice's clinical laboratory services or DHS qualifies for the exception only if it is used *exclusively* by the group practice or group practice physicians, that is, it is wholly owned by the group practice (other than a security interest held by an unrelated lender or mortgagor) or is leased or subleased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week, for at least 6 months). This rule precludes group practice shared facilities in off-site buildings. Second, part-time ''centralized'' DHS arrangements are precluded. For example, a group practice may not rent an MRI facility one day per week and treat that facility as a ''centralized'' building. Third, a mobile facility (for example, an x-ray van) owned and used exclusively by the group practice will be considered a ''centralized building.''

Notwithstanding, group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis. However, DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the ''same building'' requirements are met. Finally, referrals for ancillary services to a group practice from physicians not in the group practice or other group practices do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

Comment: Many commenters urged us to establish a separate exception for shared facilities. Several commenters argued that shared facilities pose no greater risk of overutilization than DHS furnished by solo practices or group practices. Moreover, commenters believe that shared facilities overseen by referring physicians are likely to be more convenient, efficient, and accountable than other facilities. A number of commenters suggested that failure to protect shared facilities would disrupt existing arrangements that are widespread in the industry (as one commenter stated, shared facilities are the ''reality of what's going on''), leaving many solo practitioners with only two options: merge with others to form group practices or disband their shared facilities. One physician commenter believes that if his shared radiology and clinical laboratory facilities are not permitted, the result would be a shift of income to commercial laboratory ventures, pathologists, and radiologists, further ''dichotomizing'' the incomes of primary care physicians and specialists. The physician claimed that his income would drop by 25 percent and that he would have to fire employees and default on a lease. Commenters representing the interests of solo practitioners asserted that there is no meaningful distinction between DHS facilities shared by solo practitioners and group practice-owned DHS facilities.

A physician-oriented trade association and other commenters urged us to add a new exception to allow the legitimate use of shared office facilities by physicians modeled on language included in BBA 1997, but never enacted. Other commenters offered different formulations, including allowing shared facilities if they are in the same building or complex of

buildings as the solo practitioners' office practices.

Response: In the August 1995 final rule and the preamble to the January 1998 proposed regulation, we observed that the in-office ancillary services exception would allow certain shared facility arrangements among solo practitioners who do not wish to become a group practice. For example, we noted that two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician (1) furnishes physician services unrelated to the furnishing of DHS in the office (that is, the arrangement meets the ''same building'' requirements), (2) directly supervises the laboratory services for his or her own Medicare or Medicaid patients while they are being furnished, and (3) bills for the services. We further noted that if only one of the solo practitioners owns the laboratory in a shared office, the nonowning physician can refer to the laboratory as long as he or she is not receiving compensation from the owner in exchange for referrals. We solicited comments on the effects of section 1877 of the Act on other shared facility arrangements.

After careful review of the public comments, we are persuaded that our original approach in the January 1998 proposed regulations is most consistent with the purposes of section 1877 of the Act. Under that approach, shared facilities are permitted if they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. With respect to the location of the shared facility, Phase I of this rulemaking permits shared facilities that meet the ''same building'' requirements. (However, shared facilities do not qualify under the ''centralized building'' standard because they will not meet the *exclusively used* requirement). Thus, as noted above, two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes substantial physician services unrelated to the furnishing of DHS in the building where the laboratory is located, provides (directly or through an independent contractor if permitted under applicable payment and coverage rules) the appropriate level of supervision for DHS for his or her own Medicare or Medicaid patients, and bills for the services. We believe the relaxation of the direct supervision requirement under these regulations will enable additional shared facilities to come within the exception. Additionally, if only one of the solo practitioners owns the laboratory in a shared facility arrangement, the nonowning physician can refer to the laboratory as long as he or she is not compensated by the owner in exchange for referrals.

We are not persuaded, however, that a separate exception for shared facilities is warranted. The BBA 1997 language that several commenters proffered would apply to services that are furnished—

- Personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
- By a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services;
- To a patient of a shared facility physician; and
- That are billed by the referring physician or a group practice of which the physician is a member.

Given that we are revising the supervision standards under the in-office ancillary services exception, we believe that the in-office ancillary services exception will cover most, if not all, of the nonabusive shared facility arrangements that would have been protected by this commenter's proposed additional exception.

Comment: A commenter questioned the application of the proposed regulations if physicians who share a building, but for legal or personal reasons are not formally organized into a professional structure (that is, a ''single legal entity''), form a joint venture to establish a clinical laboratory or other ancillary service provider.

Response: As explained above, solo practitioners may own and operate shared DHS facilities so long as they fit in the in-office ancillary services exception. If the practitioners form a separate joint venture to provide the services, they may run into problems complying with the billing requirements of the in-office ancillary services exception, if the joint venture does the billing (that is, the joint venture will not qualify as a wholly owned entity and, therefore, will not fit into any of the in-office ancillary billing requirements under section 1877(b)(2)(B) of the Act or § 411.355(b)).

4. The Billing Requirement

The Existing Law: To qualify for the in-office ancillary services exception under the statute, the DHS must be billed by one of the following:

- The physician performing or supervising the service;
- The group practice of which such physician is a member, under that group practice's billing number; or
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

The Proposed Rule: In the proposed regulation, we interpreted the billing requirements to allow a single group to bill under more than one billing number assigned to the group and to allow an agent to bill for the group in the group's name, using the group's number, provided the billing arrangement meets the requirements in § 424.80(b)(6). We further interpreted the ''wholly owned'' entity provision to mean that a physician or group practice can establish a wholly owned provider of DHS that can bill Medicare or Medicaid on its own behalf, under its own billing number that is not a group billing number.

The Final Rule: As with the other requirements in this exception, the billing requirements serve to tie the ancillary services for which self-referrals will be permitted to the physician's routine medical practice. Phase I of this rulemaking incorporates the OBRA 1993 amendment clarifying that in-office ancillary services that are billed by a group practice of which the referring or supervising physician is a member must be billed under a billing number assigned to the group practice. However, group practices may have, and bill under, multiple group practice billing numbers, subject to any applicable Medicare or Medicaid program restrictions. Wholly owned entities that qualify to do the billing under the rule may use their own billing numbers and need not use a number assigned to the physician or group practice that owns them. The entities must be *wholly* owned either by the physician performing or supervising the services or by the group practice; joint ventures between group practices and individual group practice physicians or that include other providers or investors do not qualify as wholly owned entities.

Billing may be done by independent third party billing companies if they are acting as agents of a solo practitioner, group practice, or entity, but the billing must be done under billing numbers assigned to the solo practitioner, group practice, or entity, and the services may not be separately billed under a billing company's number. The billing arrangements must meet the requirements of § 424.80(b)(6).

The express billing requirements of section 1877(b)(2)(B) of the Act contain

no billing method applicable to supervising independent contractor physicians who are ''physician in the group'' under section 1877(b)(2)(A)(i) of the Act and § 411.351, but who are not members of the group under § 411.351 (these physicians cannot bill themselves as the supervising physician because they are required to reassign their billing rights to the group in order to qualify as ''physicians in the group''). We believe the Congress intended the billing requirements of section 1877(b)(2)(B) of the Act to correspond with the supervision requirements of section 1877(b)(2)(a)(i) of the Act and that this omission was simply a legislative drafting oversight. Accordingly, we are interpreting the billing requirements to be consistent with the supervision requirements, which permit supervision by a ''physician in the group.'' Therefore, the billing conditions will be satisfied if the DHS are billed by the group practice when the supervising physician is a ''physician in the group.''

In summary, under the regulations in Phase I of this rulemaking, to qualify for the in-office ancillary services exception, DHS must be billed by one of the following:

- The physician performing or supervising the service.
- The group practice of which such physician is a member, under that group practice's billing number.
- The group practice if the physician is a ''physician in the group practice,'' under that group practice's billing number.
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

Comment: One commenter objected to our interpretation of the ''wholly owned'' entity provision as unsupported by the statute. The commenter believes that allowing separate and distinct entities to provide services and bill on their own behalf would frustrate efforts to detect fraud and abuse, because the provider numbers of the physician making the referral and the entity providing the DHS would not be clearly linked on a claim form. The commenter believes that the Congress likely intended to exempt only wholly owned entities that primarily provide administrative and billing services.

Response: We find nothing in the statutory language that would limit wholly owned entities under section 1877(b)(2)(B) of the Act to entities that provide only administrative and billing services. Rather, we believe the wholly owned entity provision can be read reasonably to permit group practices to provide DHS and bill through these entities. A narrower interpretation would seem to imply that the group practices could only bill using third party billing companies if these companies were wholly owned by the group. We believe it unlikely that the Congress intended such an interpretation.

Comment: A commenter suggested that the billing provisions in the in-office ancillary services exception be changed to include billing by a hospital for physician services furnished under arrangements. This change would allow physician services for hospital patients to come within the in-office ancillary services exception.

Response: The in-office ancillary services exception is designed to exempt from the referral prohibition certain DHS that are provided within a group practice. As discussed in section VIII of this preamble, DHS provided under arrangements with a hospital are inpatient or outpatient hospital services for purposes of the statute. We believe the Congress did not intend to protect inpatient and outpatient hospital services under the in-office ancillary services exception. In fact, in describing the in-office ancillary services exception in H. Rep. No. 111, 103d Congress, 1st Sess. 546 (1993), the Congress pointed out that services provided by a hospital or other provider ''under arrangement'' with a group practice are not protected under the general exception for in-office ancillary services. ''Under arrangements'' issues are further discussed in section VIII.M of this preamble.

C. Group Practice Definition (Section 1877(h)(4) of the Act)

The Existing Law: As defined in section 1877(h)(4) of the Act, a ''group practice'' is a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets certain conditions. Section 1877(h)(4) of the Act was promulgated as part of the original section 1877 law and later amended by OBRA 1993. The current law contains the following conditions applicable to ''group practices'' for purposes of section 1877 (those conditions added by OBRA 1993 are so noted):

- Each physician member of the group furnishes substantially the full range of services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel (the ''full range of services'' test).
- Substantially all of the services of the physician members of the group are furnished through the group, are billed under a billing number assigned to the group, and amounts so received are treated as receipts of the group (the ''substantially all test'') (revised by OBRA 1993).
- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined (modified by OBRA 1993).
- No physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician, with the exception of certain profits and productivity bonuses (added by OBRA 1993).
- Members of the group personally conduct at least 75 percent of the physician-patient encounters of the group practice (the ''75 percent physician-patient encounters test'') (added by OBRA 1993).
- The group practice complies with all other standards established by the Secretary in regulations.

In addition, section 1877(h)(4)(B) of the Act establishes two ''Special Rules''—

- A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on services personally performed or services incident to the personally performed services, so long as the share or bonus is not determined in any manner that is directly related to the volume or value of referrals by the physician (added by OBRA 1993); and
- In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may furnish a variety of different specialty services and furnish professional services both within and outside the group, as well as perform other tasks such as research, the conditions contained in the definition of ''group practice'' apply only with respect to the services furnished within the faculty practice plan.

Our August 1995 final rule covering clinical laboratory services referrals defined ''group practice'' at § 411.351 based on the statute as it read effective January 1, 1992. At that time, we interpreted the ''substantially all test'' to mean that at least 75 percent of the patient care services (defined as services addressing the medical needs of specific patients) of the group practice members must be furnished through the group. We interpreted members of the group to

include owners, employees, and independent contractors. We required that the group practice be ''a single legal entity.'' Finally, we stated that the ''substantially all test'' would not apply to any group practice that is located solely in a health professional shortage area (HPSA). For group practices located outside of a HPSA, the rule provided that any time spent by group practice members providing services in a HPSA would not be used to calculate whether the group practice located outside the HPSA had met the ''substantially all test.''

The Proposed Rule: We proposed several changes to the definition of ''group practice'' in § 411.351 to incorporate OBRA 1993 changes. We also proposed several other significant changes. First, we proposed a ''unified business test''—targeted at sham group practices—that would require group practices to exhibit ''centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise.'' Second, we proposed excluding independent contractors as members of the group to ease compliance with the ''substantially all test.'' Third, we proposed expanding our definition of ''patient care services'' to include any of a physician's tasks that address the medical needs of specific patients or patients in general or that benefit the group practice.

Final Rule: As with the in-office ancillary services exception, we have been guided in developing the final definition of ''group practice'' by twin goals: (1) To minimize the regulatory intrusiveness of the definition while giving meaning to the statutory language and intent; and (2) to provide clear guidance as to what constitutes a ''group practice'' for purposes of section 1877 of the Act. We understand the importance of group practice status to physicians: simply stated, it allows group members to refer patients to one another (or to the group itself) for DHS payable by Medicare or Medicaid, and it allows group members to share in profits derived from such DHS. Section 1877 of the Act recognizes that referrals within groups are commonplace and may be appropriate adjuncts to a group's core medical practice.

As an initial matter, the definition of ''group practice'' promulgated in the statute and these regulations applies only for purposes of section 1877 of the Act and may have little or no bearing for purposes of other Medicare or Medicaid provisions. For example, the definition of a ''physician group'' under the physician incentive plan rules is broader than the definition of ''group practice'' under section 1877 of the Act.

A common complaint about our January 1998 proposed regulation was that it would exclude many *bona fide* group practices, intrude too far into the business and financial operations of physician practices, and chill group practice integration that is crucial in an increasingly managed care environment. We have been mindful of these concerns in developing Phase I of this rulemaking. It is not our intent to micro-manage group practices or dictate their organization or operation; rather, our intent is to define ''group practice'' so as to create, consistent with our understanding of the statutory intent, a meaningful exception to the general referral prohibition under section 1877 of the Act, an exception that permits certain traditional and commonplace referral patterns within group practices, without permitting the exception to swallow the rule. In general, Phase I of this rulemaking is more expansive than our January 1998 proposed rule and affords physicians substantial flexibility in designing and managing their medical practices (subject, of course, to any other legal impediments imposed by Federal or State law).

We believe the group practice definition set forth in section 1877(h)(4) of the Act is premised on two assumptions. First, internal group practice referrals should only be protected under the physician services or in-office ancillary services exceptions (both of which apply in specific ways to group practices) if the group practice is a *bona fide* group practice and not a loose confederation of individual physicians bound together primarily to profit from DHS referrals. We believe the Congress intended a true group practice to consist of physicians whose practices are fully integrated, medically and economically. In short, the physicians practice medicine together in a single group, not separately, and their financial prospects are interdependent. Thus, the Congress imposed certain tests that demonstrate the requisite integration and gave the Secretary regulatory authority to impose additional tests. If true integration is present, we do not believe the Congress otherwise intended to regulate the formal structure and operation of the group. Second, the financial incentives for group practice physicians to generate referrals of Medicare or Medicaid payable DHS for the group should be attenuated. Thus, the group practice definition provides that group practice physicians may not be paid directly or indirectly based on the volume or value of DHS referrals, unless the compensation is a profit share or productivity bonus that is only indirectly related to those referrals.

With these precepts in mind, Phase I of this rulemaking incorporates the following significant revisions:

- Broadening of the types of arrangements that qualify as a ''single legal entity'' to include, among other things, multi-entity legal structures and structures owned by a single physician.
- Adoption of our proposal to exclude independent contractors from the definition of a ''member of the group.'' However, independent contractors who meet the conditions set forth at § 411.351 may qualify as ''physicians in the group practice'' who may receive profit shares and productivity bonuses under section 1877(h)(4)(B)(i) of the Act.
- Adoption of our proposed expanded definition of ''patient care services'' so that patient care services include all services a physician performs that address the medical needs of specific patients or patients in general or benefit the group practice (for example, administrative services for the group).
- Expansion of our 1998 proposal to gauge compliance with the ''substantially all test'' by measuring a physician's actual time spent on patient care services by permitting groups to adopt other reasonable methods for determining compliance.
- Creation of a substantially more flexible definition of a ''unified business'' that will permit group practices to use cost- and location-based accounting with respect to services that are not DHS, and, in some cases, with respect to services that are DHS if the compensation method is not directly related to the volume or value of the physician's referrals and other conditions are satisfied.
- Revision of the productivity bonus rules so that group practices may pay member physicians and independent contractors who qualify as ''physicians in the group'' productivity bonuses based directly on the physician's personal productivity (including services incident to such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual, Part 3), but may not pay such physicians any bonus based directly on their referrals of DHS that are performed by someone else.
- Promulgation of specific methods for ensuring that compensation for DHS is only indirectly related to referral income. In addition, parties may use other methods that are reasonable and documented.

• Elimination of the group practice attestation requirement.

These revisions and others are discussed in the comments and responses that follow. Each comment and response section begins with an overview of the relevant provision in the group practice definition and a summary of the final rule relating to that provision. The sections are divided as follows: General comments, the single legal entity requirement, members of the group, the ''full range of services'' test, the ''substantially all'' test, and the ''75% physician-patient encounters'' test.

1. General Comments

Comment: Many commenters, including a group practice trade association, criticized the proposed regulations for group practices as overly intrusive into the internal operations of physician practices, unnecessarily complex, and incapable of implementation in a fair and reasonable manner. The association and other commenters believe that the Congress intended the group practice provisions in the law predominately to regulate the external ownership, compensation, and referral arrangements of physicians and not the inner workings of group practices themselves. The association and other commenters protested that the rules create arbitrary distinctions among different types of physicians. These commenters contended that no tenable reason exists to treat group practices, pathologists, radiologists, and radiation oncologists—all of whom are permitted under the statute or various exceptions to make referrals to entities with which they have financial relationships under certain circumstances—differently than other physicians, since they have an equal incentive to self-refer.

Response: As indicated above, in preparing Phase I of this rulemaking, we have been mindful of the commenters' concerns about the intrusiveness of the proposed rule, and have sought to minimize the regulatory impact of the group practice definition and to provide clear guidance as to what constitutes a ''group practice'' for purposes of section 1877 of the Act. We do not intend to use these regulations to micro-manage group practices or to dictate their organization or operation, except as is necessary to give effect to the statutory intent of the Congress to create a limited exception to the general referral prohibition for DHS referrals by physicians within their own group practices. In general, Phase I of this rulemaking is broader than the January 1998 proposed rule and affords physicians substantial flexibility in designing and managing their medical practices.

While we have endeavored to apply these rules as equally as possible to solo and group practitioners and among various types of practitioners, some differences in regulation and outcomes are unavoidable, and in some cases desired, given the wide array of arrangements to which the statute applies and the distinctions inherent in the statutory scheme. For example, the Congress included a specific exception for referrals by consulting pathologists, diagnostic radiologists, and radiation oncologists that does not apply in the case of other consulting physicians. The Congress intended disparate treatment of these consulting physicians, reasonably, we believe, because of the limited ability of pathologists, diagnostic radiologists, and radiation oncologists to generate patient referrals of services they either perform or supervise. Similarly, the Congress judged referrals within group practices (and solo practices) deserving of special consideration based, we believe, on a recognition of physicians' traditional practice of delivering DHS in their own offices to their own patients.

Comment: A commenter sought clarification as to whether a group practice was exempt from section 1877 of the Act. Several commenters observed that group practice status does not, by itself, protect against the risk of overutilization of ancillary services provided by the group.

Response: A group practice is not exempt from section 1877 of the Act by virtue of being a ''group practice'' under the definition in section 1877(h)(4) of the Act and § 411.352 of these regulations. A relevant exception, such as the in-office ancillary services or the physician services exceptions, must still apply.

Comment: Several commenters suggested that section 1877 of the Act and the regulations should focus on referrals of medically unnecessary tests to entities with which physicians have prohibited financial relationships. Some commenters suggested that we use our utilization data to develop norms for each physician specialty that could be the basis for measuring appropriate utilization and preventing inappropriate referrals.

Response: We disagree that section 1877 of the Act should apply only to referrals of unnecessary items and services. While overutilization is a principal concern of the statute, and a primary focus of this rule, nothing in the statute suggests that the Congress intended to limit the statute's reach to referrals of medically unnecessary tests or procedures. Rather, the statute applies to all referrals of DHS to entities with which a referring physician has a prohibited financial relationship. The statute is designed to create a bright line that prohibits a high risk category of financial relationships and relieves the government from having to ''look behind'' every physician referral.

2. Single Legal Entity Requirement

The Existing Law: Under the statute, a group practice must consist of ''two or more physicians who are legally organized as a partnership, professional corporation (PC), foundation, not-for-profit corporation, faculty practice plan, or similar association.'' The August 1995 final rule took the position that a group practice could consist of only one legal entity and that any individual or entity could organize, operate, or control a group practice, as long as two or more physicians had a role in providing services and the group met all of the other specific requirements for being a group practice under section 1877 of the Act. Thus, for example, a hospital could ''own or operate'' a group practice, provided no State law prohibited it.

The Proposed Rule: The January 1998 proposed regulations retained the interpretation of the single legal entity requirement from the August 1995 rule, requiring the legally organized group practice to consist of a ''single legal entity'', that is, one legal entity identified as the group practice that meets all of the group practice definitional tests. In addition, the January 1998 proposed regulations proposed allowing individual physicians who are incorporated as individual professional corporations to form a group practice, subject to meeting the remaining conditions of the group practice definition.

The Final Rule: We are retaining and incorporating into the regulations text the ''bright line'' rule that a group practice must be a single legal entity. The single legal entity can assume any form recognized by the State in which the entity achieves its legal status, including, but not limited to, a corporation (for-profit, professional, or nonprofit), partnership, foundation, faculty practice plan, or limited liability company. The single legal entity can be legally organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. The single legal entity must be formed primarily for the purpose of being a physician group practice. Hence, for example, a hospital that employs physicians is not a ''group practice'' for purposes of

section 1877 of the Act, although the hospital can form or acquire a group practice that is a separate single legal entity. The following structures are among those that may qualify under Phase I of this rulemaking, assuming all other requirements of the group practice definition are satisfied:

- A partnership between two or more physicians.
- A partnership between one physician and another party, provided that the partnership employs at least one other physician. (Similarly, a partnership between two nonphysician parties can qualify if it employs at least two physicians).
- A corporation or limited liability company with one or more physician shareholders or members, provided that a corporation or limited liability company with only one physician shareholder or member employs at least one other physician.
- A corporation or limited liability company owned by nonphysicians, provided it employs at least two physicians.
- A single legal entity owned by two or more physicians through their individual professional corporations.
- A solo practitioner who is organized as a legal entity (for example, a professional corporation) and employs at least one other full-time physician.
- A single legal entity (whether a corporation, limited liability company, or other form) owned by one or more other legal entities (that is, a multi-entity arrangement) that involves two or more physicians through employment or indirect ownership, provided that the ''investing'' or ''owner'' entities are not themselves functioning group practices. (In other words, existing groups may not band together to form a group practice primarily to share in-office ancillary referrals.) It is our understanding that the prevalent practice in these kinds of arrangements is for the physicians who own the investing entities to become employees of the new group practice, and for the investing entities themselves to cease functioning as group practices.

This list is illustrative only, and other variations are possible. What is essential is that there must be one identifiable legal entity that is a *bona fide* group practice of two or more physicians. The definition of group practice does not include a loose confederation of physicians, a substantial purpose of which is to share profits from referrals (sometimes referred to as a ''group practice without walls''), or separate group practices under common ownership or control through a physician practice management company, hospital, or health care system, or other entity or organization.

We have responded to public comments regarding problems faced by faculty practice plans under section 1877 of the Act by using our regulatory authority under section 1877(b)(4) of the Act to create a new exception applicable to faculty practice plans. This new exception is discussed in section VII.A of this preamble.

While several commenters requested accommodation in the group practice definition for bifurcated foundation-model group practices (that is, arrangements between a nonprofit entity that provides health care services and a physician group, typically used in States that restrict the corporate practice of medicine), we have determined that those arrangements are better addressed by the personal service arrangements exception. As noted elsewhere in this preamble, we intend to apply our uniform interpretation of the volume or value standard to all exceptions in which it appears. (See the discussion in section V of this preamble.)

Comment: Many commenters concurred with our position that a group practice can be organized by any individual or entity, but took issue with other aspects of our group practice organizational tests. As a threshold matter, a number of commenters maintained that the statute does not require a ''single legal entity.'' These commenters generally fell into three categories: (1) Commenters seeking protection for foundation model ''groups'' in States that follow the corporate practice of medicine doctrine, (2) commenters seeking protection for physician ''groups'' practicing in academic medical settings, and (3) commenters seeking protection for ''groups'' that are under common ownership or control, but that are not bound together in a single legal entity. Comments on the first two issues—foundation models and academic medical settings—are summarized and addressed elsewhere in this section and in section VII.A of this preamble.

As to the third category—common ownership and control—commenters generally requested that we recognize organizations under common control as a single unit or group practice, as we do in our definition of ''hospital'' in § 411.351 (Definitions) of the regulations. (Section 411.351 reads as follows: ''*Hospital* * * * refers to any separate legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills.'') Specifically, the commenters suggested we interpret this portion of the group practice definition as covering a single legal entity that includes any separate, legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the group practice's patients and for which the group practice bills. Some commenters noted that the ability to have subsidiaries is important for groups for valid, nonabusive business reasons, such as to operate in more than one State when States have different corporate requirements, to organize components of the continuum of care such as home health or skilled nursing care, and to operate as multi-entity integrated delivery systems. Some commenters indicated that some State laws require physicians to practice in a different entity when working in a bordering State. Also noted was that complex corporate structures are sometimes required for a variety of other legitimate business reasons, such as allowing groups to meet State licensing requirements, to allocate the risk of liability, to comply with inconsistent State regulations, or to meet corporate practice of medicine requirements. Similarly, these commenters maintained that an aggregation of groups managed by the same physician practice management company or multiple groups owned by the same hospital should be considered a ''group practice'' for purposes of section 1877 of the Act.

Response: Having considered the comments, we iterate our view that a group practice must be a ''single legal entity.'' A standard that would allow entities under common ownership or control to be a group practice under section 1877(h)(4) of the Act does not sufficiently protect against sham group practice arrangements or loose confederations of physicians operating as a group practice substantially for purposes of profiting from DHS referrals. We find nothing in the statute that suggests that the Congress intended for a ''group practice'' to be so broadly construed as to include multiple group practices that happen to use the services of the same management company or that happen to be affiliated with the same health system. Single legal entities owned by multiple entities are permitted, as discussed in the response to the next comment. We address the special needs of foundation-based practices and faculty practice plans in this section and in section VII.A of this preamble, respectively.

Comment: Many commenters considered our proposed parameters for the composition of the ''single legal entity'' too restrictive, taking issue, in particular, with our statement that ''the

statute specifically requires that a partnership consist of two or more physicians who are partners and that a PC consist of two or more physicians who are incorporated together.'' While several commenters commended our proposal to allow group practices to include individual professional corporations that employ their own shareholders, commenters generally espoused expanding the group practice definition to include any physician group (regardless of its ownership) that is organized as a distinct legal entity and that employs more than one physician, provided that all of the other group practice definitional tests are met.

In these commenters' view, prohibiting a sole practitioner from owning a group practice that employs multiple physicians is unfair, inconsistent, anticompetitive, and not supported by the statutory language. The commenters pointed out that, under our January 1998 proposed rule, a hospital could own a group practice, but an individual physician could not. Commenters believe that the other requirements for meeting the group practice definition prevent any sham practice arrangements and that an interpretation requiring direct ownership by two physicians does not further Federal fraud and abuse policy.

A number of commenters asked that we clarify that a group practice may be owned by any legal corporate structure or arrangement including, but not limited to, limited liability companies, multi-member professional corporations, sole physician shareholder companies that employ at least one physician, hospitals that employ physicians, entities owned jointly by physicians and a hospital (for example, a physician hospital organization (PHO)), or general corporations that employ two physicians without any physician ownership. This interpretation is consistent with the August 1995 final rule. In particular, several commenters observed that group practices commonly are formed through the merger of existing group practices. The merging practices typically contribute assets and transfer physicians and other employees to the new group practice entity, which bills for the physician services under a group billing number and treats amounts received as receipts of the new group practice, and which meets the other group practice definitional requirements. The commenter urged that the new group practice entity should qualify for group practice status, without having to dissolve the merging shareholder entities, which are often maintained for tax or other purposes unrelated to Medicare or the fraud and abuse laws.

To prevent sham group practices, one commenter suggested that, in the case of a new group practice formed by the merger of existing group practices or professional corporations, we should require the new group practice to employ its members rather than allowing the multiple professional corporations (PCs) that formed the new group to continue employing practice members (except in the case of an individual professional corporation that employs a physician and owns a stake in a group practice). Similarly, another commenter recommended requiring all group practices (regardless of layers of composition) to be fully integrated into a single operating medical business at the top or ''group'' level. A group practice would be deemed fully integrated if it met the group practice definitional tests and presented itself as a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. A fully-integrated group would be required to employ or contract with all physicians at the group level so that physician compensation and accounts receivable of all members of the group would be ''at risk'' in the event of losses due to poor management of the group or in the event of a malpractice claim against any member of the group.

Response: We generally agree with the commenters. We have reconsidered the statutory language and believe that the provision requiring ''a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—'' can be interpreted in several ways. It can reasonably be read to mean that a group must consist of some kind of legally organized entity, owned by virtually any combination of individuals or other entities, provided that there are at least two physicians providing services to patients as group practitioners. We have amended the definition of a group practice accordingly in § 411.351. We believe this interpretation allows us to treat all practices, regardless of who owns or operates them, more uniformly. The introduction to this section provides an illustrative list of possible group practice organizational structures.

We are adopting the commenters' suggestion that no entity that owns all or part of a group practice (that is, no equity holder in the group) may itself function or qualify as a group practice (whether a group practice under section 1877(h)(4) of the Act or otherwise). Thus, for example, in the case of a new group practice formed through the merger of existing group practices, the merging or defunct group practices may not themselves operate as medical group practices (that is, they may not furnish or bill for health care services); however, the defunct practices are not required to dissolve. The merging group practices should transfer all medical assets to the new group practice, and the new group practice should employ the physicians and bill for their services, treating receipts as receipts of the new group practice.

We also generally agree that a group practice should consist of a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. This aspect of a group practice is addressed by the unified business test in § 411.352 of the regulations. (See section VI.C.7 of this preamble for additional information).

Comment: Commenters questioned whether a hospital could qualify as the ''single legal entity'' needed to establish group practice status. In the August 1995 regulations, we stated that ''* * * if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic).'' (60 FR 41937) One commenter interpreted this language to mean that a hospital, which is itself a legal entity, could employ physicians and, therefore, qualify as a group practice if the other requirements of the group practice definition were met. Thus, the hospital would not need to establish a separate legal entity for its employed physicians to be considered a group practice. A related concern was whether a single hospital could encompass multiple group practices. According to the commenter, the ability of hospitals to establish multiple groups is especially important for a hospital entity that may operate several campuses in different cities as unincorporated divisions, a situation likely to increase as providers consolidate into regional networks.

Response: We believe the commenter's interpretation would stretch the meaning of a ''group practice'' too far. We do not believe that a hospital can reasonably be construed

as a ''group practice.'' We find no basis to conclude that the Congress thought otherwise. The statement from the August 1995 regulations was made in response to a comment regarding an arrangement in which a tax-exempt hospital had affiliated group practices and established a separate tax-exempt physician-directed clinic as the group practice's operating entity, but employed the physicians in the affiliated groups directly. In responding to the comment, we attempted to make two points: (1) That a group practice need not be legally organized by physicians; and (2) that a physician-directed clinic could qualify as a group practice.

We iterate that a group practice may be legally organized by a hospital or other nonphysician person or entity; however, neither the hospital itself nor any other facility the primary purpose of which is something other than to operate a physician group medical practice, can *be* a group practice. A hospital may establish multiple group practices through subsidiaries or affiliated entities that are separate legal entities. Each entity may be a group practice for purposes of section 1877 of the Act, although the aggregation of groups will not be. Exceptions, such as the in-office ancillary services exception, would only apply to referrals within one of those groups and not across multiple groups within the same hospital entity.

Comment: A commenter noted that the August 1998 proposed rule clearly states that a hospital may own and operate a group practice (assuming there is no State law impediment to such ownership) and that physicians may own a group indirectly through individual professional corporations. In light of these statements, the commenter sought clarification on three points: (1) Whether a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were satisfied; (2) whether the ''single legal entity'' test could be met by a limited liability company; and (3) whether several physicians organized as a limited liability company could, in turn, own another entity (for example, a second limited liability company) that could qualify as a group practice.

Response: In responding to the commenter's questions, we apply the principles described above. First, a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were satisfied. Second, a limited liability company duly organized under applicable State law could qualify as a ''single legal entity.'' Third, several physicians organized as a limited liability company could, in turn, own another entity that could qualify as a group practice provided that the first limited liability company is not, and does not operate as, a group practice. In this last case, the physician members of the first limited liability company would be considered members of the group by virtue of their indirect ownership interest in the second entity.

Comment: Commenters note that health systems, management companies, hospitals, and other nonprofit and for-profit corporations must comply with State laws governing the corporate practice of medicine. In some States, these laws restrict or prohibit a corporation from directly employing physicians. In some cases, the corporations form a ''captive'' or ''friendly'' professional corporation with one physician owner who holds the ownership rights to the professional corporation in trust for the corporation. The friendly professional corporation directly employs physicians who then form the group practice. The corporation manages the business of the group practice, with the sole physician shareholder acting primarily as a ''figurehead.'' The arrangement ensures that the corporation only indirectly employs the physicians and does not violate the corporate practice of medicine rules. Commenters noted that typically only one physician is a shareholder in the friendly professional corporation so that day-to-day transactions are less cumbersome.

Response: Since we have amended the group practice definition to cover groups that consist of one physician owner and one or more physician employees, we believe that the types of ''captive'' or ''friendly'' professional corporations described in the comment can both meet our definition and comply with corporate practice of medicine requirements. Groups must continue to meet all of the other criteria in the group practice definition in section 1877(h)(4) of the Act and § 411.351.

Comment: Several commenters asked that we clarify whether the ''single legal entity'' requirement precludes a group practice from having subsidiary entities that, for example, own real estate or equipment, provide billing services, or operate ancillary services.

Response: As we noted in the August 1995 final regulations, we believe that the statute does not preclude a single group practice from owning other legal entities for the purposes of providing services to the group practice. Thus, to cite the example in the August 1995 final regulation at 60 FR 41936, a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients. The physicians could qualify for the in-office ancillary services exception provided they meet the requirements for supervision, location, and billing. The billing requirement in section 1877(b)(2)(B) of the Act allows services to be billed by the referring or supervising physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a group practice may wholly own separate legal entities for billing or for providing ancillary services. Parties should be aware, however, that the group practice safe harbor under the anti-kickback statute (§ 1001.952(p) of this title), does not protect group practice ownership of ancillary services; for purposes of the anti-kickback statute, these arrangements are evaluated on a case-by-case basis.

3. Members of the Group

The Existing Law: Under the August 1995 final regulations, owners, employees, and independent contractors were all considered ''members of a group'' practice for purposes of the group practice definitional tests.

The Proposed Rule: The proposed regulations proposed modifying the definition of the term ''members of the group'' to include only physician partners, shareholders, and full-time and part-time physician employees. Independent contractors would no longer be considered members of the group. This change was proposed to aid group practices attempting to comply with the 75 percent ''substantially all test.'' Physicians would be considered members of the group during the time that they furnish patient care services to the group.

The Final Rule: We are adopting our January 1998 proposal to define a member of a group practice as any physician who owns, or is employed by, the group practice. In the case of a group practice owned by professional corporations or defunct group practices, the physicians who own those entities will be considered members of the group practice. Also, those physicians who own all or part of the group practice through their own professional corporations and who are employed by their own professional corporations (which contract with the group practice to provide physician services) will be

considered members of the group. Physicians are members of the group during the time they furnish ''patient care services'' (as defined at § 411.351) to patients of the group or for the benefit of the group, even if those services cannot be billed by the group (for example, certain administrative services, *pro bono* services).

Independent contractors and leased employees will not be considered members of the group. The exclusion of independent contractors is intended to aid many group practices in complying with the ''substantially all test'' described below. Although not group practice members, under certain circumstances, independent contractors may provide the required supervision for the in-office ancillary services exception, as described in section VI.B.2 of this preamble.

While nonphysicians, such as nurse practitioners and physicians assistants, may be group practice ''members'' for general purposes under section 1877 of the Act, their membership will have no practical effect, since they are not ''physicians'' for purposes of the three group practice ''tests'' (the ''full range of services,'' ''substantially all,'' and ''75 percent physician-patient encounters'' test), nor for purposes of the profits and productivity bonuses provisions. While referrals by nurse practitioners and physician assistants generally do not trigger section 1877 of the Act, which applies only to physicians (as defined at section 1861(r) of the Act), referrals made by nonphysician health care professionals may implicate the statute if those referrals are directed or controlled by a physician. In other words, a physician or group practice cannot channel referrals through a nurse practitioner, physician assistant, or other nonphysician health care professional in order to circumvent the prohibition under section 1877, and any channeled referrals would be imputed to the responsible physician.

Comment: Many commenters supported our proposal to count owners and employees as members of the group, but not independent contractors. This change would facilitate compliance with the group practice definition by group practices that use part-time independent contractor physicians to supplement and expand the range of services the group offers to patients. Some commenters recommended that independent contractors be excluded only for purposes of the ''substantially all test,'' but not for other purposes, including the direct supervision requirement of the in-office ancillary services exception and the 75 percent physician-patient encounters test. Some commenters objected to excluding independent contractors from the definition of ''members of the group'' because they perceived that such exclusion would prevent group practices from paying independent contractors productivity bonuses for the work they personally perform under section 1877(h)(4)(B)(i) of the Act.

Response: We are retaining our proposal to exclude independent contractors from the definition of ''members of the group practice.'' On balance, we believe this change will benefit many group practices that wish to qualify for group practice status. As to the other concerns raised by commenters, we believe those concerns have largely been addressed by other changes in these regulations. We have liberalized the direct supervision standard in the in-office ancillary services exception to permit supervision by independent contractors who meet certain conditions that establish that the independent contractors are ''physicians in the group practice.'' (See discussion in section VI.B.2 of this preamble). As discussed below, in greater detail, we are permitting group practices to pay productivity bonuses to independent contractors who are ''physicians in the group practice.'' (See discussion in section VI.C.8 of this preamble).

Comment: A number of commenters advocated a flexible approach to the definition of ''member of the group,'' urging that groups be permitted to elect whether to include independent contractors as members on an annual or other basis. These elections would apply uniformly for purposes of qualifying under all of the group practice definitional tests and the in-office ancillary services exception, and would be reported to us.

Response: The election process described by the commenters strikes us as unnecessary given the significant changes in this final rule with respect to the treatment of independent contractors under the in-office ancillary services exception and the group practice productivity bonus provisions. In our view, an election process would impose an additional administrative burden on groups and the government, with minimal offsetting benefit.

Comment: To accommodate multi-entity group arrangements, a commenter suggested that ''members of a group'' should include owners of the group, employees of the group, and owners of any sole or multiple shareholder professional corporation that has an ownership interest in the group (that is, indirect owners).

Response: For purposes of the definition of ''members of the group,'' we are including any physician owners of a sole or multiple shareholder PC or other entity that has an ownership interest in the group. In essence, we intend to ''look through'' any corporate or entity owners to the ultimate physician owners. Thus, members of the group include physicians who are owners (directly or indirectly) and *bona fide* employees of the group.

Comment: Several commenters suggested that independent contractors be permitted to qualify as group practice members on a *locum tenens* basis. Thus, for example, a group would be allowed to use independent contractors to provide coverage when a member of the group is ill and unable to practice medicine temporarily. Other reasons to use *locum tenens* physicians could include death or disability of a physician, resignation of a physician, accommodating seasonal increases in patient loads, and ''trial runs'' of physicians being recruited to join a practice. According to commenters, *locum tenens* providers are typically paid on a fee-for-time basis by the staffing organizations with which they are affiliated. Thus, they typically have no direct financial relationships with any of the health care entities to which they are assigned. The health care entities retain all patient receipts and, when possible, Medicare payments are reassigned to the health care entity.

Response: Nothing in section 1877 of the Act or these regulations prevents the use of *locum tenens* physicians in situations like those described in the comments. The issue raised, however, is how these physicians should be treated for purposes of a group practice's compliance with the group practice definition and how referrals by such physicians should be treated under the general prohibition under section 1877. As to the first issue, we believe an appropriate use of *locum tenens* physicians in exigent situations should not prevent a group practice that otherwise complies with the definition at section 1877(h)(4) and § 411.352 of these regulations from qualifying for group practice status. We are applying the rules at section 3060 ''Reassignment,'' of the Medicare Carrier's Manual (HCFA Pub. 14–3), Part 3—Claims Process (the reassignment provisions) as the test for whether a physician is a *locum tenens* physician. A *locum tenens* physician will be considered as ''standing in the shoes'' of the regular physician (as defined in section 3060.7) if he or she replaces the regular physician in accordance with section 3060.7. We note that section 3060.7 does not treat a physician hired

on a ''trial run'' basis as a *locum tenens* physician.

Comment: One commenter sought clarification that on-call physicians who are independent contractors would be exempted from the group member and group practice requirements but would be able to provide and supervise care on behalf of a group member. On-call physicians for one group may be members of other group practices. They may or may not be compensated for their services or bill under the group practice billing number of the group for which they are serving in an on-call capacity. According to the commenter, on-call arrangements are commonplace, especially among groups that do not have sufficient numbers of specialists to cover for each other. The commenter requested a specific exemption under the statute so that on-call physicians do not impede groups from meeting the group practice definition and are not precluded from ordering DHS when they are serving in an on-call capacity. The commenter suggested an on-call physician be treated as ''standing in the shoes'' of the member while providing on-call services for purposes of the ''substantially all test,'' the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception.

Response: We agree that it is appropriate to treat on-call physicians as ''standing in the shoes'' of the member while providing on-call services for purposes of the ''substantially all test,'' the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception, provided that the services are billed by the practice for which the physician is serving on an on-call basis.

Comment: Several commenters questioned whether nurse practitioners, physician assistants, or other nonphysician providers could be group members, and if so, whether their services would count in the calculation of the 75 percent physician-patient encounters test.

Response: We perceive nothing in the statute that would prevent group practices from admitting nurse practitioners, physician assistants, or others as members of the group for purposes other than section 1877 of the Act. However, the definition of a ''group practice'' in section 1877(h)(4) of the Act contains several requirements that apply specifically to *physician* members of the group. Provisions of the in-office ancillary services exception and the physician services exception also refer specifically to physician members or physicians in the same group practice. The term ''physician'' is specifically defined under the Medicare statute at section 1861(r) of the Act and does not include nurse practitioners or physician assistants. Any services that these individuals provide are not counted under the ''substantially all test'' or under any other part of the group practice requirements or exceptions that apply to physician members.

The referral prohibition in section 1877 of the Act applies only to referrals that are made by a physician to an entity with which that physician, or an immediate family member, has a financial relationship. If a nonphysician practitioner is referring a physician's patients at the physician's suggestion or in lieu of the treating physician, we would impute the referrals to the physician. Simply stated, physicians may not delegate their own referrals to avoid the referral prohibition. On the other hand, we would not impute the referrals if the nurse practitioner or the physician assistant is independently treating the patients and initiates the referrals on his or her own. We think the determination will depend on the specific facts and circumstances.

Comment: One commenter asked that we exclude from the definition of members of the group any employees who provide interpretation or supervision services only and are not otherwise involved in patient care.

Response: Given the revisions we have made in Phase I of this rulemaking to the in-office ancillary services exception and the group practice definition, we see no need for a special exclusion for physicians who provide interpretation or supervision services only. We recognize that these physicians may affect, among other things, a group practice's ability to comply with the 75 percent physician-patient encounters test because they generally do not see patients. But to exclude physicians who generally do not see patients would undermine the purpose of the test, which is to ensure that group practices are first, and foremost, joint medical practices for the provision of physician services to patients and not primarily designated health care services enterprises. The Congress addressed the special circumstances of pathologists, diagnostic radiologists, and radiation oncologists in a separate provision. (See discussion of section 1877(h)(5)(C) in section III.B of this preamble).

Comment: A commenter sought clarification that physicians who are employees of their own individual professional corporations instead of the group practice are considered ''group members.'' The definition of a group member in § 411.351 already includes physicians whose ownership interest in the group is held through an individual professional corporation. Many physicians wish to not only hold ownership interests in an individual professional corporation, but to be employees of these corporations for pension and tax reasons. To avoid potential abuse, the commenter suggested that we add the following parenthetical to the definition of ''member of group'' in § 411.351: ''(including physicians who are employed by an individual professional corporation, as long as the group has legal authority over the terms of the physician's employment and is legally responsible for services provided by the physician on the group's behalf).''

Response: We agree with the commenter that these physicians are ''members'' of the group. If a physician already qualifies as an ''owner'' of the group through his or her individual professional corporation, then his or her status as an employee or contractor is irrelevant for purposes of qualifying for group practice status. The amendatory language proposed by the commenter is not necessary, although we are revising the regulations text to clarify that a physician who is employed by an individual professional corporation that has an ownership interest in the group practice is a ''member of the group.'' Physicians who are employed by their own individual professional corporations and who have no ownership interest in the group (directly or through an individual professional corporation), but provide services to the group, are independent contractors and therefore not members of the group.

Comment: A commenter suggested that a physician who opts out of, and is not receiving any payments from, the Medicare program should not be bound by the limitations in section 1877 of the Act, and, thus, should be able to refer to entities with which he or she has a financial relationship. The commenter also asked that we clarify whether a physician who opts out of the Medicare program pursuant to the private contracting authority in the BBA 1997, but continues to practice with a particular group of physicians, is a group ''member'' for purposes of the physician self-referral law. The commenter reported that we have elsewhere stated that a group physician's opting out does not affect the ability of the rest of the group members to provide and bill for services they furnish to Medicare beneficiaries. The commenter stated that physicians who reassign benefits to organizations that participate in Medicare may not opt

out, and that consequently physicians who belong to groups that participate in Medicare and who opt out may not bill and accept payments from Medicare beneficiaries through the group practice unless the entire group practice opts out. Thus, a physician who opts out would have to bill under his or her own name instead of through the group.

The commenter also questioned whether a physician's time spent treating Medicare beneficiaries that is billed through the physician's own name must be counted against the amount of time the physician has spent treating other patients of the group practice. (We assume this means that, for the ''substantially all test,'' the commenter wishes to know whether the physician's private billing constitutes ''patient care services'' provided outside the group context that would affect whether the physician provides substantially all of his or her services through the group and bills substantially all of his or her services under a billing number assigned to the group.)

The commenter urged that we consider physicians who have opted out as ''members'' of the group practice only for those services furnished through the group, but not count the physician services in calculating whether the group has met the ''substantially all test.''

Response: We agree with the commenter that a physician who opts out of the Medicare program and is not receiving any payments from the Medicare program is not bound by the limitations in section 1877 of the Act and, therefore, can refer to entities with which he or she has a financial relationship. Section 1877 prohibits only referrals for services ''for which payment otherwise may be made under Medicare,'' and Medicare would not otherwise pay for services under a private contract. The commenter also is correct in stating that when a group physician has opted out, it does not affect the ability of the rest of the group members to furnish and bill for services they furnish to Medicare beneficiaries.

The commenter is not correct, however, that when a group physician has opted out, the group may not bill in its own name for services provided by the opt-out physician under a private contract. The Medicare statute does not prevent an opt-out physician's group—regardless of whether the group has a participation agreement with Medicare—from billing payers other than Medicare for services furnished under a private contract. Of course, neither the physician nor the group is allowed to bill Medicare for services furnished under a private contract. Thus, a physician who opts out can remain a group member during the time he or she provides services to group patients, provided the services are billed through the group practice to payers other than Medicare. We believe the requirements in the group practice definition are meant to demonstrate that the physicians involved in the group are actually practicing medicine together. A physician can demonstrate a significant level of participation by treating either program or nonprogram patients, as long as they are group patients.

We also believe that any services the physician bills in his or her own name are not group services and, therefore, should be factored into the ''substantially all test'' as outside patient care services.

Comment: Several commenters were concerned about the proposed rule's effects on nonprofit medical foundations, particularly in light of our statement that a group practice can consist of only *one* legal entity. One commenter was specifically concerned about medical foundations in California, where such entities are established so that practices can comply with the corporate practice of medicine prohibition. One of the key exceptions to the prohibition allows nonphysician (''lay'') participation in arranging for the delivery of physician services if the nonphysician is a qualified medical foundation. (These entities are nonprofit and exempt from Federal income taxation under section 501(c)(3) of the Internal Revenue Code). In California, for example, these foundations provide patient care through a separate, contracted medical group that is comprised of at least 40 physicians who collectively practice in at least 10 specialty areas. A chief concern was that our proposed rules would prevent the nonprofit foundation-model group practice from furnishing DHS under the in-office ancillary services exception because it has no employed physicians or physician owners who can qualify as ''members of the group'' for purposes of the group practices definitional tests.

The commenter considers the California nonprofit medical foundation to be, in essence, one bifurcated medical services provider that should be treated as a ''single legal entity'' for purposes of section 1877 of the Act. That is, under California law, the medical foundation is itself a health care provider; yet this can only work if the medical foundation encompasses the physicians who contract to provide the professional services. The IRS currently regards the physician-foundation relationship as comprising an integrated whole and grants tax-exempt status to those truly integrated foundations as providers of professional medical care. The foundation operates and owns all elements of the practice, but cannot provide the physician services, and the physicians have agreed to furnish all patient care services through the foundation model; it is the foundation, and not the physicians, who own the medical practice.

The commenter stated that entities such as management service organizations do not merit tax-exempt status because they support the provision of services, but do not actually provide services, while the foundations actually provide services. The IRS scrutinizes the entire foundation relationship to assure that its interdependent functions and operations comply with the fundamental requirements for tax exemption.

Response: As an initial matter, that an arrangement is subject to IRS regulation is not determinative under section 1877 of the Act. The IRS's goals in regulating business structures do not necessarily take into account preventing fraud and abuse in the Medicare and Medicaid programs. As to foundation-model practices in corporate practice of medicine States, we recognize that they present special problems under section 1877 of the Act. On the one hand, section 1877(h)(4)(A) clearly authorizes group practices that are ''foundations.'' On the other hand, in the typical foundation-model arrangement, the physicians are not legally organized as a ''foundation.''

In reviewing the statute and legislative history, we have reached the following conclusions. First, the Congress used the term ''foundation'' in the group practice definition in a generic sense to cover any situations in which the single legal entity, that is, the group practice, consists of a foundation; the reference was not necessarily intended to encompass bifurcated foundation-model arrangements. Second, the Congress intended for foundation-model arrangements to be excepted under the personal service arrangements exception. The OBRA 1993 Conference Report states that the ''conferees intend that this exception [personal service arrangements] would apply to payments made by a nonprofit Medical Foundation under a contract with physicians to provide health care services and which conducts medical research.'' H. Rep. No. 213, 103d Cong., 1st Sess. 814 (1993).

The personal service arrangements exception should provide foundation-model arrangements with additional

flexibility in structuring their arrangements and that most foundation-model arrangements will be able to fit in the exception, in accordance with the congressional intent. The ''volume or value of referrals'' and ''other business generated'' standards will apply uniformly to all exceptions in which they are included. (See the discussion in section V of this preamble and the regulations at § 411.354(d).)

Comment: Several commenters noted that another arrangement commonly used in corporate practice of medicine States is the use of ''friendly'' or ''captive'' PCs to create hospital-affiliated group practices in States that prohibit hospitals from employing physicians directly. For example, a commenter explained that in Ohio, a single physician may own stock in a PC, but hold the stock in trust for a hospital or other nonprofit corporation. The PC itself employs physicians who operate as a group practice and would fulfill all of the other group practice requirements. The commenter suggested that this arrangement would satisfy section 1877 of the Act if the rule were changed to permit groups to be owned by a single physician owner.

Response: As noted in section VI.C.2 of this preamble, we have made the change suggested by the commenter. Group practices may be owned by a single physician provided that the group practice employs at least one other physician. Therefore, we believe that ''friendly'' or ''captive'' PCs can qualify as group practices if they meet all of the other conditions of the group practice definition.

Comment: Several commenters noted that the sole owner of the ''captive'' or ''friendly'' PC may be a hospital-based physician who does not practice medicine as part of the group. These commenters wondered whether a nonparticipating physician owner would be a member of the group for purposes of the group practice definitional tests, particularly the ''substantially all test.''

Response: We believe that a hospital-based physician, who does not practice medicine as part of the group, is not a member of the group practice for purposes of the definitional tests. However, that means that the physician is not a member for any other purpose either. Thus, for example, a captive or friendly PC owned by such a physician would need to employ at least two physicians to qualify as a group practice. In addition, the sole physician owner described in the comment would not be eligible for sharing in overall profits or productivity bonuses under section 1877(h)(4)(B)(i) of the Act and § 411.352(i) of the regulations.

Comment: Commenters generally supported our position in the proposed regulations that a physician's financial relationship with an entity under section 1877 of the Act would not be imputed to his or her group practice. Thus, other members of the group practice could continue to make referrals to the entity, provided that the members did not have financial relationships with the entity and the physician with the financial relationship was not in a position to control the referrals of other group members. However, one commenter suggested that we include as members (who could continue to make referrals) physicians who are employed by their own PC (instead of the group) as long as the group has legal authority over the terms of the physician's employment and is legally responsible for services provided by the physician on behalf of the group. This commenter noted that for tax and pension reasons, many physicians prefer to be employed by their PCs rather than the group practice entity.

Response: We are adopting the position we discussed in the proposed regulations, that is, that a physician's financial relationship with an entity under section 1877 of the Act will not be imputed to his or her group practice. Thus, other members of the group practice can continue to make referrals to the entity, provided that the members do not have financial relationships with the entity and the physician with the financial relationship is not in a position to control the referrals of other group members. As we have indicated elsewhere in this preamble, physicians who are employed by their own individual PCs are considered members of the group if the PC has an ownership interest in the group. If not, the physician would be considered an independent contractor who is not a member of the group.

4. The ''Full Range of Services Test''

Existing Law: The definition of a group practice in section 1877(h)(4)(A)(i) of the Act provides that, among other requirements, each physician who is a member of the group must provide substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel. In the August 1995 final rule covering referrals for clinical lab services, we required physician members to furnish the full range of ''patient care services,'' defined as services addressing the medical needs of specific patients.

The Proposed Rule: In the January 1998 proposed rule, we proposed expanding ''patient care services'' to include any physician's tasks that address the medical needs of specific patients or patients in general or that benefit the practice. These activities could include, for example, time spent training group staff members, arranging for equipment, or performing administrative or management tasks, as long as these activities benefit the operation of the group practice. Services wholly outside the group's medical practice, such as teaching, do not count as patient care services. This proposed test was designed to ensure that a physician is actually practicing medicine as he or she ordinarily would as part of the group and has not simply joined the group in name only. It further ensures that physicians are practicing as part of the group and not simply using the group to profit from DHS referrals.

The Final Rule: We are promulgating the test as proposed in the January 1998 proposed rule.

Comment: Commenters generally favored our proposal to revise the definition of ''patient care services'' to include any physician task that addresses the medical needs of specific patients or patients in general, or that benefits the group practice. However, commenters requested clarification whether activities that are conducted outside the group practice, such as teaching, overseeing residents, or conducting medical research, but that nonetheless benefit patients in general, are covered within the definition. Other similar activities might include administrative positions within hospital systems or independent physicians' associations that involve oversight of patients beyond those of the group practice.

Response: It does not appear to us that the activities listed by the commenter would particularly benefit group practice patients, except possibly in a very attenuated way. (The answer might change if the group itself was contracted to perform these ''outside'' tasks.) Therefore, we would generally not regard them as patient care services performed for the group. Instead, they might qualify as patient care services provided outside of the group. For example, the physician could be supervising residents in a hospital while the residents treat patients, the volunteer activities might involve treating indigent patients, or the administrative work could involve

overseeing the efficient delivery of care to patients.

If the physician furnishes patient care services exclusively within the group, then whatever services he or she furnishes should constitute the full range of that physician's routine patient care services. If the physician furnishes patient care services both inside and outside of the group, then the services for the group's patients should be comparable in scope to those provided outside of the group setting. Any of a physician's services that do not involve caring for patients should not affect this test. For example, if a physician teaches medicine outside of the practice, but does not oversee patient care, we would not expect that the physician would also be performing teaching services as part of his or her group services.

5. The ''Substantially All Test''

The Existing Law: Under the definition of a ''group practice'' in section 1877(h)(4)(A)(ii) of the Act, substantially all of the services of the physician members must be provided through the group and billed under a billing number assigned to the group, and amounts so received must be treated as receipts of the group. In § 411.351, we interpreted ''substantially all'' to mean at least 75 percent of the total patient care services of the group practice's members. We promulgated special rules for group practices located solely in HPSAs and for physician members' time spent providing services in HPSAs.

The Proposed Rule: We proposed measuring patient care services (using the same definition of ''patient care services'' applied in the full range of services test described above) by the ''total patient care time'' each member spends on these services. We concluded that patient care time was the most straightforward and least burdensome method for measuring a physician's patient care services, but we solicited comments on other viable methodologies. Again, this test ensures that physicians who are members of the group practice are economically bound to the group for other than DHS referrals and are not just members of the group for purposes of profiting from DHS referrals.

The Final Rule: We are promulgating this test as proposed in our January 1998 proposed rule, except as discussed in this preamble. As proposed in our January 1998 proposed rule, the ''substantially all test'' could be measured based on the member physician's actual time spent performing patient care services, whether performed inside or outside the group practice. Having reviewed the comments regarding alternative methods for meeting the test, we are amending the ''substantially all test'' to allow group practices greater flexibility. While ''actual time spent'' remains the default standard, group practices may adopt alternative measures, provided those measures are reasonable, fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), uniformly applied over time, verifiable, and documented. Independent contractors and leased employees are not defined under the final rule as members of the group; therefore, their services need not be counted for purposes of complying with the ''substantially all test.''

Comment: Many commenters appreciated our expansion of the definition of patient care services to include services that benefit group patients in general or the group practice itself, but suggested that group practices be allowed to adopt alternative methods for measuring compliance with the 75 percent ''substantially all test,'' depending on the particular circumstances of the group and the most reasonable manner available for the group. These commenters pointed out that many physicians do not maintain time records and to do so would create an unnecessary administrative burden. Additionally, some commenters believe that it would be difficult or misleading to calculate the exact number of patient care hours as we suggested in the proposed regulations because many full-time physicians tend to work more than 40 hours per week. (Data submitted by a major physician trade association reflected that the ''average'' physician works 57.9 hours a week, with 53.2 hours spent on patient care activities). For example, one physician in a practice may work a full-time schedule of 40 hours per week for the group and another 60 hours per week; it would be inconsistent to count both as furnishing the same 100 percent of their time to the practice. Alternatively, a physician may work a full 40-hour week at his or her practice and then an additional 20 hours at a hospital or clinic. To count this physician as working only two-thirds time for the group, based on a straight calculation of hours, would be unreasonable. One commenter thought that the regulations should establish a presumption that 40 hours per week of patient care time for physicians equals 100 percent of such time for purposes of calculating the 75 percent ''substantially all test''; any hours spent beyond 40 hours on professional patient care time would fall outside of the 75 percent ''substantially all test.'' Some groups expressed a preference for using relative value units (RVUs) to measure patient care services, while others preferred a revenue based calculation or a test based on patient encounters furnished and billed through the group. One commenter thought that the ''patient care time'' standard was ambiguous and not objectively verifiable, since physician timekeeping often does not account for time spent on activities not involving direct patient care.

Response: We are persuaded that it would be appropriate to permit group practices additional flexibility in measuring compliance with the ''substantially all test'' based on their unique circumstances. The ''actual time spent'' standard described in the preamble of the January 1998 proposed rule remains the default standard. Group practices that employ that standard can be assured that they are appropriately measuring ''patient care services.'' As we noted in the January 1998 proposed rule, we are not requiring that physicians use detailed time sheets or time cards; in most cases, appointment calendars, personal schedules, billing records, or other existing sources will be sufficient to establish the time spent on patient care services. Group practices may adopt alternative means of satisfying the ''substantially all test,'' provided the means used are (1) reasonable, (2) fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), (3) uniformly applied over time, and (4) verifiable. The data used to calculate compliance with the ''substantially all test'' and supporting documentation must be made available to the Secretary upon request.

Comment: Several commenters sought clarification whether the 75 percent ''substantially all test'' for patient care services is measured based on total patient services across all specialities in a group or whether it is measured on a specialty-by-specialty basis.

Response: Section 1877(h)(4)(A)(ii) of the Act provides that a group practice is a legally organized entity ''for which substantially all of the services of the physicians who are members * * * are provided through the group * * *.'' In § 411.351, we interpreted ''substantially all'' to mean at least 75 percent of the total patient care services of each of the group practice's members. It is our view that a group practice should aggregate all of the patient care services that each of its members provides, both inside and outside of the practice, including all varieties of patient care services, to determine whether 75 percent of those

services are furnished through the group. However, any services that are provided by a group through independent contractors would not be figured into the test. The test is designed to demonstrate that the activities of each member are conducted through the group. Services performed by independent contractors would have no bearing on this measure.

Comment: One commenter sought clarification in applying the 75 percent rule to new group practices that may be owned by, or employ, part-time physicians who are practicing elsewhere during the group's initial 12-month start-up period. In some cases, these groups will not meet the group practice definition during the start-up period.

Response: We agree with the commenter that some accommodation should be made for new group practices. Nothing in the statutory language precludes such accommodation. Accordingly, the final regulations provide that during the ''start up'' period for a new group practice (not to exceed 12 months), a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the ''substantially all test'' as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This ''start up'' provision does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

Comment: A commenter related the following scenario: A specialist provides professional services for a hospital outpatient under a contract with the hospital that allows a hospital employee to perform the technical component of the service. The specialist reassigns his or her payments for the professional services to the hospital. The hospital then bills Medicare for a global payment that includes the professional and technical components. Under this arrangement, the hospital pays the specialist a contractual amount for the professional component. The commenter requested that we explicitly permit the professional component of these types of services to be counted as part of the 75 percent requirement for purposes of the ''substantially all test,'' even though the hospital and not the group practice bills Medicare for the specialist's services. Alternatively, commenters recommended that we change the two compensation exceptions that deal with hospitals (located in regulations in §§ 411.357(g) and (h)) to exclude compensation paid to a physician for professional services.

Response: We agree that a group practice should be able to count the professional component of services provided by a member physician under a global payment when calculating the ''75 percent of patient care services requirement'' for purposes of the ''substantially all test,'' even though the hospital actually bills Medicare directly for the physician services. We regard the ''substantially all test'' as designed to guarantee that a physician is providing a substantial amount of his or her own services through the group practice. If the group's business includes providing professional services to another entity, which, in turn, pays the group for those services, it is our view that these are services that should count as services a physician provides through the group. We are, therefore, interpreting the requirement that substantially all of a physician's services be provided through the group and be billed ''under a billing number assigned to the group'' and amounts so received treated as receipts of the group to include any physicians' professional services billed by a group under any group billing number regardless of the payer of the services, provided the receipts are treated as receipts of the group. In other words, the phrase ''billed under a billing number assigned to the group'' in section 1877(h)(4)(A)(ii) of the Act does not refer exclusively to Medicare or Medicaid billing numbers.

Comment: Several commenters objected to the proposed regulation because they believe it would require groups to bill under a group billing number and would force physicians in a group to bill individually when a patient has been seen in the hospital.

Response: While we are somewhat unclear as to the commenters' concern, we see nothing in these regulations that affects how group practice physicians bill for services provided to their own patients seen in a hospital.

6. The ''Seventy-Five Percent Physician-Patient Encounters Test''

The Existing Law: Under section 1877(h)(4)(A)(v) of the Act, physician members of a group practice must personally conduct at least 75 percent of the group practice's patient encounters (measured per capita, not by time). The test ensures that the group practice is a legitimate medical practice and not primarily a business for the provision of lucrative ancillary services.

The Proposed Rule: The proposed rule would exclude independent contractors or leased employees from the test because they would not be considered members of the group.

The Final Rule: We are promulgating this test as proposed in our January 1998 proposed rule.

Comment: A commenter requested confirmation that *bona fide* employed physicians count for purposes of the 75 percent physician-patient encounters test.

Response: As discussed in section VI.C.3 of this preamble, members of a group practice include employed physicians. Thus, patient encounters by *bona fide* employed physicians count for purposes of the 75 percent physician-patient encounters test.

7. Unified Business Test

The Existing Law: For purposes of the group practice definition, section 1877(h)(4)(A)(iii) of the Act requires that ''the overhead expenses of and the income from the group practice are distributed in accordance with methods previously determined.''

The Proposed Rule: In our January 1998 proposed rule, we proposed exercising our discretion under section 1877(h)(4)(vi) of the Act to impose an additional standard under the definition of group practice that would require groups to be a ''unified business.'' Our purpose was to ensure that group practices are substantially integrated business operations and that their allocation of group expenses and income to members reflect this. Absent a unified business test, we are concerned about the development of sham groups that are formed primarily for the purpose of profiting from self-referrals, but not for other, *bona fide* purposes. Thus, in the proposed regulations, we interpreted section 1877(h)(4)(A)(iii) of the Act as requiring that the group's overhead expenses and income be distributed according to methods that are—

- Determined prior to the time period during which the group has earned the income or incurred the costs, and
- Distributed according to methods indicating that the group practice is a unified business.

We indicated that the methods must reflect ''centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise.''

The Final Rule: The statute requires that the overhead expenses of, and income from, the group practice be distributed in accordance with methods ''previously determined.'' Unlike the January 1998 proposed rule, which interpreted ''previously determined'' as meaning before the group earned the income or incurred the cost, the final rule treats a distribution methodology as ''previously determined'' if it is determined prior to receipt of payment for the services giving rise to the

overhead expense or producing the income. Apart from this limitation, the rule does not prevent group practices from adjusting their compensation methodologies prospectively as frequently as they desire (subject to the restrictions on the distribution of DHS revenues in section 1877(h)(4)(B)(i) of the Act).

Commenters were nearly uniform in their criticism of the proposed unified business test, claiming that it invalidated many *bona fide* and common group practice compensation structures and discouraged beneficial integration of group practices. Reflecting these comments, Phase I of this rulemaking retains the general unified business test, but offers groups considerable additional flexibility in satisfying the requirement. Importantly, Phase I of this rulemaking permits many forms of cost center and location-based accounting, provided that compensation formulae with respect to DHS revenues otherwise meet the requirements of the law. To meet the unified business test, a group practice must be organized and operated on a bona fide basis as a single integrated business enterprise with legal and organizational integration. Essential elements are: (1) Centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities (including budgets, compensation, and salaries); (2) consolidated billing, accounting, and financial reporting; and (3) centralized utilization review (for example, utilization review conducted on a group-wide basis). We designed the rule to preclude group practice status for loose confederations of physicians that are group practices in name, but not operation. As adopted in Phase I of this rulemaking, the unified business test sets general parameters indicative of integration, but does not dictate specific compensation practices. Compensation, with respect to DHS, is subject to separate limitations described in these regulations.

Comment: Many commenters objected to our proposal to interpret the phrase ''previously determined'' to mean that the methodology for setting group members'' compensation must be fixed before the group has earned the income or incurred the costs of providing the designated health care services. One commenter stated that this proposed interpretation would overly restrict a group practice's ability to adjust physician compensation periodically to reflect a physician's contribution to the group practice or to pay discretionary bonuses. Some commenters observed that groups have traditionally used ad hoc compensation systems that allow groups to ''wait and see how the year goes.'' These systems afford groups flexibility to deal with business realities as they occur without, in the commenters' view, increasing the risk of self-referral compensation. In lieu of our proposed ''prior to incurrence'' rule, a number of commenters favored a ''prior to distribution'' rule. One commenter recommended coupling a ''prior to distribution'' rule with a requirement that distributions not relate to the volume or value of Medicare or Medicaid DHS referrals and that distributions not be retroactively adjusted in a manner that establishes a relationship between compensation and referrals. Another commenter suggested that ''previously determined'' be interpreted to mean that the compensation formula must be reported at the same time groups report their financial relationships to us.

Response: It is a statutory requirement that a group's compensation methodology be determined in advance. Unrestricted ad hoc compensation systems would allow groups to compensate physicians directly based on the number of designated health care services referrals they generate—the very conduct the statute is intended to prohibit. A ''prior to distribution'' rule would be circular, since any distribution scheme would be determined prior to the distribution. We agree, however, that groups should have some flexibility in designing and implementing compensation systems that are responsive to changing circumstances. It is our understanding that most groups operate on a cash basis. In the final rule, we are requiring that group practices determine the methodology for distributing overhead expenses of, and income from, the provision of designated health care services prior to the receipt of payment for those services. The methodology may be determined at any time until payment has been received, even if the income has been earned or costs incurred. This rule permits groups to adjust their methodologies *prospectively* as often as they deem appropriate. We believe Phase I of this rulemaking provides groups with sufficient flexibility to respond to business realities, while complying with the statutory requirement that the distribution system be ''previously determined.''

Section 1877(h)(4)(A)(iv) of the Act prohibits a physician member of the group from being compensated in a manner that takes into account the volume or value of DHS referrals, except as provided in section 1877(h)(4)(B)(i) of the Act. Thus, a compensation method that directly relates to the volume or value of Medicare referrals or is retroactively adjusted would violate section 1877(h)(4)(A)(iv) of the Act.

Comment: A commenter asked whether a group practice can distribute unexpected income which, by its nature, was not ''previously'' part of the group's distribution methodology. The commenter cited as an example a group practice opening a new site without specifically determining in advance how revenues or profits would be distributed to group members.

Response: We are unclear as to the circumstances under which a group practice would open a new office without considering distribution of the revenues or profits from that new office. We see no reason to deviate from the ''prior to payment'' rule established in these regulations for ''unexpected income.''

Comment: Although many commenters generally recognized the appropriateness of precluding group practice status for groups that are merely confederations of independent, unintegrated medical groups, many commenters expressed concerns about the unified business requirement promulgated in the proposed regulations. First, commenters questioned our legal authority to graft this new condition onto the statutory group practice definition. Second, commenters expressed the view that the unified business standard as proposed would have a chilling effect on legitimate group practices and discourage beneficial integration. Of particular concern was the perception that the regulations would completely prohibit or unduly complicate the group practices' use of profit and cost center or location-based accounting and distribution of expenses and income. In this regard, many commenters argued that site-specific or specialty-specific accountability encourages efficient management of expenses and practice patterns and eliminates a ''free rider'' problem that impedes cost effective integration, which groups find increasingly important with the growth of managed care. One commenter, representing a physician practice management company, noted that one reason groups prefer cost center accounting is that many physicians in newly-acquired group practices want to minimize changes in income levels they have historically realized; cost center accounting facilitates more absolute integration over time.

Instead of barring cost center or location-based accounting and distribution of expenses and income, commenters encouraged us to rely on

other indicators of integration. One commenter suggested that we could address our concern about loose confederations of groups by revising the rule to require that a group practice be organized and operated on a *bona fide* basis as a single business enterprise integrated legally and operationally. According to the commenters, while many legitimately integrated medical practices allow their satellite offices to make day-to-day, local practice decisions, almost all significant decisions, such as hiring and firing physicians and approval of annual operating budgets, are made by the entire practice's governing body. Moreover, the costs of central business activities such as billing, collections, managed care contracting, and purchasing of some products and services are, in most cases, shared by all practice sites, either per capita or based on a generally applied formula. Commenters offered numerous suggestions as to relevant criteria for ascertaining that a group practice is a unified business.

Response: Our statutory authority to impose a unified business test resides in section 1877(h)(4)(A)(vi) of the Act, which vests in the Secretary the ability to impose additional standards on group practices by regulation. Upon further consideration, we agree with the commenters that our proposed unified business test was too restrictive. The unified business test was designed to ensure that group practices are substantially integrated business operations and that their distribution of group expenses and income to members reflects this. The unified business test guards against the development of sham groups formed primarily for the purpose of profiting from self-referrals.

Phase I of this rulemaking, described in detail above, retains the general unified business test, but offers groups considerable flexibility in satisfying the requirement. Importantly, many forms of cost center and location-based accounting are permitted, provided that compensation formulae with respect to the distribution of DHS revenues otherwise meet the requirements of the law.

Comment: A physician trade association asked whether groups that compensate their physicians under more than one methodology can qualify as a ''unified business.'' This issue is especially significant for larger groups that have expanded through the acquisition of other existing group practices, each of which may have negotiated different compensation arrangements. Typically, the methodology for compensating each new physician who joins the group is set in advance, based on the negotiations between the parties and approved by the governing body of the acquiring group (or an authorized committee of the governing body).

Response: We see no impediment in the revised unified business test to groups like those described in the comment from qualifying as a unified business. In order to qualify for group practice status, the group would have to meet all of the other group practice tests, including the limitations on compensation based directly or indirectly on the volume or value of referrals and the restrictions on profit sharing and productivity bonuses. (See the discussion in section VI.C.8 of this preamble.)

Comment: One commenter expressed concern that the proposed unified business standard could be interpreted to prevent integrated medical practices from compensating their physicians on an individual collections minus expenses basis. A commenter urged that groups be allowed to compensate physicians based on their own productivity (excluding any revenue or expense related to the group's DHS), and that it be permissible to calculate the physician's compensation by allocating to the physician all of the physician's direct medical expenses of practice (including, but not limited to, for example, malpractice insurance, continuing medical education, space cost, supplies) and his or her pro rata share of general overhead not based on any volume or value of his or her referrals (for example, administrative and management costs). Similarly, another commenter stated that it is common practice for groups to compensate their members according to formulae that take into account ''office profits,'' described as collected revenues attributable to a physician's medical services performed by that physician or personnel under his supervision, not including revenues for DHS or direct or indirect expenses of that physician.

Response: Distribution of group practice revenues derived from DHS is subject to the compensation rules set forth at § 411.352. With respect to income derived from other sources, groups are free to divide it in any manner they choose, provided they can demonstrate that they are a unified business under the three principles discussed in section VI.C.7 of this preamble. Depending on individual circumstances, we believe that most of the compensation methodologies described in the comment can be accommodated within the parameters of the revised unified business test.

Comment: One commenter questioned whether a total contingent revenue pool, distributed on an aggregate basis (after subtracting expenses that include allocated central practice or ''home office'' expenses) to the practitioners in a given branch or satellite office of a larger statewide PC according to a predetermined formula, would meet the requirements of the unified business test.

Response: Whether the described scheme fits in the exception would depend on whether the three factors described above are present. The scheme would also have to meet the requirements of sections 1877(h)(4)(A)(iv) (compensation for group members) and (h)(4)(B)(i) (profits and productivity bonuses) of the Act with respect to DHS. In particular, under the overall profit shares rule as set forth in Phase I of this rulemaking, as discussed in section VI.C.8, overall profit shares must be derived from aggregations of the entire practice or a component of the practice consisting of at least five physicians.

Comment: A commenter sought clarification as to whether the financial allocation requirements under the unified business standard apply solely to the DHS furnished by the group or whether they extend more broadly to all health care services furnished by the group. The commenter viewed the latter approach as beyond the statutory authority, which applies only to furnishing DHS, and as contrary to our own statements in the preamble to the proposed regulations that compensation arrangements for services that are not DHS are outside the scope of the statute and regulations.

Response: The Congress specifically conferred on the Secretary in section 1877(h)(4)(A)(vi) of the Act authority to impose additional standards in the definition of a group practice. For the limited purposes of establishing that a group practice is a unified business, we believe it is appropriate to consider the group practice's methods of distributing revenues derived from all sources, not just DHS. Group practices can distribute the revenues from services that are not Medicare-DHS in any manner they wish. However, if the payment methods do not indicate a unified business (or indicate a business that is unified solely with respect to the provision of DHS), the group may not qualify as a group practice under section 1877(h)(4) of the Act and § 411.352. Compensation paid to a physician creates a compensation arrangement within the meaning of § 411.354, even if the compensation relates only to services that are not DHS. Absent an applicable exception (for

example, the in-office ancillary services or employee exceptions), this compensation arrangement triggers the self-referral prohibition as to any of the physician's referrals of DHS.

8. Profit Shares and Productivity Bonuses

The Existing Law: In general, the statute provides that a physician who is a member of the group may not be compensated directly or indirectly based on the volume or value of his or her referrals of DHS. In addition, the statute provides that a ''physician in a group practice'' may receive shares of overall profits of the group or a productivity bonus based on services personally performed or incident to such personally performed services, provided the share or bonus is not determined in a manner that is directly related to the volume or value of referrals by such physician. In other words, group practice compensation formulae that are only indirectly related to the volume or value of referrals of DHS are permissible.

The Proposed Rule: We proposed to interpret the statute to mean that productivity bonuses could only relate to work personally performed by the physician that results from referrals from other physicians in the group, and could not relate (directly or indirectly) to work that results from self-referrals or DHS referrals to other physicians and other office personnel. Thus, we said that a physician could only receive compensation for his or her own DHS referrals through the aggregation that occurs as part of the overall sharing of group profits. As to the overall sharing of profits, we indicated that profits must be aggregated at the group level and not at a component level.

The Final Rule: In section IV of this preamble, we provide an overview of the physician compensation provisions of section 1877 of the Act. In general, a group practice can segregate its DHS revenues from its other revenues for purposes of compensating physicians; section 1877 of the Act applies only to a practice's DHS revenues. Generally, this income is likely to comprise a relatively small portion of the total revenues of most practices.

Under Phase I of this rulemaking, group practices may pay member physicians and independent contractors who qualify as ''physicians in the group'' productivity bonuses based directly on the physician's personal productivity (including services incident to such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual, Part 3), but may not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else. The statute also permits group practice members (and independent contractors who qualify as ''physicians in the group'') to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of DHS referrals generated by the physician that are provided by someone else. We are defining ''share of overall profits'' as meaning a share of the entire profits of the entire group or any component of the group that consists of at least 5 physicians derived from DHS.

Under the statutory scheme, revenues generated by DHS may be distributed to group practice members and physicians in the group in accordance with methods that indirectly take into account DHS referrals. In general, we believe a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's DHS referrals (regardless of whether the services are personally performed). Phase I of this rulemaking contains specific methodologies that describe compensation methods that are deemed to be indirect. In addition, Phase I of this rulemaking contains additional provisions that allow group practices to devise other reasonable indirect compensation methodologies.

The distribution methods for overall profit shares are as follows:

1. A per capita (that is, per physician) division of the overall profits.

2. A distribution of DHS revenues based on the distribution of the group practice's revenues attributable to services that are not DHS payable by Federal or private payers.

3. Any distribution of DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group practice.

The methods for productivity bonuses are as follows:

1. A productivity bonus based on the physician's total patient encounters or RVUs.

2. A productivity bonus based on the allocation of the physician's compensation that is attributable to services that are not DHS payable by Federal or private payers.

3. Any productivity bonus that includes DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group.

Comment: Many commenters objected to our proposed interpretation of the statute to mean that productivity bonuses can relate only to work personally performed that results from referrals from other physicians in the group, and cannot relate (directly or indirectly) to work that results from self-referrals. Commenters protested that this interpretation barred any compensation based on a physician's personal productivity for self-referred DHS and was, therefore, contrary to clear statutory intent. Several commenters explained that our interpretation would produce anomalous results in some circumstances. For example, an internist refers a patient with a gastrointestinal complaint to a gastrointestinal specialist, and the specialist evaluates the patient at an initial visit. The specialist subsequently performs an endoscopy on the patient. Under the proposed January 1998 regulations, the endoscopy would be a self-referral by the specialist, and the specialist could not receive a productivity bonus for performing the endoscopy. However, if the specialist referred the patient to another physician in the same group practice for the endoscopy, the specialist could receive compensation indirectly based on that endoscopy. Thus, in the commenter's view, the rule creates a disincentive to perform services and an incentive to refer (which may be contrary to good patient care and not cost effective). The commenter further noted that specialists who perform substantial amounts of DHS are disadvantaged by the proposed interpretation because they cannot be rewarded for personal productivity, while their counterparts, for whom the performance of DHS is a less significant part of their practices, can.

Commenters suggested an interpretation that would permit productivity bonuses for DHS personally performed by the referring physician, but not for DHS referred to others. The commenters generally requested that the final rule allow group practices to compensate members of the group based upon the volume or value of DHS, so long as the services are personally performed by the physician or are incident to the physician's personally performed services. One commenter noted that ancillary services (including ''incident to'' services) performed for one's own patients are more ''personal'' to the ordering or

supervising physician than are services he or she performs on colleagues' patients. Commenters also complained that our proposed interpretation would lead to disparate treatment of solo and group practitioners, since solo practitioners could receive the profits from personally performed DHS that they self-refer, whereas group practitioners could not. One commenter thought that this discrepancy would make solo practitioners reluctant to join group practices, thereby discouraging beneficial market integration.

Finally, some commenters noted that many group practices have insufficient information technology systems to track whether a service performed by a physician resulted from a self-referral or a referral from another physician. Commenters asserted that our proposed interpretation would impose a significant additional administrative burden on those groups.

Response: In light of the comments, the changes we have made to our interpretation of the definition of a ''referral'' and the volume or value standard, and our further review of the statutory language, we are persuaded that our proposed interpretation of the scope of productivity bonuses was unnecessarily restrictive. Accordingly, we have revised the regulation to make clear that group practices may pay member physicians (and independent contractors who qualify as ''physicians in the group'') productivity bonuses based directly on the physician's personal productivity (including services ''incident to'' such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050, ''Services and Supplies,'' of the Medicare Carrier's Manual (HCFA Pub. 14–3), Part 3—Claims Process), but may not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else.

Comment: Commenters sought clarification about the treatment of productivity bonuses for ''incident to'' services. One commenter observed that according to long-standing regulatory policies, ''incident to'' services are services that are an incidental although integral part of a physician's personal, professional service to a patient. Thus, in the commenter's view, there cannot be a referral for ''incident to'' services in any ordinary sense, since what the ancillary service provider does is part of the physician's service itself. Several commenters expressed their belief that one purpose of the productivity bonus provision was to allow physicians to receive ''credit'' for ''incident to'' services in their compensation. One commenter pointed out that it would be hard to exclude ''incident to'' services in the calculation of productivity bonuses since claim forms typically do not indicate who performed the ''incident to'' service (that is, whether the service was performed by the supervising physician or someone else). Other commenters interpreted the statutory reference as equating ''incident to'' services with ''in-office ancillary'' services. Under this view, commenters asserted that the statutory language plainly allows productivity bonuses based indirectly on the volume or value of the physician's in-office ancillary services and opposed our proposed interpretation that prohibited any compensation based on referrals for in-office ancillary services.

Response: We agree with the essence of these comments with respect to group practices. Under the final regulation, group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services, provided the ''incident to'' services comply with the requirements of section 1861(s)(2)(A) of the Act and section 2050, ''Services and Supplies,'' of the Medicare Carrier's Manual (HCFA Pub. 14–3), Part 3—Claims Process, and any subsequent or additional HHS rules or regulations affecting ''incident to'' billing. This means that the ''incident to'' services must be directly supervised by the physician. In other words, the physician (or another clinic physician in the case of a physician-directed clinic) must be present in the office suite and immediately available to provide assistance and direction. Moreover, the person performing the ''incident to'' services must be an employee of the physician (or the physician-directed clinic). We believe that the heightened supervision requirement imposed by the ''incident to'' rules provides some assurance that the ''incident to'' DHS will not be the primary incentive for the self-referral. However, we may revisit the issue of compensation tied to ''incident to'' services if we find that abuses are occurring, especially in the area of physician-directed clinics.

Comment: We received a number of comments seeking clarification related to the methods of paying compensation that are not *directly* based on the volume or value of referrals. First, commenters urged that we allow pooling of revenues that are not DHS revenues, because such revenues are not governed by the statute. Second, a number of commenters objected to our position in the proposed regulations that overall profits are not profits that ''belong only to a particular specialty or subspecialty group'' (even if the group is located in several States or has several locations in one State) because ''the narrower the pooling, the more likely it will be that a physician will receive compensation for his or her own referrals.'' Commenters urged that pooling at practice sites with more than a few physicians should not result in any individual's compensation being directly related to the volume or value of his or her referrals, even if DHS revenues are included in the pool. Commenters generally advocated that we allow pooling if at least three physicians are included in the pool and the distribution formula is not related to DHS referrals. Third, commenters offered a variety of suggestions about how to calculate ''indirect'' compensation. For example, one commenter suggested that compensation be considered ''indirect'' if the referrals have no mathematical effect on compensation. Others suggested that compensation be considered ''indirect'' if it is based on per capita calculations, RVUs, patient encounters, hours worked, ownership shares in the practice, or seniority.

Response: First, we are persuaded that we should permit some additional flexibility related to the distribution of shares of overall profits by group practices. Thus, we are defining a ''share of overall profits'' to mean a share of the entire profits derived from DHS of the entire group practice or any component of the group that consists of at least five physicians. We believe a threshold of at least five physicians is likely to be broad enough to attenuate the ties between compensation and referrals. We are rejecting the suggestion to use a threshold of three physicians because we believe that the lesser threshold would result in pooling that would be too narrow and, therefore, potentially too closely related to DHS referrals. Second, we recognize the need for clear guidance as to appropriate indirect compensation methodologies. For that reason, we are including in Phase I of this rulemaking methodologies that describe compensation distribution systems that we deem to be indirect. In other words, if a group practice wants absolute assurance that its productivity bonuses or profit shares are not directly related to referrals, the group practice may employ one of the regulatory methodologies set forth in § 411.352 of the regulations. Group practices are not required, however, to use these methods. The regulations clarify that

other methods (including distributions based on ownership interests or seniority) are acceptable so long as they are reasonable, objectively verifiable, and indirectly related to referrals. These compensation methods should be adequately documented and supporting information must be made available to the Secretary upon request. Under this latter ''catch-all'' provision, the group practice essentially bears the risk of noncompliance.

Comment: Several commenters sought clarification as to whether an independent contractor could be compensated under the productivity bonus provision of the group practice definition as a ''physician in the group'', even though independent contractors are not members of the group.

Response: Independent contractors who qualify as ''physicians in the group'' under the provisions of § 411.351 can receive productivity bonuses under section 1877(h)(4)(B)(i) of the Act.

Comment: One commenter sought clarification as to how providers should treat capitation payments that cover more than one service for purposes of allocating profit shares and productivity bonuses.

Response: In general, we believe that capitation payments are not likely to lead to increased utilization. Parties may use any reasonable allocation method with respect to such payments.

Comment: On page 1691 of the preamble to the January 1998 proposed regulations, we explained our view that ''profits should not be pooled and divided between group members so that they relate directly to the number of designated health services for Medicare or Medicaid patients physicians referred to themselves or the value of those self-referrals (such as a value based on complexity of the service).'' A commenter objected to the parenthetical statement, asserting that barring consideration of the complexity of the service is contrary to other Medicare payment provisions, which take into consideration the level of training necessary to perform, and difficulty of, certain procedures.

Response: Given our revised interpretation, we believe the parenthetical statement (''such as value based on complexity of the service'') is no longer relevant to these regulations. Group practice members can be compensated directly based on their personal productivity (that is, the fruits of their own labors), but not on their productivity in generating referrals. They may only be compensated based indirectly on DHS referrals to other physicians or providers. So long as the compensation is only indirectly related to the volume or value of DHS referrals, we believe it makes little difference if the value of the DHS referrals reflects the complexity of the services.

Comment: A commenter sought clarification that when a physician is a member of a group practice and is also an employee of the group practice, his or her compensation may be determined under the group practice's rules without regard to the employee exception.

Response: We agree that when a physician is a member of a group practice, his or her compensation need only comply with the group practice rules. Meeting the group practice definition allows physicians in the group to refer within the group under the in-office ancillary services exception or the physicians' services exception. However, nothing prevents a physician and group practice from using the employee exception instead. It is important to remember that referrals of DHS are only permitted if an exception, such as the in-office ancillary services exception or employee exception, applies.

Comment: Several commenters were confused by our use of the terms ''revenues'' and ''profits'' throughout the preamble to the January 1998 proposed regulations. For example, on page 1691 we stated that ''the referring physician can receive a portion of the group's overall pooled *revenues* from these services as long as the group does not share these *profits* in a manner that relates directly to who made the referrals for them.'' Similarly, on the same page we stated that we ''regard 'over-all *profits* of the group' to mean all of the profits *or revenues* a group can distribute in any form to group members * * *.'' These commenters requested that the terms ''profits'' and ''revenues'' be used in a manner that is consistent with their generally accepted meanings or that definitions of the terms be provided in the regulations.

Response: We agree that the terms ''revenues'' and ''profits'' were used inconsistently in the January 1998 proposed regulation. In Phase I of this rulemaking, we have endeavored to use those terms consistent with their generally accepted meanings.

9. Group Practice Attestations

The Existing Law: In § 411.360 of the August 1995 final rule covering referrals for clinical laboratory services, we included the requirement that group practices provide their carriers with a written statement annually to attest that, during the most recent 12-month period, 75 percent of the total patient care services of group members was furnished through the group. Any group that intended to meet the definition of a group practice in order to qualify for one of the exceptions provided in the regulations was required to submit the required attestation to its carrier by December 12, 1995. On December 11, 1995, we published in the **Federal Register**, at 60 FR 63438, a final rule that delays the date by which a group of physicians must file an attestation statement. The December final rule amended § 411.360 to require that a group that intends to meet the definition of a group practice must submit an attestation statement to its carrier no later than 60 days after the group receives attestation instructions from its carrier. The preamble to the December rule points out that a group could regard itself as a group practice in the interim period before it receives attestation instructions, provided the group believes that it meets the definition of a group practice under § 411.351.

The Proposed Rule: The proposed rule retained § 411.360, as amended by the December 1995 final rule, with several minor changes.

The Final Rule: We have eliminated the attestation requirement.

Comment: One commenter suggested that group practice attestations not be required until 1 year after final regulations are published, while another recommended 1½ years after publication of the final rule. Otherwise, the commenter stated, a group practice would have to attest to membership requirements for the previous 12 months, without benefit of having had the membership requirements published in advance and an opportunity to comply with them.

One commenter also questioned whether we will actually use the information gained from group practice attestations. The commenter believes that imposing a civil money penalty for failing to submit an attestation is overly harsh when compared to the minimal benefit that may be derived from the attestations. The commenter recommended that we remove the requirement for attestations or, at least, reduce the related penalties.

Response: We agree with the commenters. After reviewing the attestation requirement, we have concluded that it would impose an unwarranted burden on group practices. We intend instead to allow groups to treat the information they need to establish that they are a group practice in the same manner as any information a furnishing entity must provide to us under the reporting requirements in § 411.361. In order to make reporting requirements more manageable, we

intend to develop a streamlined ''reporting'' system that does not require entities to retain and submit large quantities of data. We believe instead that entities should retain enough records to demonstrate, in the event of an audit, that particular relationships are excepted under the law. In the case of the in-office ancillary services exception and physician services exceptions in section 1877(b)(1) and (b)(2), an entity may need to establish that the services it provided were referred by members of a genuine group practice. Thus, a group should retain records that demonstrate that it meets the requirements in section 1877(h)(4) of the Act and § 411.351.

D. Prepaid Plans (Section 1877(b)(3) of the Act)

The Existing Law: In the August 1995 final rule, we interpreted the prepaid plan exception, section 1877(b)(3) of the Act, as creating an exception to the general prohibition on referrals for services furnished by certain prepaid health plans to their enrollees, including Federally qualified health maintenance organizations (HMOs) or prepaid health care organizations with a contract or agreement under sections 1876 or 1833(a)(1)(A) of the Act, or organizations participating in demonstration projects under section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972. The August 1995 final rule incorporated section 1877(b)(3) into the regulations in § 411.355(c), concerning clinical laboratory services furnished by an organization (or its contractors or subcontractors) to enrollees of these prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization).

The Proposed Rule: The January 1998 proposed rule proposed an additional exception for services provided by organizations participating in the Medicaid program that are analogous to those cited in section 1877(b)(3) of the Act, including managed care organizations (MCOs) that contract with Medicaid under section 1903(m) of the Act, entities operating under a demonstration project under section 1115(a) of the Act, prepaid health plans contracting with a State, and health insuring organizations furnishing services as managed care contractors. (Although we proposed including demonstration projects under section 1115(a) of the Act in the preamble of the January 1998 proposed rule at 63 FR 1697, they were not listed in proposed § 435.1012 as the result of a drafting error. We will include a technical correction for this section in Phase II of this rulemaking.) In addition, the rule proposed to extend the protection of section 1877(b)(3) of the Act to providers, suppliers, and other entities that provided services to enrollees of the protected organizations under contracts with these organizations, either directly or indirectly.

The January 1998 proposed rule also took a number of other positions that directly affected physicians' financial relationships with managed care entities and plans other than Medicare and Medicaid managed care plans. Most importantly, we proposed that MCOs would be deemed to be *entities ''furnishing'' DHS* provided by other entities if the MCOs billed Medicare for DHS provided to Medicare patients by providers and suppliers pursuant to a contractual arrangement with the MCOs (other than services under a plan protected under section 1877(b)(3) of the Act or other protected arrangement).

The preamble of the January 1998 proposed rule also discussed whether an MCO network physician could refer private fee-for-service patients to other physicians and providers that were participating in an MCO network. According to the preamble, a physician who had a contractual relationship with an MCO could refer a nonenrolled Medicare fee-for-service patient for a designated health service to another physician who also had a contract with the MCO provided that the physician to whom he or she referred the patient was not otherwise affiliated with the MCO. However, if the same physician referred the same patient to a laboratory owned by the MCO, the general prohibition would apply and the financial arrangement between the MCO and the physician would have to qualify for an exception. In other words, the referring physician would not have a financial relationship with the second physician, but he would have one with the laboratory. Of course, the arrangement could still be protected under the personal service arrangements exception.

The M+C interim final rule (63 FR 35066) amended § 411.355(c) of the regulations covering referrals for clinical laboratory services to include a new paragraph (5). This paragraph added to the list of prepaid plans coordinated care plans (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with us under section 1857 of the Act. Section 1877(b)(3) of the Act was also amended by section 524(a) of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, enacted on November 29, 1999), which added a new paragraph (E). Paragraph (E) includes in the prepaid plans exception services referred by a physician to an organization that is an M+C organization under Part C that is offering a coordinated care plan described in section 1851 of the Act [42 U.S.C. 1395w–21(a)(2)(A)] to an individual enrolled with the organization.

The Final Rule: Virtually all commenters agreed with our decision to interpret the prepaid plan exception to protect any referrals by physicians for DHS covered by the listed Medicare managed care plans to an MCO that has a Medicare managed care contract or any entity, provider, or supplier furnishing these services under a contract or subcontract with the MCO, directly or indirectly (''downstream providers''). Several commenters asked that we amend the regulations text to reflect the interpretation. We are amending the text of § 411.355(c) to make clear that downstream providers are protected.

We are not finalizing at this time the proposed new § 435.1012 (Limitation on FFP related to prohibited referrals), paragraph (b) (Exception for services furnished to enrollees on a predetermined, capitated basis), which would have extended the protection to certain prepaid plans under Medicaid. A number of commenters agreed with our proposed exception for services provided by organizations analogous to those cited in section 1877(b)(3) of the Act. These and other commenters suggested that a number of other Medicare or Medicaid arrangements be included in the exception, including M+C coordinated care plans, Medicaid managed care plans under the BBA 1997, Medicaid managed care entities operating under a waiver pursuant to section 1115 of the Act, any demonstration project approved by us, including primary care case management programs (PCCMs) and managed long term care programs (MLTCs), programs of all-inclusive care for the elderly (PACE), capitated Medicare demonstration programs (including social health maintenance organizations (SHMOs), the Medicare subvention demonstration, and the Medicare prepaid competitive pricing demonstration). The commenters pointed out that although the preamble to the January 1998 proposed rule had proposed to include some of the above programs in the new exception, they had not been referenced in the regulations text. We agree with the commenters on adding the Medicaid organizations that are analogous to those

in section 1877(b)(3) of the Act as described in the January 1998 proposed rule and on some of the other listed areas; however, we will address Medicaid managed care, and potentially other suggestions related to Medicaid managed care raised by the commenters, in Phase II of this rulemaking.

We are also revising in Phase I of this rulemaking the proposed regulations in response to comments expressing concerns about the impact of the January 1998 proposed rule on commercial and employer-provided managed care arrangements. First, we are creating a new compensation exception for remuneration pursuant to a *bona fide* ''risk-sharing arrangement'' between a physician and a health plan for the provision of items or services to enrollees of the health plan, even when such an arrangement does not fall within existing statutory exceptions. (We note that the new risk-sharing arrangement exception differs from the shared risk exception to the anti-kickback statute at §§ 1001.952(t) and (u); for example, unlike the anti-kickback exception, the new exception under section 1877 of the Act contains no conditions related to the volume of Medicare beneficiaries enrolled in the health plan or the quantification of the financial risk.) Physicians generally are compensated for services to managed care enrollees in one of three ways, the first two of which do not vary based on the volume or value of referrals: (1) A salary in the case of a physician who is an employee, (2) a ''fee-for-service'' contractual arrangement under which the physician assumes no risk, or (3) a risk-sharing arrangement, under which the physician assumes risk for the costs of services, either through a capitation arrangement, or through a withhold, bonus, or risk-corridor approach. The first two compensation arrangements are eligible for the statutory exceptions for *bona fide* employment relationships and personal service arrangements, while the third is potentially eligible for the new risk-sharing arrangement exception we are creating in this final rule in § 411.357(n).

Second, we are revising the definition of ''entity'' in § 411.351 to permit physician ownership of network-type HMOs, MCOs, provider-sponsored organizations (''PSOs'') and independent practice associations (''IPAs''). Specifically, we are clarifying the definition of *entity furnishing DHS,* to provide that a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

We believe these changes address the comments we received from the commercial and employer-sponsored managed care plans.

Comment: While commenters uniformly welcomed the broad protection given in the January 1998 proposed rule to referrals for services covered by Medicare prepaid health plans, several commenters stated that we interpreted several provisions of the statute in a manner that, taken together, would severely limit MCOs' use of physician incentive plans, whether under commercial or Medicare contracts. The commenters strongly objected to our statement that the prohibition on DHS referrals applies to referrals to entities that arrange for the furnishing of the DHS to Medicare or Medicaid patients by contracting with other providers, whenever the arranging entity also bills Medicare or Medicaid for the services. (*See* 63 FR 1706.) The commenters explained that this view, when joined with our interpretation of section 1877(e)(3)(B) of the Act (the physician incentive plan provision in the personal service arrangements exception), could effectively preclude the use of risk-sharing arrangements with physicians in any health plan, including commercial plans. The commenters explained the problem as follows:

- Physicians that participate in a managed care network will have a compensation arrangement with the MCO for payment for services to the MCO's enrollees. That payment arrangement will create a financial relationship for purposes of section 1877 of the Act. (Even participation in the network of an organization eligible for the Medicare prepaid plans exception would not entirely avoid this result, since the prepaid plans exception only protects referrals for DHS furnished to beneficiaries enrolled under the Medicare contract). Many of these compensation arrangements use withholds, capitation, bonuses, or other methodologies that take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician.
- Most, if not all, commercial or employer-provided group health plans offered by MCOs include some enrollees who are Medicare beneficiaries. Typically, these enrollees either are retired employees who have expanded benefits under an employer-provided plan (in which case Medicare is the primary insurer and the employer plan secondary) or are beneficiaries who have group health plan coverage based on current employment status (in which case the employer plan is the primary insurer and Medicare secondary). Even the MCOs that have Medicare managed care lines of business that are protected by the prepaid plans exception commonly have commercial lines of business that include some Medicare beneficiaries who are not enrolled under the organization's Medicare contract (that is, Medicare's payment is made on a fee-for-service basis under the traditional Medicare program).
- When a Medicare beneficiary is enrolled in a commercial or employer-provided group health plan, Medicare often pays for services provided by the plan to the beneficiary/enrollee on a fee-for-service basis. In such a case, if Medicare is the primary insurer, it will reimburse the provider according to the same provisions as any fee-for-service provider; if Medicare is the secondary insurer, it will pay based on a formula prescribed by law.
- Generally, if an enrollee of a commercial or employer-provided health plan has primary coverage under Medicare, the network physician or supplier (not the MCO) will submit the claim to Medicare directly, since Medicare is the primary insurance. However, many, if not all, such MCOs will occasionally bill Medicare for services provided by network providers to these Medicare beneficiaries. Most often, the purpose of the billing is to coordinate with Medicare when Medicare is the secondary payer. Occasionally, the MCOs may bill Medicare as the primary payer; for example, when there has been a recent change in beneficiary status, such as when a beneficiary's group health plan coverage ceases being based on current employment status because the beneficiary retires and Medicare becomes the primary insurer. Of course, MCOs may bill and be paid by Medicare only where the MCO meets the criteria

for direct payment, assignment of benefits or reassignment of benefits. (*See* §§ 424.73 and 424.80 of these regulations.)

• Accordingly, under the interpretation in the January 1998 proposed rule, a physician in the MCO network will be deemed to make a referral to the MCO for the provision of a DHS whenever the physician refers an enrollee of the MCO's commercial plan who also happens to be a Medicare beneficiary to another network provider for DHS. (Referrals of enrollees in any of the excepted prepaid plans would not be affected since they are not referrals of DHS by virtue of the prepaid plans exception.)

• As a result, unless all of the MCO's payment arrangements with network physicians, regardless of the line of business, fit in an exception under section 1877 of the Act, the referral of any enrollee with primary or secondary coverage under Medicare for a designated health service would be prohibited.

• The only kinds of physician compensation arrangements that are protected by the personal service arrangements exception in the proposed rule are (1) fixed per-service payments based on fair market value (for example, discounted fee-for-service arrangements) or (2) payment arrangements that incorporate risk-sharing elements, such as bonuses or withholds, provided they qualify as a physician incentive plan under section 1877(e)(3)(B) of the Act.

• However, many payment arrangements in commercial or employer-provided health plans contain risk-sharing elements that take into account a physician's referrals or the volume of services provided but that do not currently comply with the physician incentive plan regulations. These arrangements would have to be restructured. Moreover, even if restructured, the physician incentive plan regulations contain a number of requirements that would require revision if they are to be implemented with respect to non-M+C plans.

• Lastly, in the preamble to our January 1998 proposed rule, we stated that section 1877(e)(3)(B) of the Act only applied to compensation arrangements directly between the ''entity'' (that is, the MCO) and the physician; any compensation arrangements between a physician and party other than the MCO, such as an IPA or other subcontractor, would not qualify as a physician incentive plan.

The commenters asserted that the net effect of our interpretation in the January 1998 proposed rule of when an entity was furnishing DHS provided by another entity would be the total disruption of commercial and employer-provided health plans. The only way an MCO could assure that its physician compensation arrangements were in compliance with section 1877 of the Act would be to restructure all its payment arrangements to pay all physicians for all lines of business on a discounted fee-for-service basis. Moreover, since the MCOs and, in many instances, subcontractors such as IPAs would also be entities furnishing DHS, any physician ownership of such entities would be a prohibited investment interest unless an appropriate exception applied.

Response: Nothing in the legislative history suggests that section 1877 of the Act was intended by the Congress to require the wholesale restructuring of commercial managed care arrangements with physicians. Accordingly, we are making two major changes to the January 1998 proposed rule that we believe will address the commenters' concerns. First, as noted above, we are creating a new compensation exception for *bona fide* risk-sharing arrangements between a health plan and providers for services provided to plan enrollees that do not otherwise qualify for an existing statutory exception. This exception will address concerns related to the prohibition on compensation arrangements in section 1877 of the Act. Second, we are revising our definition of ''entity'' to clarify that a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier. We believe this change should address the possible adverse impact on physician ownership of MCOs and IPAs.

With respect to the first change, we are creating in § 411.357(n) a new exception under section 1877(b)(4) of the Act for *bona fide* risk-sharing compensation arrangements between an MCO and a physician (either directly or indirectly through a subcontractor) for services to enrollees of a health plan. (For purposes of the new exception, we are incorporating the definitions of ''health plan'' and ''enrollees'' found in § 1001.952(l).) The vast majority of Medicare and Medicaid beneficiaries in managed care plans are either in M+C plans or Medicaid managed care plans, both of which are already required to comply with the physician incentive plan regulations. As to the relatively small number of Medicare beneficiaries in commercial or employer-sponsored plans that do not necessarily satisfy physician incentive plan requirements, or otherwise qualify for an existing exception under section 1877 of the Act, we are not currently aware of any fraud or abuse involving the Medicare program or Medicare beneficiaries arising from physician risk-sharing arrangements in these commercial or employer-provided health plans. Given the potential for the unintended disruption of these arrangements described by the commenters and the administrative need for ''bright line'' rules, we believe the new physician risk-sharing arrangements exception to section 1877 of the Act is needed. We will continue to monitor these arrangements for possible abuse and, if necessary, may revisit the issue in the future.

With respect to the second change, the potential impact of the January 1998 proposed rule on physician ownership of MCOs and IPAs was attributable to our interpretation that an MCO or IPA was an entity furnishing DHS provided by another entity whenever it billed for the services provided by another entity pursuant to a contract with the MCO or IPA. As noted above, in response to the above comment, we are amending the definition of ''entity'' in § 411.351 to clarify that a health plan, or an MCO, PSO, or IPA with which the plan contracts directly or indirectly for services to plan enrollees, will only be considered to be furnishing DHS when the health plan, MCO, PSO, or IPA furnishes the services directly (that is, through an employee), or otherwise is the entity to which we make payment for the DHS, either directly or upon assignment on the patient's behalf, or pursuant to a valid reassignment under the Medicare rules and regulations to (i) an employer pursuant to § 424.80(b)(1), (ii) a facility pursuant to § 424.80(b)(2), or (iii) a health care delivery system, including clinics, pursuant to

§ 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees). We are providing further that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

We believe this change should allow for physician ownership of most types of network IPAs and MCOs. Ownership or investment interests in entities, including MCOs and IPAs, that provide DHS directly would still be prohibited (absent an applicable exception). Moreover, any indirect financial arrangements between physicians and the entities directly providing DHS would need to be analyzed to ensure there are no prohibited indirect financial relationships. For example, an MCO may have an investment interest in a lab, and a physician that contracts with that MCO may refer a Medicare beneficiary to that lab for DHS, for which Medicare is billed on a fee-for-service basis. While the MCO would not be considered to be furnishing the DHS for purposes of section 1877 of the Act, the lab in which the MCO has an investment interest would be furnishing DHS. Since the physician has a financial relationship with the MCO, and the MCO has an investment interest in the lab, there may be an indirect financial relationship that would then have to fit in an exception, most likely the indirect compensation arrangement exception or the risk-sharing arrangement exception. (See discussion in section III.A of this preamble.)

Finally, in Phase II of this rulemaking, we expect to amend the January 1998 proposed regulations for the personal service arrangements exception to reflect that risk-sharing compensation arrangements between entities downstream of a Medicare MCO can qualify as physician incentive plans within the meaning of section 1877(e)(3)(B) of the Act; this interpretation is consistent with our interpretation in the Medicare physician incentive plan regulations in §§ 422.208 and 422.210.

We believe these provisions will address the commenters' concerns.

Comment: One commenter stated that even if the MCO itself directly provided DHS pursuant to a physician referral, the MCO's compensation arrangement with the referring physician should not be deemed to take into account the volume or value of referrals for DHS unless the risk-sharing arrangement was based in part on the utilization or cost of the DHS provided directly by the MCO.

Response: For purposes of the personal service arrangements exception, the compensation from the MCO does not take into account ''the volume or value of referrals or other business generated between the parties'' unless the compensation varies based on the volume or value of the MCO's business that is generated by the physician. (See the discussion of ''volume or value'' and ''other business generated'' in section V of this preamble.) We have addressed the issue of physician risk-sharing arrangements (including, but not limited to, capitation payments, bonuses, and withholds) with commercial and employer-sponsored managed care plans by creating a new exception under section 1877(b)(4) of the Act for *bona fide* risk-sharing compensation arrangements between an MCO and a physician (either directly or indirectly through a subcontractor) for services to enrollees of a health plan.

Comment: Several commenters were unclear whether physicians who participate in a managed care network would be prohibited from referring Medicare fee-for-service patients who are not enrollees of a managed care plan for DHS to other providers in the managed care network simply because both providers had contractual relationships with the same MCO.

Response: Physicians who participate in a managed care network would not be prohibited from referring Federal fee-for-service patients who are not enrollees of a managed care plan for DHS to other providers with contractual relationships with the same MCO solely on the basis of the parallel contractual arrangement with the MCO. In other words, two physicians who contract with an MCO do not have a financial relationship with each other for purposes of section 1877 of the Act on that basis alone. However, they may have other financial relationships (including indirect financial relationships) that would bar their referrals (in the absence of an applicable exception).

Comment: Several commenters asked that we create an exception for nongovernment plans that include any significant cost-sharing elements. This exception would be similar to the exception in the Federal anti-kickback statute for risk-sharing arrangements.

Response: As discussed earlier, we have created a new exception for *bona fide* risk-sharing compensation arrangements between health plans and physicians. The exception we are creating is substantially broader than the shared risk exception in the Federal anti-kickback statute.

Comment: Another commenter asked that we create an exception to permit public hospitals to enter into incentive arrangements with physician groups for the treatment of the public hospital's patients. One commenter also suggested that we create an exception for commercial managed care product lines that serve fewer than 20 percent Medicare patients as part of the group and that are not marketed directly to Medicare patients.

Response: As described above, we have created a risk-sharing arrangements exception in § 411.357(n) that should address the commenter's concern regarding commercial managed care arrangements. With respect to the request to create an exemption for public hospital patients, the commenter provided no explanation of the types of arrangements proposed to be excepted, and we see no reason why these arrangements could not be subject to abuse.

Comment: Two commenters asked us to clarify that the prepaid plan exception protects any DHS provided to any enrollee of any plan (including commercial or employer-sponsored plans) offered by an entity that either is a Federally-qualified HMO or has a contract under one of the programs cited in section 1877(b)(3) of the Act. One of the commenters asked us to clarify that services to persons covered under an employer self-funded health plan that is administered by an entity with a qualified contract under section 1877(b)(3) of the Act and uses the MCO's network of providers would also be exempt under the prepaid plan exception.

Response: We believe that the Congress intended that the exception in section 1877(b)(3) of the Act protect only the financial arrangements for services to enrollees of the prepaid plans identified in section 1877(b)(3). We see no basis for concluding that because an entity has one contract covering a specific population, there is any protection against abusive relationships in other product lines. Accordingly, we are clarifying the regulation to state that the protection extends only to financial arrangements for the services to enrollees of the plans specifically identified in the regulation and does not protect enrollees in any other plan or line of business furnished by the MCO or to which the MCO provides administrative services.

Comment: One commenter suggested that we use the definition of health plan and enrollee set forth in the managed

care safe harbor regulations to the Federal anti-kickback statute, § 1001.952 (Exceptions), paragraph (l) (Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans). The commenter stated that it was unclear from the preamble of the January 1998 proposed rule whether employees covered by an employer self-funded plan that utilized a commercial insurer to administer the plan would be considered ''enrollees'' of the commercial insurer for purposes of the prepaid plan exception and for application of the physician incentive plan provision of the personal service arrangements exception.

Response: We agree that employer self-funded plans should be able to qualify for protection of their physician compensation arrangements. We believe the new risk-sharing compensation exception will address the commenters' concerns. For purposes of the new exception, we are incorporating the definitions of ''health plan'' and ''enrollee'' from the safe harbor regulations for certain health plans set forth in § 1001.952(l)(2). This definition would result in equal treatment for self-funded plans and insured plans.

Comment: One commenter requested that we interpret section 1877 of the Act to ''grandfather'' any pre-existing managed care arrangements. The same commenter asked that we broaden the exception for personal service arrangements to protect quality-related incentive plans that take into account the volume or value of DHS referrals.

Response: The statutory provisions clearly envision their application to managed care plans. Accordingly, a blanket ''grandfather'' provision for these plans is inappropriate. With respect to the request for protection of quality-related incentive plans, the commenter did not provide any details as to the kind of incentives being described. We do not perceive any impediment in the regulation that would preclude basing compensation on quality measures unrelated to the value or volume of DHS referrals or other business generated by the physician. However, absent further clarification, we are not inclined to protect any arrangement that takes into account referrals or business generated by the physician.

Comment: One commenter requested that we create a new exception for payer-directed services. According to the commenter, in managed care arrangements, the payer is the party that directs the referrals for DHS and not the physician who is contractually obligated to refer in the network. Another commenter stated that, in the managed care environment, our proposed presumption in the January 1998 proposed rule that a physician has referred a patient to an entity with which he or she has a financial relationship if the patient, in fact, procures the services from this entity—even if there is no order or written plan of care—should not be applied.

Response: We believe the changes we have made to accommodate various financial relationships between managed care organizations and physicians should address the referral issues in the managed care environment.

Comment: Several commenters asked that the provision in the group practice definition permitting employees to receive productivity bonuses be expanded to permit remuneration based on volume or value of DHS referrals if the arrangement complies with the physician incentive plan regulations as permitted in the personal service arrangements exception. The commenters noted that in some arrangements, the employed physicians have separate contracts with the MCO, while in others the contract is between the MCO and the group, making it important to permit the group to incentivize its employed physicians. According to the commenters, employers should have at least as much latitude in structuring their compensation arrangements with employees as with independent contractors. The commenters suggested that the group practice definition already expressly permits productivity bonuses indirectly tied to referrals—a greater concern since overutilization is the primary concern of section 1877 of the Act. In light of that provision, one commenter believes it is incongruous to prohibit physician incentive plan arrangements that discourage utilization if they comply with the physician incentive plan regulations.

Response: We agree that, at least in the managed care environment, there is little reason to impose a more restrictive requirement on compensation arrangements between a group and its employees than on arrangements between the group and its independent contractors. However, this concern is only one aspect of the broader relationship between the group practice, personal service arrangement, and *bona fide* employment relationship exceptions that is discussed in sections IV and VI.C.8 of this preamble.

Comment: Several commenters asked that we clarify the reporting obligations of plans that are not technically subject to the physician incentive plan regulations, since they are not Medicare or Medicaid managed care plans (or M+C plans), but that are complying with the regulations to qualify their financial arrangements with physicians for the personal service arrangements exception in section 1877 of the Act.

Response: The various reporting requirements associated with, or triggered by, the regulation will be addressed in Phase II of this rulemaking.

VII. New Regulatory Exceptions

This section describes new regulatory exceptions that are not in the statute, but which appeared in the January 1998 proposed rule or that we have created in response to comments and pursuant to statutory authority conferred on the Secretary. The new exceptions discussed here include: Academic medical centers, fair market value, and non-monetary compensation up to $300 (and medical staff benefits). Other new exceptions described elsewhere in this preamble include: Implants in an ASC (§ 411.355(e); section VIII.J of this preamble); EPO and other dialysis-related drugs (§ 411.355(f); section VIII.L of this preamble); preventive screening tests, immunizations, and vaccines (§ 411.355(h); section VIII.L of this preamble); risk-sharing arrangements (§ 411.357(n); section VI.D of this preamble); compliance training programs (§ 411.357(o); section VII.C of this preamble); eyeglasses and contact lenses (§ 411.355(i); section VIII.J of this preamble); and indirect compensation arrangements (§ 411.354(c)(3); section III.A of this preamble).

A. Academic Medical Centers

The Existing Law: Section 1877(h)(4) of the Act contains a special rule for faculty practice plans. The rule provides that ''in the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) [the definition of ''group practice''] shall be applied only with respect to the services provided within the faculty practice plan.''

Several commenters to the August 1995 final rule suggested that we create a separate exception for faculty practice plans, since these plans are typically involved in complex organizational arrangements that do not fit comfortably—or at all—in the group practice definition. At the time of the August 1995 final rule, we rejected the suggestion for a new exception based on

our view that the personal service arrangements exception and the employment exception would provide physicians in academic medical settings with appropriate protection under section 1877 of the Act.

The Proposed Rule: We proposed no changes.

The Final Rule: We have revisited our prior position. The comments have persuaded us that academic medical practices raise numerous questions under section 1877 of the Act that are not adequately addressed by existing exceptions.

Though the relevant provision in the group practice definition is somewhat obscure, we believe it demonstrates congressional intent to address the circumstances of physicians practicing in academic medical settings. We do not believe, however, that the core problem of how to treat academic medical practices under section 1877 of the Act is amenable to resolution under the group practice definition; the problem lies elsewhere.

Academic medical settings often involve multiple affiliated entities that jointly deliver health care services to patients (for example, a faculty practice plan, medical school, teaching hospital, outpatient clinics). There are frequent referrals and monetary transfers between these various entities, and these relationships raise the possibility of indirect remuneration for referrals. The exceptions under section 1877 of the Act do not easily apply. For example, faculty practice plan physicians refer patients for ancillary services to entities that are outside of (and not wholly owned by) the single legal entity in which they conduct their medical practices (that is, the ''group practice''), but with which they may have direct or indirect compensation relationships (for example, part of the physician's compensation may come from an affiliated medical school or teaching hospital). These referrals typically will not qualify under the in-office ancillary services exception, and it may be difficult to structure compensation relationships for faculty practice plan physicians that securely fit in the personal service arrangements exception because the physician's compensation often comes directly or indirectly from several separate sources.

Having reviewed the comment letters addressing the problems facing faculty practice plans under section 1877 of the Act, we believe the fundamental need of faculty practice plans is for a separate compensation exception for payments to faculty of academic medical centers that takes into account the unique circumstances of a faculty practice, including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings. Therefore, we are using our regulatory authority under section 1877(b)(4) of the Act to create a separate compensation exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangement poses essentially no risk of fraud or abuse. This exception is in addition to other exceptions that may apply in particular circumstances; an arrangement need only fit in one available exception.

The conditions applicable under the new exception in § 411.355(e)(1)(i) are that the referring physician is a *bona fide* employee of a component of an academic medical center on a full-time or substantial part-time basis, is licensed to practice medicine in the State, has a *bona fide* faculty appointment at the affiliated medical school, and provides either substantial academic or substantial clinical teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. The purpose of this condition is to ensure that protected physicians are truly engaged in an academic medical practice. The exception does not apply to payments to physicians who provide only occasional academic or clinical teaching services or who are principally community rather than academic medical center practitioners.

Under the new exception in § 411.355(e)(1)(i)(A), a ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation. For purposes of this exception, an academic medical center may have some, but need not have all, of these components. As indicated in the preceding provision, however, the minimum requirements are a medical school, a faculty practice plan, and a hospital.

Under the new exception in § 411.355(e)(1)(ii), the total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated within the academic medical center. As with the corresponding provisions in the personal service arrangements, employee, and fair market value exceptions, this provision requires that remuneration to physicians be for *bona fide* services provided by the physicians and not for referrals. In determining fair market value for services in an academic medical practice, we believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace. Nothing in this regulation is intended to preclude productivity bonuses paid to academic medical center physicians on the basis of services they *personally* perform.

Under the new exception in § 411.355(e)(2), the ''academic medical center'' for purposes of this section shall consist of—(1) an accredited medical school (including a university, when appropriate); (2) an affiliated faculty practice plan that is a nonprofit, tax-exempt organization under section 501(c)(3) or (c)(4) of the Internal Revenue Code (or is a part of such an organization under an umbrella designation); and (3) one or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members, and where a majority of all hospital admissions are made by physicians who are faculty members. This provision ensures that the exception only protects physician compensation in genuine academic medical settings. This new exception reflects our view that the predominant purpose of an academic medical center is to teach new physicians and to run medical practices that support the teaching mission.

To fit within the new exception in § 411.355(e)(3), the academic medical center must meet the following conditions:

- All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service. This provision ensures that the academic medical center is *bona fide* and that transfers of funds are not inappropriate payments of indirect compensation for referrals. We believe that patient care is integral to an academic medical center's community service mission.
- The relationship of the components of the academic medical center must be set forth in a written agreement that has

been adopted by the governing body of each component. This provision requires a *bona fide* affiliation between the medical center components.

• All money paid to a referring physician for research must be used solely to support *bona fide* research. We are concerned that research funding could be used to disguise additional payments for referrals. We are including this provision to ensure that money earmarked (intended or designated) for research is used solely for research purposes.

Under the new exception in § 411.355(e)(4), the referring physician's compensation arrangement must not violate the anti-kickback statute (section 1128B(b) of the Act) and billing and claims submission must be proper. As with all exceptions created under section 1877(b)(4) of the Act, this provision is necessary to ensure that the arrangement poses no risk of fraud or abuse.

Comment: As noted above, commenters pointed out that the structure of faculty practice plans can be very complicated; for example, physicians in a faculty practice plan may be compensated by one entity, but conduct their medical practice through a separate entity and order laboratory and other ancillary services from additional related entities (for example, the teaching hospital, the university's research laboratory for highly specialized testing, in-office laboratories within the faculty departments that may or may not be incorporated as professional corporations). As a result, arrangements between and among the various sub-entities of such faculty practice plans can raise a number of issues under section 1877 of the Act. In particular, the question arises whether each separate legal entity and relationship among legal entities must meet an exception under section 1877 of the Act.

Commenters appealed for a separate exception for faculty practice plans, insisting that faculty practice plans pose a minimal risk of abuse under section 1877 of the Act. First, they asserted that physicians in faculty practice plans are less likely to make abusive referrals than their more entrepreneurial counterparts in private practice because they practice in a setting that focuses on academic pursuits and patient care at affiliated teaching hospitals and clinics. Second, they stated that many faculty practice plans include not-for-profit organizations that are regulated under IRS rules that forbid private inurement and private benefit.

Response: As explained in the introduction to this section of the preamble, we have revisited the issue of academic medical practices and are persuaded that academic medical practices present unique concerns under section 1877 of the Act that warrant a separate exception. Our new exception is described in the introduction. We believe that faculty practice plans will pose little risk of fraud or abuse under the conditions set forth in the new exception. We are not persuaded that physicians in faculty practice plans are necessarily less economically-motivated than their private practice counterparts or that regulation under IRS rules, though beneficial, is sufficient to prevent fraud or abuse.

Comment: A commenter suggested that the group practice definition and the requirements of the in-office ancillary services exception or personal service arrangements exception should be applied only at the level of the ''umbrella'' organization (that is, the organization that encompasses all the physicians within the faculty practice plan) for the entire faculty practice, thus obviating the need for each legal entity within the same academic setting to meet the provisions of section 1877 of the Act.

Response: In light of the new exception, we see no need to create new rules under existing exceptions for faculty practice plans. Parties may use the new exception or existing exceptions, depending on their individual circumstances.

Comment: As an alternative to a separate exception for faculty practice plans, one commenter urged that faculty practice plans be permitted to have independent contractors as ''members'' during the time they are providing services to the group. The commenter expressed the view that this solution would be preferable to requiring the faculty practice plan to employ such individuals.

Response: In light of the new compensation exception for physicians in faculty practice plans, we see no need to alter the definition of ''member of the group'' for academic medical practices. The definition of a ''group practice'' expressly includes a ''faculty practice plan,'' and any faculty practice plan that fits in the definition is a ''group practice'' for purposes of section 1877 of the Act.

Comment: A commenter observed that under section 1877(b)(4)(B)(ii) of the Act a faculty practice plan qualifies as a group practice based solely on the services provided and revenue generated by the participating physicians within the faculty practice plan, regardless of the outside activities of those physicians. The commenter sought clarification that the converse would also be true, that time and revenue allocable to a physician's faculty practice would not count against the ''group practice'' status of his outside medical group.

Response: The outside medical group must qualify for group practice status under the tests described in section 1877(h)(4) of the Act (§ 411.352 of the regulations) and in this preamble at VI.C. Time and revenue allocable to a physician's faculty practice would be treated as all other outside time and revenue for purposes of those tests. In other words, such time and revenue would be treated no differently than time group practice physicians who are not in faculty practice plans spend supervising residents or conducting research.

B. Fair Market Value (§ 411.357(l))

The Proposed Rule. This proposed rule created an exception for compensation relationships that are based upon fair market value and meet certain other criteria. This exception is available for compensation arrangements between an entity and either a physician (or immediate family member) or any group of physicians (even if the group does not meet the definition of group practice set forth in § 411.351), as long as the compensation arrangement—

• Is in writing, is signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;

• Covers all of the items and services to be provided by the physician (or immediate family member) to the entity or, alternatively, cross refers to any other agreements for items or services between these parties;

• Specifies the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;

• Specifies the compensation that will be provided under the arrangement, which has been set in advance. The compensation must be consistent with fair market value and not be determined in a manner that takes into account the volume or value of any referrals (as defined in § 411.351), payment for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated between the parties;

• Involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and

• Meets a safe harbor under the anti-kickback statute or otherwise is in compliance with the anti-kickback provisions in section 1128B(b) of the Act.

The Final Rule: Except for the revisions described below, Phase I of this rulemaking adopts the proposed regulation. The revisions include:

• Elimination of the requirement that the written document cross-reference other agreements between the parties.

• Revision of the ''set in advance'' language to conform the exception to other exceptions in which that language appears. ''Set in advance,'' as used in the fair market value exception, will have the uniform meaning described in section V of this preamble and § 411.354(d) of the regulations.

• Revision of § 411.357(l)(3) to conform to our uniform interpretation of the volume or value standard in § 411.354(d) (discussed at section V of this preamble).

• Revision of the proposal in § 411.357(l)(5) that required ''compliance with'' the anti-kickback statute. Under the final regulations, the compensation arrangement must—(1) not violate the anti-kickback statute, (2) comply with a statutory or regulatory anti-kickback safe harbor, or (3) have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 (Advisory Opinions of the OIG) of this chapter. In addition, billing and claims submission must be proper.

• Addition of a provision to mirror section 1877(e)(3)(A)(vi) of the Act, which clarifies that the services performed under the agreement cannot involve the counseling or promotion of a business arrangement or other activity that violates Federal or State law. While we believe this condition is implied throughout the statute, we are conforming the new fair market value exception to the Congress's inclusion of this same standard in the personal service arrangements exception.

Comment: Several commenters objected to the requirement that an arrangement must meet a safe harbor under the anti-kickback statute or otherwise be in compliance with the anti-kickback provisions in section 1128B(b) of the Act. First, commenters pointed out that the anti-kickback statute is an intent-based statute that prohibits certain knowing and willful conduct, whereas section 1877 of the Act is not based upon intent. In addition, one commenter was concerned that a violation of the anti-kickback statute by one party would preclude both parties from using the fair market value exception. Thus, the innocent party who might be unaware of the other party's violation of the anti-kickback statute and relying on the fair market value exception could unknowingly violate section 1877 of the Act. Second, several commenters stated that few arrangements would meet the requirements necessary to obtain safe harbor protection under the anti-kickback statute. Therefore, such arrangements would be excepted from section 1877 of the Act only if they met the standard of being ''in compliance with the anti-kickback statute.'' These commenters were concerned that ''being in compliance with the anti-kickback statute'' was a nebulous standard that could only be accomplished with certainty by obtaining an OIG advisory opinion.

Response: In response to the concerns of commenters, we have revised § 411.357(l)(5) of the regulations to make it clear that for a compensation arrangement to qualify for the fair market value exception, it must meet one of the following criteria:

• It must not violate the anti-kickback statute.

• It must comply with a statutory or regulatory anti-kickback safe harbor.

• It must have been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 of this title.

This revision is both a clarification of the text set forth in the January 1998 proposed rule and an expansion of the types of arrangements that may qualify for the fair market value exception. In particular, we are changing the requirement from ''being in compliance with'' the anti-kickback statute to requiring that the arrangement not violate the anti-kickback statute. The revised language is more appropriate with respect to a criminal statute, such as the anti-kickback statute. In addition, since the broad statutory language of the anti-kickback statute technically covers some relatively innocuous commercial arrangements, and since the OIG has promulgated regulations granting safe harbor protection for some of these arrangements (§ 1001.952 of this title), we are revising the criteria to permit compensation arrangements that comply fully with a regulatory safe harbor. Arrangements that comply with the statutory exceptions at section 1128B(b)(3) of the Act also satisfy the new criteria. Finally, any compensation arrangement that has been approved by the OIG pursuant to a favorable advisory opinion issued in accordance with part 1008 of this title would meet the criteria of § 411.357(l)(5). (We caution, however, that only the requestor of an OIG advisory opinion may rely on the opinion for any purposes, including, without limitation, the fulfillment of this criteria. Therefore, all parties that intend to rely on the advisory opinion should be included as requestors.)

Finally, we address the scenario where only one party has the requisite intent (that is, acting knowingly and willfully) to violate the anti-kickback statute. In such a case, only the party with the requisite intent would have violated the anti-kickback statute. However, if both parties relied on meeting the ''not in violation of the anti-kickback statute'' standard to qualify for the fair market value exception, the anti-kickback statute violation would preclude the use of the fair market value exception to section 1877 of the Act and both parties would have violated section 1877 of the Act. Although we understand the dilemma, we believe that it would be unusual that only one party to a compensation arrangement would have the requisite intent for violation of the anti-kickback statute. If any *one* purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated. (See *United States* v. *Kats,* 871 F.2d 105 (9th Cir. 1989); *United States* v. *Greber,* 760 F.2d 68 (3d Cir.), *cert. denied,* 474 U.S. 988 (1985).) Also, if the ''innocent'' party knows that the compensation arrangement would violate the anti-kickback statute but for the lack of the requisite intent, that party should be aware of the risk he or she is facing and take action to ensure that prohibited payments are not made. In that situation, we would advise structuring the arrangement to fit within a safe harbor, if possible, or obtaining an OIG advisory opinion.

For a discussion on the differences between section 1877 of the Act and the anti-kickback statute, together with an analysis of the impact that the anti-kickback statute has on these regulatory exceptions, see section II of this preamble.

Comment: Some commenters requested clarification regarding whether services provided by an entity to a physician would fit within the fair market value exception. One commenter was confused by the fact that the preamble to the January 1998 proposed rule implied that the exception would cover any compensation arrangements based upon fair market value, but the rule itself implied that it only covered arrangements where the physician (or

immediate family member) provided items or services.

Response: This fair market value exception only covers items or services provided by a physician or any immediate family member to an entity. Depending on the facts, payments made by a physician to an entity for items or services furnished by the entity might qualify for the exception for payments by a physician which is set forth under § 411.357(i), provided that the compensation is consistent with fair market value and the payments are not specifically excepted under another provision in §§ 411.355 through 411.357.

Comment: One commenter requested clarification regarding whether this exception would be available if another exception could apply.

Response: In the preamble to the January 1998 proposed rule, we stated that parties involved in a compensation arrangement should use the fair market value exception if they have doubts about whether they meet the requirements in the other exceptions listed in § 411.357. We have reconsidered our position. The parties may use the fair market value exception even if another exception potentially applies. We believe that the safeguards against overutilization included in the fair market value exception are sufficient to cover various types of compensation arrangements, including some arrangements that are covered by other exceptions.

Comment: A couple of commenters expressed concern regarding the application of the fair market value exception to legitimate physician recruitment practices that do not otherwise qualify for exception under the physician recruitment exception set forth at § 411.357(e). One commenter was concerned that in order to meet the ''commercially reasonable'' and ''legitimate business purposes'' prerequisites, hospitals would be forced to obtain costly experts' reports regarding recruiting incentives provided in comparable situations. Another commenter sought clarification regarding whether the ''commercially reasonable'' prerequisite was based upon the specific business in which the parties are involved or business in general. This commenter was concerned that some arrangements (for example, loan forgiveness programs) might be commercially reasonable in the context of hospital/physician relationships, but might not be commercially reasonable from a general business perspective.

Response: Physician recruitment arrangements might be covered by this fair market value exception or the physician recruitment exception, depending on the specific facts involved. However, we recognize that many physician recruitment arrangements that offer ''extra'' payments to induce physicians to relocate will not be covered by the fair market value exception, because compensation offered for the physician's services exceeds the fair market value for such services. We will consider the comments on the recruitment exception in Phase II of this final rule.

With respect to determining what is ''commercially reasonable,'' any reasonable method of valuation is acceptable, and the determination should be based upon the specific business in which the parties are involved, not business in general. In addition, we strongly suggest that the parties maintain good documentation supporting valuation. Finally, with respect to difficult cases, the parties could seek an advisory opinion under section 1877 of the Act. (See § 411.370.) However, we cannot express opinions on whether compensation represents fair market value. (See § 411.370(c)(1).) For further discussion of ''fair market value'', see section VIII.B.3 of this preamble.

Comment: One commenter thought that it would be burdensome to require inclusion of all items and services provided by the physician (or immediate family member) or a cross reference to other pertinent agreements. First, the commenter noted that there may be no written agreement for certain *bona fide* employment arrangements. Therefore, if an immediate family member of a physician is employed by the entity and there is no written employment agreement, the physician's compensation arrangement with the entity could not satisfy this requirement of the fair market value exception. Second, the commenter stated that arrangements between an entity and a physician (or immediate family member) may change from time to time as a result of new arrangements, terminations, renewals, etc. Therefore, the list of other agreements would become outdated quickly. Third, the commenter asserted that the requirement duplicated the information that was already required under the reporting requirements. To rectify the foregoing problems, the commenter suggested that the exception should only require a reference to a master list of contracts that could be updated periodically. Finally, the commenter requested clarification regarding what contracts must be cross-referenced when there is a compensation arrangement between an entity and a member of a physician group practice. The commenter questioned, with respect to a contract between an entity and an immediate family member of a physician who is a member of a group practice, whether the contract must cross-reference arrangements between the entity and—(1) the group practice, (2) each member of that group practice, and (3) any family member of a member of the group practice.

Response: We agree that it is burdensome to require that the written agreement either cover all items and services to be provided by the physician or immediate family member to the entity, or cross refer to any other agreements for items or services between any of these parties. To alleviate this burden, we are eliminating the requirement that the agreement cross refer to any other agreements. Nevertheless, we note that cross-referencing other agreements and arrangements is a good practice and will enable contracting entities, as well as auditors, to review more efficiently the full scope of a physician's relationship to the entity. In cases where a physician or an immediate family member of a physician is employed by the entity and there is no written employment agreement, the commenter's conclusion that the physician's compensation arrangement with the entity could not satisfy this requirement of the fair market value exception is correct. Another exception, such as the employment exception, may apply, since it does not require a written agreement.

Comment: Some commenters were concerned that by requiring that the compensation not be related to the volume or value of program referrals, non-program referrals, or other business generated between the parties, we had undermined the usefulness of the fair market value exception, as well as many other exceptions which are subject to the same restriction. One commenter suggested that an arrangement should not pose a risk of abuse as long as the compensation does not reflect the volume or value of the physician's own referrals.

Response: For a discussion of the ''value or volume of referrals'' standard, refer to the discussion at section V of this preamble. We are conforming the language of the new fair market value exception to our uniform interpretation of the standard, which is discussed at section V of this preamble.

C. Non-Monetary Compensation up to $300 (and Medical Staff Benefits (§§ 411.357(k) and (m))

The Proposed Rule. Physicians and their immediate family members are often given noncash items or services that have a relatively low value and are not part of a formal, written agreement. For example, a physician might receive free samples of certain drugs or chemicals from a laboratory or free coffee mugs or note pads from a hospital. Although these free or discounted items and services fall within the definition of ''compensation arrangement,'' we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits. Therefore, we proposed a new exception, titled De Minimis Compensation, for compensation from an entity in the form of items or services that would not exceed $50 per gift and an aggregate of $300 per year. In addition, to qualify for the proposed exception, the entity providing the compensation would have to make it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services, and the compensation could not be determined in any way that would take into account the volume or value of the physician's referrals to the entity.

The Final Rule. Except for the revisions discussed below, the regulations in Phase I of this rulemaking are the same as the proposed rule:

- Changing the name of this exception from ''De Minimis Compensation'' to ''Non-Monetary Compensation Up To $300'' to avoid any unintentional implication that the dollar limits set forth in the exception are minimal or inconsequential in all circumstances. That is, although the $300 dollar limit may be relatively low when compared to the average physician's annual income, we believe the amount could be sufficient to induce referrals. However, we believe that the dollar limit, together with the other conditions of the exception, are sufficient to protect against abuse.
- Elimination of the $50 per gift limit. Therefore, if the other conditions of the exception are met, an entity can give a physician one noncash gift per year valued up to $300 or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed $300.
- Addition of a provision that precludes protection for gifts solicited by physicians to prevent physicians from making such gifts a condition or expectation of doing business.
- Elimination of the ''similarly situated'' standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated between the parties.
- Addition of a new exception (§ 411.357(m)) to allow certain incidental benefits of low value provided by hospitals to their medical staffs.

Comment: Several commenters argued that section 1877 of the Act does not apply to relationships between physicians and drug manufacturers, because a drug manufacturer is not an ''entity'' that furnishes health services to which a physician purchasing drugs makes a ''referral'' under section 1877 of the Act. Applying this interpretation, commenters concluded that free drug samples, free training, and other gifts (for example, pens, notepads, and other items) provided to physicians by drug manufacturers are not prohibited by section 1877 of the Act, and, therefore, do not need to qualify for any of the exceptions. Also, many expressed concern that, if section 1877 of the Act is interpreted as applying to physicians' relationships with drug manufacturers, then free drug samples and training provided to physicians by pharmaceutical companies would be prohibited, because they would exceed the proposed per gift and annual dollar limits of the *de minimis* exception. They reasoned that free drug samples should be exempt from section 1877 of the Act, because they are extensively regulated by Federal law that restricts their use and prohibits their sale, and, therefore, free drug samples pose little risk of abuse. They also stressed that free training given in connection with free samples should be exempt, because it is part of the sales effort which benefits patients, as well as physicians.

Response: We agree that drug manufacturers typically are not ''entities'' that furnish health services to which physicians purchasing drugs make ''referrals'' under section 1877 of the Act. (See section VIII.B of this preamble.) Therefore, as a general rule, neither free drugs, free training, nor gifts provided to physicians by drug manufacturers are prohibited by section 1877 of the Act. We caution, however, that free or discounted items or services provided by drug manufacturers to physicians must be scrutinized to ensure compliance with other applicable laws and regulations, including, without limitation, the anti-kickback statute and the Federal laws restricting the sale and distribution of drug samples, 21 U.S.C. § 353(c) through (d).

Comment: Many commenters expressed concern regarding the per gift and annual dollar limits. In particular, they stated that the dollar limits were so low that they precluded protection for many legitimate compensation arrangements. For example, many commenters were concerned that no protection would be provided for free or discounted benefits provided by a hospital for its medical staff. Commenters believe that free or discounted benefits (for example, free or discounted meals and refreshments, free or discounted parking, free continuing medical education or other training, free computer/Internet access, free laboratory coats, free or discounted malpractice insurance, free transcription of medical records, and free photocopying) would add up and exceed the dollar limits quickly. Concern was also expressed about the administrative burden of tracking the exact dollar amounts for benefits provided to each medical staff physician.

Finally, one commenter questioned whether, with respect to group practices, the dollar limit would apply to each individual member of the group or to the group as a whole. Another commenter suggested that the dollar limits should be indexed for inflation.

Response: First, we have added a new exception (§ 411.357(m)) for incidental benefits given to a hospital's medical staff members. The question of incidental benefits given by a hospital to members of its medical staff was addressed previously in the preamble to the January 1998 proposed rule at 63 FR 1713–1714. In particular, we noted that:

> Entities, such as hospitals, often provide physicians with certain incidental benefits, such as their malpractice insurance, or with reduced or free parking, meals or other incidental benefits. We believe the answer to this question hinges on the nature of any other financial relationship the physician has with the entity. For example, if a physician receives free ''extras'' such as malpractice insurance, parking, or meals while he or she serves as the entity's employee, then these extras might qualify as part of the compensation that the physician receives under a *bona fide* employment relationship, provided they are specified in the employment agreement. If the physician or entity can demonstrate that the extras constitute part of the payment that such entities typically provide to physicians, regardless of whether they make referrals to the entity, the extras constitute payment that

is consistent with fair market value, and that furthers the entity's legitimate business purposes. If an incidental benefit cannot meet the requirements under a statutory exception or the new general exception for compensation arrangements we have included in § 411.357(l), it might still meet the *de minimis* exception we have included in § 411.357(k) if it has limited value. We have also been asked about parking spaces that a hospital provides to physicians who have privileges to treat their patients in the hospital. It is our view that, while a physician is making rounds, the parking benefits both the hospital and its patients, rather than providing the physician with any personal benefit. Thus, we do not intend to regard parking for this purpose as remuneration furnished by the hospital to the physician, but instead as part of the physician's privileges. However, if a hospital provides parking to a physician for periods of time that do not coincide with his or her rounds, that parking could constitute remuneration.

We recognize that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the employment exception because most members of a hospital's medical staff are not hospital employees, and do not qualify for the fair market value exception because, to the extent that the medical staff membership is the only relationship between the hospital and certain physicians, there is no written agreement between the parties to which these incidental benefits could be added. While we still believe that medical staff incidental benefits could be structured in a way that would reward physicians for referrals and, thereby, lead to overutilization, we also recognize that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients. For example, free computer/Internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information. Consequently, we have added a new exception (§ 411.357(m)), which provides that medical staff incidental benefits are excepted from section 1877 of the Act, if the benefits in question are—

- Offered by a hospital to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties;
- Offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital and its patients;
- Provided by the hospital and used by the medical staff members only on the hospital's campus;
- Reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;
- Consistent with the types of benefits offered to medical staff members by other hospitals within the same local region or, if no such hospitals exist, by comparable hospitals located in comparable regions; and
- Of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each benefit must be of low value).

Regardless of compliance with the foregoing, we caution that medical staff incidental benefits should be reviewed to ensure compliance with other applicable laws and regulations, including, without limitation, the anti-kickback statute.

Medical staff incidental benefits that do not meet the foregoing conditions could constitute prohibited remuneration and, therefore, would be permitted under section 1877 of the Act only if an exception applies. For example, malpractice insurance offered by a hospital only to its emergency room physicians would not meet the foregoing conditions. Therefore, to be exempt from section 1877 of the Act, it would have to qualify for one of the exceptions. Malpractice insurance would not qualify for the exception for non-monetary compensation up to $300, because it would exceed the applicable dollar limits. Nor would it qualify for the exception for remuneration unrelated to the provision of DHS, because such payments would be related to the provision of emergency services, which are included in the definition of inpatient hospital services and, therefore, are DHS. Malpractice insurance provided to emergency room physicians might qualify for the employee exception if the physician is employed by the hospital and the insurance is part of the employment agreement. Similarly, we do not believe medical transcription services are an incidental benefit of nominal value.

We are aware that some hospitals are offering compliance training programs for physicians on their medical staffs or in their local communities. Because we believe such programs are beneficial and do not pose a risk of fraud or abuse, we are creating a new exception for such compliance training programs.

We intentionally set the dollar limits in the proposed exception at a low level to decrease the likelihood that the items or services would influence utilization. However, in response to the comments, we have eliminated the $50 per gift dollar limit. Therefore, under the final rule, an entity could give a physician either one noncash gift per year of up to $300 in value or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed $300. This change permits larger one-time gifts. For example, a noncash gift valued at $150 would have exceeded the per gift dollar limit of the proposed rule, but would be permitted under the final rule, as long as the annual aggregate does not exceed $300 and the other conditions of the exception are met.

The exception for non-monetary compensation up to $300 only protects gifts to individual physicians. Thus, gifts given to a group practice would not qualify for this exception. Noncash gifts could, however, be given to one member, several individual members, or each member of a group practice, if each such gift meets all of the conditions of the exception for non-monetary compensation up to $300. We caution, however, that the exception will not apply to gifts, such as holiday parties or office equipment or supplies, that are valued at not more than $300 per physician in the group, but are, in effect, given or used as a group gift. Notwithstanding the foregoing, we recognize that the aggregate dollar amount could be substantial for gifts to individual physician members of very large groups. For example, if a group consists of 50 physicians, each physician of the group could be given an aggregate of $300 in non-cash gifts within a given year, equaling a total of $15,000 from one entity. Such a large gift could provide an economic incentive for overutilization. Therefore, to counter-balance the removal of the $50 per gift limit and to further guard against abuse, we have added a provision that excludes gifts solicited by the receiving physicians or their group practice. This change also serves to clarify that our use of the term ''gift'' refers to the ordinary meaning of the term; that is, a gift must involve a voluntary transfer made without consideration or compensation expected or received in return. This new provision prevents members of group practices, as well as solo practitioners, from making noncash gifts a condition of doing business with a particular entity. We intend to monitor the provision of gifts to group practice physicians under this exception and may revisit our position if abuses occur. Such gifts remain subject to the anti-kickback statute.

Finally, we have decided not to index the $300 annual aggregate dollar limit for inflation. Removal of the per gift dollar limit gives entities much greater

flexibility with respect to the value of noncash gifts. That is, under the proposed rule, a single gift could not exceed $50; whereas, under the final rule, the value of a single gift could be up to $300, as long as the other conditions are met. We believe that this revision decreases the need for adjustment for inflation. In addition, we think it would create confusion as to the actual limit in succeeding years if we were to provide for an inflation adjuster. The rule as it stands creates an easy-to-follow bright line. However, we will continue to monitor the effect of the $300 limit and may revisit the limit in the future.

Comment: One commenter asked for clarification regarding the relationship between the de minimis exception and the statute's exception for remuneration provided by a hospital to a physician ''if such remuneration does not relate to the provision of designated health services.'' (See section 1877(e)(4) of the Act.)

Response: The exception for non-monetary compensation up to $300 and the statutory exception for remuneration unrelated to the provision of DHS are totally separate exceptions with different criteria. The determination as to which of these exceptions, if any, is applicable depends on the facts and circumstances of the case involved.

Comment: One commenter questioned whether the requirement that compensation must be made available to all similarly situated individuals would prohibit hospitals from hosting meals on a person-to-person basis. Another commenter suggested that the similarly situated requirement should be eliminated because the type of promotional items that would be covered by the exception would probably be provided only to referrers or potential referrers, and such minimal gifts were unlikely to cause overutilization.

Response: We agree that, on balance, the ''similarly situated'' test does not add significantly to the protections of the exception. Accordingly, we have eliminated the ''similarly situated'' standard. This standard was designed to ensure that compensation was not paid primarily to reward high referrers. To ensure the same end, we are augmenting the standard that prohibits compensation that takes into account the volume or value of referrals by also prohibiting compensation that takes into account the volume or value of any other business generated by the referring physician.

Comment: Two commenters questioned how professional courtesy discounts (that is, free or discounted services provided to physicians) would be handled under section 1877 of the Act. One of the commenters suggested that professional courtesy discounts should not violate section 1877 of the Act, because they fall within the non-monetary compensation up to $300 exception or they do not constitute ''remuneration.''

Response: The term ''professional courtesy'' is used (or misused) to describe a number of analytically different practices, including the practice by a physician of waiving the *entire fee* for services provided to the physician's office staff, other physicians, and/or their families (the traditional meaning); the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (that is, insurance only billing); and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. Therefore, we cannot generalize about the application of section 1877 of the Act to such arrangements. Some such arrangements may fit in an existing exception, depending on the circumstances (for example, the non-monetary compensation up to $300 exception if the value of the courtesy services is less than $300 and the other conditions of the exception are satisfied). However, some such arrangements may not fit in an exception. We are considering whether an exception could be developed for such arrangements and will address the matter further in Phase II of this rulemaking. We are soliciting comments about appropriate conditions for such an exception and an appropriate definition of ''professional courtesy.'' In addition to conducting an analysis of professional courtesy arrangements under section 1877 of the Act, these arrangements must be analyzed with respect to other fraud and abuse, as well as payment, authorities, including the anti-kickback statute, the False Claims Act (31 U.S.C. § 3729 *et seq.*), and the prohibition of inducements to beneficiaries (section 1128A(a)(5) of the Act).

VIII. Definitions of the Designated Health Services

A. General Principles

Basis for the Definitions

As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1673), section 1877(h)(6) of the Act lists the DHS, but does not define them. Moreover, the list in section 1877(h)(6) of the Act does not necessarily correspond to specific service categories as they are defined under either Medicare or Medicaid. For example, section 1877(h)(6)(D) of the Act uses the phrase, ''[r]adiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services,'' although ultrasound is not usually considered a radiology service. In defining the DHS in § 411.351 of the January 1998 proposed rule, we stated that we chose, as much as possible, to base the definitions in section 1877 of the Act on existing definitions in the Medicare program. We also explained that in situations in which it was not clear whether a service was included, we would look to the intent of the statute. In general, we believe the Congress meant to include specific services that are or could be subject to abuse.

Because we had received a number of inquiries from individuals who were confused about whether a particular service fell under one of the DHS categories, we proposed defining the DHS whenever we could by cross-referencing existing definitions in the Medicare statute, regulations, or manuals or by including specific language whenever we believed the definitions should deviate from standard Medicare definitions.

Many of the comments we received on the proposed rule reflected that commenters were still unclear about which services fall under the DHS categories. Many commenters specifically requested that we establish a ''bright line'' test for identifying these services, and suggested that we base the services on an established list, such as the Current Procedural Terminology (CPT) codes. We agree that more precise definitions will make it much easier administratively for physicians and entities to comply with the law.

Accordingly, we have determined that we will define certain DHS (clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services, and radiation therapy services (sections 1877(h)(6)(A)through (h)(6)(E) of the Act) by publishing specific lists of CPT and HCFA Common Procedure Coding System (HCPCS) codes that physicians and providers most commonly associate with a given designated health service. The lists of codes will define the entire scope of the designated services category for purposes of section 1877 of the Act. While the definitions section of the regulations will contain a general explanation of the principles used to select the codes, in all cases the published list of codes will be controlling.

For services described in section 1877(h)(6) of the Act, paragraphs (F)

through (K), we will not be publishing a service-by-service list. The codes for these services may be just one component used for identifying the service; the codes may be all those that appear in a specific ''level,'' such as all HCPCS level 2 codes, for a service; or the service is not defined using HCPCS codes at all. The definitions for the services in paragraphs (F) through (K) are explained in detail below under each service category.

The HCPCS is a collection of codes and descriptors that represent procedures, supplies, products, and services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs. We believe that these codes will already be familiar to many in the health care industry. These codes must be used when billing Medicare for Part B services and supplies. The codes are divided into three levels, the first two of which are used in this final rule and are described below; they are listed in HCPCS 2001:

Level I: Codes and descriptors copyrighted by the American Medical Association in its Current Procedural Terminology, Fourth Edition (CPT–4). These are 5-position numeric codes primarily representing physician services.

Level II: These are 5-position alpha-numeric codes representing primarily items and nonphysician services that are not represented in the level I codes. Included are codes and descriptors copyrighted by the American Dental Association's Current Dental Terminology, Second Edition (CDT–2). These are 5-position alpha-numeric codes comprising the ''D'' series. All other level II codes and descriptors are approved and maintained jointly by the alpha-numeric editorial panel (consisting of HCFA, the Health Insurance Association of America, and the Blue Cross and Blue Shield Association).

Because these specific codes change and can quickly become out-of-date, we are not including the lists of DHS codes in the regulations text, but rather in an accompanying attachment. The definitions of specific services in the regulations text will cross refer to a comprehensive table that will appear initially in the **Federal Register** along with Phase I of this rulemaking and thereafter in an addendum to the annual final rule concerning payment policies under the physician fee schedule rule. This list titled, ''List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act),'' will also be posted on the HCFA web site at http://www.hcfa.gov on the date of **Federal Register** publication of this final rule. The table published each year will be a comprehensive listing of all codes for DHS and not merely a listing of changes to the prior year's table. The updates will also be posted on the HCFA web site. The physician fee schedule rule is generally published in late October or early November. We will consider comments on each year's revised list if we receive them during the applicable comment period for that rule. If any changes are made, we will then publish a revised table and respond to any public comments that we receive. This approach will provide an annual comprehensive list of codes for those DHS noted above (sections 1877(h)(6)(A)through (h)(6)(E) of the Act).

We are not providing lists of codes for the following categories of DHS (sections 1877(h)(6)(F) through (h)(6)(K) of the Act): Durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; or inpatient and outpatient hospital services. We believe the definitions in Phase I of this rulemaking for these DHS provide sufficiently clear ''bright line'' rules.

In the preamble to the January 1998 proposed rule, we had stated that we believed the Congress intended to include specific services that are or could be subject to abuse and that we would attempt to define the services accordingly. In the January 1998 proposed rule preamble and regulations text, we then attempted in some cases to include or exclude services or types of services based on our view as to their potential for abuse. Many commenters disagreed with our views about particular services (for example, lithotripsy), and many more argued that the particular service they provided should also be excluded because it was not overutilized. In light of these comments and upon further review of the statutory scheme, we have decided that the Congress did not intend that we categorize DHS by determining the potential for overutilization or abuse on a service-by-service basis. Accordingly, in Phase I of this rulemaking, we are including all services that we believe come within the general categories; we have created limited exceptions for a few specific cases (that is, implants in ambulatory surgical centers, legislatively mandated preventive screening tests and immunizations subject to frequency limits, eyeglasses and contact lenses subject to frequency limits, and erythropoietin (EPO) provided by end-stage renal disease (ESRD) facilities) for which we believe an exception poses a limited risk of abuse and is necessary to avoid needless disruption of patient care. However, even for those rare exceptions, we will continue to monitor the services for abuse and, if necessary, revisit the exclusions.

We also stated in the preamble to the January 1998 proposed rule (63 FR 1673) that we consider a service to be a designated health service, even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes. We gave as an example skilled nursing facility (SNF) services, which can encompass a variety of DHS, such as physical therapy (PT), occupational therapy (OT), or laboratory services. Commenters complained that this interpretation would result in an expansion of the DHS beyond the services specifically listed in the law. According to the commenters, when the Congress intended to cover specific Medicare services (including composite rate services, such as hospital or home health services), it did so expressly. Upon review, we agree with the commenters. Under the final rule, services that would otherwise constitute DHS, but that are paid by Medicare as part of a composite payment for a group of services as a separate benefit (for example, ambulatory surgical center (ASC) or SNF rate), are not DHS for purposes of section 1877 of the Act. (As expressly provided in section 1877(h)(6) of the Act, hospital and home health services remain DHS although they are paid through a composite rate.) We note, however, that because of SNF consolidated billing, most, if not all, SNFs will also be considered entities providing DHS (for example, PT or OT) under Part B to SNF patients who have exhausted their Part A benefit or to other nursing home residents (that is, patients for whom the services are not covered as part of a composite rate). The consolidated billing requirement places with the SNF the Medicare billing responsibility for most of the services that a SNF resident receives (except for certain practitioner services and a limited number of other services) under Part A and under Part B. (Presently, consolidated billing is in effect only for patients in a covered Part A stay, but will become effective for Part B services in the near future.) Accordingly, a physician will not be able to refer Medicare patients who will require DHS to a SNF in which he or she has an

ownership or investment interest, unless the interest is protected under an exception to section 1877 of the Act.

In the August 1995 final rule relating to clinical laboratory services, we created an exception for laboratory services furnished in an ASC or ESRD facility or by a hospice if the services were included in a composite rate or per diem hospice charge. (See § 411.355(d)). In the January 1998 proposed rule, we had proposed extending this composite rate exception to include all DHS furnished in an ASC or ESRD facility or by a hospice if payment is included in the ASC payment rate, the ESRD composite payment rate, or as part of the hospice payment rate. This proposal was intended to address problems faced by ASCs, ESRD facilities, and hospices in the light of our proposed stance on DHS subsumed by bundled payments. However, since under the final rule DHS that are subsumed by a bundled payment do not implicate section 1877 of the Act, we have not adopted our proposal to extend § 411.355(d) beyond clinical laboratory services. Moreover, given our final interpretation, we are reconsidering the need for § 411.355(d) as applied to clinical laboratory services and intend to address the matter further in Phase II of this rulemaking. We are soliciting comments on this issue.

B. General Comment: Professional Services as Designated Health Services

Comment: Many commenters expressed the view that the professional component of DHS (particularly clinical laboratory and radiology services) should not implicate section 1877 of the Act. Commenters asserted that the Congress did not intend for professional services to come within the physician self-referral law prohibition and that we exceeded our authority to promulgate regulations by including them. Commenters also contended that limiting DHS under section 1877 of the Act solely to the technical components of services would sufficiently control the risk of program or patient abuse. Other commenters stated that if we included professional components of some DHS, we should do so for all DHS. The commenters pointed out that our proposed position on productivity bonuses (that is, that they may not reflect the volume or value of any DHS referrals) would require special bookkeeping to segregate professional fees when calculating bonuses that will burden practices, without serving a public policy purpose.

Response: We believe that it was not the intent of the statute to exclude all professional services from the list of DHS. Many of the DHS, such as radiology and radiation therapy, have substantial physician service components. If the Congress intended to exclude them, we would expect the statute to specifically do so. While some services are not viewed as having a professional component that is paid separately, Medicare still requires professional supervision of them to qualify for Medicare payment.

We agree to some extent that limiting referrals for the technical component of a service should greatly reduce the number of unnecessary referrals. Nonetheless, there are some DHS that consist only of a professional component (for example, some radiation therapy services) or are primarily professional in nature, and these would not otherwise be subject to the law if we carved out all professional components.

We agree with the commenters that we should include professional components when relevant in all DHS categories. Therefore, we have revised the definitions of each of the DHS to include the professional components in each case in which a professional component is included in the CPT or HCPCS codes that represent one of those services.

We understand that these rules may impose an administrative burden on some group practices, depending on how they choose to comply with section 1877 of the Act. We think Phase I of this rulemaking has a number of substantive changes that will ease the administrative burden of compliance, including the exception from the definition of ''referral'' for personally performed services and the greater flexibility afforded group practices over their distribution of revenues. As a practical matter, the professional component of many of these services will be excluded from the definition of a referral as services personally performed by the referring physician.

Individual Designated Health Services

We discuss below each designated health service category in the order in which it appears in section 1877(h)(6) of the Act. Each discussion includes a general summary of the category, summaries of the relevant public comments, and our responses.

C. Clinical Laboratory Services

In the August 1995 final rule covering a physician's referrals for clinical laboratory services, we defined these services in § 411.351 as—

> The biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

We had stated in the August 1995 final rule, in response to a commenter who requested a definition of clinical laboratory services, that we believed the most appropriate way for a physician or clinical laboratory to determine if a diagnostic test is a clinical laboratory test subject to the requirements of section 1877 of the Act, is to find out if the test is subject to categorization under the Clinical Laboratory Improvement Act (CLIA). We pointed out that there is a list of clinical laboratory test systems, assays, and examinations categorized by complexity and published by the Center for Disease Control (CDC). We also stated that, given this definition, CPT codes would not be the sole references to identify clinical laboratory services for physician referral purposes.

Commenters also had asked about the professional components of laboratory services. We stated that we believed that CLIA covers the actual examination of materials, their analysis, and any interpretation and reporting of the results that are performed by a facility that qualifies as a laboratory, as defined in § 493.2 (Definitions). However, if a laboratory sent test results to an independent physician, any interpretation performed by the physician would not be performed by the laboratory facility. As a result, the services would not constitute part of the clinical laboratory test.

We stated in the January 1998 proposed rule covering referrals for the other DHS that we would retain the definition of clinical laboratory services that was incorporated into our regulations by the August 1995 final rule. However, in line with our revised approach for identifying the DHS in this final rule, we have amended the rule to refer specifically to CPT and HCPCS codes. We have included as DHS the professional components of laboratory tests when they are listed as such in the codes. It is our belief that the specification of the codes in the attachment to this final rule is consistent with, although not identical to, the definition of clinical laboratory services in our January 1998 proposed rule.

D. Physical Therapy Services

We proposed to define physical therapy services in § 411.351 as those

outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act and in § 410.100 (Included services), paragraphs (b) and (d). Under section 1861(p) of the Act, the term ''outpatient physical therapy services'' specifically includes speech-language pathology services. Because section 1877(h)(6) of the Act lists physical therapy services in general, and not just *outpatient* services, we also included in the definition any other services with the characteristics described in § 410.100(b) and (d) that are covered under Medicare Part A or Part B, regardless of who provides them, the location in which they are provided, or how they are billed.

We pointed out that services that are essentially the same as ''outpatient physical therapy services'' are also covered by Medicare in other contexts and in different settings, and may be billed under different categories. For example, we have a longstanding policy of covering physical therapy and occupational therapy as diagnostic or therapeutic inpatient hospital services. Similarly, these services can also be covered as SNF services, and can be furnished as ''incident to'' physician services under section 1861(s)(2)(A) of the Act. (Section 1877 implications for DHS provided by SNFs are discussed earlier in this section.)

It was our view in the January 1998 proposed rule that covered outpatient physical therapy services basically included three types of services, which were best described in § 410.100(b) (which specifically concerns services provided by a comprehensive rehabilitation facility (CORF)). This definition covers the testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular, and respiratory systems; assessment and treatment related to dysfunction caused by illness or injury and aimed at preventing or reducing disability or pain and restoring lost function; and the establishment of a maintenance therapy program for an individual whose restoration has been reached. Many commenters asserted that the proposed definition was imprecise or improperly included some procedures that are not generally considered physical therapy services.

We have responded to these concerns by redefining physical therapy services, as some commenters suggested, by using a list of HCPCS codes. We believe the list is limited to services that are more traditionally regarded as physical therapy. In general, these services are described in the ''Physical Medicine and Rehabilitation'' section (the 97000 series) of the CPT and in other relevant sections of the HCPCS.

In the January 1998 proposed rule, we also included speech-language pathology services as a designated health service since section 1861(p) of the Act includes ''speech-language pathology services'' in the definition of ''outpatient physical therapy services.'' These services are defined in section 1861(ll)(1) of the Act as speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as this pathologist is legally authorized to perform under State law (or the State regulatory mechanism) as would otherwise be covered if furnished by a physician. Section 1861(ll)(3) of the Act defines a ''qualified speech-language pathologist.''

We used in the proposed rule the brief description of speech-language pathology services in § 410.100(d), which applies to services provided in CORFs, as those services that are necessary for the diagnosis and treatment of speech and language disorders that create difficulties in communication. In an effort to furnish a ''bright line'' test, we are defining the services in Phase I of this rulemaking by the specific codes that correspond to the services that we consider to be speech-language pathology services.

As we developed the list of CPT and HCPCS codes relevant to speech-language pathology, we realized that our proposed definition, which cross-refers to the CORF definition in § 410.100(d), did not encompass the full range of services that are commonly considered to be speech-language pathology services. It failed to recognize that speech-language difficulties can be caused by cognitive disorders and failed to recognize that speech-language pathology may be used to treat swallowing and other oral-motor dysfunctions. Therefore, in developing the list of codes for speech pathology in Phase I of this rulemaking, we included the diagnosis and treatment of cognitive disorders including swallowing and other oral-motor dysfunctions.

Finally, because of the overlap between physical therapy, occupational therapy, and speech-language pathology services, we are listing the codes for all three services together. We believe that this set of HCPCS codes represents what most clinicians would define as PT/OT/speech therapy services that are covered by the Medicare program. The list is set out in the attachment to this final rule.

Comment: A number of commenters were particularly concerned that the proposed definition of physical therapy services implies that physical therapists can perform diagnostic testing and measurements, such as electromyography tests (EMGs). These tests are used primarily to provide medical diagnostic information regarding neuromuscular diseases and occasionally to measure neuromuscular function. Although some States permit physical therapists to perform these tests, the commenters believe that EMGs are typically performed by a physician as part of a physical examination to determine whether a patient is a surgical candidate or if some other course of treatment is warranted.

In addition, other commenters stated that the proposed definition of physical therapy services could be interpreted to include therapeutic procedures such as nerve blocks and arthrocentesis that the commenters believe are physician services. One commenter, a physician who practices physical medicine and rehabilitation, asserted that our proposed definition of physical therapy included services that could be administered by physicians and physical therapists. He feared that this could prohibit him from treating patients he diagnoses. Several commenters responded to the inclusion in the definition of physical therapy of any ''assessment and treatment'' designed to alleviate pain or disability. The commenters asserted that this phrase captures a large portion of modern medicine, given that pain is the most common presenting symptom in a physician's office, and virtually any assessment or treatment following therefrom would have as its purpose the alleviation of that pain.

Response: Nothing in the proposed definition affected the scope of any practitioner's practice. We agree with the commenters that only in certain States are physical therapists licensed to perform EMGs. Additionally, we agree that therapeutic procedures such as nerve blocks and arthrocentesis are typically performed by a physician and are not generally considered to be a part of physical therapy. These procedures are not included on the list of codes that defines the scope of physical therapy for purposes of section 1877(h)(6)(B) of the Act. In the January 1998 proposed rule, we did not intend to convey the message that what is generally considered physical therapy would change. We proposed to use an existing definition of physical therapy (in § 410.100(b), which covers physical therapy services in CORFs) precisely because we did not want to change the existing perception of physical therapy.

In order to avoid confusion, we are revising our proposed definition by providing a list of CPT and HCPCS codes that are, collectively, the PT/OT/speech-language therapy DHS. This list of codes defines the entire scope of PT/OT/speech-language therapy services for purposes of section 1877 of the Act. Finally, we note that under Phase I of this rulemaking, if a physician personally provides a designated health service to his or her patient, there is no ''referral'' for purposes of section 1877(a)(1) of the Act. See section III.B of this preamble.

Comment: One commenter asserted that pulmonary function tests are for the measurement of the function of the respiratory system and have nothing to do with physical therapy. However, another commenter recommended that the definition of physical therapy include the neuromuscular and pulmonary function tests that test for functional capacity ratings and that are usually performed by a physical therapist without the direct supervision of a physician.

Response: We agree with the commenter that pulmonary function tests for the measurement of the function of the respiratory system are not physical therapy. The only pulmonary function test that may be considered to be a physical therapy service is pulse oximetry testing, CPT code 94762, when it is used to test for functional capacity ratings. A pulse oximetry test that is performed to determine whether a patient has enough oxygen to perform certain activities of daily living is, for example, a physical therapy service.

Comment: One commenter recommended that we define physical therapy as those therapeutic exercises and physical medicine modalities described in the 97000 series of the CPT codes, included in the patient's written plan of physical therapy treatment, and provided by a physical therapist or physical therapy aide.

Response: We agree with the commenter that PT services should be based on the CPT codes and have modified the rule accordingly. With respect to which professionals can provide a given service, we defer in this rule to existing Medicare policy. Many of these DHS can be provided by physicians.

Comment: A number of commenters opposed the inclusion of speech-language pathology services in the definition of physical therapy services. The commenters stated that the Congress did not intend to include these services within the ban on physician referrals and asserted that including these services as DHS is unnecessary (although they did not state why this would be the case). One commenter asserted that when the Congress intended to include outpatient speech-language pathology services within the category of outpatient physical therapy services, the Congress enacted explicit language that made that intention clear. The commenter pointed to section 4541(a)(1) of the BBA 1997, which added paragraph (8)(A) to section 1833(a) of the Act. That provision states that, for covered individuals, amounts will be paid from the Medicare Trust Fund for ''outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services furnished—'' * * * by certain entities.

Response: The definition of ''outpatient physical therapy services'' in section 1861(p) of the Act specifically states that ''the term 'outpatient physical therapy services' also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others. * * *'' Thus, by definition, speech-language pathology services are a subset of outpatient physical therapy services under the Medicare statute. We believe that the parenthetical language under the BBA 1997 simply confirms our interpretation.

E. Occupational Therapy Services

In the January 1998 proposed regulations text, we proposed to include those OT services described in section 1861(g) of the Act and the CORF regulations in § 410.100(c). We proposed that occupational therapy services would also include any other services with the characteristics described in § 410.100(c) that are covered under Medicare Part A or Part B, regardless of who furnishes them, the location in which they are furnished, or how they are billed. In proposed § 411.351, OT services included the following:

- Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.
- Evaluation of an individual's level of independent functioning.
- Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function.
- Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

As discussed in the preceding section, we are revising our proposed definition by providing a list of CPT and HCPCS codes that collectively are the PT/OT/speech therapy DHS. Also, as described above, we are excluding from the definition of DHS any designated health service that is paid for as part of a ''bundled'' payment (for example, services covered by the SNF Part A rate or the ASC rate), unless the statute otherwise provides that a ''bundled'' set of services is itself a designated health service (for example, home health services and inpatient and outpatient hospital services).

Comment: A major OT association asserted that the definition of OT is too narrow because it does not adequately capture the scope of the OT benefit. For example, OT is furnished to patients with cognitive impairments as well as to patients with physical impairments and limitations. As another example, OT may also be furnished in partial hospitalization programs for patients with a psychiatric illness. The commenter believes that it is important for the definition in § 411.351 to be as complete and accurate as possible to assure appropriate compliance with the law, and that § 410.100(c) is too narrow to be used as the complete definition of OT services for purposes of these regulations. The commenter suggested that we broaden the definition by adding to it the coverage guidelines stated in section 3101.9, ''Occupational Therapy Furnished by the Hospital or by Others under Arrangements with the Hospital and under its Supervision,'' of the Medicare Intermediary Manual (HCFA Pub. 13–3), Part 3— Claims Process, and section 2217, ''Covered Occupational Therapy,'' of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process. The commenter recommended that we use the following definition for OT in § 411.351:

> Occupational therapy services means those services described at section 1861(g) of the Act, § 410.100(c) of this chapter, and in the occupational therapy coverage guidelines contained in section 3101.9 of the Medicare Intermediary Manual and section 2217 of the Medicare Carriers Manual. Occupational therapy services also include any other services with the characteristics described in § 410.100(c) and the occupational therapy coverage guidelines that are covered under Medicare Part A or B, regardless of who furnishes them, the location in which they are furnished, or how they are billed.

Response: We agree with the commenter that the proposed definition does not clearly recognize that OT is furnished to patients with cognitive impairments. As we have stated previously in this preamble, we did not intend to change what is commonly regarded as OT. We referred to the existing definition in § 410.100(c) so

that we would not be proposing any change. However, as the commenter pointed out, the existing definition at § 410.100(c) is not complete. Therefore, we are expanding the proposed definition by including codes for the ''teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities.''

However, the commenter is correct that a partial hospitalization program may provide OT services. This is in accordance with section 1861(ff) of the Act, which defines ''partial hospitalization services'' and specifically includes OT as a partial hospitalization service. However, with respect to partial hospitalization, we have determined that services provided as part of a group of services paid under a bundled rate are not DHS. Partial hospitalization services are paid under a bundled rate. Therefore, partial hospitalization services (including OT services provided as part of the partial hospitalization benefit) furnished by a community mental health center are not DHS. However, partial hospitalization services furnished by a hospital are outpatient hospital services, which is a category of DHS.

In order to eliminate any confusion the January 1998 proposed regulations may have caused and to make Phase I of this rulemaking clear, we are defining OT by a list of specific HCPCS/CPT codes. In light of the changes we have made in Phase I of this rulemaking, it is not necessary for us to include the references to the intermediary and carrier manuals that the commenter suggested.

Occupational therapy services may be furnished by an occupational therapist, an occupational therapy aide who is supervised by an occupational therapist, or by a physician. Section 1861(r) of the Act allows a physician to furnish any medical service that his or her State allows the physician to furnish.

F. Radiology and Certain Other Imaging Services

In the January 1998 proposed rule, we combined the DHS in section 1877(h)(6)(D) of the Act—''radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services''—and 1877(h)(6)(E) of the Act—''radiation therapy services and supplies'' into the following definition:

> Radiology services and radiation therapy and supplies means any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation, or nuclear medicine, and diagnostic mammography services, as covered under section 1861(s)(3) and (4) of the Act and §§ 410.32(a), 410.34, and 410.35 of this chapter, including the professional component of these services, but excluding any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately.

Commenters found the proposed definition to be confusing in two main respects:

- The definition both combined two different categories of radiology-related services (that is, radiology and radiation therapy and supplies) and included other services not commonly considered to be radiology-related (ultrasound and nuclear medicine). Many commenters thought that all services not strictly considered radiology should be excluded.
- At different places in the January 1998 proposed regulation preamble, we stated that we were excluding DHS that were peripheral, incidental, or secondary to a nondesignated health service. In the proposed definition, however, we only excluded imaging modalities used to ''guide a needle, probe, or catheter.'' Many commenters thought the scope of excluded radiology and other imaging services should be broader than just guidance, while others thought the distinction between primary and secondary services would be difficult to apply in practice.

Based on the comments, we have redefined this category of DHS in a manner that should provide greater clarity. First, we have segregated radiation therapy and supplies from radiology and other imaging services and returned them to a separate category, as in the statute. (We discuss comments relating to radiation therapy services in section VIII.G of this preamble). Second, we are excluding nuclear medicine since those services are not commonly considered to be radiology. Third, for purposes of these regulations we have renamed the category of services covered by section 1877(h)(6)(D) of the Act ''Radiology and Certain Other Imaging Services'' to make clear the Congress's intent to include in subsection (D) some imaging services other than radiology. Fourth, consistent with the approach we are following with several other of the DHS categories, we are defining the entire scope of covered services under section 1877(h)(6)(D) of the Act by using lists of CPT and HCPCS codes, which lists control in all circumstances. The lists include those services typically considered as radiology or ultrasound services, or as constituting an MRI or a computerized axial tomography (CAT) scan. Fifth, we have excluded certain covered preventive screening procedures, such as screening mammography, that are subject to HCFA-imposed frequency limits that mitigate the potential for abuse. In these circumstances, we believe the Congress did not intend the physician self-referral law to interfere with a physician's or entity's attempts to provide these preventive procedures to Medicare patients.

Sixth, based on the comments we received, we concluded that the terms ''invasive'' radiology and radiology ''incidental'' or ''secondary'' to a non-DHS procedure used in our proposed definition of ''radiology services'' created confusion and uncertainty. We agree with commenters that ''invasive'' radiology includes more than just those procedures used to ''guide a needle, probe or catheter.'' Consequently, we are revising our definition of radiology and certain other imaging services to exclude from the definitional list of codes x-ray, fluoroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe. Thus, cardiac catheterizations and endoscopies will not fall within the scope of ''radiology services'' for purposes of section 1877 of the Act. All MRIs or CAT scans, however, are within the scope of DHS because excluding some on the basis that they are ''invasive'' tests would have the effect of excluding all MRIs and CAT scans that use contrast injection. The use of contrast is not mandatory for the performance of a scan, as it is for the performance of a barium enema, excretory urogram, or traditional vascular angiography. Thus, an exclusion from the DHS definition of contrast for MRIs and CAT scans could have the effect of encouraging the use of contrast when it is not necessary.

In addition, we have concluded that radiology procedures that are integral to the performance of, and performed during, a nonradiology medical procedure are not within the scope of DHS. The list of codes that defines the scope of ''radiology and certain other imaging services'' will make this distinction clear. Examples of these integral services include, but are not limited to, imaging guidance procedures and radiology procedures used to determine, during surgery, whether surgery is being conducted successfully. In the CPT, these radiology procedures are identified as cross-references to the principle procedures with which they are associated. A radiology procedure, such as a CAT scan or a chest x-ray, performed before or after another

procedure, such as a lung cancer resection, is considered to be a diagnostic radiology procedure that is not integral to the principle procedure (that is, the lung cancer resection). While these radiology procedures are essential to the performance of the principle procedure, physicians have discretion in choosing which entity provides the radiology service independent of the entity providing the principle surgical service. These nonconcurrent services are DHS.

Regardless of our definition of ''radiology and certain other imaging services,'' some services that are not within the scope of that definition may still be DHS if they are inpatient or outpatient hospital services, a separate category of DHS under section 1877(h)(6)(K) of the Act. These services would be subject to the physician referral rule if the referring physician has a financial relationship with the hospital. We anticipate most of these financial arrangements will meet an exception under section 1877 of the Act (for example, the exception for hospital ownership or either the employment or personal service arrangements exception).

We address comments related to the definition of services covered by section 1877(h)(6)(D) of the Act below. To the extent some commenters raised issues such as the general effects of section 1877 of the Act on physicians' practices or on medicine in general, those issues are addressed elsewhere in the preamble, where relevant.

Comment: Several commenters asserted that the proposed definition of ''radiology services'' that included all sound-based or imaging-based technologies is contrary to congressional intent. The commenters argued that the Congress intended to limit the definition by removing original language that included the phrase ''other diagnostic services'' along with radiology services.

Response: The phrase ''radiology, or other diagnostic services'' was added in section 1877(h)(6)(D) of the Act by OBRA 1993 as one of the categories of DHS the Congress chose to cover in addition to clinical laboratory services. This one set of services appeared to include the extremely broad category of ''other diagnostic services,'' in addition to radiology services. The Congress narrowed this category in section 152 of the Social Security Act Amendments of 1994 (SSA 1994), Public Law 103–432, enacted on October 31, 1994, perhaps because it realized the huge scope of ''diagnostic services.'' The amendments revised section 1877(h)(6)(D) of the Act, effective January 1, 1995, by replacing the category with ''radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services.'' While all of these services might not be subsumed in the category ''radiology services,'' the Congress clearly intended to include them as DHS. We have renamed the category ''radiology and certain other imaging services'' to reflect the Congress's intent.

Comment: One commenter questioned why cardiac, vascular, and obstetric ultrasound procedures could not be referred. The commenter stated that in most institutions these procedures are not considered radiology procedures since radiologists may never supervise or interpret them. Another commenter argued that although echocardiography is a type of ultrasound procedure, it should not be considered a radiology service because echocardiography is a service developed and performed primarily by cardiologists, billed under cardiology CPT codes, and furnished to cardiac patients. As a result, the commenter argued that it is inaccurate and inappropriate to include echocardiography within the definition of radiology services.

Response: Cardiac, vascular, and obstetric ultrasound procedures are subject to the physician self-referral provisions because section 1877(h)(6)(D) of the Act specifically includes ultrasound as a designated health service, not because they are ordinarily considered to be ''radiology services.'' Simply stated, the term ''radiology services'' as applied to the services described by section 1877(h)(6)(D) of the Act is a misnomer. Section 1877(h)(6)(D) of the Act includes any services that are traditionally regarded as ''radiology'' services, as well as MRIs, CAT scans, and ultrasound services. Cardiac echography and vascular echography are clearly ultrasound services. Nothing in the regulation would prohibit a vascular surgeon, neurologist, or other specialist from ordering a particular service from an entity with which he or she has no prohibited financial relationship.

Comment: Several commenters were opposed to our proposal to exclude as ''invasive'' radiology only those invasive procedures used to guide a needle, probe, or catheter accurately. Two of the commenters were concerned that invasive radiology procedures, which use an imaging modality not only to guide a needle, probe or catheter, but also to record an accurate picture of the areas of the body being probed or catheterized, would be included in the definition of radiology. (An example of this would be an ultrasound device placed at the end of a catheter or endoscope.)

Response: We agree and have not included x-ray, fluoroscopy, and ultrasound services that require the insertion of a needle, catheter, tube, or probe on the list of HCPCS/CPT codes that defines the full scope of radiology and other imaging services for purposes of section 1877 of the Act. Some of these services may still be DHS when they fall within the category of inpatient and outpatient hospital services.

Comment: Several commenters objected to our proposal to exclude radiology services that were ''merely incidental or secondary'' to another procedure that the physician has ordered. (See our January 1998 proposed rule, 63 FR 1676.) Some commenters noted that it is generally not possible to establish, based on the CPT code used, whether or not the primary purpose of the procedure was the interventional procedure itself (with the imaging being an adjunct procedure) or whether the primary purpose was to take a picture with an imaging modality. Because it is extremely difficult and impractical in the commenters' view to separate the radiology component from the underlying procedure, the commenters recommended that we exclude all invasive radiology services, encompassing those procedures that may include an adjunct radiology procedure performed at the same time as the interventional procedure. Other commenters thought that the definition of radiology services should also exclude imaging services when they are performed before and/or after a surgical procedure. For example, a commenter requested that we add language to the proposed definition of radiology to exclude any radiology procedure in which the imaging modality is used to plan the invasive procedure. The commenter noted that for many invasive procedures, an ultrasound before the actual procedure might be routinely necessary in order to plan the manner in which the needle, catheter, or probe would be guided during the actual invasive procedure. In these circumstances, the patient already has received the diagnosis that the invasive procedure is necessary. The commenter believes that we should maintain the view that a physician would not refer a patient for these procedures in order to profit from unnecessary radiology services. Another commenter stated that under our proposed interpretation of invasive procedures, an echocardiogram that showed a need for bypass surgery would be a designated health service, while one that ruled out surgery would not, since there would be no surgical

procedure to which the imaging service would be ''incidental.'' Finally, a neurologist commented that there are a number of radiology procedures performed by neurologists that are incidental to other procedures, particularly certain surgical services. One of the examples given by the commenter was carotid duplex or transcranial Doppler ultrasound, which are tests performed after carotid endarterectomy to look for clots. The commenter believes these radiology services should be excluded.

Response: We agree with the commenter that the ''incidental/secondary'' test in the January 1998 proposed rule has led to some confusion and uncertainty and have abandoned it in Phase I of this rulemaking. We believe the list of codes set forth in Phase I of this rulemaking (and annually thereafter in the physician fee schedule rule) will create a ''bright line'' test that will ease compliance. In selecting the codes for radiology and ultrasound, we are not including any codes for radiology or ultrasound procedures that have an invasive component; that is, that include the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice. (''Invasive'' would encompass radiology services involving contrast that must be injected, but not contrast materials that are ingested by the patients themselves.) In addition, we are not including radiology and ultrasound procedures that are integral to and performed during the time a nonradiology procedure is being performed, such as ultrasound used to provide guidance for biopsies and major surgical procedures or used to determine, during surgery, whether surgery is being conducted successfully. Phase I of this rulemaking requires that to be considered integral to a nonradiology procedure (and therefore not a radiology or other imaging service for purposes of section 1877(h)(6)(D) of the Act), the imaging procedure must be performed during the nonradiology procedure. A radiology or ultrasound procedure performed before or after another procedure (for example, a scan or a chest x-ray before a lung cancer resection, an echocardiogram before a bypass, or a duplex carotid ultrasound before or after surgery) is a diagnostic radiology procedure that is not integral to another procedure and therefore is a radiology or other imaging service under section 1877(h)(6)(D) of the Act. In the case of services performed before or after a procedure, referring physicians have discretion in choosing the entity that provides the radiology service independent of the entity providing the surgical service. Depending on the facts, referrals for these services to entities with which the referring physician has a financial relationship may be protected under the various exceptions to the statute.

In all cases, the definitional list of codes controls in determining whether a service falls within the scope of ''radiology or certain other imaging services'' for purposes of section 1877 of the Act.

Comment: Two commenters were opposed to our proposal to exclude ''invasive'' or ''interventional'' radiology procedures from the definition of radiology services. The commenters believe that these procedures should be included as DHS in order to safeguard against overutilization and ensure that appropriately trained physicians perform the services. One commenter argued that as a clinical matter, ''invasive'' or ''interventional'' radiology services rarely are performed in an office setting. Typically, interventional radiologists perform such procedures as angiography or angioplasty in a hospital because they involve significant and delicate work on a patient's cardiovascular system. Patients who undergo invasive procedures must then be monitored for a period of time in an appropriate medical setting. Consequently, that commenter, as well as another, objected to our statement in the preamble to the January 1998 proposed rule (63 FR 1676) that invasive procedures ordinarily are ''merely incidental or secondary to another procedure that the physician has ordered.'' One of the commenters stated that the radiology services are neither incidental nor secondary, but a vital and integral part of the invasive procedure performed. The procedures are as much radiological as they are any other portion. One commenter stated that if invasive procedures occur in an office, they should be performed by a radiologist. The commenter believes that excluding invasive or interventional radiology procedures could result in certain referral arrangements by physicians that might pose some risk of patient or program abuse. One of the commenters noted that when interventional radiologists perform invasive radiology procedures, there is no risk of program or patient abuse. This is because interventional radiologists do not typically make referrals; they merely perform the invasive radiology procedures and return the patient to the care of the referring physician. The commenter believes, however, that physicians other than interventional radiologists may have an incentive to self-refer.

Response: We agree with the commenter that we were incorrect to characterize interventional radiology as ''secondary'' to many procedures, when it can in fact be a vital and integral part of the invasive procedure being performed. It is not the purpose of the physician self-referral law to discourage any physicians from furnishing their own services, such as interventional radiology, within their own practices, provided the physicians are functioning within the scope of their license to practice.

Comment: Many commenters asserted that all or particular invasive cardiology services should be excluded from the definition because they are not subject to program or patient abuse. Another commenter asked that we be consistent with regard to all forms of cardiac catheterizations and endoscopy procedures. The commenter stated that providers want to be able to perform all endoscopy services or cardiac catheterization services in the same setting and not have to limit their services.

Response: Cardiac catheterizations and endoscopy procedures are not included on the CPT code list that defines the scope of ''radiology and certain other imaging services,'' because they do not involve imaging services that are covered under any of the categories in section 1877(h)(6)(D) of the Act. These services may still constitute DHS as inpatient or outpatient hospital services.

Comment: Two commenters noted that in the preamble to the January 1998 proposed rule (63 FR 1676), we stated that percutaneous transluminal angioplasty was an example of an invasive radiology procedure that we would exclude from the definition of radiology. The commenters stated that this procedure is not commonly considered to involve ''invasive radiology.''

Response: The commenters are correct in stating that percutaneous transluminal angioplasty is not fundamentally radiological in nature; it is predominantly a therapeutic intervention. Our wording in the examples for invasive radiology may have been confusing. We intended to convey that the imaging procedures associated with percutaneous transluminal angioplasty would be considered integral to the performance of the angioplasty. However, by using specific CPT codes to define the scope of services covered by section 1877(h)(6)(D) of the Act, we have now narrowed the definition of radiology services so that it does not include radiology that is integral to

interventional procedures, such as angioplasty.

Comment: One commenter supported our proposal to exclude screening mammography from the definition of DHS. The commenter believes that we should expand the exclusion to cover all DHS for which we have specified coverage or frequency limits. The commenter stated that screening tests by definition are not subject to overutilization.

Response: We agree with this commenter and have modified Phase I of this rulemaking to exclude from the reach of section 1877 of the Act certain legislatively mandated preventive screening and immunization services that are subject to HCFA-imposed frequency limits and are paid based on a fee schedule. The preventive services to which this exception applies are identified in Appendix A. We will add codes for new preventive screening tests and immunizations, as appropriate, through the annual updating of the attachment to this final rule.

Comment: One commenter recommended that all mammography be excluded from the definition of ''radiology services.'' The commenter argued that generally diagnostic mammography procedures are performed only when a woman has clinical indications for a diagnostic mammogram. Thus, any risk of program or patient abuse is significantly reduced, if not eliminated. The commenter also mentioned that the quality-centered requirements of the Mammography Quality Standards Act of 1992 minimize the risk of potential overutilization of mammography services. Another commenter recommended the exclusion of ''diagnostic'' mammography services because he stated that it is necessary to perform the mammography on the same equipment for purposes of comparing the initial screening with the second diagnostic mammography. To prohibit patients from using the same facility adds an unnecessary element of potential error to the equation.

Response: Diagnostic mammography is clearly a radiological service under section 1877(h)(6)(D) of the Act, and it could be subject to abuse. It is our understanding that most women receive mammography from a radiologist who is requesting diagnostic radiology services. These physicians have not made a referral under section 1877(h)(5)(C) of the Act if they request diagnostic mammography as the result of a consultation requested by another physician. We are regarding this exception as applying to diagnostic mammography that results when a radiologist has first performed a screening mammography as the result of a consultation, and then recommends follow-up diagnostic mammography, or begins his or her consultation with diagnostic mammography. (The physician who initiated the consultation with the radiologist has made a referral that could fall within the scope of the physician self-referral law if he or she has a financial relationship with the radiology facility.)

Comment: A commenter asked if stress tests are DHS. The commenter noted that some stress tests use nuclear medicine procedures.

Response: Stress tests are generally considered to be a physician service that does not involve radiology, and stress tests are not specifically listed in the law as DHS. Some stress tests use nuclear medicine procedures to create an image of the heart. Because these services are not included on the definitional CPT code list for radiology or other imaging services, they are not DHS.

Comment: One commenter stated that unless changed or clarified, the proposed regulations could inhibit the development and application of telemedicine technology to populations covered by the physician referral rules. Of specific concern was the area of ultrasound and a ''unified'' payment (that is, a combined payment for the technical and professional components of the service). The commenter asserted that Medicare and many State Medicaid programs provide a unified payment for ultrasound. The commenter described the problems of a unified payment with an example of a community physician performing the technical component of an ultrasound service and a distant tertiary hospital's physician performing the professional component. If the tertiary provider billed for the ultrasound service under a ''unified'' (that is, global) fee-for-service payment to cover the professional component of the ultrasound service, the tertiary facility logically should determine a payment for the technical component to pay the community physician who provides that service. However, since the community physician would be referring to the tertiary facility for the ultrasound study, such a payment could violate the physician referral regulations (that is, it would not fall within an exception).

At the time of the comment period for the January 1998 proposed rule, the commenter was aware that we were considering the publication of a separate proposed rule that would specify an appropriate ''split'' of global payments in the area of telemedicine; that is, it would specify separate payment amounts for the technical and professional components of services. The commenter suggested that if we did issue those regulations, we should also recognize in the physician referral rules that payment by the tertiary provider to the referring community physician for providing the technical component of an ultrasound service performed via telemedicine should be exempted if it is under a HCFA-designated, or insurer-designated, allocation between the two aspects of an otherwise ''global'' payment.

Response: We believe that Phase I of this rulemaking addresses this issue satisfactorily. The basic principle of Phase I of this rulemaking is that any payment from an entity furnishing a designated health service to a referring physician must be at fair market value, not taking into account the volume or value of any referrals or other business generated by the referring physician (when this latter language is included in an exception). We are revising Phase I of this rulemaking to make clear that ''per service'' payments are allowed, even with respect to DHS ordered by the physician, provided the payment meets the fair market value standard. In the situation described by the commenter, the split is determined by the Medicare program based on its independent view of the value of the services provided. Of course, any split between a referring physician and another provider may also raise concerns under the Federal anti-kickback statute.

With respect to Medicare reimbursement for telehealth services, we published a proposed rule on June 22, 1998 (63 FR 33882) and final rule on November 2, 1998 (63 FR 58814) to implement section 4206 of the BBA 1997. Specifically, the November 1998 final rule permitted payment for professional consultations via interactive telecommunication systems in rural HPSAs and established separate payment amounts for the referring and consulting practitioners of a teleconsultation in a rural HPSA. As we noted in the preamble (63 FR 58883) to that November 1998 final rule, the rule specifies that the consulting practitioner must submit the claim for the consultation service and must share 25 percent of the total payment with the referring practitioner.

We clarified in the November 1998 telehealth final rule that these provisions only apply to teleconsultation services. Under Medicare, a teleconsultation is a consultation service delivered via telemedicine. These services are represented by CPT codes 99241 through 99275. Diagnostic ultrasound

(CPT code 76506) on the other hand, is a radiology service and would not fall within the purview of a teleconsultation under Medicare. Therefore, the payment methodology requiring the sharing of payment between the consulting and referring practitioners would not apply to diagnostic ultrasound services. In the case of diagnostic ultrasound, the physician providing the interpretation of the image typically would bill for the interpretation, while the technical component (that is, conducting the test) is billed by the practitioner or facility that captured the ultrasound image. Medicare has no national rule stating that the professional and technical components of a service, including ultrasound services, must be billed in a ''global'' manner. In fact, in the annual update to the physician fee schedule, separate codes for the professional component as well as the technical component of a service are listed, including the diagnostic ultrasound codes. Of course, in those cases in which there is no technical component, one code is used for Medicare payment and billing.

G. Radiation Therapy

Section 1877(h)(6)(E) of the Act includes radiation therapy services and supplies. In the January 1998 proposed rule, we combined radiation therapy with radiology in a single definition.

Because commenters found the combined definition to be confusing, we are amending the January 1998 proposed regulation so that radiology services and radiation therapy services are now separate categories (as in section 1877 of the Act itself). This change makes it clear that the two categories are actually very separate kinds of services. We are basing our definition of radiation therapy services and supplies on section 1861(s)(4) of the Act. This provision includes, as ''medical and other health services'' covered by Medicare, ''x-ray, radium, and radioactive isotope therapy, including materials and services of technicians.'' However, we want to clarify that, for physician referral purposes, the list of codes that defines ''radiation therapy services and supplies'' in Phase I of this rulemaking does not include nuclear medicine services. While nuclear medicine involves the injection of radioactive isotopes directly into a patient's bloodstream, these services are not generally regarded as radiation therapy, they involve different equipment and procedures, and physicians who provide nuclear medicine have a separate certification. We have included in the attachment to this final rule a list of codes that will define radiation therapy services and supplies. This list will be updated and reprinted in full annually as part of the physician fee schedule.

Comment: A commenter noted that because the January 1998 proposed regulations bundle radiology services and radiation therapy and supplies into a single category of DHS, the professional component of radiation therapy services has also been included within the definition of DHS. The commenter stated that some radiation oncologists would effectively be precluded from being paid on a productivity basis for their services, given that virtually all of the professional services that some physicians perform are radiation therapy services for Medicare patients. The commenter believes that the Congress did not intend this result.

Response: The law excludes from the definition of a ''referral'' any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we are amending the definition of a ''referral'' to exclude any professional components personally performed by referring physicians themselves. Together, these provisions should largely address the commenter's concerns.

Comment: Several commenters recommended that we exclude prostate brachytherapy from the definition of radiation therapy. Prostate brachytherapy is the placement of radioactive sources into the prostate, through ultrasound guidance, for the purpose of treating prostate cancer. The commenters argued that this procedure should be excluded because it is performed once and is only performed on persons with a biopsy-proven diagnosis of prostate cancer. They advocated the use of physician ownership of brachytherapy facilities and equipment because it means that the urologists and radiation oncologists involved are actually performing the procedure themselves in a facility contracting with those physicians. The design of this model includes the supervision of every case by an experienced brachytherapist present in the operating room. According to the commenter, physician ownership of the equipment also ensures quality of physician education and of surgical technique.

The commenters asserted that we should allow multiple physicians to own brachytherapy equipment because centralized planning for radiation physics results in all cases being planned in a controlled and uniform fashion. Uniformity eliminates many empirical physician decisions that in the past led to dosimetry errors. In addition, having two or more physicians owning the equipment encourages reporting of outcome data collection to a central agency, resulting in a continuous and rapid review of treatment results and complications. Commenters pointed out that experts have published restrictive dose guidelines for the various stages of prostate cancer treated with brachytherapy, so there is no risk of overutilization. Also, brachytherapy is less expensive and has a lower complication rate than the other forms of treatment (radical prostatectomy or external beam radiation therapy).

The commenters believe that because of all of these factors the procedure has little potential for program or patient abuse and should be exempt from the physician self-referral prohibition.

Response: We are aware of no logical or empirical evidence that physician ownership improves quality of services or physicians' skills. On the other hand, brachytherapy is one of several therapy options for certain prostate conditions. We believe that ownership of a brachytherapy center by urologists could well influence their recommended therapy and, therefore, affect utilization. In short, the relationship is exactly the type of financial relationship section 1877 of the Act is intended to address. The law excludes from the definition of a ''referral'' any request by a radiation oncologist for radiation therapy if these services are furnished by (or under the supervision of) the radiation oncologist pursuant to a consultation requested by another physician. In addition, we have amended the definition of a ''referral'' to exclude any professional components performed by referring physicians themselves.

H. Durable Medical Equipment (DME)

In § 411.351 of the January 1998 proposed rule, we defined DME as having the meaning given in section 1861(n) of the Act and § 414.202 (Definitions). In the preamble to the January 1998 proposed rule (63 FR 1677 through 1678), we offered explanations of the terms and a list of the general DME categories. However, we stated in the preamble (63 FR 1677) that because the number of items considered to be DME was so extensive, we could not in the proposed rule identify all of them. Commenters were concerned about our failure to articulate a ''bright-line'' definition of DME. The commenters

stated that if we could not do that, physicians would have to assume that the dispensing of all DME falls under the referral prohibition.

The most frequent complaint was the difficulty the commenters had in determining whether a given item was DME or a prosthetic, prosthetic device or orthotic. (The distinction is significant since under section 1877(b)(2) of the Act prosthetics, prosthetic devices, and orthotics may be provided to a patient by a physician under the in-office ancillary services exception, while DME (other than infusion pumps) cannot.) The easiest way to determine the proper classification of an item is to consult the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) fee schedule, which is updated quarterly and available on the internet under HCFA's public use files (www.hcfa.gov/stats/pufiles.htm). Under the DMEPOS fee schedule, items are identified by their HCPCS code and also include a category designation that identifies whether the item is DME, prosthetics, orthotics, or prosthetic devices. DME items include the following categories:

CR, capped rental DME.

FS, DME requiring frequent and substantial servicing.

IN, inexpensive or routinely purchased DME.

OX, oxygen and oxygen equipment.

SU, DME supplies.

TE, transcutaneous electrical (or electronic) nerve stimulator.

Additionally, DME includes the HCPCS code E1399. This code covers a number of miscellaneous DME items, but does not appear on HCFA's national fee schedule. Each DMERC (regional DME carrier) is responsible for creating a fee schedule for individual items that are not included on HCFA's fee schedule.

We note that Phase I of this rulemaking does not change existing definitions for DME, prosthetics, prosthetic devices, or orthotics. Thus, the existing classification of an item (that is, its classification as either DME, prosthetic, prosthetic device, or orthotic) will remain the same.

In sum, if, after reviewing the definitions and accompanying explanations that we provided in the January 1998 proposed rule, as well as the DMEPOS fee schedule and the HCPCS codes covering miscellaneous items, physicians and their staffs still have questions about whether a specific item is considered to be DME, we would suggest that they contact their local carrier or DMERC for clarification.

Comment: One commenter asked for clarification on whether prosthetic and orthotic devices that seem to meet the criteria for DME are considered DME supplies and whether they could be provided under the in-office ancillary services exception. The commenter expressed some confusion regarding whether crutches are DME or a prosthetic or orthotic device.

Response: The categories of prosthetics, orthotics, prosthetic devices or DME are mutually exclusive; no item can fall into more than one of these categories. If individuals are concerned about a particular type of equipment or a supply, we would suggest that they review the HCPCS codes or DMEPOS fee schedule or contact their local carrier or DMERC for clarification. Again, we note that DMERCs process more than DME claims. They also are responsible for claims for other types of devices and supplies. Crutches are DME.

Comment: A commenter recommended that we exempt crutches from the definition of DME. The commenter suggested that crutches are provided as peripheral parts of a major service (that is, a diagnosis of a broken leg) and that it is unlikely a physician would over-prescribe crutches for a diagnosis of a broken leg just so that the physician can bill for the crutches. The commenter believes that having the physician provide the crutches and instruct the patient on how to use them helps to prevent further damage to the patient and is essential to good patient care.

Response: We believe that crutches are clearly DME and therefore DHS under section 1877(h)(6)(F) of the Act. As we stated in the January 1998 proposed rule, although we cannot justify excluding crutches as a designated health service, we recognize that including crutches could greatly inconvenience patients if physicians were barred from providing them to patients who need them to ambulate following treatment for an injury or an incapacitating procedure. For this reason, we proposed expanding the in-office ancillary services exception to cover crutches when furnished in a manner that meets the in-office ancillary services exception requirements and in which the physician realizes no direct or indirect profit from furnishing the crutches. We have adopted the proposal in an expanded and modified form—without the proposed profit restriction—as described in section VI.B.1 of this preamble.

Comment: Several commenters opposed the inclusion of DME as a designated health service and argued that the inclusion of DME will result in additional delays in treatment and barriers to access for the nation's poor and elderly populations. Two of the commenters urged us to support a legislative change to remove DME from the DHS list, while others urged us to revise the January 1998 proposed rule to remove DME entirely as a designated health service. Those commenters argued that when DME is furnished as an in-office service, it has not been associated with program abuse and offers little or no opportunity for overutilization. One of the commenters contended that an unintended effect of the inclusion of DME on the DHS list would be underutilization, because physicians would be prohibited from furnishing DME in their offices.

Response: We believe that we cannot create a separate exception for DME because we cannot guarantee that such an exception would always be free from program or patient abuse. The Congress explicitly included DME as a designated health service in section 1877(h)(6)(F) of the Act; we have no authority to vitiate that judgment. We note that physicians would only be prohibited from furnishing DME services when they have an unexcepted financial relationship with the DME supplier. Moreover, although we are not removing DME from the list of DHS, we are substantially revising the manner in which the in-office ancillary services exception applies to DME. These changes will expand the provision of DME under the in-office ancillary services exception as detailed in section VI.B.1 of this preamble.

I. Parenteral and Enteral Nutrients, Equipment and Supplies

Section 1877(h)(6)(G) of the Act includes as DHS the category of parenteral and enteral nutrients, equipment, and supplies (PEN). Enteral and parenteral therapy as a Medicare Part B benefit is provided under the prosthetic device benefit provision in section 1861(s)(8) of the Act. The regulations cover prosthetic devices in § 410.36 (Medical suppliers, appliances, and devices: Scope), paragraph (a)(2). Details for enteral and parenteral therapy are set forth in section 65–10, ''Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,'' of the Medicare Coverage Issues Manual (HCFA Pub. 6). When the coverage requirements for enteral or parenteral nutritional therapy are met, Medicare also covers related supplies, equipment, and nutrients.

We proposed in § 411.351 of the January 1998 rule to define ''enteral nutrients, equipment, and supplies'' as

items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. (See section 65–10, ''Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,'' of the Medicare Coverage Issues Manual (HCFA Pub. 6) for additional information.)

We proposed in § 411.351 to define ''parenteral nutrients, equipment, and supplies'' as items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10, ''Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,'' of the Medicare Coverage Issues Manual (HCFA Pub. 6).

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services. We believe this list will address any uncertainties that physicians and providers might have about what constitutes PEN, and is consistent with our definition in the proposed rule.

We also pointed out in the preamble to the January 1998 proposed rule that, like DME, section 1877(b)(2) of the Act specifically excludes PEN as services that can qualify for the in-office ancillary services exception.

Comment: A physician representing himself and an infusion therapy association asserted that physicians should be allowed to prescribe, provide, and be reimbursed for parenteral nutrition for their own patients as an extension of their practices. The commenter asserted that there has been no evidence of abuse, while there have been major problems with fraud and abuse and excessive profits by nonphysician home infusion providers, which function essentially without physician control and minimal input from physicians. The commenter believes that because patients with increasingly complex medical problems are sent home earlier from the hospital, the role of the physician office-based model is increasingly important. The January 1998 proposed referral regulations, the payment schedule for medications, and the restriction on physician reimbursement for ambulatory infusion pumps all discourage a physician's involvement in these services.

Response: Section 1877 of the Act does not prohibit physicians from prescribing enteral and parenteral nutrition for their own patients; nor does it prohibit infusion companies from contracting with expert or knowledgeable physicians for consulting services provided the remuneration is fair market value and does not take into account referrals or other business between the parties. Section 1877 of the Act does, however, prohibit a physician from furnishing enteral and parenteral nutrition in his or her own office and billing for it unless the physician's arrangement qualifies for an exception, such as the rural provider exception in section 1877(d)(2) of the Act. The Congress specifically excluded the provision of enteral and parenteral nutrition and durable medical equipment (DME, other than infusion pumps) from the in-office ancillary services exception in section 1877(b)(2)of the Act.

We have the authority to create additional exceptions to the referral prohibition for financial relationships under section 1877(b)(4) of the Act, but only if we determine that there is no risk of program or patient abuse. However, we believe that physicians could potentially over-prescribe parenteral nutrition if they have the financial incentive to do so.

We only cover parenteral nutrition when there is a permanent need (except when covered under the home health benefit). (See the Medicare Coverage Issues Manual (HCFA Pub. 6), section 65–10, ''Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device,'' for additional information. Because coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, the patient must have a permanently inoperative internal body organ or function.) We see no reason why a patient should have to go to a physician's office regularly to receive parenteral nutrition. Medicare already covers parenteral nutrition delivered in the home through the home health benefit or the prosthetic device benefit. Because enteral nutrition is widely available through grocery stores, drug stores, and other retail outlets, we see no reason why a patient must purchase enteral nutrition from a physician. A patient can purchase certain more specialized types of enteral nutrition that are not widely available from a DME supplier.

If a patient is to receive nutrition via an infusion pump, the in-office ancillary services exception cannot be used for the furnishing of the pump, since this exception only allows physicians' offices to furnish infusion pumps that are DME. See section VI.B.1 of this preamble for more details about infusion pumps. (To furnish an infusion pump that is DME for use in the home, a physician would have to meet all of the supplier requirements in § 424.57.)

As for the commenter's concerns about the payment schedule for medications, that issue is not addressed by the physician referral regulation.

J. Prosthetics, Orthotics, and Prosthetic Devices and Supplies

Prosthetics, orthotics, and prosthetic devices and supplies are included as DHS under section 1877(h)(6)(H) of the Act. We proposed in the January 1998 rule to define ''prosthetics'' at § 411.351 as artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act. We defined ''orthotics'' as leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act. We proposed to define a ''prosthetic device'' as a device (other than a dental device) listed in section 1861(s)(8) of the Act that replaces all or part of an internal body organ, including colostomy bags and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, as well as services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. We proposed defining ''prosthetic supplies'' as ''supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).''

We are clarifying in Phase I of this rulemaking that this category includes all HCPCS level 2 codes for these services that are covered under Medicare. Physicians and other persons can readily determine the classification of an item by consulting the DMEPOS fee schedule. However, as with DME, there are several specific HCPCS codes representing miscellaneous items classified as prosthetics, orthotics, or prosthetic devices that do not appear in the fee schedule.

We explained in the preamble of the January 1998 proposed rule (63 FR 1678) that Medicare regards intraocular lenses (IOLs) used as part of cataract surgery as prosthetic devices. We also stated in the preamble that if these lenses are implanted in an ASC, they would be covered under the ASC payment rate and would have been excluded under the exception we proposed to create in § 411.355(d). As explained above, we are no longer considering DHS that are included in a bundled ASC payment to be DHS.

Accordingly, when an IOL is included in an ASC bundled payment rate, it will not be considered to be a designated health service.

We are also addressing a number of commenters' requests by creating exceptions (through our authority under section 1877(b)(4) of the Act) for prosthetic devices that are implanted in a Medicare-certified ASC and for eyeglasses or contact lenses that are prescribed after cataract surgery. We explain our reasons for these exceptions in our responses to specific comments.

Comment: One commenter asserted that the final rule should allow physicians to provide durable medical equipment, orthotics, and prosthetics directly to patients when they are medically necessary. Physicians currently supply splints, braces, or other devices directly to patients who have injuries, thereby ensuring that the patient gets the appropriate device, that the item is properly fitted, and that the patient is properly instructed in its use. To require a patient with an injury to leave the office, go to a DME supplier, purchase the necessary equipment, and return to the physician's office for fitting or placement and instructions on use, would be unwise, inconvenient, and could frequently cause unnecessary pain or further injury.

Response: The splints, casts, and other devices used to treat fractures and dislocations the commenter mentions are covered under section 1861(s)(5) of the Act, a benefit category that is different from the benefit categories that include DME, prosthetics, orthotics, and prosthetic devices. They are therefore not DHS under section 1877(h)(6) of the Act. Leg, arm, back, and neck braces are considered to be ''orthotics'' and are thus included as DHS. These can be provided by a physician within his or her own practice under the in-office ancillary services exception in section 1877(b)(2) of the Act, which excepts a physician's referral if the services meet certain supervision, location, and billing requirements. This exception could apply to referrals for any prosthetics, orthotics, or prosthetic devices. As modified by these regulations, the in-office ancillary exception could also apply to referrals for certain DME services. (See section VI.B.1 of this preamble.)

Comment: A number of commenters favored our proposal to exclude IOLs implanted during cataract surgery performed in an ASC because the IOLs are included in the ASC payment rate. The commenters asserted that a substantial number of ASCs are owned by the physicians who perform surgical procedures in them and that these physicians are not members of one group practice. The commenters see the ASCs as an extension of the physician's own office and believe they provide a high quality, low cost setting for outpatient surgery.

Commenters requested that we exempt from the physician self-referral prohibition other prosthetic devices implanted in conjunction with surgical procedures because the provision of the prosthetic devices is incidental to the provision of ASC facility services, which are exempt from the physician self-referral prohibition. The commenter asserted that, as we noted in the January 1998 proposed rule, a physician would not unnecessarily subject patients to a surgical procedure to profit from the implant. In addition, there is no risk of program abuse because the Medicare payment for prosthetic devices implanted in conjunction with ASC facility services is limited to the lower of the actual charge for the device or a fee schedule amount. Commenters emphasized that the use of implanted prosthetic devices in reconstructive surgery is immensely beneficial to patients.

Response: We agree with the commenters that all prosthetic devices implanted in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice should be excluded. We have chosen this position because, if surgeons refer to an ASC in which they have an ownership interest, there will, in many cases, be no exception that would apply to their financial relationship with the ASC. Implanted prosthetic devices, implanted prosthetics, and implanted DME are not included in the bundled ASC payment rate and thus would retain their character as DHS even when implanted in an ASC. As a practical matter, the absence of an exception for all of these items implanted in ASCs is likely to result in these procedures moving to more costly hospital outpatient settings. We believe that the exclusion of these implants from the reach of section 1877 of the Act (using our authority under section 1877(b)(4)) will not increase the risk of overutilization beyond what is already presented by the surgeon's Part B physician fee and is consistent with the Congress's decision not to include ambulatory surgical services as a specific designated health service. We are specifically providing that the exception does not protect items implanted in other settings. Nor does it protect arrangements between physicians and manufacturers or distributors of implants where the manufacturers or distributors furnish DHS, for example, through subsidiaries or affiliates. We are providing that the arrangement for the provision of the implant in the ASC may not violate the anti-kickback statute and all billing and claims submission must be proper.

Comment: Some commenters recommended that we exclude some or all implants to assure that there is no chilling of the ability and opportunity of Medicare patients to obtain the most appropriate and up to date technology that will be both effective and cost efficient. In addition, commenters pointed out that invasive surgery always entails a risk to the patient and is not undertaken without a physician seriously evaluating that risk in relation to the therapeutic or diagnostic benefit likely to be brought by the device to be implanted and determining what specialized model and brand of device will be most effective. Commenters believe that including implants in the definition of prosthetic devices will have the counterproductive effect of preventing surgeons from participating in research and development of these products, thereby curtailing research activity and blunting future development. This chilling effect would dramatically affect the quality of patient life and severely limit progress in reducing the cost to patients.

Response: Surgeons should be able to provide implants to their patients in any appropriate setting by meeting exceptions to the physician self-referral law. As we described in responses to earlier comments, we are creating an exception for implants that are performed in Medicare-certified ASCs. As to implants in other settings or those in ASCs that do not meet the new exception, other exceptions may still apply. Physicians who perform implants within their own practices may be able to use the in-office ancillary services exception in section 1877(b)(2) of the Act, which is discussed in section VI.B.1 of this preamble. If a physician performs the surgery in a hospital, and the hospital bills for the implant, the service would be a designated hospital service, regardless of whether the implant is a prosthetic or prosthetic device. In these cases, any financial relationship between the physician and the hospital would have to fit in an exception or the physician could not perform the surgery, much less the implant, since all hospital services are DHS. There are several exceptions that apply to referrals for hospital services.

The commenters seem to be under the misapprehension that section 1877 of the Act would prevent financial relationships between the manufacturer of an implant and a physician. These

financial relationships would not be subject to section 1877 of the Act unless the manufacturer were an entity that bills Medicare directly. However, arrangements between physicians and manufacturers may be problematic under other legal authorities, including, for example, the Federal anti-kickback statute.

Comment: One commenter believes that we should not interpret the definition of prosthetics, orthotics, and prosthetic devices and supplies for physician referral purposes to include hip and knee implants. The commenter believes that hip and knee implants do not fall within the definitions of prosthetics, orthotics, and prosthetic devices and supplies that we included in the January 1998 proposed rule. The commenter pointed out that ''prosthetics'' is defined as artificial legs, arms, and eyes, that ''orthotics'' is defined as leg, arm, back and neck braces, and ''prosthetic devices'' is defined as devices that replace all or part of an internal body organ. The commenter believes that hip and knee replacements do not fall under any of these categories.

The commenter further stated that, if hip and knee implants are somehow considered as prosthetic devices under Medicare, they should be excluded from the referral prohibition on the basis that they are only a component of a primary surgical procedure meant to repair damaged or painful joints. The commenter believes physicians will not ask patients to undergo painful and debilitating surgery for the sake of implanting an unnecessary artificial knee or hip implant. Also, if these items are billed as part of the hospital diagnosis-related group (DRG) payment for a surgical procedure, there is no financial incentive to use more costly or unnecessary implants and there is no increased cost to the program if one implant is chosen over another.

Response: Knee implants are considered to be ''prosthetics.'' They are components of the artificial legs that are identified as prosthetics under section 1861(s)(9) of the Act. Artificial hips are only furnished to hospital inpatients under Medicare Part A, so we consider them to be a component of an inpatient hospital service. If a physician sends a patient to a hospital for a hip or knee implant or the insertion of a prosthetic device, all the services billed by the hospital would qualify as DHS under section 1877(h)(6)(K) of the Act because they are ''inpatient or outpatient hospital services.'' The implants would therefore be subject to the physician self-referral law, even if we excluded them from the separate category of ''prosthetics, orthotics, or prosthetic devices and supplies.''

Comment: A commenter asserted that we should exclude cochlear implants from the definition of prosthetic devices. In the January 1998 proposed rule, we had indicated our concern that a physician would choose a particular device because he or she had supplied it to the ASC where the patient's implant surgery was performed or because the physician receives money from a supplier for ordering the particular device. The commenter stated that the professional association he represents is unaware of any abuses in this area and, if there were abuses, they would be subject to the anti-kickback law.

Another commenter from an association of audiologists agreed with us that cochlear implants are a type of prosthetic device that is properly within the scope of the proposed rule. The commenter regards a cochlear implant as clearly being a prosthetic device because it replaces all or part of an internal body organ. A cochlear implant is an electronic device specifically designed to replace the function of a damaged cochlea.

Response: We agree with the second commenter that cochlear implants are covered as prosthetic devices under Medicare and are categorized as such in the CPT codes in the attachment to this final rule. As noted above, we are excepting all implants performed in a Medicare-certified ASC by the referring physician or a member of the referring physician's group practice, subject to certain conditions set forth in the exception.

Comment: A commenter noted that in the January 1998 proposed rule we stated that a prosthetic device includes services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. The commenter requested that we expressly clarify that certain services provided to patients after a cochlear implant are subject to the physician self-referral provisions. These services include device mapping, aural rehabilitation programs for adults to enable them to learn to use the device, and aural habilitation programs for children to maximize speech and language development.

The commenter asserted that these postsurgical services are provided by audiologists without physician involvement or supervision of any kind. In addition, the commenter stated that cochlear rehabilitation services are not included in the global fee for cochlear implantation surgery. Instead, these services are billed under a unique CPT code, 92510.

Response: The Medicare definition of a prosthetic device ordinarily includes the services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct patients in its proper usage. In fact, the costs of delivery, fitting, measuring and instructing the patient are bundled into the fee schedule payment amount for not only prosthetic devices, but for DME, orthotics, and prosthetics as well. However, cochlear implants are somewhat unique. Because it can be particularly difficult for a patient to learn to use the implant, cochlear rehabilitation services are categorized separately as speech-language pathology services. These services are billed under CPT code 92510 (which is included as a PT service because it is a speech-language pathology service). Therefore, all of these services qualify as ''designated health services,'' but under different categories.

Comment: A commenter pointed out that items such as rib belts, slings, and basic braces (those not custom-fitted) are in the prosthetic/orthotic section of the HCPCS. The commenter asked whether these items would be considered orthotics or DME, since the patient would be wearing the item home. The commenter believes that, in either case, it would be inappropriate to prevent a physician from supplying and billing for these items when the patient has come to the office with an injury. The commenter asserted that requiring a patient to leave the physician's office to purchase necessary equipment is inconvenient and unwise because it may result in unnecessary pain or injury to the patient.

Response: The items described as ''rib belts'' and ''slings'' are not included in any DHS category. The items described as ''basic braces'' are orthotics. Nothing in Phase I of this rulemaking moves any item or device from one coverage category to another coverage category. If the items qualify as in-office ancillary services under section 1877(b)(2) of the Act, a physician who supplies them in his or her office in the course of seeing a patient should be able to use the in-office ancillary services exception in order to provide them to the patient, even if the patient takes the items home. We regard the physician as ''furnishing'' an item in his or her office if the physician dispenses the item to the patient there.

Comment: Several commenters urged us to exclude eyeglasses and contact lenses from the definition of prosthetic devices. Commenters noted that there is

no incentive to overutilize or abuse this benefit because we acknowledge that one pair of conventional eyeglasses or contact lenses is medically necessary after cataract surgery; Medicare coverage is limited to one pair of conventional eyeglasses or contact lenses; and Medicare payment is on a reasonable charge basis.

Response: We agree with the commenters that eyeglasses and contact lenses should be excluded from the reach of section 1877 of the Act for purposes of Medicare referrals. The Medicare coverage of these items is unique in that it is limited to one pair of either item after each cataract surgery and is available to any patient who has had this surgery. In that respect, the coverage is similar to the coverage of preventive screening services that are subject to frequency limits, as discussed earlier in this section. In addition, the Medicare-approved amount of payment does not vary based on the expense of a particular pair of glasses or contact lenses. Medicare pays fixed amounts for eyeglasses and contact lenses that are single focal, and fixed amounts for eyeglasses and contact lenses that are bifocal. In sum, we see little opportunity or incentive for a physician to either under or overutilize these items in the Medicare program. Accordingly, we are creating a new exception under the authority in section 1877(b)(4) of the Act for eyeglasses and contact lenses after cataract surgery. Like other section 1877(b)(4) exceptions, the new exception is subject to there being no violation of the anti-kickback statute or any billing or claims submission law or regulation.

K. Home Health Services

In the January 1998 proposed rule, we proposed to define home health services as the services described in section 1861(m) of the Act and part 409, subpart E. We included in the preamble to that rule (63 FR 1679), a discussion of how we proposed to reconcile section 1877 of the Act and the physician certification requirements for home health services in § 424.22 (Requirements for home health services), paragraph (d) (Limitations on the performance of certification and plan of treatment functions). In that discussion, we explained that the home health agency (HHA) rule and its exceptions have been superseded by section 1877 of the Act. Phase I of this rulemaking reflects this change. Our responses to comments mostly serve to clarify how the modified home health rule will work.

Comment: Four commenters supported our proposal to reconcile the physician self-referral law with the physician certification requirements for home health services contained in § 424.22(d). One commenter specifically expressed agreement with our proposed position that the exceptions to the physician self-referral law would also apply to physician certification requirements for home health services. Another commenter specifically supported the proposed changes that would eliminate the 5 percent ownership and $25,000 financial or contractual relationship limits and replace them with the prohibition on self-referral contained in section 1877 of the Act. The commenter stated that this change would allow HHAs to provide for medical oversight by a salaried physician as permitted under the Medicare hospice benefit. (We believe that commenter meant that the proposed elimination of the $25,000 financial or contractual relationship provision would allow an HHA to pay a physician medical director more than $25,000 as long as the HHA meets relevant ownership and compensation exceptions described in the proposed rule.) Another commenter asked that we clarify whether the current $25,000 limit on financial or contractual relationships as it relates to medical directors of home care agencies will be removed.

Response: We are removing the current 5 percent ownership limit and the $25,000 limit on financial or contractual relationships from § 424.22(d). The new § 424.22(d) appears exactly as we proposed it: ''The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, 'Definitions,' with that HHA, unless the physician's relationship meets one of the exceptions in §§ 411.355 through 411.357 of this chapter * * *.'' The elimination of the $25,000 financial or contractual relationship provision will allow an HHA to pay a physician medical director more than $25,000 as long as the financial relationship meets a relevant ownership or compensation exception under section 1877 of the Act.

Although we are delaying the effective date for most of Phase I of this rulemaking for 1 year, we are making the change in § 424.22(d) effective February 5, 2001. Having weighed the alternatives, we believe an effective date of February 5, 2001 for the revision of § 424.22(d) is desirable, even though the revisions to §§ 411.355 and 411.357 will not be effective until later. In the interim, the references to §§ 411.355 and 411.357 will cross-refer to the statutory exceptions set forth in section 1877 of the Act. It is our view that during the interim period, the exceptions set forth in those sections would apply under § 424.22(d) for services other than laboratory services.

Comment: One commenter requested that we retain the provisions in § 424.22(e) (Exceptions to limitations), (f) (Procedures for classification as a sole community HHA) and (g) (Basis for classification as a sole community HHA) that except governmental entities and sole community HHAs from the prohibition on certification of need for home health services by related physicians. The commenter noted that keeping this language would remove the threat of unfair competition for agencies that have historically been the sole providers in their communities. The commenter explained that the ''rural provider'' exception to the physician self-referral law would permit an urban physician to establish a new HHA in a rural area, as long as the agency's service population is at least 75 percent rural. This would create new and unfair competition for many rural agencies that are small, nonprofit organizations.

Response: We realize that eliminating the exceptions for governmental entities and sole community HHAs in combination with the ownership exception for rural providers under the physician self-referral law may create new competition for small, nonprofit HHAs. Nonetheless, we believe that we do not have the legal authority to retain these exceptions in any meaningful way. As we pointed out in the preamble to the January 1998 proposed rule (63 FR 1680), even if a physician and an HHA are involved in an arrangement that meets one of the home health exceptions at issue, the arrangement simultaneously remains subject to the requirements in section 1877 of the Act. That is, if an exception under the HHA certification regulations is subsumed within the exceptions in section 1877 of the Act, a physician will be able to refer; if it is not, the arrangement will disqualify the physician from referring in spite of § 424.22. Thus, the HHA exceptions have been superseded by section 1877 of the Act.

The Secretary does have the authority to create additional exceptions to the referral prohibition under section 1877(b)(4) of the Act, but only in situations in which she determines that there is no risk of program or patient abuse. We believe that the fact that an entity is run by the government or is a sole community HHA does not guarantee that there will be no

unnecessary referrals. In addition, it is our view that we should treat all providers equally and allow them an equal opportunity to compete, particularly in areas where there have historically been too few providers. In fact, the purpose of the ''rural provider'' exception in section 1877(d)(2) of the Act is to encourage physicians to invest in or remain invested in under-served areas. (Note that hospitals do not have similar exceptions for governmental entities or sole community hospitals.) Therefore, we do not intend to include the exceptions for governmental entities and sole community providers in the revised HHA certification regulations because we believe that our proposed approach provides the best protection against possible program abuse and fulfills the intent of the law.

Comment: A commenter representing home care physicians asked that we clarify whether physicians making home visits are providing services that qualify as DHS under the January 1998 proposed regulations.

Response: Under the Medicare program, when a physician performs a physician service, including a visit to a home health patient, the physician service is billed as a physician service and is not considered a home health service. This is the case even when the physician has an employment contract with the HHA, such as when a physician is employed as a medical director. Thus, the commenter is correct in noting that physician home visits are not themselves on the list of DHS in section 1877(h)(6) of the Act, and would only qualify as such if the physician was actually performing a specific designated health service (for example, performing physical therapy). In these cases, the service would still be protected if it is personally performed by the referring physician, since it would not be considered a referral under the final rule. (See section III.B of this preamble.) In addition, some in-home services provided by a home care physician may qualify under the in-office ancillary services exception. (See section VI.B of this preamble.)

L. Outpatient Prescription Drugs

Section 1877(h)(6)(J) of the Act provides that ''designated health services'' includes the category of ''outpatient prescription drugs,'' but does not define this term. Because Medicare does not cover a category of services called ''outpatient prescription drugs,'' we proposed to define this term in the regulation. We proposed to include only drugs (including biologicals) defined or listed under section 1861 (s) and (t) of the Act, and in part 410, furnished under the Medicare Part B benefit that patients can obtain from a pharmacy with a prescription, even if patients can only receive the drug under medical supervision. In the preamble to the January 1998 proposed regulation (63 FR 1680), we included as an example oncology drugs that are routinely furnished in a physician's office, under the physician's direct supervision, provided the drugs could be obtained by prescription from a pharmacy.

We proposed specifically to exclude from the definition of ''outpatient prescription drugs'' erythropoietin (EPO) and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility.

Upon further review of the law, existing regulations, and the public comments, we have concluded that our proposed definition of ''outpatient prescription drugs'' was not clear enough. In Phase I of this rulemaking, we are revising the definition of outpatient prescription drugs to make clear that it includes all prescription drugs covered by Medicare Part B. We are not excluding any outpatient prescription drugs from the DHS category of ''outpatient prescription drugs.'' Including all outpatient prescription drugs is consistent with our policy throughout these final regulations of avoiding carving services out of DHS definitions through service-by-service analyses of the potential for fraud and abuse. Our definition of outpatient prescription drugs provides physicians and DHS entities with a ''bright line,'' common sense rule. Moreover, the breadth of the definition is ameliorated to a very large extent by our expansion of the exception for in-office ancillary services, which includes much greater flexibility with respect to the direct supervision requirement, and our promulgation of a new limited exception under section 1877(b)(4) of the Act for the provision of EPO and certain other dialysis-related drugs by or in ESRD facilities (described in greater detail below). Those changes, together with the changes in the definition of ''group practice'' and ''referral,'' should permit a physician to furnish patients with covered drugs, either by administering or dispensing the drugs to patients in his or her office or, in the case of EPO and other specific dialysis drugs, by furnishing the drugs in or through a physician-owned ESRD facility. We wish to make clear that nothing in this regulation affects, or is intended to affect, current or future coverage of any particular prescription drug.

We are creating an exception for EPO and certain other specific drugs that are required for the efficacy of dialysis when they are furnished by an ESRD facility with which the referring physician has a financial arrangement. We are similarly excepting certain vaccinations, immunizations, and preventive screening tests that are subject to HCFA-imposed frequency limits. We are also clarifying that physicians who provide drugs in their own offices are not required to pass on to Medicare discounts they receive in purchasing these drugs, unless otherwise required to do so by the Medicare program. These issues are discussed in detail below.

Comment: A number of commenters raised the issue of whether drugs and biologicals provided incident to physician services are included in the definition of outpatient prescription drugs. The commenters pointed out that most drugs and biologicals are covered under Medicare Part B only if they require administration by a physician, and thus typically are covered in the physician office setting only if furnished as ''incident to'' physician services. Thus, the resulting ''self referral'' is effectively a requirement for Medicare coverage. In the commenters' view, excluding drugs furnished incident to physician services from the definition of ''outpatient prescription drugs'' would ensure that the physician self-referral law does not discourage the types of ''referrals'' that are prerequisites to Medicare coverage.

One commenter asserted that drugs that are covered under Medicare only as a component of a physician service should be excluded because physician services were never intended to be included within the referral prohibition. Another commenter recommended that we make all injectable drugs exempt from the referral prohibition under the in-office ancillary services exception.

Several commenters were particularly concerned about antigens and serums that a patient receives in a physician's office, stating that they should be excluded from the category of outpatient prescription drugs, along with chemotherapy. Another commenter pointed out that if our definition of outpatient prescription drugs includes drugs administered during a patient's office visit, patients could have serious access problems to such drugs as antibiotics, renal therapy, and vaccines. Another commenter recommended that we limit outpatient prescription drugs to those that are self-administered, such as oral cancer drugs, oral antiemetics, and immunosuppressives, for which there is Medicare coverage that does not

depend on administration in a physician's office.

Response: We believe the commenters are conflating two issues: (1) What drugs fit in the term ''outpatient prescription drugs'' in section 1877(h)(6)(J) of the Act and (2) the scope of the in-office ancillary services exception in section 1877(b)(2) of the Act. Upon review, for purposes of defining ''outpatient prescription drugs'' under section 1877(h)(6)(J) of the Act, we can ascertain no meaningful distinction between prescription drugs dispensed by pharmacies or those mixed and administered in a physician's office. To the extent the latter is permitted, it is through the vehicle of the in-office ancillary services exception. The scope of that exception is discussed in section VI.B.1 of this preamble.

Comment: Many commenters stated that oncology drugs administered to patients by injection or infusion in a physician's office should be excluded from the definition of outpatient drugs because a patient essentially cannot obtain these drugs from a pharmacy before visiting his or her physician. When a patient comes to a physician's office for chemotherapy, the patient receives a series of blood tests to determine the patient's physiological state. Based on these tests, the chemotherapy agents are mixed and tailored by the oncologist's staff to address the patient's current health status. Therefore, a patient cannot pick up from a pharmacy the medication he or she needs before visiting the physician. We may have misunderstood how chemotherapy drugs are actually administered.

In addition, the commenters pointed out that a great majority of retail pharmacies are not currently prepared to provide chemotherapeutic mixing and dispensing services for infusion drugs. That is because Federal regulations and accepted standards of practice for physicians, oncology nurses, technicians, and pharmacists require that the preparation, storage, transportation, and disposal of chemotherapy drugs and applicable supportive agents be conducted under the most rigorously controlled circumstances.

Response: We agree that chemotherapy agents are not commonly available from retail pharmacies, but are prepared for individual patients. However, these drugs are outpatient prescription drugs; they are available only upon a physician's order and are provided in an outpatient setting. (When provided in an inpatient setting, they would be inpatient hospital services under section 1877(h)(6)(K) of the Act.) We believe these drugs are usually administered in oncologists' offices and typically should qualify for the in-office ancillary services exception. (See discussion in section VI.B.1 of this preamble.)

Comment: Several commenters have stated that in-office x-rays and laboratory tests that are performed in conjunction with the provision of chemotherapy should be excluded from the definition of DHS. The commenters seemed particularly concerned that if these services are regarded as DHS, a physician would have to directly supervise them. The commenters expressed concern that requiring a physician to be present during the times these services are provided would run directly counter to common practice in oncology offices and would greatly inconvenience patients.

These commenters asserted that it is extremely unlikely that a physician would refer a patient for chemotherapy simply to obtain the revenue from the x-ray and laboratory tests that are performed in conjunction with the provision of chemotherapy. They regard as a precedent for this exception our proposals to exclude from the definition of radiology certain invasive radiology services in which an imaging modality is used to guide a needle, probe, or catheter properly and to exclude EPO from the definition of outpatient prescription drugs when EPO is provided incidental to dialysis treatment. We had proposed to exclude these invasive radiology procedures and EPO because they are merely furnished incidental to, or secondary to, another procedure that the physician has ordered.

Response: The Congress has imposed certain constraints on physicians' financial arrangements with entities to which they refer patients for DHS. The provision of chemotherapy is a designated health service, as is the provision of radiology and clinical laboratory services. In order for a physician to refer patients to an entity with which the referring physician has a financial arrangement, the physician's financial relationship with the entity must come within an exception to section 1877 of the Act.

As discussed elsewhere, we are not prepared to limit the scope of DHS under section 1877(h)(6) of the Act except in rare situations. We believe that most arrangements for the provision of chemotherapy and related ancillary services by physicians to their patients can be restructured to come within the in-office ancillary services exception as modified by this final rule. (See section VI.B of this preamble.) As discussed above, we are abandoning the ''peripheral/incidental'' test that was proposed in the January 1998 proposed rule; we point out that even under that test, the primary procedure could not itself be a designated health service.

Finally, we wish to clarify that we are excepting EPO under certain circumstances because we believe that the Congress did not intend to preclude physician ownership of ESRD facilities. Commenters have noted that when the Congress intended to cover specific Medicare services, including composite rate services, it did so expressly. We agree. The Congress did not list ESRD facility services under section 1877(h)(6) of the Act, while it did list home health services and hospital services. Therefore, we do not regard services furnished under a composite rate by an ESRD facility as DHS. Given the high correlation between EPO and ESRD services, the inclusion of EPO as a DHS would vitiate the Congress' apparent intent. Accordingly, we are excepting from the reach of the statute under our section 1877(b)(4) of the Act authority EPO or other drugs required for dialysis when furnished in or by an ESRD facility owned by physicians. The list of these drugs is set forth in the attachment to this final rule. Given the strict utilization and coverage criteria for EPO in particular and ESRD in general, we conclude this narrow exception presents no quantifiable risk of fraud or abuse. We are not protecting any physician investment in a home dialysis supply company or other entity that supplies EPO to ESRD facilities or that supplies EPO to patients pursuant to a contract with an ESRD facility; in such situations, the physician's investment in the dialysis supply company is no different from any other investment in a DHS entity and there is no indication in the legislative history that home dialysis supply companies were not meant to be covered by the statute.

Comment: A substantial number of commenters requested that we not require physicians to pass on to Medicare discounts they receive in purchasing oncology drugs. Commenters pointed out that the proposed regulations appear to require this result. Some commenters believe that this proposed requirement conflicts with section 1877(e)(8)(B) of the Act, which excepts any payment made by a physician for items and services if the price is consistent with fair market value.

Response: Nothing in this section 1877 of the Act or these regulations is intended to impose on physicians a requirement to pass discounts on drugs

on to the Medicare and Medicaid programs; whether a discount must be passed on to a Federal health care program by physicians or others, however, remains the subject of other statutory and regulatory provisions.

Comment: One commenter asked that we confirm that the definition of ''outpatient prescription drugs'' would apply only to those drugs that are furnished to ''outpatients'' of any facility, including a SNF or nursing facility. The commenter believes that if the Congress had intended that the statute cover drugs provided to ''inpatients'' of facilities, it could have easily written the statute to do so. The commenter pointed out that drugs provided to ''inpatients'' are generally covered under Medicare Part A and are peripheral components of the services being provided and billed for, particularly under the prospective payment system for SNFs under which SNFs receive a per diem rate for virtually all items and services furnished to a Medicare Part A patient.

Response: In the January 1998 proposed rule, we proposed to include only drugs furnished to an individual under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. We have reflected this in Phase I of this rulemaking. A patient may reside in a SNF under a Part A stay or a patient may reside in a SNF without being covered under Part A. If the stay is not covered under Part A, it is possible that the patient may receive some drugs under the Part B benefit that are considered ''outpatient prescription drugs'' under these physician self-referral provisions. In addition, under section 1835(a) of the Act, a SNF may furnish services to an individual who is not a SNF inpatient. That is, it is possible for a SNF to provide services to an individual who does not reside in the SNF. For example, a SNF with an x-ray machine may furnish x-ray services to a nonresident if the individual has a referral for an x-ray and he or she wishes to receive the x-ray at this location. We assume the individuals who receive these services are the ''outpatients'' to whom the commenter is referring. (We note that drugs provided to patients in a hospital setting would be inpatient or outpatient hospital services under section 1877(h)(6)(K) of the Act.)

Patients in nursing facilities are typically covered under the Medicaid program. We intend to address all Medicaid-related physician referral issues in a separate rulemaking.

Comment: A commenter requested that we amend the January 1998 proposed rule to clarify that immunizations are not DHS under the definition of ''outpatient prescription drugs.'' The commenter pointed out that immunizations, particularly in pediatric and family care practices, are often personally administered by a physician to his or her own patients or are furnished on an ''incident to'' basis under the physician's direct supervision. In the adult population, there is also an increasing public awareness of the need for preventive immunizations, such as pneumococcal vaccine and influenza vaccine. These immunizations are widely and actively promoted in this country as constituting good preventive medicine. The commenter believes that the January 1998 proposed regulation could discourage immunizations because under the proposed interpretation of productivity bonuses in the group practice definition, a physician would be unable to share in a productivity bonus based on his or her own administration of, or direct supervision of, these immunizations.

Response: The commenter raised issues relating to immunizations that are covered by Medicare under section 1861(s)(10) of the Act, which covers pneumococcal vaccine and influenza vaccine and their administration, as well as hepatitis B vaccine and its administration if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. Under our authority to create additional exceptions in section 1877(b)(4), we are excluding from the reach of section 1877 of the Act certain immunizations and vaccines covered under section 1861(s)(10) of the Act that are subject to HCFA-imposed frequency limits and that are paid by Medicare on the basis of a fee schedule. We believe that under the terms of the exception the risk of abuse for these services is extremely low and that this exclusion is consistent with the statutory language and structure and the expressed Congressional intent to provide preventive care to Medicare beneficiaries.

In referring to drugs furnished in pediatric and family practices, we assume that the commenter was interested in the definition of outpatient prescription drugs under the Medicaid program. We intend to address the effects of the physician self-referral prohibition on the Medicaid program in Phase II of this rulemaking.

Comment: A commenter raised questions about our decision to exclude EPO and other drugs furnished as part of a dialysis treatment from the definition of ''outpatient prescription drugs.'' The commenter considered this exclusion ambiguous and requested clarification about whether a particular drug provided by a facility is ''part of a dialysis treatment.'' The commenter pointed out that EPO and other pharmaceuticals are typically administered during the course of treatment to avoid the painful process of injecting the patient multiple times, but that it could be argued that these pharmaceuticals are not ''part of'' the treatment itself. Therefore, the commenter requested that we revise the exclusion of ''other drugs furnished as part of the dialysis treatment'' to instead apply to ''other drugs furnished to an individual who dialyzes at home or in a facility, as part of an ESRD patient's plan of care.''

Response: When we carved out of the definition of ''outpatient prescription drugs, EPO and other drugs furnished as part of the dialysis treatment,'' we did not aim to carve out the far broader category of all ''other drugs furnished * * * as part of an ESRD patient's plan of care.'' We regard ''other drugs furnished as part of the dialysis treatment'' to be those furnished so that the dialysis treatment can be effective and to counteract the problems that can be caused directly by dialysis. For example, dialysis makes some patients anemic, so EPO is provided to deal with this dialysis-related problem. In addition, iron therapy is covered to make EPO therapy effective and Vitamin D hormone therapy is covered to correct for bone density loss caused by dialysis. Other drugs furnished to an individual who dialyzes at home or in a facility may include drugs that a patient uses for reasons other than to make the dialysis treatment effective. In fact, these other drugs may have nothing whatsoever to do with a patient's renal problems.

Comment: Another commenter agreed with our proposal to exclude EPO in the January 1998 proposed rule because it would allow physicians who own a dialysis facility to prescribe Medicare-covered medications to patients of the dialysis facility on the basis that the drugs are an integral part of the dialysis procedure. The commenter asked that we clarify that self-administered medications for home dialysis such as EPO can only be furnished by the dialysis provider or a supplier that has an agreement with the dialysis provider (a Method II supplier) and cannot be provided through the referring physician's office. The commenter contended that teaching the home dialysis patients to self-administer medications and monitoring the effects

of self-administered medications is the responsibility of the dialysis facility.

Response: We agree with the commenter. As provided in § 414.335 (Payment for EPO furnished to a home dialysis patient for use in the home), medications for home dialysis can only be furnished by the dialysis provider or a Method II supplier that has an agreement with a provider. If a referring physician has a financial agreement with a Method II supplier, the arrangement must meet an exception.

Comment: A commenter asked that immunosuppressant drugs prescribed for patients following organ transplants and covered by Medicare be excluded from the definition of ''outpatient prescription drugs.'' The commenter believes that the rationale for excluding these drugs is similar to the rationale for excluding EPO, since the use of these drugs is peripheral to the transplant surgery, but medically integral to the success of the surgery.

The commenter contended that excluding immunosuppressants from the definition will not provide an opportunity for program or patient abuse because their cost is an economically minor, though medically critical, part of a large and immensely complicated treatment. In addition, the commenter believes that physicians have no motivation to overprescribe these drugs, because the drugs are only used for transplant patients according to clinically accepted protocols that are designed to prevent organ rejection while avoiding unnecessarily high levels of toxicity. The commenter believes that the transplant community adheres to the prevailing standards of medical care with only minor deviations. In addition, each transplant center is required to report its transplant survival rates to an HHS contractor. Centers with survival rates below established thresholds can lose their certification.

Response: Immunosuppressant drugs furnished in an outpatient setting are ''outpatient prescription drugs'' under Phase I of this rulemaking. (They are inpatient or outpatient hospital services when furnished in a hospital setting.) We are not persuaded that an exception is appropriate or necessary. We believe that to the extent physicians provide transplant drugs to patients in their offices, they will generally be able to do so under the in-office ancillary services exception. If a referring physician has an ownership or investment interest in a free-standing transplant pharmacy or other pharmacy that provides transplant drugs to his or her patients pursuant to a referral, the financial relationship would have to fit in an applicable exception.

M. Inpatient and Outpatient Hospital Services

In § 411.351 of the January 1998 proposed rule, we defined inpatient hospital services as services that a hospital provides for its patients that are furnished either by the hospital or by others ''under arrangements'' with the hospital. For outpatient services, we explained in the preamble of the January 1998 proposed rule (63 FR 1683) that we would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services. We have revised the definition of outpatient hospital services in the regulations text to clarify that it includes services furnished ''under arrangements.'' Inpatient services are not coded by HCPCS codes. Any outpatient hospital service, regardless of the HCPCS code, is a designated health service.

In the January 1998 proposed rule, we requested comment on whether we should exclude lithotripsy from the definition of inpatient or outpatient hospital services on the theory that it could not be overutilized, since the procedure itself apparently documents the medical necessity to prescribe it. Commenters were also concerned about physician services that are ''bundled'' into hospital payments and about services furnished by a hospital ''under arrangements'' with an outside facility. We discuss each of these topics below.

Comment: We received hundreds of comments on the subject of lithotripsy, mostly from urologists who have ownership interests in a lithotriptor that a hospital rents. These commenters requested that lithotripsy be excluded from the definition of inpatient and outpatient hospital services so that they could continue to refer to the hospitals without being concerned about how the hospital compensates them. According to these commenters, urologist-owned lithotriptors increased quality of care and patient access without any risk of overutilization of lithotripsy. We also received comments on this topic from individual hospitals, a State and national hospital trade association, and nonphysicians who rented lithotriptors to hospitals in competition with physician owners. These commenters asserted that hospitals pay more for the use of physician-owned lithotriptors than hospitals pay for the use of their own lithotriptors or lithotriptors owned by nonphysicians and urged us to include lithotripsy in the definition of inpatient and outpatient hospital services.

Response: We have determined that there is no reason to treat lithotripsy any differently than other inpatient or outpatient hospital services. As we have said elsewhere in the preamble, we believe the Congress did not intend that we make service-by-service decisions on whether a service is a designated health service based on the service's potential for overutilization. Even were we able to determine that there is no potential for overutilization of lithotripsy (including comparisons to alternative treatments), there is a substantial potential for urologists who own lithotriptors to extract higher than market rate rents for their equipment or for the financial arrangement between the lessor urologists and the lessee hospital to encourage overutilization of other hospital services. Commenters provided no evidence to support their claims that physician ownership of lithotriptors increased quality of care or access to treatment.

In any event, the exclusion of lithotripsy from the definition of inpatient and outpatient services would not obviate the need for the physician-owners to structure their rental arrangements to comply with section 1877 of the Act. Whether lithotripsy is a designated health service or not, the rental arrangement itself would create a financial relationship between the physician-owners and the hospital. Unless the financial relationship (that is, the lithotriptor lease) fit into a compensation exception (such as the equipment rental exception), the physicians could not refer any Medicare patients to the hospital for any inpatient or outpatient services. In short, the relief sought by these commenters would be illusory.

We believe that the changes we have made in § 411.354(d) of these regulations to the volume or value standard (discussed in section V of this preamble) will enable hospitals and urologists to protect *bona fide* arrangements either under an equipment lease or a personal service arrangements exception or under the fair market value exception. Most importantly, Phase I of this rulemaking clarifies that ''per service'' or ''per use'' rental or services payments are permitted, even for services performed on patients referred by the urologist-owner, provided the rental or services payment is fair market value and does not take into account any Federal or private pay business generated between the urologist and the hospital (and provided all other conditions of an

exception are met). Because the prevalence of physician ownership of lithotriptors may distort pricing in the marketplace, we believe valuation methods that look to the prices charged by persons not in a position to refer to the hospital or that consider acquisition cost and rate of return are especially appropriate. We also are aware that some manufacturers of lithotriptors lease the machines to urologists on a ''per use'' basis with the urologists, in turn, leasing the lithotriptors to hospitals on a ''per use'' basis. In these circumstances, any disparity in the ''per use'' fee charged by the manufacturer to the urologists and the ''per use'' fee charged in turn by urologists to the hospital would call into question whether both sets of fees could be fair market value.

Comment: Several commenters suggested that section 1877 of the Act was only intended to address diagnostic procedures. Accordingly, they asked that we exclude therapeutic treatments such as lithotripsy from the definition of inpatient or outpatient hospital services in cases in which the referring urologist or a member of his practice actually treats the referred patient.

Response: The list of DHS in section 1877(h)(6) of the Act contains both therapeutic and diagnostic types of service (for example, physical therapy services are therapeutic and clinical laboratory services are diagnostic). This indicates that the Congress believed that both types of services could be subject to abuse. We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity under section 1877 of the Act. However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service. If the referring physician has a financial relationship with the hospital, that relationship must fit in an exception. Potentially available exceptions, depending on the circumstances, include, for example, the personal service arrangements exception, the employee exception, the space or equipment rental exception, the whole hospital exception, and the fair market value exception.

Comment: Several commenters stated that the only reason extracorporeal shock wave lithotripsy (ESWL) is even subject to the physician self-referral provisions is because Medicare only pays for lithotripsy if it is billed through a hospital, thus forcing the procedure into the realm of inpatient or outpatient hospital services. Many commenters have cited debate language pertaining to adopting the Conference Report for OBRA '93, which language suggests that the sponsor of section 1877 of the Act, Representative Stark, did not intend for ESWL to come under the law.

Response: We believe that lithotripsy was meant to be a ''designated health service'' under the law, since the law does not exclude any particular hospital services, nor does the legislative history indicate that the Congress meant to exclude them. The House Report for the first version of the physician self-referral law mentioned a specific exception for a facility providing lithotripsy services performed personally by the referring physician. (See H. Rep. No. 101–247, 101st Cong. 1041 (1989).) This exception did not apply to the hospital services at issue, nor was it enacted. In adding hospital services to the list of DHS, the legislative history reveals that the Congress was concerned about increased admissions to hospitals, regardless of the reason for the admission. (We discuss this issue further below, where we address hospital services provided ''under arrangements.'')

Comment: Another commenter pointed out that we proposed excluding from the definition of inpatient hospital services those services performed by physicians and other providers who bill independently. The commenter asked us to clarify whether physician and individual professional services are excluded from the definition of inpatient hospital services when they are billed by a hospital. Hospitals bill for these services when they are part of a global fee that covers both the technical and professional components of a service or when they bill on an assignment (or reassignment) basis. This commenter argued that if these services are not excluded under section 1877 of the Act, a hospital may not be able to compensate a physician for services performed in, and billed by, the hospital, or to compensate a doctor who supervises a nurse practitioner in a hospital. The commenter also suggested that we clarify that we will treat both inpatient hospital services and outpatient hospital services the same way.

Response: Professional services that Medicare pays independently of an inpatient or outpatient hospital service do not become DHS if they are billed by a hospital under assignment or reassignment; they remain physician services and are not considered hospital services. Any other service for which a hospital bills is a hospital inpatient or outpatient service, even though it may consist of both a technical and professional component. Therefore, these services constitute DHS under section 1877 of the Act. However, if a hospital is paying the physician for his or her professional services under either a personal services contract or an employment agreement, the physician can still refer to the hospital as long as the compensation arrangement meets an exception, such as the exception that applies to personal service arrangements or the exception for employment agreements. These exceptions require, among other things, that the hospital pay the physician an amount that is based on a fair market value standard.

Comment: Several commenters expressed concern with the effect the definitions of inpatient and outpatient hospital services may have when a hospital purchases services ''under arrangements'' from an entity owned in whole or in part by a referring physician. Commenters fear that if services are deemed to be inpatient or outpatient hospital services for the purposes of 1877 of the Act when furnished by a hospital ''under arrangements'' with an entity owned by a physician, physicians may be unwilling to invest in equipment using new technologies. One commenter specifically proposed an exception that would apply to any service that would be exempt from the physician self-referral prohibition if the physician referred directly to the entity, outside of the hospital context. According to several commenters, it is the nature of the service itself that should determine whether or not a referral may be made, not the inpatient or outpatient status of the patient. Commenters were concerned that a physician will not be able to refer a patient to a hospital if the hospital has an arrangement with an entity that the physician owns. The commenters believe that, as long as the actual services are compensated at fair market value, there should be no risk of program or patient abuse.

Response: The Congress specifically chose to include inpatient and outpatient services as DHS under section 1877(h)(6)(K) of the Act. Inpatient and outpatient hospital services include any services that a hospital provides to a hospital patient, whether it provides them itself or provides them by purchasing them from another entity under arrangements; any

other policy would encourage hospitals to purchase as many services as possible under arrangements in order to avoid the effects of the physician self-referral provision. In light of the description of ''volume or value'' in Phase I of this rulemaking, we believe that *bona fide* ''under arrangements'' relationships can easily be structured to comply with the personal service arrangements exception, or, in some cases, the fair market value exception. We believe this approach is consistent with section 1877(e)(7) of the Act, which provides a limited exception for certain ''under arrangements'' relationships that were established before 1989 and met several other requirements.

We are concerned that the provision of services ''under arrangements'' could be used to circumvent the prohibition in section 1877(c)(3) of the Act of physician ownership of parts of hospitals. We understand that some hospitals are leasing hospital space to physician groups, which the groups then use to provide services ''under arrangements'' that the hospital had previously provided directly. These arrangements, especially when they involve particularly lucrative lines of business, raise significant issues under section 1877 of the Act, as well as the anti-kickback statute.

However, we also recognize that ''under arrangements'' relationships are pervasive in the hospital industry and that many of the services being provided by physician groups ''under arrangements'' are services that the physicians provide in physician-owned facilities primarily to their own patients who are hospital inpatients. In these situations, an ''under arrangements'' relationship can avoid unnecessary duplication of costs and underutilization of expensive equipment.

While we believe section 1877 of the Act could reasonably be interpreted to prohibit ''under arrangements'' relationships as constituting prohibited ownership interests in a part of a hospital, we decline to do so at this time for several reasons. First, given the sheer number of these arrangements, we think prohibiting these arrangements would seriously disrupt patient care. Second, almost all these arrangements could be restructured to fit into a combination of the personal service arrangements and equipment lease exceptions (or fair market value exception), although this restructuring will in some cases be administratively burdensome. Third, we believe there is precedent in the statute for treating this situation solely as a compensation arrangement. In section 1877(e)(7) of the Act, the Congress created a specific compensation exception for certain hospital services provided by physician groups ''under arrangements.'' Since, by definition, all services protected under section 1877(e)(7) of the Act—and the resources used to produce them—were ''owned'' by the physician groups, the Congress would not have created a protected compensation relationship unless it had first determined that these arrangements did not create a prohibited ownership or investment interest in the hospitals. Simply stated, the Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest.

In sum, for purposes of section 1877 of the Act, we will treat ''under arrangements'' financial arrangements between hospitals and physician-owned entities as compensation and not ownership relationships. These arrangements can be protected provided they meet an appropriate compensation exception. We will, however, monitor these arrangements and may reconsider our decision if it appears that the arrangements are abused. We also caution physician groups and hospitals that these arrangements remain subject to the Federal anti-kickback statute.

Comment: One commenter requested that we clarify how the physician self-referral law applies in cases in which a financial relationship arises solely because of Medicare requirements. The commenter discussed a situation in which a radiation therapy group and a radiation therapy facility (owned by some or all of the group members) are located in a medical office building across the street from a hospital in a nonrural area. The closest comparable facility is over 35 miles away. Occasionally, the hospital sends an inpatient for radiation therapy to the radiation facility, which provides the services as ''arranged for'' inpatient hospital services. The hospital pays the facility for use of the radiation equipment from money it receives from Medicare for the inpatient hospital stay. (The group practice bills Medicare for the professional services of the radiation oncologists.) The commenter erroneously asserted that Medicare requires the hospital to pay the radiation facility for the amount that it would have received under Medicare Part B if the radiation therapy had been provided as an outpatient service. The commenter believes that the payment by the hospital to the radiation therapy facility creates a compensation arrangement with the facility and, in turn, the physicians.

Often, a radiation oncologist will refer a patient of the radiation facility to the hospital for certain tests and other services. The radiation oncologist receives no economic benefit for referring patients to the hospital and refers there for the patient's convenience, not because there is any requirement to do so. The commenter believes that, under our proposed rule, the ''under arrangements'' compensation arrangement would trigger the physician self-referral law, preventing the radiation oncologists from referring Medicare patients to the hospital for services, even though this financial relationship is not voluntary and not subject to abuse.

The commenter requested clarification whether the proposed § 411.355(d)(2), covering services furnished under composite types of payment rates that the Secretary determines provide no financial incentive for underutilization or overutilization, or any other risk of program or patient abuse, would apply. The commenter also wished to know whether we could include an additional described compensation arrangement exception under § 411.357(d) (the personal service arrangements exception) or clarify § 411.357(g) (the exception for remuneration from a hospital to a physician if the remuneration does not relate to the furnishing of DHS) to include the arrangements the commenter mentioned, or create some variation in the fair market value exception in § 411.357(l)(3) that would allow compensation determined on the basis of the volume of services (that is, fee-for-service payments as covered under Medicare Part B) in the type of situation the commenter described.

Response: As discussed above in section VIII.A of this preamble, we have determined not to include the proposed § 411.355(d)(2) in Phase I of this rulemaking for DHS other than clinical laboratory services. However, as discussed in the preceding response, the arrangement described by the commenter would be a compensation arrangement that could be structured to fit in one of the compensation exceptions, such as the equipment rental, personal service arrangements, or the new fair market value exceptions.

N. Other Definitions

1. Consultation

The definition of ''consultation'' is addressed in section III.B.2 of this preamble and in the regulations in § 411.351.

2. Entity

In § 411.351 of the August 1995 final rule covering referrals for clinical laboratory services, we defined the term ''entity'' broadly to cover a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We revised this definition in the January 1998 proposed rule to make it clear that the definition covers a physician's sole practice or a practice of multiple physicians that provides for the furnishing of DHS, or any other sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association. We explained in the preamble to the January 1998 proposed rule at 63 FR 1706 that we regard an ''entity'' for purposes of the referral prohibition as the business organization, or other association that actually furnishes, or provides for the furnishing of, a service to a Medicare or Medicaid patient and bills for that service (or receives payment for the service from the billing entity as part of an ''under arrangements'' or similar agreement). We explained that we meant that the referral prohibition applies to a physician's referrals to any entity that directly furnishes services to program patients, or to any entity that arranges for the furnishing of these services under arrangements. We are clarifying in Phase I of this rulemaking that, for purposes of section 1877 of the Act, a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

A number of commenters pointed out, in various contexts, that they did not believe a physician could make a ''referral'' to himself or herself. We agree and discuss this issue in section III.B of this preamble, which covers the definition of a referral. In our analysis of this issue, we also concluded that when a physician is referring to himself or herself, that act is not a referral to an ''entity,'' as we have defined it in § 411.351. However, when the physician requests a service from another member of his or her group practice or from the practice's staff, that would be a referral to the practice for purposes of the physician self-referral law. These concepts are discussed in more detail in our responses to specific comments on the definition of a ''referral'' and on some of the DHS.

In the preamble to the January 1998 proposed regulation (63 FR 1710), we addressed the question of when the owner of a DHS provider is considered to be equivalent to the entity providing DHS. We had proposed to equate a referring physician with the entity when the physician (or a family member) has a significant ownership or controlling interest that allows the physician to determine how the entity conducts its business and with whom. We used two examples to illustrate this concept. Commenters found both our analysis and those examples to be confusing. As a result, we have abandoned this analysis and will simply apply the rules related to indirect financial relationships and indirect referrals as described in detail in section III of this preamble, which covers the general referral prohibition under section 1877(a) of the Act. Section III.A of this preamble includes a discussion about when there is a financial relationship between a physician and an entity.

Comment: A commenter suggested that we clarify in both the preamble and regulations text that a medical device manufacturing company is not an ''entity'' for the purposes of section 1877 of the Act, and that the manufacturer does not receive payments from billings ''under arrangements.'' Another commenter requested that we clarify that drug manufacturers are not ''entities'' for purposes of section 1877 of the Act, and that a referral for outpatient prescription drugs only occurs when a physician sends a patient to a particular entity that actively furnishes drugs, such as a pharmacy.

Response: We generally do not regard manufacturers as entities that furnish items or services directly to patients, or as entities that furnish services ''under arrangements.'' Thus, the commenters are correct in stating that a medical device manufacturer or a drug manufacturer is unlikely to be an entity furnishing DHS for purposes of section 1877 of the Act, while a pharmacy, which delivers outpatient prescription drugs directly to patients, would be one. (We discuss this issue in more detail in section VIII.B of this preamble.) A person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to (i) an employer pursuant to § 424.80(b)(1); (ii) a facility pursuant to § 424.80(b)(2); or (iii) a health care delivery system, including clinics, pursuant to § 424.80(b)(3) (other than a health care delivery system that is a health plan (as defined in § 1000.952(l)), and other than any MCO, PSO, or IPA with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) is the entity furnishing DHS for any services provided by such supplier.

Comment: A commenter asked us to clarify that State governments and their instrumentalities are not ''entities'' for purposes of section 1877 of the Act. The commenter noted that many State and local governments create integrated delivery systems and payment arrangements in order to increase access to and decrease the cost of publicly provided care. If the governments or their instrumentalities were to be considered ''entities,'' the commenter argued that State-sponsored clinics and programs may cease to exist, thus restricting access to, and raising the costs of, public programs.

Response: The referral prohibition applies whenever a physician has an unexcepted financial relationship with ''an entity'' that furnishes DHS. The statute makes no distinction between private and governmental entities, nor do we believe that we have the authority to make such a distinction. We have no basis for concluding that referrals to governmental entities are always free from potential patient or program abuse, so we see no grounds for creating an additional exception under section 1877(b)(4) of the Act. However, we would assume that many governmental entities have compensation arrangements with physicians, rather than being owned in any way by physicians. If this is the case, there are a number of compensation related exceptions in the statute and regulations that are designed to allow physicians who receive fair compensation to continue making referrals.

3. Fair Market Value

The term ''fair market value'' appears in most of the compensation related exceptions. These exceptions, among other things, require that compensation between physicians (or family members) and entities be based on the fair market value of the particular items or services that these parties are exchanging. We defined this term in the August 1995 final rule covering referrals for clinical laboratory services by using the definition that appears in section 1877(h)(3) of the Act. This provision defines fair market value as the value in arm's-length transactions, consistent with the general market value, with other specific terms for rentals or leases.

In the January 1998 proposed rule, we discussed what constitutes a value that is ''consistent with the general market value.'' We drafted the definition as follows so that it applies to any arrangements involving items or services, including, but not limited to, employment relationships, personal service arrangements, and rental agreements:

> ''General market value'' is the price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

The definition of ''fair market value'' in the proposed rule continued to include the additional requirements in section 1877(h)(3) of the Act for rentals or leases. Among other things, the statute defines the fair market value of rental property as its value for general commercial purposes, not taking into account its intended use. Most of the comments we received addressed the question of how to establish the fair market value of an asset or agreement and how to value rental property ''for general commercial purposes.'' We have tried to clarify these concepts in our responses.

Comment: Several commenters asked that we clarify the documentation that will sufficiently establish a transaction as consistent with fair market value (and general market value) for the exceptions that apply to compensation arrangements. The proposed definition of fair market value states that ''usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.'' One commenter stated that using the word ''usually'' may create ambiguities and suggested making clear in the definition of fair market value that the standard of comparable transactions is only one potential means of establishing fair market value.

Another commenter stated that the January 1998 proposed rule is unclear about the steps that must be taken to confirm fair market value. The commenter asked that we adopt the position that a valuation from an independent person experienced in the valuation of health care operations is sufficient as one approach (but not the only approach) to establishing fair market value. However, the commenter further stated that, because sales of medical practices are private and not reported to any central data base, and because there is often a lack of a representative pool upon which to draw comparisons, we should adopt the position that confirmation of fair market value does not necessarily require the finding of comparable entities for comparison. Another commenter stated that the Internal Revenue Service (IRS) guidelines for determining fair market value with respect to tax exempt organizations are too restrictive and are inappropriate for application to for-profit entities.

Response: To establish the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another. (As discussed in section V of this preamble, in most instances the fair market value standard is further modified by language that precludes taking into account the ''volume or value'' of referrals, and, in some cases, other business generated by the referring physician. Depending on the circumstances, the ''volume or value'' restriction will preclude reliance on comparables that involve entities and physicians in a position to refer or generate business.) The amount of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations. The burden of establishing the ''fairness'' of an agreement rests with the parties involved in the agreement. Depending on the circumstances, parties may want to consider obtaining good faith, written assurances as to fair market value from the party paying or receiving the compensation, although such written assurances are not determinative.

For example, a commercially reasonable method of establishing fair market value (and general market value) for the rental of office space can include providing us with a list of comparables. We would also find acceptable an appraisal that the parties have received from a qualified independent expert. Although some transactions are not subject to public scrutiny, we believe generally that there should be sufficient documentation of similar public transactions that the parties can use as a basis of comparison. In regions with inadequate direct comparables, such as rural areas, a reasonable alternative may involve comparing institutions or entities located in different, but similar, areas where property is zoned for similar use. For example, a hospital affiliated with a university in one part of the country could be comparable to other hospitals affiliated with universities that are located in similar types of communities. In other cases, all the comparables or market values may involve transactions between entities that are in a position to refer or generate other business. For example, in some markets, physician-owned equipment lessors have driven out competitive third-party lessors of similar equipment. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors.

In contrast, there may be cases in which finding a commercially reasonable representation of fair market value (or general market value) could be as simple as consulting a price list. As for using the IRS guidelines for determining fair market value that applies to tax exempt organizations, we recognize that in some cases they may not be appropriate for for-profit entities. Nonetheless, it is our view that some elements of the IRS guidelines could be applied under certain circumstances, depending upon the specifics of any particular agreement. We do not wish to either mandate their use or rule them out if they can be appropriately used to demonstrate fair market value.

Comment: One commenter noted that, as part of our definition of ''fair market

value,'' we include the term ''general market value,'' which applies to any arrangement involving items and services, including employment relationships, personal service arrangements, and rental agreements. The commenter pointed out that in the January 1998 proposed rule we do not address the specific documentation requirements necessary to verify and document that the price of an asset or the compensation for certain services actually reflects the market rate. The commenter requested that we confirm that internally generated surveys are sufficient for establishing the market rate, and that there is no requirement to use an independent valuation consultant.

Response: We agree that there is no requirement that parties use an independent valuation consultant for any given arrangement when other appropriate valuation methods are available. However, while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.

Special Rule for Rental Property. Under section 1877(h)(3) of the Act, fair market value means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. We incorporated this provision into the August 1995 final rule covering referrals for clinical laboratory services and into the January 1998 proposed rule at § 411.351. Commenters raised questions about the meaning of the statutory provision.

Comment: With respect to the rental of property, commenters questioned our definition of fair market value as ''the value of rental property for general commercial purposes (not taking into account its intended use).'' The commenters believe this language is problematic for appraising a medical office building because it requires the appraiser to compare the property to the broad category of properties that are ''used for general commercial purposes.'' This latter category can include properties that are highly dissimilar in character and value. For example, the appraisal for medical office property could include retail or industrial rates. Such an approach conflicts with the fundamental principle that appraisals should be based on comparing properties with similar attributes.

Response: We believe that a rental property meets the requirement that a payment reflect the ''value of property for general commercial purposes, not taking into account its intended use'' when the payment takes into account any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added. That is, the rental payment can reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. On the other hand, we also believe that rental payments would specifically take into account the intended use of the property if the lessee paid inflated amounts solely to enhance his or her medical practice. For example, rental payments by a physical therapist would not be fair market value for purposes of section 1877 of the Act if the physical therapist agreed to pay an inflated rate that was not justified by improvements or other amenities and was higher than the rate paid by other, similarly situated medical practitioners in the same building just because the building was occupied by several orthopedic practices.

A rental payment cannot be adjusted to reflect the *additional* value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a physician and a potential source of patient referrals to the lessee. We interpret this requirement to allow rental payments that reflect the fair market value of the area in which the property is located, even if a lease is for medical property in a ''medical community.'' To qualify, the payments should not reflect any *additional* value, such as an amount that is above that paid by other medical practitioners in the same building or in the same or in a similar location, just because the lessor is a potential source of referrals to the lessee. That is, the rental payments should be roughly equivalent to those charged to similarly situated parties in arrangements in which referrals are not an issue.

Also, the statute requires that the rental payments not reflect the additional value either party attributes to the proximity or convenience to the lessor where the *lessor* is a potential *source of patient referrals* to the lessee. The definition of a ''referral'' by a ''referring physician'' in section 1877(h)(5) of the Act focuses only on actions and requests for services that are initiated by physicians; it does not include any requests for services initiated by entities or other providers or suppliers, nor does the referral prohibition itself apply to anything but physician referrals. Thus, we believe that it is fair to interpret the limitation in the fair market value definition as confined to situations in which a physician is the lessor and a potential source of referrals to an entity lessee. That limitation does not appear to us to apply when an entity, such as a hospital, is the lessor that rents space to physicians, even if the hospital is in a position to refer to the physicians. As a result, we believe a hospital should factor in the value of proximity when charging rent to lessee physicians.

4. Group Practice

The definition of a group practice under section 1877(h)(4) of the Act is addressed in this preamble at section VI.C and in the regulations at § 411.352.

5. Health Professional Shortage Areas

The existing regulations covering referrals for clinical laboratory services define a health professional shortage area (HPSA) for purposes of section 1877 of the Act as ''an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in 42 CFR part 5, appendix A, part I—Geographic Areas)'' and, in addition, ''an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals. We proposed no changes to the existing rule.

The definition of a HPSA for purposes of Phase I of this rulemaking is intended to track the definition of a HPSA as promulgated by the Health Resources Services Administration (HRSA), which administers the HPSA designation process. HRSA has proposed revising the existing HPSA regulations. (See 63 FR 46538; 64 FR 29831.) We have modified the definition of a HPSA in these regulations to track current HRSA interpretations of the HPSA regulations and to make clear that the definition incorporates any future changes or amendments to HRSA's definition of a HPSA, which is codified in 42 CFR part 5.

6. Employee

We defined an ''employee'' in the existing regulation and in the January 1998 proposed regulation in § 411.351 by reiterating the statute. Section 1877(h)(2) of the Act specifically defines an ''employee'' of an entity as an individual who would be considered to be an employee under the usual common law rules that apply in determining the employer-employee relationship, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986.

Comment: Two commenters recommended an expansion of the proposed definition of ''employee'' to include ''leased employees'' to better reflect the realities of the market place. The current definition, which references income tax law, limits an employee to an individual who meets the definition of a ''common law'' employee. But the definition of a common law employee does not include leased employees, who are defined by State law and have a quasi-common law status.

Response: We do not believe we have the authority to expand the definition of employee that appears in the law. It is our understanding that leased employees are essentially regarded by the courts, the IRS, and Federal legislators as ''contingent employees.'' Contingent workers are generally described as workers who are not part of the employer's regular work force, but are hired to meet certain needs. These workers are technically employed by an entity other than the one for whom the services are performed. Other types of contingent workers include independent contractors and consultants.

A leased employee is defined in section 414(n) of the Internal Revenue Service Code as an individual who performs services under an agreement between the service recipient and a leasing/staffing organization; performs services under the primary direction or control of the service recipient; and performs services for the service recipient on a substantially full-time basis for a 12-month period. The labeling of a worker as a leased employee under a leasing/staffing arrangement does not mean that the worker will be defined as a ''leased employee'' under section 414(n) of the Internal Revenue Code for employee benefit plan purposes. The IRS determines the common law employment relationship between a worker and an organization by analyzing the facts and circumstances of each particular situation. The IRS uses guidelines, in the form of a list of factors, for classifying workers as either employees or independent contractors, in order to determine whether there is actually an employer/employee relationship. We would regard any leased employee that qualifies as an ''employee'' under the IRS test as an employee for purposes of section 1877 of the Act.

7. Immediate Family Members

The referral prohibition in section 1877(a) of the Act states that if a physician, or immediate family member, has a financial relationship with an entity, the physician cannot refer a Medicare patient to that entity for the furnishing of DHS, unless an exception applies. In the August 1995 final rule, we listed in § 411.351 the individuals who qualify as a physician's ''immediate'' family members. These individuals include a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. We adopted this definition without any changes in the January 1998 proposed rule.

We did not receive any comments on this definition. We did receive comments that relate to whether physicians should be precluded from referring to people who qualify as members of their immediate family. We have addressed these comments in section VI.B of this preamble. To conform to common usage, we have amended the definition to substitute the term ''birth'' for ''natural'' parent.

8. Referral

The definition of ''referral'' is addressed in this preamble in section III and in § 411.351 of the regulations.

9. Remuneration and the Exceptions in Section 1877(h)(1)(C) of the Act

The definition of ''remuneration'' in section 1877(h)(1)(B) of the Act is drafted broadly to include ''any remuneration, directly or indirectly, in cash or in kind.'' However, a ''compensation arrangement'' is defined in paragraph (h)(1)(A) of section 1877 of the Act to specifically exclude various kinds of remuneration that are listed in paragraph (h)(1)(C) of section 1877 of the Act. These are arrangements involving only the following remuneration:

(i) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors;

(ii) the provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity furnishing the item, device, or supply, or

(II) to order or communicate the results of tests or procedures for such entity.

(iii) a payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(I) the health services are not furnished, and the payment is not made under a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

We incorporated these exclusions from the definition of ''remuneration'' into the August 1995 final rule and into the January 1998 proposed rule in § 411.351. We interpreted the exclusions in the January 1998 proposed rule at 63 FR 1693 through 1694 to mean that the portion of any business arrangement that consists of the remuneration listed in paragraph (h)(1)(C) of section 1877 of the Act alone does not constitute a compensation arrangement. The final regulation adopts our proposed regulations text and incorporates expressly the interpretation applicable to arrangements that include portions of remuneration that meet the exclusions in section 1877 (h)(1)(C) of the Act.

a. Minor Billing Errors.

Comment: One commenter, in referring to the exclusion from remuneration of forgiveness for amounts due to corrections of minor billing errors, stated that even a ''minor'' billing error might have large dollar consequences, particularly if the same minor mistake were repeated on numerous bills. This could easily happen because virtually all bills are now computer-generated. The commenter stated that the term ''minor'' should refer to the type of error, rather than the sum of money that may be involved.

Response: We agree with the commenter's suggestion that a ''minor'' billing error could have large dollar consequences, particularly in situations in which bills are computer generated. We also agree that the term ''minor''

should refer to the kind of billing error rather than the sum of money involved. Therefore, we are interpreting ''minor billing errors'' to cover isolated or infrequent instances in which an administrative error, such as a typographic, keying, or other transcribing error, results in an incorrect charge or bill. On the other hand, a pattern of similar or consistent billing error ''corrections'' may suggest improper remuneration and subject the business arrangement to scrutiny.

b. Medicare as an Insurer.

Section 1877(h)(1)(C)(iii) of the Act ''excepts'' from the definition of a compensation arrangement situations involving payments made by an insurer or self-insured plan to a physician. The payments must satisfy a physician's fee-for-service claim for furnishing health services to an individual who is covered by a policy with the insurer or the self-insured plan.

Comment: One commenter asked whether the term ''insurer'' includes the Medicare program. The commenter believes that Medicare is included within the meaning of the term ''insurer,'' and cited for support references in the preamble, as well as the designation of Medicare in the Act as ''Health Insurance for the Aged and Disabled.''

Response: In the preamble to the January 1998 proposed rule at 63 FR 1694, we pointed out that we believed this provision was designed for situations in which an insurer is also involved in the delivery of health care services. If the insurer owns a health care facility, a physician might otherwise be precluded from referring to that facility just because the physician receives compensation from the insurer in the form of payments that satisfy the physician's claims.

The Medicare program is not directly involved in the delivery of services, but is simply a payer of services; that is, Medicare never actually furnishes services to program patients but pays for claims from providers and suppliers or makes payments to managed care organizations. The physician self-referral law is only implicated if a physician refers a patient to an entity for DHS and the physician has an ownership or investment interest in the entity or receives direct or indirect remuneration from the entity. Since a physician would never refer a patient to the Medicare program to receive a designated health service, these payments from Medicare to a physician are totally irrelevant under this law.

c. *Items, Devices, or Supplies Used Solely To Collect Specimens.*

Comment: One commenter thought there was a possible inconsistency in the preamble to the January 1998 proposed rule in the section discussing whether biopsy needles are excluded from the definition of remuneration under section 1877(h)(1)(C)(ii) of the Act. Section 1877(h)(1)(C)(ii) of the Act covers items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies. First, the commenter noted our conclusion at 63 FR 1693 through 1694 that biopsy needles do not function solely as specimen collection devices and therefore are categorically excluded from ''items, devices, or supplies that are used solely'' for specimen collection purposes. In other words, biopsy needles may constitute remuneration under section 1877 of the Act. This discussion is followed in the preamble by a statement that any items, supplies, or devices provided to a physician must be used solely in connection with specimens sent by the physician to the entity that supplied the items, devices, or supplies. Accordingly, the preamble indicates that the number of items, supplies, or devices furnished should not exceed the number of specimens sent to the laboratory for processing. The commenter suggested that the proximity and sequence of these discussions in the preamble has caused confusion in the industry; some have concluded that, regardless of the first discussion and conclusion, biopsy needles might not constitute remuneration if the number of biopsy needles provided by a laboratory were to correlate to the number of biopsy specimens sent to the laboratory.

The commenter urged us to adopt the view that biopsy needles are surgical or medical devices, rather than items, devices, or supplies solely used for specimen collection purposes in all cases. The commenter noted that this interpretation would be consistent with statements made by the OIG that the free provision of biopsy needles from a laboratory to a physician would be suspect under the anti-kickback statute because the needles have independent value to the physician as a surgical device used in surgical procedures. (See the letter dated August 4, 1997, available on the OIG website at http://www.dhhs.oig/gov.) A second commenter concurred with this conclusion, and suggested that the same analysis should apply to other surgical or medical devices that may be used during a procedure to collect specimens, but have independent value to physicians, such as snares and reusable aspiration and injection needles.

Response: We agree with the first commenter that the proximity and sequence of our discussion of this topic in the preamble might have been confusing. We wish to clarify our views on the ''items, devices, and supplies'' provision here. First, in enacting section 1877(h)(1)(C)(ii) of the Act, we believe that the Congress did not intend to allow laboratories to supply physicians with surgical instruments for free or below fair market value prices. Rather, we believe the Congress intended to include in this section items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are primarily provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them. In many cases, the cost of these items may already be included in the practice expense portion of the Medicare payment made to the physician. In addition, to the extent the items are reusable, they may have value unrelated to the collection of specimens for processing by the laboratory providing the items. The provision of such items for free or below fair market value poses a risk that the items may constitute compensation from the laboratories for the physician's referrals and increase the risk of overutilization. Accordingly, biopsy needles and like devices, such as snares and reusable aspiration and injection needles, are categorically excluded from the items, devices, and supplies covered by section 1877(h)(1)(C)(ii) of the Act, although arrangements for providing such items may be structured to fit into the exception for payments by a physician for items and services to an entity if the items or services are furnished at a price that is consistent with fair market value. (See section 1877(e)(7) of the Act and § 411.357(i).) This view is consistent with the guidance published by the OIG noted in the preceding comment.

The discussion of the correlation of the number of supplies to the number of specimens sent to the laboratory has no application to biopsy needles and other devices that fall outside section 1877(h)(1)(C)(ii) of the Act. As to those single use, low value items, devices, and supplies that come within the scope of section 1877(h)(1)(C)(ii) of the Act, the fact that the number of supplies provided to a physician approximates the number of specimens sent by the physician to the laboratory providing

the supplies is merely one indicator that the supplies have been provided in connection with specimen collection *for the entity* providing the supplies. The numerical correlation is not a statutory or regulatory requirement. However, the provision of an excessive number of supplies creates an inference that the supplies are not provided solely to collect, transport, process, or store specimens for the entity providing them.

Comment: A commenter noted that certain supplies that are used in connection with the collection of specimens, such as gloves, can also be used by a physician for other purposes. Since the laboratory cannot guarantee that the gloves it supplies are used by the physician only for collecting specimens, the commenter recommended that the laboratory monitor the volume of the items supplied. The commenter asserted that if the number of gloves supplied equals, or is close to, the number needed for the collection of specimens by this physician, we should consider the conditions in the exception in section 1877(h)(1)(C)(ii) of the Act to have been met.

Response: While we recognize that sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies used solely to collect, transport, process, or store specimens. To be sure, sterile gloves are essential to the specimen collection process, but their main function is to prevent infection or contamination. Also, sterile gloves are fungible, general purpose supplies typically found in a physician's office and used for a wide range of examinations and procedures. We believe it would be impractical for physicians' offices to monitor and regulate the use of gloves so as to limit their use to the collection of specimens for the laboratory that provided them. Accordingly, we believe the provision of free gloves is remuneration subject to the general prohibition of section 1877 of the Act, in the absence of an applicable exception.

Comment: A commenter questioned how a laboratory should measure the volume of specimen collection supplies it provides to a new physician or group client with whom it has no experience. In such a situation, the commenter believes the laboratory should be allowed to rely on the anticipated volume of services, until an actual pattern of referral can be established, to meet the requirement that items furnished by the laboratory be consistent with the number of tests referred to the laboratory.

Response: As noted above, there is no explicit requirement in the statute that the volume of supplies provided by a laboratory correlate with the volume of specimens sent to the laboratory for processing. Rather, a correlation is one indicator that the provision of the supplies meets the requirement that they be used to collect, transport, process, or store specimens for the laboratory that provided them and that the supplies are not for the physician's general office use. We understand that a laboratory may not have a pattern of referrals on which to base the provision of items, devices, and supplies to a new physician or group practice client. In these instances, the laboratory may elect to provide supplies based on the number of tests typically ordered by physicians or group practices of like type and size in that community until the physician or group practice establishes a pattern of referrals with the laboratory sufficient to determine the appropriate number of supplies. The laboratory or physician should be prepared to demonstrate that the items, devices, or supplies were furnished based on a community standard and to describe the standard.

Comment: One commenter asked that we clarify how section 1877 of the Act applies to a clinical laboratory's provision of a phlebotomist to a physician, group practice, or ESRD facility without charge to the physician, group, or ESRD facility.

Response: Under section 1877(h)(1)(B) of the Act, remuneration includes ''any remuneration, directly or indirectly, overtly or covertly, in cash or in kind,'' with the exception of certain items of potential value listed in section 1877(h)(1)(C) of the Act. The provision of personnel, such as a phlebotomist, does not fit in any category listed in section 1877(h)(1)(C). Thus, the provision of a phlebotomist, as described by the commenter, may constitute remuneration, and therefore create a compensation arrangement, for purposes of section 1877 of the Act. Whether a particular phlebotomist arrangement confers a benefit on a physician or group practice depends on the specific facts and circumstances. (The provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act, unless the arrangement conferred a direct or indirect benefit on a physician or physician group; such laboratory-ESRD facility arrangements may implicate the anti-kickback statute.)

The OIG has issued a special fraud alert addressing the provision of free goods and services to physicians under the anti-kickback statute, 59 FR 242 (December 9, 1994). We believe the fraud alert is instructive here. Discussing the issue of laboratory phlebotomists placed in physicians' offices, it observes:

> When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory. While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services. Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics and hospitals. Furthermore, the mere existence of a contract between the laboratory and the health care provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not closely monitored by his [or her] employer or where the contractual prohibition is not rigorously enforced.

Like the OIG, we believe that if the phlebotomist is purely performing laboratory functions for the laboratory that places the phlebotomist, then there would be no remuneration to the physician or group practice (that is, no compensation arrangement). Put another way, there would be no services to the physician or group for which they should pay. However, if the phlebotomist performs services that are not directly related to the collection or processing of laboratory specimens *for the laboratory* that has provided the phlebotomist, he or she may be providing a benefit to the physician or group practice, thus creating a compensation arrangement between the physician and the clinical laboratory that furnished the phlebotomist. Such arrangements may be structured to fit in an exception to section 1877 of the Act, such as the personal service arrangements exception, the fair market value exception, or the exception for payments by physicians for items or services.

Comment: Another commenter asked that we establish a clear standard governing the use by ESRD facilities of

personnel from a clinical laboratory. The commenter recommended that employees of clinical laboratories only be allowed to perform duties directly associated with collecting and preparing specimens, and making test results available to the ESRD facility. Activities involved in ESRD facility administration, patient care, or handling of specimens or data from other laboratories would not be allowed.

Response: As noted above, the provision of a phlebotomist to an ESRD facility would not implicate section 1877 of the Act unless the arrangement benefits a physician or physician group.

Comment: One commenter inquired whether a laboratory may provide medical waste disposal supplies and services to physicians free of charge. The commenter asserted that the services would be provided only for medical waste generated in connection with the collection, transportation, processing, or storage of specimens.

Response: Section 1877(h)(1)(C)(ii) of the Act excludes from the definition of a compensation arrangement remuneration that consists of ''the provision of items, devices, or supplies that are used solely to—(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply * * *.'' The provision does not specifically allow laboratories to furnish physicians and group practices with medical waste disposal supplies and services at no charge. However, we believe that supplies and the disposal of items used solely in connection with the collection of specimens for this clinical laboratory are part of the process the laboratory engages in when it collects, transports, and processes specimens. If a laboratory can provide a needle for collection and it can take away the specimen, we believe that the laboratory can also take away the needle and other items that are used in the process. However, we do not believe this exception covers the disposal of needles or other waste items that have been used by the physician practice for other purposes.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 411.352 Group Practice

Paragraph (d) requires that, except as provided in paragraphs (d)(2) and (d)(3) of this section, substantially all of the patient care services of the physicians who are *members of the group* (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group; the amounts received must be treated as receipts of the group; and ''patient care services'' must be measured and documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries) or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (i) requires that supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.354 Financial Relationship, Compensation, and Ownership or Investment Interest

Paragraph (d) requires that, when special rules are applied to compensation under section 1877 of the Act and under these regulations in subpart J of this part, the compensation will be considered ''set in advance'' if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement, in writing, between the parties in sufficient detail so that it can be objectively verified, and meets the terms and conditions of this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.355 General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation

Paragraph (e) requires that the relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Section 411.357 Exceptions to the Referral Prohibition Related to Compensation Arrangements

Paragraph (l) requires that compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, must be set forth in an agreement, be in writing, and meet the conditions of the section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5 CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

Paragraph (p) requires that, for indirect compensation arrangements, as defined in § 411.354(c)(2), the compensation described in § 411.354(c)(2)(ii) is part of an arrangement that is set out in writing and meets all of the conditions and requirements set forth in this section.

While this requirement is subject to the PRA, the burden associated with it is exempt from the PRA because it meets the requirements set forth in 5

CFR 1320.3(b)(2) and/or (b)(3) and 5 CFR 1320.4(a).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 411.352, 411.354, 411.355, and 411.357. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Heron Eydt, HCFA Desk Officer; and

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–1809.

X. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of Phase I of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354, enacted September 19, 1980). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). We do not believe that Phase I of this rulemaking is a major rule that will have an economically significant effect. We have no way of determining with any certainty the aggregate amount of savings or costs Phase I of this rulemaking will impose, but do not believe it will approach $100 million or more annually.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, most physician practices are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We do not believe Phase I of this rulemaking will have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. Phase I of this rulemaking will not have such an effect on the governments mentioned, and we do not believe the private sector costs will meet the $100 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate that Phase I of this rulemaking will have a substantial effect on State or local governments.

B. Anticipated Effects

We stated in the impact analysis in the January 1998 proposed rule that any estimate of the individual or aggregate economic impact of the provisions of the final rule would be purely speculative. We explained that we could not gauge with any certainty the number of physicians and entities that would be affected, or the extent of any changes they would have to make to comply with the rule. As we noted in the January 1998 proposed rule at 63 FR 1716, various studies have indicated that the degree of conflict of interest presented by a physician's investment in entities to which he or she refers patients is unknown. We pointed out that ownership information or information on the compensation arrangements between physicians and all of their immediate family members and the entities that furnish any of 11 DHS constitutes an enormous amount of data that is continually subject to change. We also expected that the American Medical Association's declaration that self-referrals are unethical outside of a physician's practice, in conjunction with State laws restricting or qualifying self-referrals and the referral prohibition under section 1877 of the Act itself, have already led to a decline in self-referral activity and financial relationships between physicians and entities. However, we lack the data necessary to either confirm or refute this supposition. We also lack data that would tell us how many of the financial relationships that physicians have with a furnishing entity would already be exempted under the statute.

We stated that, although the provisions in the rule do not lend themselves to a quantitative impact estimate, we did not anticipate that they would have a significant economic impact on a substantial number of small entities. We based this assessment on the many exceptions in the rule (including a broad exception for ownership in rural entities), as well as the actions parties can take to revise their business arrangements to avoid the referral prohibition. We still believe this to be the case. In fact, we expect that Phase I of this rulemaking will have a much smaller impact than the provisions that we proposed. However, because Phase I of this rulemaking may have significant effects on some health care practitioners, or be viewed as controversial, we wish to inform the public of what we regard as the possible major effects of Phase I of this rulemaking.

We stated in the January 1998 proposed rule that we expected that physicians who refer Medicare patients for DHS and entities that furnish DHS, including hospitals, would be the parties that are primarily affected by this rule. In response to comments on the January 1998 proposed rule, we have liberalized a wide variety of the provisions that could affect these parties. We have tried to create a more manageable regulation that includes ''bright line'' rules to help the health care community determine more easily when a physician's referrals are in compliance with the law. We have made numerous changes to the rule to try to mold it around existing business practices, and have attempted to reinterpret the law so that it has a more practical and realistic effect on physicians and the entities that provide DHS. The result, we believe, is an overall approach that should have far less impact on the business relationships of individuals and entities

than the provisions of the January 1998 proposed rule. We discuss below some of the major issues affecting physicians and furnishing entities. We also briefly discuss the effects of the rule on Medicare beneficiaries.

1. Effects on Physicians

A physician can be financially related to an entity either through an ownership or investment interest in the entity, or through a compensation arrangement with the entity. A physician who has (or whose immediate family member has) a financial relationship with an entity that does not qualify for an exception is prohibited from referring Medicare patients to that entity for the provision of DHS. Also, when a physician with such a relationship makes a prohibited referral, there is a risk that the entity will receive no Medicare payment for those DHS. These provisions can have a significant effect on the business arrangements in which a physician will participate and the manner in which the physician will structure his or her practice.

The potential impact of the regulation on physicians and other individual parties was revealed to us by the voluminous comments from the public and health care community we received in response to the January 1998 proposed rule. In addition to specific complaints and objections, the commenters expressed a number of general concerns, including that the proposed regulation inappropriately intruded into the organization and delivery of medical care within physicians' offices; that the regulation in many respects was counter to our other longstanding policies on coverage and similar issues; that the rule was unclear in many areas and that in light of the severe penalty (that is, payment denial), ''bright line'' rules were essential; and that some aspects of the proposed rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and yet is consistent with the statute. Phase I of this rulemaking clarifies the definitions of DHS; substantially broadens the in-office ancillary services exception (which allows physicians to refer within their own practices) by easing the criteria for qualifying as a group practice and conforming the supervision requirements to our coverage and other payment policies; permits shared facilities in the same building where physicians routinely provide services that are neither Federal nor private pay DHS; excludes from the definition of ''referral'' services personally performed by the referring physician; expands the in-office ancillary services exception to cover certain DME provided to patients in physicians' offices; creates a new exception for compensation of faculty in academic medical centers; and clarifies when a managed care organization (MCO) is an entity furnishing DHS. All of these issues are described in greater detail elsewhere in the preamble, along with a number of lesser issues that could affect physicians.

2. Effects on Other Providers

As we stated above, Phase I of this rulemaking affects entities that furnish DHS by preventing them from receiving payment for services that they furnish as the result of a physician's prohibited referral. Entities can also be subject to various other sanctions, including fines and exclusion from Federal health care programs if they knowingly submit a claim in violation of the prohibition. We lack the data to determine the number of entities that could be affected by Phase I of this rulemaking. However, we believe they will be fewer in number than we had anticipated in the January 1998 proposed rule because, as we described above, physicians will have far more leeway to refer.

3. Effects on the Medicare and Medicaid Programs

Section 1877 of the Act was enacted primarily to address overutilization of health care services covered by Medicare. We have tried to focus Phase I of this rulemaking on financial relationships that may result in overutilization. We expect that Phase I of this rulemaking will result in savings to the program by providing physicians and entities with ''bright line'' rules on how to avoid the prohibited referrals that can result in overutilization of covered services. We cannot gauge with any certainty the extent of these savings to the program at this time. (We will discuss the effects on the Medicaid program in Phase II of this rulemaking.)

4. Effects on Beneficiaries

Some commenters thought the January 1998 proposed regulations exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services. In Phase I of this rulemaking, we have tried to ensure that the rule will not adversely impact the medical care of Federal health care beneficiaries or other patients. Where we have determined that Phase I of this rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement, so that patients could continue to receive the care in the same location. In almost all cases, we believe Phase I of this rulemaking should not require substantial changes in delivery arrangements, although it may affect the referring physician's or group practice's ability to bill for the care.

In addition, we have significantly expanded the scope of services potentially included in the in-office ancillary services exception and thus readily available to a referring physician's patients by: (1) Making clear that outpatient prescription drugs may be ''furnished'' in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of DME furnished in a physician's office for the convenience of the physician's patients.

C. Alternatives Considered

In drafting the January 1998 proposed rule covering a physician's referrals for DHS, we attempted to interpret the statute strictly and literally. After reviewing the voluminous number of comments we received, we have considered many alternative ways to interpret the statute to accommodate the practical problems that commenters raised, while still fulfilling the intent of the law. For example, we revised the ''same building'' requirements in the in-office ancillary services exception to address commenters' concerns. Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished ''in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services.'' In the January 1998 proposed rule, we made it clear that we regarded the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress's attempt to circumscribe the exception so that it applies only to services provided within the referring physician's actual sphere

of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are ''in-office'' services that are being supervised from some remote place.

Notwithstanding, we now realize that our proposed definition of a ''building'' that attempted to define a building in architectural terms could cause practical problems for some physicians and that a clearer, ''bright line'' rule would be preferable. Accordingly, having considered the various alternatives suggested by the commenters, we concluded that for purposes of Phase I of this rulemaking, we would define a ''building'' as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building would be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number. Under Phase I of this rulemaking, suites used by the same group practice or solo physician in buildings with separate street addresses will be treated as separate buildings for the purposes of the in-office ancillary services exception. While we recognize that this mailing address rule may result in an occasional anomaly, we are persuaded that it creates a ''bright line'' rule that will be easy to apply and will produce fair results in the vast majority of cases.

We have also responded to the commenters' numerous concerns that the space in the building in which the DHS are provided must be adjacent to the space in which services that are not DHS are provided. We have revised the regulation so that an adjacent space is no longer necessary (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are now permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. However, because of the increased risk of abuse in this expansion, we felt that we could not protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances.

As these examples demonstrate, our approach in Phase I of this rulemaking was to address as many of the industry's concerns as possible. We considered a variety of suggestions and alternatives, selecting only those that were consistent with the statute's goals and directives, and that would protect Federal health care program beneficiaries' access to services.

D. Conclusion

For the reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that Phase I of this rulemaking will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects

42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

A. Part 411 is amended as follows:

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

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

Subpart A—General Exclusions and Exclusions of Particular Services

2. In § 411.1, paragraph (a) is revised to read as follows:

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877 of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

* * * * *

Subpart J—Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services

3. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

4. Section 411.351 is revised to read as follows:

§ 411.351 Definitions.

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

Centralized building means all or part of a building, including, for purposes of this definition only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a

mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider (for example, a diagnostic imaging facility) is not a centralized building for purposes of this rule. This provision does not preclude a group practice from providing services to other providers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the CPT and HCPCS codes posted on the HCFA web site, http://www.hcfa.gov, (and in annual updates published in the **Federal Register** and posted on the HCFA web site), except as specifically excluded on the HCFA web site and in annual updates. All services identified on the HCFA web site and in annual updates are clinical laboratory services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a clinical laboratory service for purposes of these regulations.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1) Clinical laboratory services.

(2) Physical therapy, occupational therapy, and speech-language pathology services.

(3) Radiology and certain other imaging services.

(4) Radiation therapy services and supplies.

(5) Durable medical equipment and supplies.

(6) Parenteral and enteral nutrients, equipment, and supplies.

(7) Prosthetics, orthotics, and prosthetic devices and supplies.

(8) Home health services.

(9) Outpatient prescription drugs.

(10) Inpatient and outpatient hospital services.

Except as otherwise noted in these regulations, the term ''designated health services (DHS)'' means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1) through (10) of this definition are themselves payable through a composite rate (that is, all services provided as home health services or inpatient and outpatient hospital services are DHS).

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means a physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, not-for-profit corporation, or unincorporated association that furnishes DHS. For purposes of this definition, an entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS, directly or upon assignment on the patient's behalf, except that if the person or entity has reassigned its right to payment to an employer pursuant to § 424.80(b)(1) of this chapter; a facility pursuant to § 424.80(b)(2) of this chapter; or a health care delivery system, including clinics, pursuant to § 424.80(b)(3) of this chapter (other than a health care delivery system that is a health plan (as defined in § 1000.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees), the person or entity furnishing DHS is the person or entity to which payment has been reassigned. Provided further, that a health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §§ 424.80(b)(1) and (b)(2) of this chapter is the entity furnishing DHS for any services provided by such supplier.

Fair market value means the value in arm's-length transactions, consistent with the general market value. ''General market value'' means the price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party; or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement. With respect to the rentals and leases described in § 411.357(a) and (b), ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of

this section, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''rural primary care hospital'' under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

''Incident to'' services means those services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process. (Those wishing to subscribe to program manuals should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses: Superintendent of Documents, Government Printing Office, ATTN: New Orders, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630. In addition, individual manual transmittals and Program Memoranda can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell. Additionally, all manuals are available at the following Internet address: http://www.hcfa.gov/pubforms/progman.htm.)

Inpatient hospital services means those services as defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and includes inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient rural primary care hospital services, as defined in section 1861(mm)(2) of the Act. ''Inpatient hospital services'' do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. These services also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. Inpatient hospital services include services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. ''Inpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act) means the list of certain designated health services under section 1877 of the Act initially posted on the HCFA web site and updated annually thereafter in an addendum to the physician fee schedule final rule and on the HCFA web site.

Member of the group means, for purposes of this rule, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes ''patient care services'' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group. ''*Locum tenens* physician'' means a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a regular physician who is a member of the group, in accordance with applicable reassignment rules and regulations, including section 3060.7 of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process.

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient rural primary care hospital services, as defined in section 1861(mm)(3) of the Act. Emergency services covered in nonparticipating hospitals are excluded under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' includes services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital. ''Outpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all prescription drugs covered by Medicare Part B.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies,* meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6); and

(2) *Enteral nutrients, equipment, and supplies,* meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in section 65–10 of the Medicare Coverage Issues Manual (HCFA Pub. 6).

Patient care services means any tasks performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters; or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and speech-language pathology services means those particular services identified by the CPT and HCPCS codes on the HCFA web site (and in annual updates published in the **Federal Register**). All services identified on the HCFA web site and in annual updates are physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of these regulations. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services for purposes of these regulations includes the following:

(1) *Physical therapy services,* meaning those outpatient physical therapy services (including speech-language pathology services) described at section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment;

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services; or

(iv) Speech-language pathology services that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

(2) *Occupational therapy services,* meaning those services described at section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician, during the time the independent contractor is furnishing patient care services (as defined in this section) to the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract fits in the personal services exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules at § 424.80(b)(3) of this chapter (see also section 3060.3 of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process). Referrals from an independent contractor who is a physician in the group are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these services that are covered by Medicare):

(1) *Orthotics,* meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics,* meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices,* meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies,* meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register**. All services identified on the HCFA web site and in annual updates are *radiation therapy services and supplies* for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a *radiation therapy service or supply* for purposes of these regulations. The list of codes for radiation therapy services and supplies identified on the HCFA web site and in annual updates is based on

section 1861(s)(4) of the Act and § 410.35 of this chapter but does not include nuclear medicine procedures.

Radiology and certain other imaging services means those particular services identified by the CPT and HCPCS codes on the HCFA web site and in annual updates published in the **Federal Register** (except as otherwise specifically excluded on the HCFA web site and in annual updates). All services identified on the HCFA web site and in annual updates are *radiology and certain other imaging services* for purposes of these regulations. Any service not specifically identified on the HCFA web site, as amended from time to time and published in the **Federal Register**, is not a *radiology or certain other imaging service* for purposes of these regulations. The list of *radiology and certain other imaging services* set forth on the HCFA web site and in annual updates includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, or other imaging services, computerized axial tomography, or magnetic resonance imaging, as covered under section 1861(s)(3) of the Act and §§ 410.32 and 410.34 of this chapter but does not include—

(1) X-ray, fluoroscopy, or ultrasonic procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology procedures that are integral to the performance of, and performed during, nonradiological medical procedures; and

(3) Nuclear medicine procedures.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service *personally* performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior parking garages. For purposes of this rule, the ''same building'' does not include a mobile vehicle, van, or trailer.

5. Section 411.352 is added to read as follows:

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity formed primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, not-for-profit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may not be organized or owned (in whole or in part) by another medical practice that is an operating physician practice (regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this rule, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a

single legal entity may itself own subsidiary entities.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined in this section.

(c) *Range of care.* Each physician who is a *member of the group,* as defined in § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, substantially all of the patient care services of the physicians who are *members of the group* (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. ''Patient care services'' must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this ''substantially all test'' and related supportive documentation must be made available to the Secretary upon request.

(3) The ''substantially all test'' does not apply to any group practice that is located solely in an HPSA, as defined in § 411.351.

(4) For a group practice located outside of an HPSA (as defined in § 411.351), any time spent by a group practice member providing services in an HPSA should not be used to calculate whether the group practice has met the ''substantially all test,'' regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the ''start up'' period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or when an existing group practice reorganizes.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this rule prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries).

(ii) Consolidated billing, accounting, and financial reporting.

(iii) Centralized utilization review.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of referrals by the physician, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services ''incident to'' those personally performed services as defined in § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

(2) ''Overall profits'' means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. The share of overall profits will be deemed *not* to relate directly to the volume or value of referrals if *one* of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(iv) Overall profits are divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(3) A productivity bonus for personally performed services (including services ''incident to'' those personally performed services as defined in § 411.351) will be deemed *not* to relate directly to the volume or value of referrals of DHS if *one* of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). The methodology for establishing RVUs is set forth in § 414.22 of this chapter.

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group practice.

(iv) The bonus is calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.

(4) Supporting documentation verifying the method used to calculate the profit shares or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of

compensation, must be made available to the Secretary upon request.

6. Section 411.353 is revised to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff; however, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician, if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal laws, rules, and regulations.

7. Section 411.354 is added to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities (not including an agent of the physician, the immediate family member, or the entity furnishing DHS).

(3) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in a retirement plan;

(ii) Stock options and convertible securities until the stock options are exercised or the convertible securities are converted to equity (before this time they are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section); or

(iv) An ''under arrangements'' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS ''under arrangements'' to the hospital.

(4) An ownership or investment interest that meets an exception set forth in §§ 411.355 or 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, interest payments on secured obligations, or the like.

(5) *Indirect ownership or investment interest.* (i) An indirect ownership or investment interest exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests between them; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) The entity furnishing DHS need not know, or act in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(c) *Compensation arrangement.* A compensation arrangement can be any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An ''under arrangements'' contract between a hospital and an entity providing DHS ''under arrangements'' to the hospital creates a compensation arrangement for purposes of these regulations.

(1) A compensation arrangement does not include any of the following:

(i) The portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term ''remuneration'' in § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(ii) Payments made by a consultant to a referring physician under § 414.65(e) of this chapter.

(2) *Indirect compensation arrangement.* An *indirect* compensation arrangement exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of

persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a *direct* financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and these regulations in subpart J of this part.

(1) Compensation will be considered ''set in advance'' if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement between the parties in sufficient detail so that it can be objectively verified. The payment amount must be fair market value compensation for services or items actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician at the time of the initial agreement or during the term of the agreement. Percentage compensation arrangements do not constitute compensation that is ''set in advance'' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

(2) Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account ''the volume or value of referrals'' if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

(3) Compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account ''other business generated between the parties'' so long as the compensation is fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.

(4) A physician's compensation may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, so long as the compensation arrangement—

(i) Is fixed in advance for the term of the agreement;

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals);

(iii) Complies with an applicable exception under §§ 411.355 or 411.357; and

(iv) Complies with the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgement.

8. Section 411.355 is revised to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined in § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, ''physician services'' includes only those ''incident to'' services (as defined in § 411.351) that are physician services under § 410.20(a) of this chapter.

(3) All other ''incident to'' services (for example, diagnostic tests, physical therapy) are outside the scope of paragraph (a) of this section.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined in § 411.351), but not necessarily in the same space or part of the building, in which—

(A) The referring physician (or another physician who is a member of the same group practice) furnishes substantial physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal

health care payer, or a private payer, even though the unrelated services may lead to the ordering of DHS;

(B) The physician services that are unrelated to the furnishing of DHS in paragraph (b)(2)(i)(A) of this section must represent substantially the full range of physician services unrelated to the furnishing of DHS that the referring physician routinely provides (or, in the case of a referring physician who is a member of a group practice, the full range of physician services that the physician routinely provides for the group practice); and

(C) The receipt of DHS (whether payable by a Federal health care program or a private payer) is not the primary reason the patient comes in contact with the referring physician or his or her group practice.

(ii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They must be billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group'' (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of § 424.80(b)(6) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards located in § 424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is ''furnished'' for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the ''same building'' requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section, a private home does not include a nursing, long-term care, or other facility or institution.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with HCFA under section 1876 of the Act and part 417, subparts J through M of this chapter, which set forth qualifying conditions for Medicare contracts; enrollment, entitlement, and disenrollment under Medicare contracts; Medicare contract requirements; and change of ownership and leasing of facilities: effect on Medicare contracts.

(2) A health care prepayment plan in accordance with an agreement with HCFA under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b—1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

(d) *Clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (''Components'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation.);

(B) Is licensed to practice medicine in the State;

(C) Has a *bona fide* faculty appointment at the affiliated medical school; and

(D) Provides either substantial academic or substantial clinical

teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center.

(ii) The total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate);

(ii) An affiliated faculty practice plan that is a 501(c)(3) or (c)(4) of the Internal Revenue Code nonprofit, tax-exempt organization under IRS regulations (or is a part of such an organization under an umbrella designation); and

(iii) One or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members.

(f) *Implants in an ASC.* Implants, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME that meet the following conditions:

(1) The implant is furnished by the referring physician or a member of the referring physician's group practice in a Medicare-certified ASC (under part 416 of this chapter) with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure performed in the same ASC where the implant is furnished.

(3) The arrangement for the furnishing of the implant does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the implants complies with all Federal and State laws and regulations.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to and implanted in the patient.

(g) *EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility.* EPO and other dialysis-related outpatient prescription drugs that are identified by the CPT and HCPCS codes on the HCFA web site, http://www.hcfa.gov, and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, ''furnished'' means that the EPO or drugs are either administered or dispensed to a patient in or by the ESRD facility, even if the EPO or drugs are furnished to the patient at home. ''Dialysis-related drugs'' means certain drugs required for the efficacy of dialysis, as identified on the HCFA web site and in annual updates.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the EPO and other dialysis related drugs complies with all Federal and State laws and regulations.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that are covered by Medicare and identified by the CPT and HCPCS codes included on the HCFA web site and in annual updates published in the **Federal Register** and that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to HCFA-mandated frequency limits.

(2) The preventive screening tests, immunizations, and vaccines are reimbursed by Medicare based on a fee schedule.

(3) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all Federal and State laws and regulations.

(5) To qualify under this exception, the preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed on the HCFA web site and in annual updates.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the eyeglasses or contact lenses complies with all Federal and State laws and regulations.

9. In § 411.357, paragraph (j) is added and reserved, and paragraphs (k), (l), (m), (n), (o), and (p) are added to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(j) [Reserved]

(k) *Non-monetary compensation up to $300.* Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per year, if all of the following conditions are satisfied:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(3) The compensation arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(l) *Fair market value compensation.* Compensation resulting from an

arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.351) for the provision of items or services by the physician (or an immediate family member) or group practice to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) It is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) It specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) It specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician.

(4) It involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute in § 1001.952 of this title, has been approved by the OIG under a favorable advisory opinion issued in accordance with part 1008 of this title, or does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties.

(2) The compensation is offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is consistent with the types of benefits offered to medical staff members—

(i) By other hospitals within the same local region; or

(ii) If no such hospitals exist within the same local region, by comparable hospitals in comparable regions.

(6) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

(7) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(8) The compensation arrangement does not violate the Federal anti-kickback provisions in section 1128B(b) of the Act.

(n) *Risk sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings ascribed to those terms in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in the hospital's local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), ''compliance training'' means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

B. Part 424 is amended as follows:

1. The authority citation for part 424 continues to read as follows:

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

Subpart B—Certification and Plan of Treatment Requirements

2. In § 424.22, paragraph (d) is revised to read as set forth below, and paragraphs (e), (f), and (g) are removed.

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of treatment may not be established and reviewed, by any physician who has a financial relationship, as defined in § 411.351 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877 of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition

related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

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

Dated: October 6, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

Dated: October 16, 2000.

Donna E. Shalala,

Secretary.

Note: The following attachment will not appear in the Code of Federal Regulations.

Attachment

List of CPT [1]/HCPCS Codes Used To Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)

Clinical Laboratory Services

Include CPT codes for all clinical laboratory services in the 80000 series, except *Exclude* CPT codes for the following blood component collection services:

86890 Autologous blood process
86891 Autologous blood, op salvage
86915 Bone marrow/stem cell prep
86927 Plasma, fresh frozen
86930 Frozen blood prep
86931 Frozen blood thaw
86932 Frozen blood freeze/thaw
86945 Blood product/irradiation
86950 Leukacyte transfusion
86965 Pooling blood platelets
86985 Split blood or products

Include HCPCS level 2 codes for other clinical laboratory services:

G0001 Drawing blood for specimen
G0026 Fecal leukocyte examination
G0027 Semen analysis
G0103 Psa, total screening
G0107 CA screen; fecal blood test
G0123 Screen cerv/vag thin layer
G0124 Screen c/v thin layer by MD
G0141 Scr c/v cyto,autosys and md
G0143–G0145 Scr c/v cyto, thinlayer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
P2028 Cephalin floculation test
P2029 Congo red blood test
P2031 Hair analysis
P2033 Blood thymol turbidity
P2038 Blood mucoprotein
P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys
P7001 Culture bacterial urine
P9612 Catheterize for urine spec
P9615 Urine specimen collect mult
Q0111 Wet mounts/w preparations
Q0112 Potassium hydroxide preps
Q0113 Pinworm examinations
Q0114 Fern test
Q0115 Post-coital mucous exam

Physical Therapy/Occupational Therapy/Speech-Language Pathology

Include the following CPT codes for the physical therapy/occupational therapy/speech-language pathology services in the 97000 series:

97001 Pt evaluation
97002 Pt re-evaluation
97003 Ot evaluation
97004 Ot re-evaluation
97010 Hot or cold packs therapy
97012 Mechanical traction therapy
97014 Electric stimulation therapy
97016 Vasopneumatic device therapy
97018 Paraffin bath therapy
97020 Microwave therapy
97022 Whirlpool therapy
97024 Diathermy treatment
97026 Infrared therapy
97028 Ultraviolet therapy
97032 Electrical stimulation
97033 Electric current therapy
97034 Contrast bath therapy
97035 Ultrasound therapy
97036 Hydrotherapy
97039 Physical therapy treatment
97110 Therapeutic exercises
97112 Neuromuscular reeducation
97113 Aquatic therapy/exercises
97116 Gait training therapy
97124 Massage therapy
97139 Physical medicine procedure
97140 Manual therapy
97150 Group therapeutic procedures
97504 Orthotic training
97520 Prosthetic training
97530 Therapeutic activities
97532 Cognitive skills development
97533 Sensory integration
97535 Self care mngment training
97537 Community/work reintegration
97542 Wheelchair mngment training
97545 Work hardening
97546 Work hardening add-on
97703 Prosthetic checkout
97750 Physical performance test
97799 Physical medicine procedure

Include CPT codes for physical therapy/occupational therapy/speech-language pathology services *not* in the 97000 series:

64550 Apply neurostimulator
90901 Biofeedback train, any meth
90911 Biofeedback peri/uro/rectal
92506 Speech/hearing evaluation
92507–92508 Speech/hearing therapy
92510 Rehab for ear implant
92526 Oral function therapy
93797 Cardiac rehab
93798 Cardiac rehab/monitor
94667–94668 Chest wall manipulation
94762 Measure blood oxygen level
95831 Limb muscle testing, manual
95832 Hand muscle testing, manual
95833–95834 Body muscle testing, manual
95851–95852 Range of motion measurements
96105 Assessment of aphasia
96110 Developmental test, lim
96111 Developmental test, extend
96115 Neurobehavior status exam

Include HCPCS level 2 codes for the following physical therapy/occupational therapy/speech-language pathology services:

G0193 Endoscopic study swallow functn
G0194 Sensory testing endoscopic stud
G0195 Clinical eval swallowing funct
G0196 Eval of swallowing with radioopa
G0197 Eval of pt for prescip speech devi
G0198 Patient adapation & train for spe
G0199 Reevaluation of patient use spec
G0200 Eval of patient prescip of voice p
G0201 Modi for training in use voice pro
Q0086 Physical therapy evaluation/

Radiology

Include the following radiology and certain other imaging services in the CPT 70000 series:

70100–70110 X-ray exam of jaw
70120–70130 X-ray exam of mastoids
70134 X-ray exam of middle ear
70140–70150 X-ray exam of facial bones
70160 X-ray exam of nasal bones
70190–70200 X-ray exam of eye sockets
70210–70220 X-ray exam of sinuses
70240 X-ray exam, pituitary saddle
70250–70260 X-ray exam of skull
70300–70310 X-ray exam of teeth
70320 Full mouth x-ray of teeth
70328 X-ray exam of jaw joint
70330 X-ray exam of jaw joints
70336 Magnetic image, jaw joint
70350 X-ray head for orthodontia
70355 Panoramic x-ray of jaws
70360 X-ray exam of neck
70370 Throat x-ray & fluoroscopy
70371 Speech evaluation, complex
70380 X-ray exam of salivary gland
70450 CT head/brain w/o dye
70460 CT head/brain w/dye
70470 CT head/brain w/o&w dye
70480 CT orbit/ear/fossa w/o dye
70481 CT orbit/ear/fossa w/dye
70482 CT orbit/ear/fossa w/o&w dye

[1] CPT codes, descriptions and other data only are copyright 2000 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Clauses Apply.

70486 CT maxillofacial w/o dye
70487 CT maxillofacial w/dye
70488 CT maxillofacial w/o&w dye
70490 CT soft tissue neck w/o dye
70491 CT soft tissue neck w/dye
70492 CT sft tsue nck w/o & w/dye
70496 CT angiography, head
70498 CT angiography, neck
70540 MRI orbit/face/neck w/o dye
70542 MRI orbit/face/neck w/dye
70543 MRI orbt/fac/nck w/o&w dye
70544 MR angiography head w/o dye
70545 MR angiography head w/dye
70546 MR angiograph head w/o&w dye
70547 MR angiography neck w/o dye
70548 MR angiography neck w/dye
70549 MR angiograph neck w/o&w dye
70551 MRI brain w/o dye
70552 MRI brain w/dye
70553 MRI brain w/o&w dye
71010–71022 Chest x-ray
71023 Chest x-ray and fluoroscopy
71030 Chest x-ray
71034 Chest x-ray and fluoroscopy
71035 Chest x-ray
71100 X-ray exam of ribs
71101 X-ray exam of ribs/chest
71110 X-ray exam of ribs
71111 X-ray exam of ribs/chest
71120–71130 X-ray exam of breastbone
71250 CT thorax w/o dye
71260 CT thorax w/dye
71270 CT thorax w/o&w dye
71275 CT angiography, chest
71550 MRI chest w/o dye
71551 MRI chest w/dye
71552 MRI chest w/o&w dye
71555 MRI angio chest w or w/o dye
72010–72020 X-ray exam of spine
72040–72052 X-ray exam of neck spine
72069 X-ray exam of trunk spine
72070–72074 X-ray exam of thoracic spine
72080–72090 X-ray exam of trunk spine
72100–72120 X-ray exam of lower spine
72125 CT neck spine w/o dye
72126 CT neck spine w/dye
72127 CT neck spine w/o&w dye
72128 CT chest spine w/o dye
72129 CT chest spine w/dye
72130 CT chest spine w/o&w dye
72131 CT lumbar spine w/o dye
72132 CT lumbar spine w/dye
72133 CT lumbar spine w/o&w dye
72141 MRI neck spine w/o dye
72142 MRI neck spine w/dye
72146 MRI chest spine w/o dye
72147 MRI chest spine w/dye
72148 MRI lumbar spine w/o dye
72149 MRI lumbar spine w/dye
72156 MRI neck spine w/o&w dye
72157 MRI chest spine w/o&w dye
72158 MRI lumbar spine w/o&w dye
72170–72190 X-ray exam of pelvis
72191 CT angiograph pelv w/o&w dye
72192 CT pelvis w/o dye
72193 CT pelvis w/dye
72194 CT pelvis w/o&w dye
72195 MRI pelvis w/o dye
72196 MRI pelvis w/dye
72197 MRI pelvis w/o&w dye
72200–72202 X-ray exam sacroiliac joints
72220 X-ray exam of tailbone
73000 X-ray exam of collar bone
73010 X-ray exam of shoulder blade
73020–73030 X-ray exam of shoulder
73050 X-ray exam of shoulders
73060 X-ray exam of humerus
73070–73080 X-ray exam of elbow
73090 X-ray exam of forearm
73092 X-ray exam of arm, infant
73100–73110 X-ray exam of wrist
73120–73130 X-ray exam of hand
73140 X-ray exam of finger(s)
73200 CT upper extremity w/o dye
73201 CT upper extremity w/dye
73202 CT uppr extremity w/o&w dye
73206 CT angio upr extrm w/o&w dye
73218 MRI upper extremity w/o dye
73219 MRI upper extremity w/dye
73220 MRI uppr extremity w/o&w dye
73221 MRI joint upr extrem w/o dye
73222 MRI joint upr extrem w/ dye
73223 MRI joint upr extr w/o&w dye
73500–73510 X-ray exam of hip
73520 X-ray exam of hips
73540 X-ray exam of pelvis & hips
73550 X-ray exam of thigh
73560 X-ray exam of knee, 1 or 2
73562 X-ray exam of knee, 3
73564 X-ray exam, knee, 4 or more
73565 X-ray exam of knees
73590 X-ray exam of lower leg
73592 X-ray exam of leg, infant
73600–73610 X-ray exam of ankle
73620–73630 X-ray exam of foot
73650 X-ray exam of heel
73660 X-ray exam of toe(s)
73700 CT lower extremity w/o dye
73701 CT lower extremity w/dye
73702 CT lwr extremity w/o&w dye
73706 CT angio lwr extr w/o&w dye
73718 MRI lower extremity w/o dye
73719 MRI lower extremity w/dye
73720 MRI lwr extremity w/o&w dye
73721 MRI joint of lwr extre w/o d
73722 MRI joint of lwr extr w/dye
73723 MRI joint lwr extr w/o&w dye
73725 MR ang lwr ext w or w/o dye
74000–74020 X-ray exam of abdomen
74022 X-ray exam series, abdomen
74150 CT abdomen w/o dye
74160 CT abdomen w/dye
74170 CT abdomen w/o&w dye
74175 CT angio abdom w/o&w dye
74181 MRI abdomen w/o dye
74182 MRI abdomen w/dye
74183 MRI abdomen w/o&w dye
74185 MRI angio, abdom w or w/o dy
74210 Contrst x-ray exam of throat
74220 Contrast x-ray, esophagus
74230 Cinema x-ray, throat/esoph
74240–74245 X-ray exam, upper gi tract
74246–74249 Contrst x-ray uppr gi tract
74250 X-ray exam of small bowel
74290 Contrast x-ray, gallbladder
74291 Contrast x-rays, gallbladder
74710 X-ray measurement of pelvis
75552 Heart MRI for morph w/o dye
75553 Heart MRI for morph w/dye
75554 Cardiac MRI/function
75555 Cardiac MRI/limited study
75635 CT angio abdominal arteries
76000 Fluoroscope examination
76006 X-ray stress view
76010 X-ray, nose to rectum
76020 X-rays for bone age
76040 X-rays, bone evaluation
76061–76062 X-rays, bone survey
76065 X-rays, bone evaluation
76066 Joint(s) survey, single film
76090 Mammogram, one breast
76091 Mammogram, both breasts
76092 Mammogram, screening
76093 Magnetic image, breast
76094 Magnetic image, both breasts
76100 X-ray exam of body section
76101 Complex body section x-ray
76102 Complex body section x-rays
76120 Cinematic x-rays
76125 Cinematic x-rays add-on
76150 X-ray exam, dry process
76370 CAT scan for therapy guide
76375 3d/holograph reconstr add-on
76380 CAT scan follow-up study
76390 Mr spectroscopy
76400 Magnetic image, bone marrow
76499 Radiographic procedure
76506 Echo exam of head
76511–76512 Echo exam of eye
76513 Echo exam of eye, water bath
76516–76519 Echo exam of eye
76536 Echo exam of head and neck
76604 Echo exam of chest
76645 Echo exam of breast(s)
76700–76705 Echo exam of abdomen
76770–76775 Echo exam abdomen back wall
76778 Echo exam kidney transplant
76800 Echo exam spinal canal
76805–76815 Echo exam of pregnant uterus
76816 Echo exam follow-up/repeat
76818 Fetl biophys profil w/stress
76819 Fetl biophys profil w/o strs
76825–76828 Echo exam of fetal heart
76830 Echo exam, transvaginal
76831 Echo exam, uterus
76856–76857 Echo exam of pelvis
76870 Echo exam of scrotum
76872 Echo exam, transrectal
76873 Echograp trans r, pros study
76880 Echo exam of extremity
76885–76886 Echo exam, infant hips
76970 Ultrasound exam follow-up
76977 Us bone density measure
76999 Echo examination procedure

Include the following CPT codes for echocardiography and vascular ultrasound:

93303–93304 Echo transthoracic
93307–93308 Echo exam of heart
93320–93321 Doppler echo exam, heart, if used in conjunction with 93303–93308
93325 Doppler color flow add-on, if used in conjunction with 93303–93308
93875–93882 Extracranial study
93886–93888 Intracranial study
93922–93924 Extremity study
93925–93926 Lower extremity study
93930–93931 Upper extremity study
93965–93971 Extremity study
93975–93979 Vascular study
93980–93981 Penile vascular study
93990 Doppler flow testing

Include miscellaneous other HCPCS level 2 codes for radiology and certain other imaging services:

G0050 Residual urine by ultrasound
G0131–132 CT scan, bone density study
G0188 Xray lwr extrmty-full lngth
R0070 Transport portable x-ray
R0075 Transport port x-ray multipl

Radiation Therapy Services and Supplies

Include CPT codes for all radiation therapy services and supplies in the CPT 70000 series:

77261–77263 Radiation therapy planning
77280–77295 Set radiation therapy field
77299 Radiation therapy planning
77300–77315 Radiation therapy dose plan
77321 Radiation therapy port plan
77326–77328 Radiation therapy dose plan
77331 Special radiation dosimetry
77332–77334 Radiation treatment aid(s)
77336–77370 Radiation physics consult
77399 External radiation dosimetry
77401–77416 Radiation treatment delivery
77417 Radiology port film(s)
77427 Radiation tx management, x5
77431 Radiation therapy management
77432 Stereotactic radiation trmt
77470 Special radiation treatment
77499 Radiation therapy management
77520 Proton trmt, simple w/o comp
77522 Proton trmt, simple w/comp
77523 Proton trmt, intermediate
77525 Proton treatment, complex
77600–77620 Hyperthermia treatment
77750 Infuse radioactive materials
77761 Apply intrcav radiat simple
77762 Apply intrcav radiat interm
77763 Apply intrcav radiat compl
77776 Apply interstit radiat simpl
77777 Apply interstit radiat inter
77778 Apply iterstit radiat compl
77781–77784 High intensity brachytherapy
77789 Apply surface radiation
77790 Radiation handling
77799 Radium/radioisotope therapy

Include CPT codes for radiation therapy classified elsewhere:

31643 Diag bronchoscope/catheter
50559 Renal endoscopy/radiotracer
55859 Percut/needle insert, pros
61770 Incise skull for treatment
61793 Focus radiation beam

Preventive Screening Tests, Immunizations and Vaccines

The following CPT and HCPCS codes are excluded under § 411.355(h) as screening tests:

76092 Mammogram, screening
76977 Us bone density measure
G0103 Psa, total screening
G0107 CA screen; fecal blood test
G0123 Screen cerv/vag thin layer
G0124 Screen c/v thin layer by MD
G0141 Scr c/v cyto,autosys and md
G0143–G0145 Scr c/v cyto, thin layer, rescr
G0147 Scr c/v cyto, automated sys
G0148 Scr c/v cyto, autosys, rescr
P3000 Screen pap by tech w md supv
P3001 Screening pap smear by phys

The following CPT codes are excluded under § 411.355(h) as vaccines:

90657 Flu vaccine, 6–35 mo, im
90658 Flu vaccine, 3 yrs, im
90659 Flu vacine, whole, im
90732 Pneumococcal vacc, adult/ill
90744 Hepb vacc ped/adol 3 dose im
90746 Hep b vaccine, adult, im
90747 Hepb vacc, ill pat 4 dose im
90748 Hep b/hib vaccine, im

Drugs Used by Patients Undergoing Dialysis

The following HCPCS codes are excluded under § 411.355(g) as EPO and other dialysis related outpatient prescription drugs furnished in or by an ESRD facility:

J0635 Calcitriol injection
J0895 Deferoxamine meslyate inj
J1750 Iron dextran
J2915 NA Ferric Gluconate Complex
J2997 Alteplase recombinant
Q9920 Epoetin with hct <=20
Q9921 Epoetin with hct = 21
Q9922 Epoetin with hct = 22
Q9923 Epoetin with hct = 23
Q9924 Epoetin with hct = 24
Q9925 Epoetin with hct = 25
Q9926 Epoetin with hct = 26
Q9927 Epoetin with hct = 27
Q9928 Epoetin with hct = 28
Q9929 Epoetin with hct = 29
Q9930 Epoetin with hct = 30
Q9931 Epoetin with hct = 31
Q9932 Epoetin with hct = 32
Q9933 Epoetin with hct = 33
Q9934 Epoetin with hct = 34
Q9935 Epoetin with hct = 35
Q9936 Epoetin with hct = 36
Q9937 Epoetin with hct = 37
Q9938 Epoetin with hct = 38
Q9939 Epoetin with hct = 39
Q9940 Epoetin with hct >= 40

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Federal Register

Thursday,
January 4, 2001

Part III

Department of Transportation

National Highway Traffic Safety Administration

49 CFR Part 571

Federal Motor Vehicle Safety Standards; Head Restraints; Proposed Rule

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2000–8570]

RIN 2127–AH09

Federal Motor Vehicle Safety Standards; Head Restraints

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: Consistent with this agency's policy of seeking to adopt those regulatory requirements that produce the highest benefits at reasonable costs, this document proposes to upgrade the standard for head restraints for passenger cars and for light multipurpose vehicles, trucks and buses. The proposal would establish higher minimum height requirements for head restraints, and add a requirement limiting backset, *i.e.*, the distance between a person's head and his or her head restraint. The proposal would also extend the requirement for head restraints to rear outboard designated seating positions; establish new strength requirements for head restraints; and place limits on the size of gaps and openings in head restraints. In addition, it would modify the dynamic compliance test and amend test procedures. The proposal would harmonize the standard with the counterpart regulation of the Economic Commission for Europe (ECE) to an extent, but would set different requirements for head restraint width and gap measurement for adjustable restraints. Further, it would add two requirements not found in the ECE regulation, *i.e.*, one for backset and one for adjustment retention locks. The goal of these proposed changes is to improve the protection that head restraints provide in rear-end collisions.

This document also proposes that before compliance with the upgraded requirements becomes mandatory on the first September 1, three years following publication of the final rule, the manufacturers could chose to comply with any of three sets of requirements: the existing requirements of Standard 202, the ECE regulation, or the upgraded requirements of Standard 202. The proposal to allow compliance with the ECE regulation during the interim responds to a petition for rulemaking by the American Automobile Manufacturers Association (AAMA) and the Association of International Automobile Manufacturers (AIAM) requesting that we consider the benefits of complying with the European regulation to be at least equivalent to those of complying with the existing requirements of Standard 202.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than March 5, 2001.

ADDRESSES: You should mention the docket number of this document in your comments and submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590. Comments may also be submitted to the docket electronically by logging onto the Dockets Management System website at *http://dms.dot.gov*. Click on ''Help & Information'' or ''Help/Info'' to obtain instructions for filing the document electronically.

You may call Docket Management at 202–366–9324. You may visit the Docket from 10 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, you may contact Louis Molino of the Office of Safety Performance Standards, Vehicle Crashworthiness Standards, Light Duty Vehicle Division, NPS–11, (Phone: 202–366–2264; fax: 202–366–4329; E-mail: *lmolino@nhtsa.dot.gov*).

For legal issues, you may contact Otto Matheke of the Office of Chief Counsel, NCC–20, (Phone: 202–366–5263; Fax 202–366–3820).

You may send mail to both of these officials at the National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC, 20590.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. The Safety Problem
II. Background
  A. Studies of Head Restraint Effectiveness
  B. December 1996 Request for Comments
  C. AIAM/AAMA Petition
III. Overview of Proposal
IV. Proposed Upgraded Requirements
  A. Height Requirements
  B. Backset Requirement
  C. Height Adjustment Retention Requirement
  D. Rear Outboard Seating Positions
  E. Removability of Head Restraints
  F. Head Restraint Configuration Requirements
  1. Width
  2. Gaps
  G. Energy Absorption
  H. Test Procedures
  1. Displacement Test Procedure
  2. Dynamic Sled Test Procedure
V. Interim Compliance Options Before Upgraded Requirements Become Mandatory
VI. Benefits
VII. Costs
VIII. Effective Date
IX. Rulemaking Analyses and Notices
X. Submission of Comments
XI. Proposed Regulatory Text

I. The Safety Problem

Whiplash injuries, a set of common symptoms involving the soft tissues of the head, neck and spine, are believed to be associated with rapid motion of the head and neck relative to the torso in a crash. Symptoms of pain in the head, neck, shoulders, and arms may be present along with damage to muscles, ligaments and vertebrae, but in many cases lesions are not evident. The onset of symptoms may be delayed and may only last a few hours; however, in some cases, effects of the injury may last for years or be permanent. The relatively short-term symptoms are associated with muscle and ligament trauma, while the long-term ones are associated with nerve damage.[1]

Although whiplash injuries can occur in any kind of crash, they occur most often in rear-end collisions. When a vehicle is struck from behind, typically several things occur in quick succession to an occupant of that vehicle. First, from the occupant's frame of reference, the back of the seat moves forward into his or her torso, straightening the spine and forcing the head to rise vertically. Second, as the occupant's body is pushed forward by the seat, the unrestrained head tends to lag behind. This causes the neck to change shape, first taking on an S-shape and then bending backward. Third, the forces on the neck accelerate the head, which catches up with—and, depending on the seat back stiffness and if the occupant is using a shoulder belt, passes—the restrained torso. This motion of the head, which is like the lash of a whip, gives the resulting neck injuries their popular name. However, at what point in this motion the injury occurs is still a matter of debate.

We estimate from National Analysis Sampling System (NASS) data that between 1988 and 1996, 805,581 whiplash injuries (non-contact Abbreviated Injury Scale (AIS) 1 neck) occurred annually in all crashes in passenger cars (PCs), and in LTV's (light trucks, multipurpose passenger vehicles and vans). The average cost (excluding property damage) of such an injury is $6,485, resulting in a total annual cost of $5.2 billion.

[1] Summary of the highlights of Traffic Safety and Auto Engineering Stream, World Congress on Whiplash-Associated Disorders, February 1999, Vancouver, Canada *http://www.whiplash99.org/highlights/index.htm.*

The potential for whiplash injuries is influenced by the ability of several aspects of vehicle design, including vehicle structure, seats and head restraints, to absorb and control crash forces. In addition to integral and adjustable head restraints, which are designed to maintain their position relative to the seat back during a crash, several manufacturers have recently introduced new seat and head restraint designs that allow the head restraints to actively move closer to the occupant's head during a rear impact of the vehicle. Volvo has introduced a system it has labeled as WHIPS (Whiplash Head Impact Protection System) in which the seat back recliner is designed to give a controlled rearward motion of the seat back relative to the seat base in a rear impact—allowing the torso to move backward. In the first phase the seat back translates rearward for the purpose of reducing relative motion of the seat back—reducing relative motion of the head and torso and allowing the head to move closer to the head restraint. The second phase involves rearward folding of the seat back, with the center of motion in the recliner. This reduces acceleration of the occupant while absorbing energy. Saab has incorporated an active and adjustable head restraint into the front seat backs of its 9–3 and 9–5 models. Known as the Saab Active Head Restraint System, it moves the head restraint forward and upward as the seat occupant moves backward during and after a rear impact. Model year 2000 Infiniti I30s, Buick LeSabres and Pontiac Bonnevilles also have active front seat head restraints. The Insurance Institute for Highway Safety (IIHS) has attempted to determine the potential contributions of the advanced seats like the Volvo seat and of active head restraints through dynamic testing of those designs. More information on these tests is discussed in the Background section of this document. Two suppliers, TRW and Breed Siemens Restraint Systems, are each in the process of developing an inflatable head restraint that is activated in rear impacts.

This notice focuses on the potential for reducing whiplash through requiring improvements in head restraints. A historical examination of head restraint standards in this country indicates that the focus has been the prevention of neck hyperextension (the rearward movement of the head and neck over a large range of motion relative to the torso), as opposed to controlling lesser amounts of head and neck movement in a crash. The predecessor to Federal Motor Vehicle Safety Standard 202 (Standard 202) was General Services Administration (GSA) Standard 515/22, which applied to vehicles purchased by the U.S. Government and went into effect on October 1, 1967. GSA 515/22 required that the top of the head restraint achieve a height 700 mm (27.5 inches) above the H-point. The H-point is defined by a test machine placed in the vehicle seat (SAE J826, July 1995). From the side, the H-point represents the pivot point between the torso and upper leg portions of the test machine. It can be thought of, roughly, as the hip joint of a 50th percentile male occupant viewed laterally. Also in 1967, research using staged 48.3 kph (30 mph) crashes concluded that a head restraint 711 mm (28 inches) above the H-point was adequate to prevent neck hyperextension of a 95th percentile male.[2] Standard 202, which became effective on January 1, 1969, required that head restraints be at least 700 mm (27.5 inches) above the seating reference point or limit the relative angle between the head and the torso to 45 degrees or less during a dynamic test.

Current research indicates that whiplash may occur as a result of head and neck movements insufficient to cause hyperextension. Low speed staged impacts indicate that mild whiplash symptoms can occur without exceeding the normal range of motion.[3] Other research shows that 70.8 kph (44 mph) impacts can be sustained without injury if no relative motion occurs between the head and torso.[4] A Volvo study reported that, when vehicle occupants involved in rear crashes had their heads against the head restraint during impact, no injury occurred.[5] The same study related a rear impact simulation computer model to actual crash data and identified the rate of volume change in the cervical spinal canal as a possible predictor of whiplash injury. Other predictors identified were neck shear force, neck tensile force and head angular acceleration. A study of Volvo vehicles involved in rear impacts showed that a significant increase in injury duration occurred when the occupant's head was more than 100 mm (4 inches) away from the head restraint at the time of the rear impact.[6]

Although there seems to be no clear consensus in the biomechanics community about the mechanism for whiplash injuries, several hypotheses have been proposed based on investigations using animals, volunteers, and human surrogates. Animal research at Chalmers University suggests that rapid head/neck motion, within the normal range, can cause spinal canal pressures to damage nerve ganglia.[7] Other studies have attributed whiplash injuries to damage to the highly innervated cervical facet joints. Researchers at the Medical College of Wisconsin propose that local compression in the lower cervical spine and sliding along the facet joint may cause the excitation of local pain fibers, micro-damage to the cartilage plates and squeezing of the synovial space in the facet joints.[8] Similarly, a study performed in Japan using cineradiography (x-ray motion pictures) on human volunteers to study vertebral motion, hypothesized that the upward ramping of the torso due to the straightening of the natural spine lordotic curvature causes compression of the cervical spine and an unnatural S-shape of the cervical spine.[9] At the mid-portion of this unnatural S-shape, large rotations may occur which stretch the ligaments or damage the facet joint.

In 1995, the National Highway Traffic Safety Administration (NHTSA) performed a survey of the relative position of occupants' heads and head restraints on 282 vehicles. The survey examined relative position of the head to the restraint, how the head restraint was adjusted and if the head restraint could potentially have been adjusted higher. The tops of 59 percent of adjustable and 77 percent of integral head restraints were at or above the occupant's ear—a point equivalent to the head center of gravity. NHTSA also estimated the backset of these head restraints—the horizontal distance from the back of the occupant's head to the head restraint. Sixty-nine percent of adjustable head restraints and 77

[2] Severy *et al.* (1968) Backrest and Head Restraint Design for Rear-End Collision Protection. SAE 680029.

[3] McConnell *et al.* (1995) Human Head and Neck Kinematics After Low Velocity Rear-End Impacts—Understanding ''Whiplash.'' SAE 952724.

[4] Mertz and Patrick (1967) Investigation of the Kinematics and Kinetics of Whiplash. Proceedings of the 11th STAPP Car Crash Conference, pp. 267–317.

[5] Jacobsson *et al.* (1994) Analysis of Head and Neck Responses in Rear End Impacts—A New Human-Like Model. Volvo Car Corporation Safety Report.

[6] Olsson *et al.* (1990) An In-depth Study of Neck Injuries in Rear-end Collisions. IRCOBI, pp. 269–280.

[7] Svensson *et al.* (1993) Pressure Effects in the Spinal Canal During Whiplash Extension Motion: A Possible Cause of Injury to the Cervical Spinal Ganglia. IRCOBI, pp. 189–200.

[8] Yoganandan *et al.* (1998) Biomechanical Assessment of Whiplash. In: Frontiers in Head and Neck Trauma: Clinical and Biomechanical, pp. 344–373.

[9] Kaneoka and Ono (1998) Human Volunteer Studies on Whiplash Injury Mechanisms. In: Frontiers in Head and Neck Trauma: Clinical and Biomechanical, pp. 313–325.

percent of integral head restraints had a backset of less than 100 mm (4 inches). When combined height and backset position was assessed, 53 percent of adjustable and 70 percent of integral head restraints were both above the ear and less than 100 mm (4 inches) from the head. Half of adjustable head restraints were left in the lowest adjustable position and three quarters of these could have been raised to decrease whiplash potential by bringing the head restraint higher in relation to the occupant's head height.

The continued persistence of whiplash injuries indicates that Standard 202 should be revised. The current state of knowledge indicates that limiting hyperextension of the neck does not prevent the occurrence of whiplash and that controlling even smaller amounts of rapid head and neck movement relative to the torso would be more effective. The current regulation requires a head restraint height of 700 mm (27.5 inches) to prevent hyperextension and has been shown to accomplish this for occupants as large as 95th percentile males. However, the current regulation has no lower limit on head restraint position. Therefore, if an adjustable head restraint is not raised to the 700 mm (27.5 inch) level, hyperextension may be more likely for some occupants. Additionally, if an existing head restraint is not designed to exceed the current height requirement and to also limit backset distance, it will not be capable of controlling small amounts of head and neck movement relative to the torso for many occupants. These factors may be playing a large role in the persistence of whiplash. NHTSA has tentatively concluded that an upgrade to Standard 202 is required to foster further gains in neck injury protection in rear impacts.

II. Background

A. Studies of Head Restraint Effectiveness

Since January 1, 1969, passenger cars have been required by Standard 202 to have head restraints in the front outboard seating positions. Head restraints must either (a) be at least 700 mm (27.5 inches) above the seating reference point in their highest position and not deflect more than 100 mm (4 inches) under a 373 Nm (3,300 inch-pounds) moment, or (b) limit the relative angle of the head and torso of a 95th percentile dummy to not exceed 45 degrees when exposed to an 8 g acceleration. Standard 202 was extended to light trucks and vans under 10,000 pounds, effective September 1, 1991.

In 1982, NHTSA assessed the performance of head restraints installed pursuant to Standard 202 and reported that integral head restraints are 17 percent effective at reducing neck injuries in rear impacts and adjustable head restraints are 10 percent effective at doing so. The difference was due to integral head restraints being higher with respect to the occupant's head than adjustable head restraints, which were normally left down.

IIHS evaluated and rated head restraints in 1995, 1997 and 1999. In 1998, in conjunction with the State Farm Insurance Company (State Farm), IIHS compared the conclusions from the 1995 and 1997 evaluations to crash data.[10] In the 1997 evaluation, the head restraints of 214 1997 model year (MY) vehicles were rated based on their position relative to the 50th percentile male head. The restraints were ranked according to the prevailing view of the biomechanics community that head restraints that are in close proximity, both horizontally and vertically, to the center of gravity of the head are more effective. The vertical reference value used in the evaluation of each head restraint was the distance from the top of the head to the head's center of gravity. The vertical reference measurement of 90 mm (3.5 inches) was taken from the 50th percentile adult male dummy drawing produced by the University of Michigan. The height of a head restraint was rated as ''marginal'' if the restraint's top was 90 ± 10 mm (3.5 ± 0.4 inches) below the top of the head form. The vertical rating was ''good'' if the distance from the top of the head form to the top of the restraint was less than 60 mm (2.36 inches) (*i.e.,* the top of the head restraint was at least 30 mm (1.2 inches) above the head's center of gravity).

The reference value used to evaluate backset, 100 mm (4 inches), was based on a 1990 study showing a statistical relationship between the backset larger than 100 mm (4 inches) and the duration of neck symptoms. The backset of a restraint was rated as ''marginal'' if the horizontal distance between the head form and restraint was 100 ± 10 mm (4 ± 0.4 inches). The backset was rating as ''good'' if the distance was less than 70 mm (2.8 inches). A restraint's overall rating was the lower of the height and backset scores. The results of the IIHS study and the rating criteria are presented in Table 1.

TABLE 1.—1999 IIHS HEAD RESTRAINT STUDY

IIHS rating	Number of vehicles	Percent	Distance down from top of head	Backset
Good	10	5.4	60 mm (2.36 in.) or less	70 mm (2.76 in.) or less.
Acceptable	50	26.9	60–80 mm (2.36–3.15 in.)	70–90 mm (2.76–3.54 in.).
Marginal	60	32.3	80–100 mm (3.15–3.94 in.)	90–110 mm (3.54–4.33 in.)
Poor	66	35.5	100 mm (3.94 in.) or greater	110 mm (4.33 in.) or greater.
Total	186	100		

Scores were reduced for adjustable head restraints since IIHS contends that field observations have shown that they typically are not adjusted properly. Adjustable head restraints without locks were evaluated based on their lowest and most rearward position of adjustment. For adjustable head restraints with locks, IIHS rated the restraint according to its locked position, but downgraded the rating by one category based on data establishing that few users properly adjust head restraints.

Because of variations in the shapes of head restraints, it is not possible to accurately correlate head restraint height as measured by IIHS and the height as measured by the method in Standard 202. The IIHS method evaluates head restraint height by

[10] This study is summarized in the May 22, 1999 edition of IIHS' Status Reports (*http://www.hwysafety.org*).

measuring the difference in vertical height between the top of a special (50th percentile male) head form mounted on a standard H-point machine and the top of the head restraint. The Standard 202 method measures along the torso line (which has an angle θ with respect to the vertical—see Figure A) from the H-point on the vehicle seat to the point at which the torso line intersects with the upper surface of the head restraint.

Assuming an idealized head restraint shape, a simple relationship between the two measurement methods can be developed as shown in Figure A. The dimension of this figure assume a torso angle (θ) of 25 degrees from the vertical and a distance from the H-point to the top of the head of 755 mm (29.7 inches). Figure B is a graphical depiction of how head restraints of 700 mm (27.5 inches), 750 mm (29.5 inches) and 800 mm (31.5 inches) fare with respect to the IIHS dimensional rating technique. For any backset up to 70 mm (2.8 inches), the 800 mm (31.5 inches) high head restraint is always rated ''good.'' A 700 mm (27.5 inches) high head restraint can never be rated better than ''poor'' for any backset. A 750 mm (29.5 inch) high head restraint is ''good'' for backsets up to 30 mm (1.2 inches) and ''acceptable'' for backsets up to 73 mm (2.9 inches).

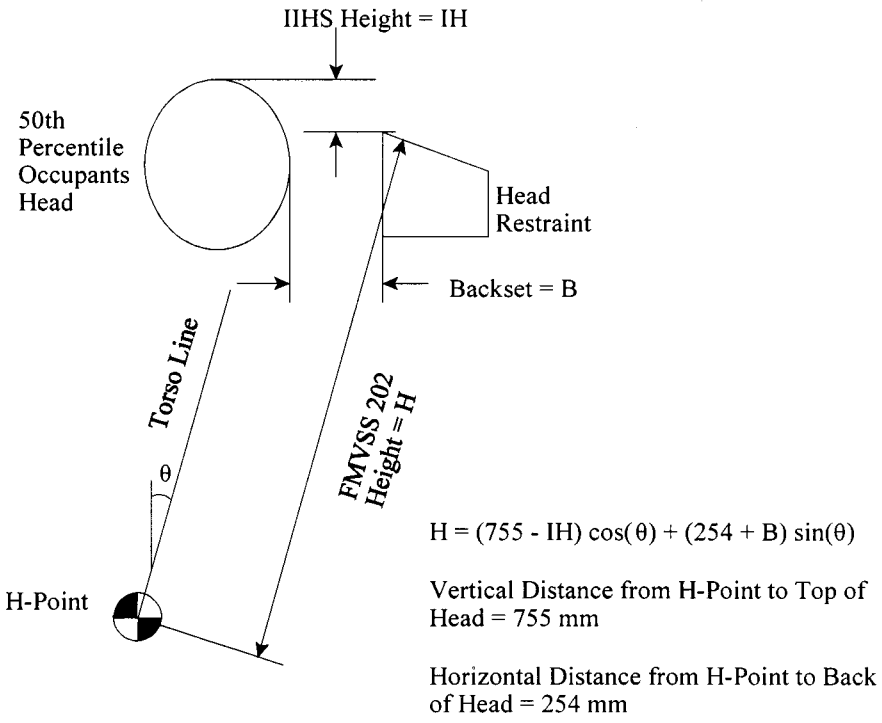

Figure A - Geometric Basis of IIHS and Standard No. 202 methods of determining head restraint height.

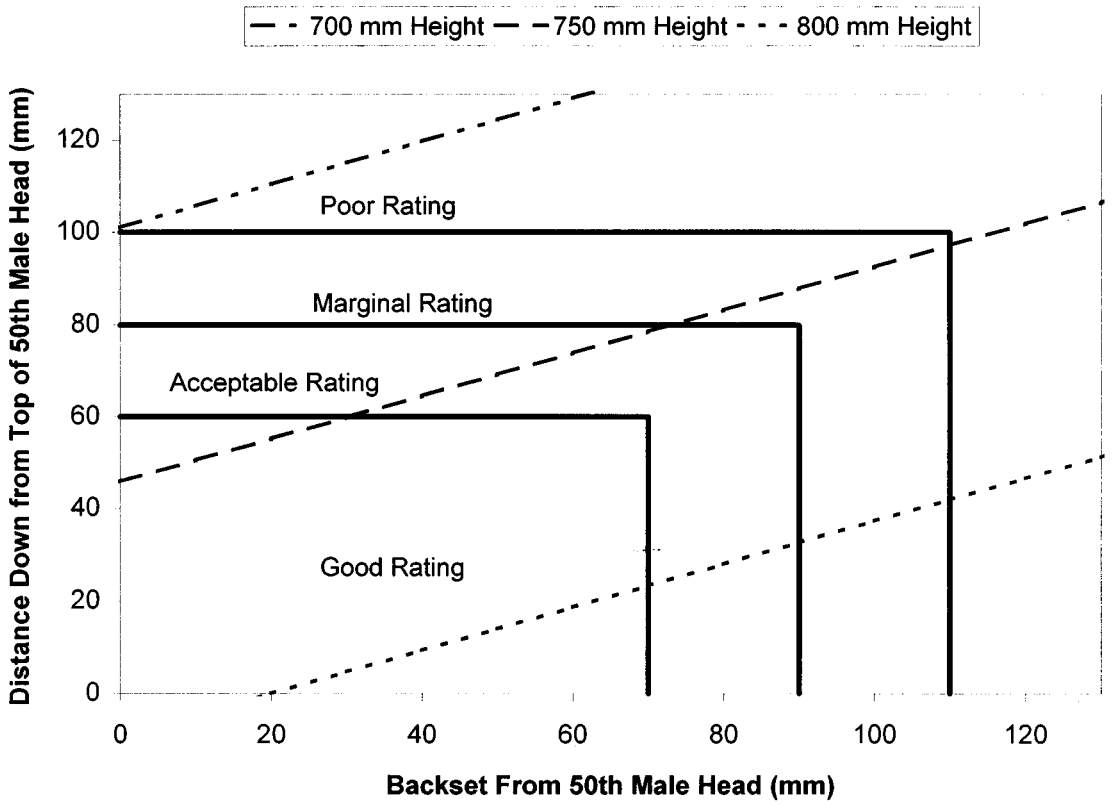

Figure B - Relationship between Standard No. 202 Measured Heights and IIHS Dimensional Ratings.

The 1998 joint State Farm-IIHS study compared the ratings applied in the 1995 and 1997 IIHS evaluations to actual whiplash claims. The new study, based on detailed analyses of more than 5,000 State Farm claims involving midsize cars struck in the rear by other vehicles, indicates that head restraints rated ''good'' in the 1995 and 1997 IIHS evaluations offered better protection in real-world crashes than those rated ''poor.'' According to the State Farm-IIHS study, drivers in cars with head restraints rated ''good'' by IIHS are 24 percent less likely to suffer neck injuries in rear-end crashes than drivers with head restraints rated ''poor.'' Percentages of drivers with neck injuries ranged from 22 percent of those with ''good'' head restraints to 27 percent of those with ''poor'' head restraints. The State Farm-IIHS study also found that female drivers have higher neck injury rates overall than male drivers—30 percent versus 23 percent, but that the likelihood of neck injury was 36 percent lower among female drivers with ''good'' head restraints than among females with ''poor'' restraints. Among male drivers, the State Farm-IIHS study found that the risk reduction was 10 percent with ''good'' head restraints. However, it should be noted that there were a limited number of ''good'' head restraints in the study (3 vehicles, all Volvos). Thus, the results are not conclusive.

The State Farm-IIHS study appears to verify that higher head restraints that are also closer to the back of an occupant's head (*i.e.,* have less backset) reduce the risk of whiplash. The study also found measurable improvement as the ratings increased between head restraints in the four categories established by IIHS—poor, marginal, acceptable and good. The State Farm-IIHS study does not, however, allow for analysis of the virtues of increases in height with no change in backset or reductions in backset independent of changes in height. Further, the IIHS methodology accounted for the fact that adjustable restraints are often not placed in their highest and closest position, resulting in only integral restraints being rated as ''good.''

IIHS reported in its 1999 head restraint evaluation that it dynamically tested two advanced head restraint designs and applied the Chalmers University NIC criterion to the results. These were moving rigid barrier to full vehicle impacts at barrier speed of 24 kph (15 mph). IIHS tested the Saab Active Head Restraint System and the Volvo WHIPS seat. The two designs had significantly lower NIC values than even ''good'' non-deploying designs.

B. December 1996 Request for Comments

In 1996, NHTSA issued a Technical Report entitled, ''Head Restraints—Identification of Issues Relevant to Regulation, Design and Effectiveness.'' This report identified and examined issues related to the biomechanics of neck injury, whiplash rates, occupant and head restraint positioning and the state of contemporary and future head restraint designs. On December 19, 1996, NHTSA published a document in the **Federal Register** (61 FR 66992) alerting the public to the existence of the report and that the agency was interested in obtaining information and comments about the performance of head restraints and potential modifications to Standard 202. The December 1996 document contained questions regarding:

(1) The effectiveness of current designs and the potential for improvements to reduce injury;

(2) The adequacy of Standard 202's height requirements and the efficacy of new requirements such as backset and adjustable head restraint locks;

(3) The continued need for and possible changes to the existing dynamic test procedure;

(4) Potential conflicts between visibility and revised head restraint requirements;

(5) Whether NHTSA should harmonize its regulations with ECE requirements;

(6) Whether changes to Standard 202 should be synchronized with changes to Standard 207, Seating Systems; and

(7) The costs of whiplash injury in the United States and the costs and benefits of modifying Standard 202.

The agency received comments from four manufacturers (Volkswagen, Toyota, Volvo, and Ford), three safety advocacy organizations (Consumers Union (CU), Advocates for Highway Safety (Advocates) and IIHS), one equipment manufacturer, Cerviguard, one insurance company, Insurance Corporation of British Columbia (ICBC), and the Chalmers University of Technology (Chalmers).

None of the respondents submitting comments stated that current head restraint designs were sufficiently effective at preventing neck injuries. While Ford indicated that current ''designs have been shown to be effective at reducing the risk of neck injuries in vehicle crashes,'' it also stated that improved designs will require additional research and testing. Chalmers, ICBC, CU and Advocates stated that they believed current head restraint designs were not sufficiently protective against neck injuries. None of the commenters stated that the current required height for head restraints of 700 mm (27.5 inches) is sufficient. IIHS, whose comments were submitted prior to the completion of the 1998 State Farm-IIHS report, referred to its 1995 and 1997 studies of head restraints. These studies, based on an examination of the head restraint positions relative to the head, concluded that the majority of head restraints were inadequate. According to IIHS, only 2.3 percent of 1997 vehicles evaluated had ''good'' head restraints, thus indicating that the current dimensional requirements are not sufficient.

Advocates indicated that most head restraint designs allow too much backset and that this should be limited to ''considerably'' less than four inches. CU stated that head restraints should have a minimum height of 737 mm (29 inches) to 762 mm (30 inches), but should be able to adjust even higher. Advocates urged the agency to require adjustable head restraints to lock in position, considering this ''a crucial aspect of restraint design and performance.'' It stated that it believes many of the current designs allow vertical collapse of the head restraints in rear crashes especially when the top of the head restraint is below the head's C.G. Chalmers and CU also endorsed adjustable head restraints having locks. Toyota said it believes that, at a minimum, the vertical adjustment should lock.

In reference to changes to test procedures, Chalmers stated that a dynamic test procedure is a necessity for new designs known as ''active'' head restraints. These head restraints move forward and/or higher in a crash. Chalmers also stated that this test should use a Rear Impact Dummy (RID) neck (developed by Chalmers) mounted on a Hybrid III dummy. The RID neck was developed at Chalmers because they thought the Hybrid III neck was too stiff in the midsagittal plane. Advocates, Toyota and Cervigard also expressed concern about the biofidelity of the Hybrid III neck. Volvo advised ''that the present 8g alternate standard in Standard 202 should be deleted and no new dynamic performance standard should be adopted until more knowledgeable injury mechanisms have been acquired and until relevant test procedures and improved test dummies have been developed.'' This would include a change to the dummy spine as well as the neck.

Comments on the impact of potential changes to head restraint requirements included concerns about effectiveness and degradation in visibility. Volvo stated that head restraint designs may not be optimal for occupant protection because manufacturers must also consider occupant comfort and visibility through the vehicle from the rear. Advocates noted that increasing the protective value of head restraints will be affected by comfort considerations as well as lateral and rear visibility issues. Chalmers said it believes that head restraints which are ''actively positioned during impact, would solve both the problems of visibility and injury prevention.''

The comments also indicated support for harmonizing Standard 202 with Economic Commission for Europe (ECE) Regulation 25.[11] Advocates favored harmonization, but said that the modified Standard 202 must go further. The organization said it believes the agency should investigate the merits of requiring head restraints in rear seats, as is required by ECE 25. However, it also mentions that this might conflict with tethered child safety seats and rear window visibility. CU recommended harmonization with ECE 25 as a move towards the goal of improving head restraints. This includes the provision for head restraints in the rear seats. However, it also endorsed other changes to the standard. Volkswagen endorsed harmonization with ECE Commission Directive 96/37/EC which combines ECE 25 (Head Restraints) and ECE 17 (Seats). Toyota stated that if the agency raises the required height for head restraints, it should match ECE 25. Volvo asked that NHTSA simply ''monitor'' the European standard. Ford stated that it ''strongly supports harmonization with other world regulations to promote world trade, providing it does not compromise safety or the integrity of the vehicle.'' It supported modification of Standard 202 on this basis.

Most of the commenters also favored coordinating changes to Standard 202 with changes to Standard 207 on the basis that seat and head restraint performance are closely linked because the longitudinal stiffness of a seat back will have an impact on the relative movement of the head and torso in the event of a crash. Chalmers indicated that their dynamic test proposal inherently coordinates changes to Standards 202 and 207. Advocates said that it believes coordinating the head restraint standard with any seat back standard is worthy of exploration and urged NHTSA to give explicit attention to the relationship between head restraints and integrated seat/head restraint systems. Volvo stated that in the short term no change should be made to either Standard 202 or 207 until more research has been done. At the same time, it provided information on its Whiplash Protection Study (WHIPS) in which Volvo modified its standard seat to optimize it for whiplash protection.

Only one commenter, ICBC, submitted data on the costs of whiplash and the benefits of reducing whiplash

[11] Economic Commission for Europe (ECE) Regulation 25—*Uniform Provisions Concerning the Approval of Head Restraints (HeadRests), Whether or Not Incorporated in Vehicle Seats* is similar to Standard 202 in that the same strength/displacement test procedure and performance values are required. The head restraint height is measured in the same way by both regulations, but the required heights differ. ECE 25 specifies that head restraints he higher than the current version of Standard 202. In addition, the current ECE 25 requires all forward facing outboard seats to have head restraints.

injuries. ICBC stated that 45,437 British Columbians suffered whiplash in 1996. Since the population of British Columbia is about 1 percent of the U.S. population, extrapolating this figure to the U.S. would imply that there were 4,543,700 whiplash injuries in the U.S. during 1996. This figure is more than five times NHTSA's estimate of the number of whiplash injuries in the U.S. ICBC estimates that each whiplash costs $8,199 U.S. If this figure were multiplied by the number of extrapolated injuries, this would suggest a total cost of $37 billion U.S. That is more than seven times greater than NHTSA's estimate. NHTSA does not know why the number of whiplashes estimated from the ICBC figures are so much higher than the NHTSA estimate. While the agency has not examined the methodology used by ICBC to calculate its estimate, it is possible that the number of insurance reported whiplashes may overstate the actual incidence of injury.[12] The agency's whiplash estimate is based on crash data generated by police reported crashes where one or all of the vehicles involved are towed away from the scene. Since many whiplashes occur in crashes where no vehicle is towed and no police report is made, a correction factor was used to adjust the estimate for these non-towed crashes.

C. AIAM/AAMA Petition

On August 13, 1997, the American Automobile Manufacturers Association (AAMA) and the Association of International Automobile Manufacturers (AIAM) submitted a joint petition for rulemaking requesting that NHTSA consider the possibility of amending five safety standards so that these standards would be ''functionally equivalent'' to corresponding ECE standards. The petition defined ''functional equivalence'' through comparison with harmonization:

> A harmonized regulation would contain and define either (1) a single set of performance requirements that a vehicle could be ''certified'' to and sold anywhere in the world or (2) common test conditions and procedures, common test devices and measurement techniques, and common test criteria limits. A functionally equivalent regulation may have any number of ''technical'' differences but would provide an equivalent level of real world performance despite these differences.

The petition did not offer any further illumination of what ''technical'' differences may exist between two regulatory schemes that are ''functionally equivalent.'' The AAMA/AIAM petition implies that two standards should be considered as functionally equivalent if they are similar and offer equivalent levels of performance.

AAMA/AIAM indicated that the European standards, ECE 17 and ECE 17.04,[13] differ from Standard 202 in the requirements for the height and width of head restraints, the energy absorption characteristics of the front surface of restraints and in the requirement for rear head restraints. The petition requested that NHTSA amend S4.3 of its standard to require that the top of a fully extended head restraint be not less than 800 mm above the seating reference point and that the top of a head restraint, when adjusted to its lowest adjustment position, be not less than 750 mm above the seating reference point. The addition of these proposed amendments, in AAMA/AIAM's view, would make Standard 202 functionally equivalent to the European regulations. Further, AAMA/AIAM requested that a new provision be added to Standard 202 indicating that head restraints meeting the requirements of ECE 17.05 or ECE 25.04 or EEC 74/408 be deemed to have met the requirements of Standard 202. In order to accommodate the product cycles of their members, AAMA/AIAM suggested that the upgraded Standard 202 have an effective date of September 1, 2004.

III. Overview of Proposal

NHTSA is proposing a series of amendments to upgrade Standard 202 to improve the protection provided to occupants. The agency anticipates that these amendments will provide safety benefits in all crashes. However, we are limiting our benefits analysis to rear end collisions only. These new requirements would require that head restraints, when adjusted to their lowest possible adjustment position, be at least 50 mm (2 inches) higher than they are currently required to be. (Note: This proposal is presented in the International System of Units (SI) with the English Units conversion provided in parenthesis for convenience. A final rule will be presented in only SI units.) It would also require front seat head restraints to be able to achieve a height 100 mm (4 inches) higher than currently required, and lock in this adjustment position as well as lock at the highest adjustment position. Rear seat head restraints would also be required to lock in the highest adjustment position. Head restraints would also be subject to a new requirement limiting the amount of backset, *i.e.,* distance between the back of an occupant's head and the front of the head restraint, to 50 mm (2 inches). NHTSA is also proposing that head restraints be required in the rear outboard seating positions. These upgraded requirements appear in the portion of the regulatory text which would apply to vehicles manufactured after the first occurrence of September 1, three years after publication of the final rule.

The agency proposal for upgrading Standard 202 would harmonize Standard 202 with the requirements for head restraints in ECE Regulation 25 in some respects. The proposed height requirements are identical to those in ECE 25. The agency proposal also contains provisions establishing performance criteria for energy absorption by the front surface of head restraints. Finally, as amended, Standard 202 would require rear seat head restraints.

However, the proposal would set different requirements for head restraint width and gap measurement for adjustable restraints than those found in ECE 25. Further, it would add requirements for backset and adjustment retention locks. It would also include a dynamic compliance option not found in ECE 25. In the current and proposed Standard 202, compliance may be measured in one of two ways. The first way is to meet all static dimension and strength requirements, while the second way is to meet a dynamic test. The proposal would modify the required level of performance in the dynamic compliance option to reflect the proposed height and backset requirements.

Prior to the first occurrence of September 1, three years after publication of the final rule on which compliance with the upgraded requirements becomes mandatory, the manufacturers would be given the option of complying with any of three different sets of requirements: the existing requirements of Standard 202, the existing requirements of ECE 25, or the upgraded requirements of Standard 202. Consistent with other recent

[12] NHTSA observes that the 1998 State Farm-IIHS study revealed that the overall neck injury rate in Michigan, the study's only no-fault state, was 13 percent compared with 26 percent in other states, without no-fault liability systems. This suggest that the availability of fault-based compensation systems may lead to higher reported rates of whiplash.

[13] The European regulations, EEC 74/408, as amended by Directive 96/37/EC, promulgated by the European Union, and ECE 17.04, established by the UN Economic Commission for Europe (ECE), apply to vehicles with a seating capacity of nine passengers or less. These regulations, which principally govern seats and seating systems, are identical to each other. ECE 25, which applies to head restraints, is incorporated into ECE 17.04. Therefore, for the purposes of head restraints, ECE 17.04 and ECE 25 may be considered to be one and the same.

amendments to our Safety Standards, the compliance option would have to be selected prior to certification of the vehicle, and the selection could not be changed thereafter.

IV. Proposed Upgraded Requirements

A. Height Requirements

Standard 202 currently requires that all head restraints be capable of achieving a height where the top of the head restraint must be at least 700 mm (27.5 inches) above the seating reference point measured parallel to the torso reference line. For vehicles produced on or after the first occurrence of September 1, three years after publication of the final rule, NHTSA proposes to change this requirement to 800 mm (31.5 inches) above the H-point for front seat head restraints. The proposal adds a lower limit on all required head restraints including those in the rear outboard seats, requiring that head restraints may not be less than 750 mm (29.5 inches) above the H-point. Therefore, under the proposal, front integral head restraints must have a minimum height of 800 mm (31.5 inches) and front adjustable head restraints must be capable of achieving a height of at least 800 mm (31.5 inches) and cannot be adjusted below 750 mm (29.5 inches). Rear integral restraints must have a minimum height of 750 mm (29.5 inches) and rear adjustable head restraints must not be adjustable to a height below 750 mm (29.5 inches). Research indicates that, for many occupants, in order to prevent hyperextension or lesser movements of the head and neck in relation to the torso that result in injury, head restraints must be higher than currently required by Standard 202 and close to the rear of the head.

The proposed alterations in the height requirements are intended to prevent whiplash injuries by requiring that head restraints be high enough to limit the movement of the head and neck, even if such movements do not result in hyperextension of the neck. The persistence of whiplash injuries in current vehicles indicates that current designs are not preventing whiplash injuries from occurring. Research has led to the conclusion that prevention of hyperextension alone does not stop whiplash from occurring. Since a 700 mm (27.5 inch) high head restraint is capable of preventing hyperextension in many occupants, it seems likely that the persistence of whiplash may be the result of the inability of current head restraints to be positioned to sufficiently limit relative head and neck motion in the normal range of motion. Research conducted since the implementation of the current height requirement has shown that head restraints should be at least as high as the center of gravity (C.G.) of the occupant's head to adequately control motion of the head and neck relative to the torso. This does not mean that there would be no additional benefits for a head restraint with a height greater than the height of the head C.G. However, this is likely to be controlled by other factors such as backset, head restraint shape and the underlying structure of the head restraint under the upholstery. Therefore, the head restraint height relative to the head C.G. height will be used here as an indication of the adequacy of the proposed height dimension.

A 750 mm (29.5 inch) high head restraint would have a height above the C.G. of a 50th percentile male if the backset were 125 mm (5 inches) or less, and assuming a head C.G. 105 mm from the top of the head (See Figure B). The difference in erect seating height between a 50th and 95th percentile male is 58 mm (2.3 inches). The size of most adult heads is essentially the same. The difference between the base of the neck and the top of the head of a 50th and 95th percentile male is only 6 mm (0.2 inches). Therefore it is reasonable to assume that the vertical dimensions from the top of the head to the C.G. is nearly the same at 105 mm (4.1 inches). A 95th percentile male with a torso angle of 25 degrees will have the top and C.G. of the head 53 mm (2.1 inches) higher than a 50th percentile male.

It is also reasonable to assume that the back of the 95th and 50th percentile male heads are essentially aligned vertically with each other. Therefore, they would have the same distance from a head restraint with a flat vertical face. This is because the longer torso of the 95th male would tend to place it closer to the head restraint and the larger lower back and buttocks would push the H-point away from the back of the seat, resulting in no net change in backset (see Figure C). These assumptions about backset are consistent with the agency's laboratory observations and a 1998 Experimental Safety of Vehicles (ESV) Conference paper by Toyota.

Based on these assumptions, a 750 mm (29.5 inch) high head restraint would be as high as the 95th percentile male head C.G. if the backset were 13 mm (0.5 inches) or less (see Figure D). It would be 17 mm (0.7 inches) below the 95th percentile male head C.G. at 50 mm of backset. A 800 mm (31.5 inch) high head restraint would be as high as the 95th percentile male C.G. if the backset were 133 mm (5.3 inches) or less. It would be 38 mm (1.5 inches) above the 95th percentile male head C.G. at 50 mm of backset.

The proposal for the front seat of requiring head restraints to be capable of achieving an 800 mm height and have a backset no greater than 50 mm should assure that the top of the head restraint is above the head C.G. of virtually all front seat occupants. The proposal for front and rear seats requiring a minimum height of 750 mm and backset no greater than 50 mm will provide head restraints higher than the head C.G. of about 86 percent of the adult males (assuming a normal distribution of height). The C.G. height of a 99th percentile female reclined at 25 degrees is about 19 mm below a 750 mm (29.5 inches) high head restraint at a 50 mm (2 inch) backset. Therefore, this will provide head restraints higher than the head C.G. of nearly all adult females and 93 percent of all adults. In term of the rear seat target population, this proposal will cover an even higher percentage of rear seat occupants than it would of the entire population of occupants. This is because more children occupy the rear seats and larger occupants rarely sit in the rear where there is generally less room.

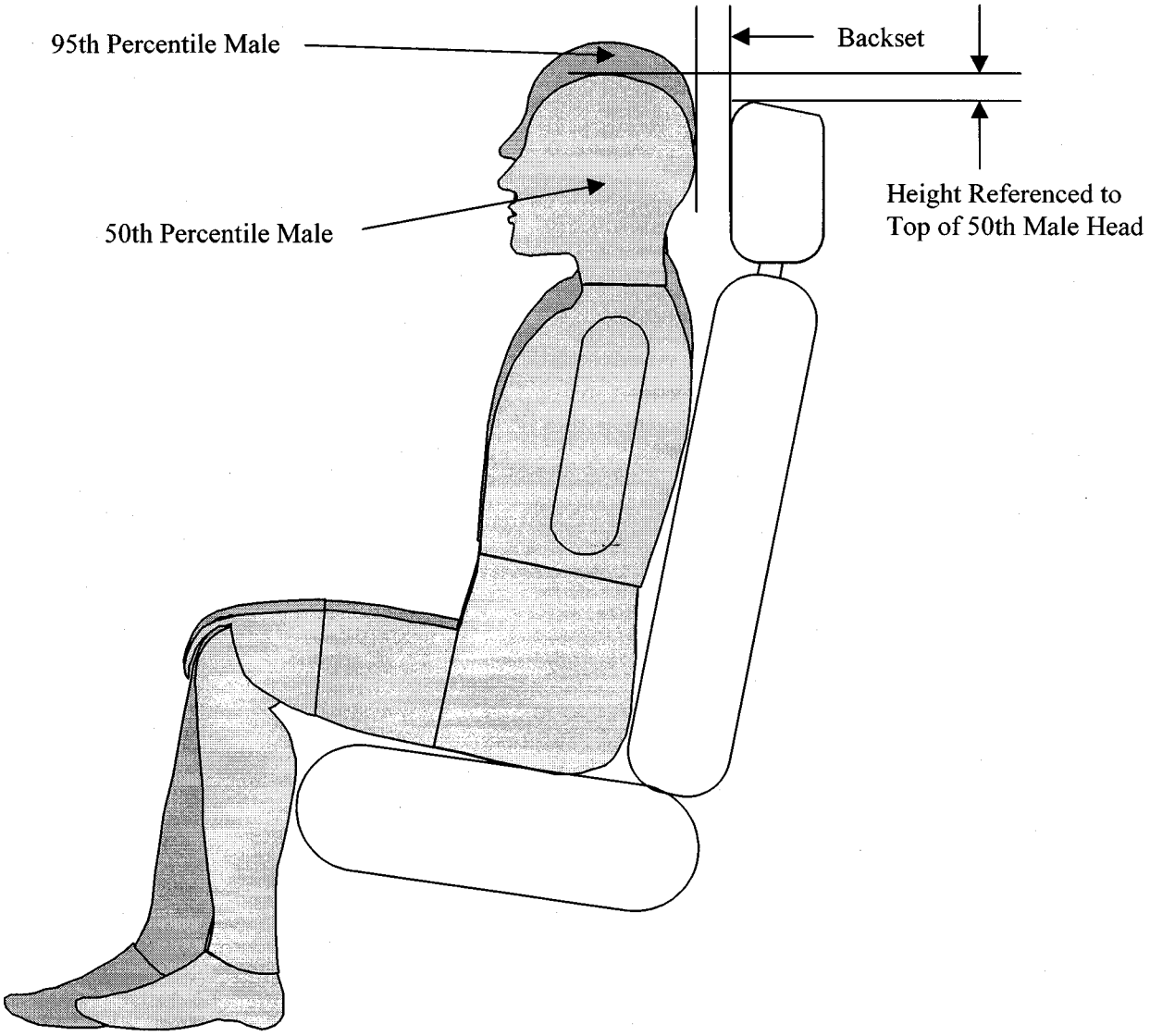

Figure C - Seated 50th and 95th percentile males. Backset dimension assumed to be the same for both occupants.

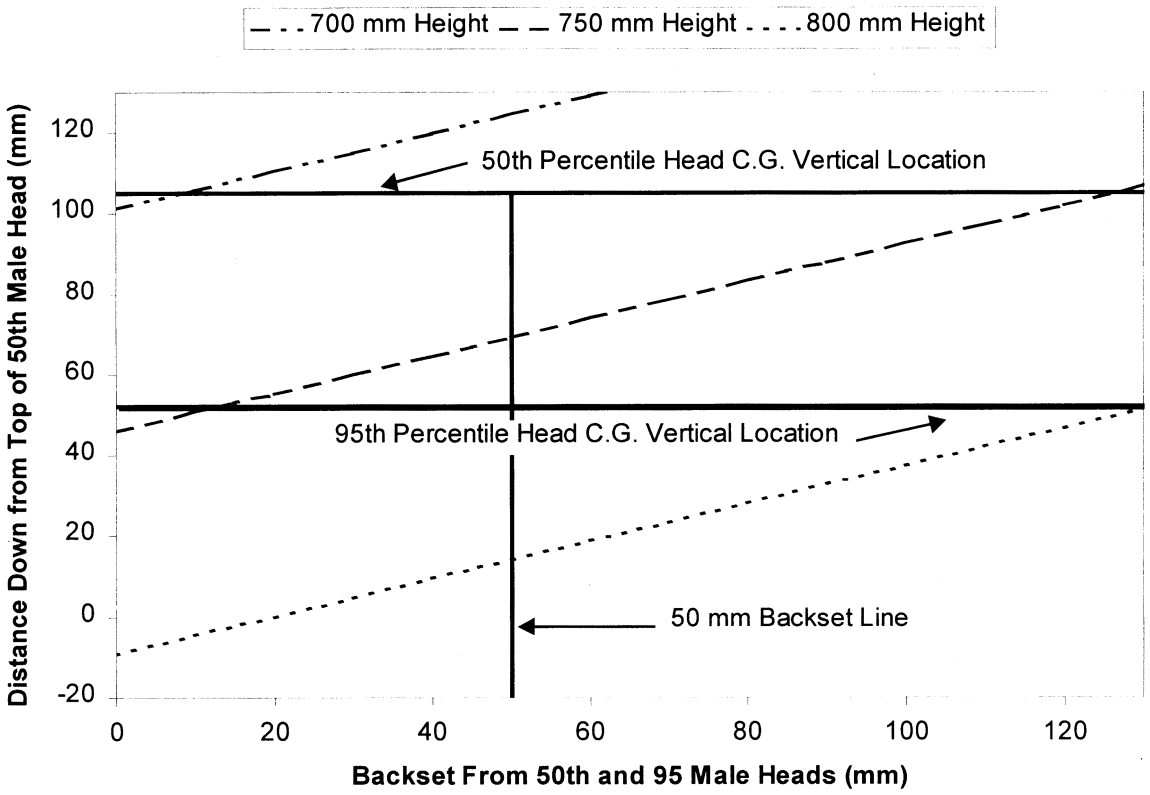

Figure D - Relative location of 50th and 95th percentile male head C.G. relative to head restraint height and backset.

The recent State Farm-IIHS study also suggests that head restraints that are higher in relation to the head center of gravity and closer to the back of the head provide greater protection against whiplash. The agency notes that head restraints rated ''good'' by IIHS—integral restraints with a height less than 60 mm (2.36 inches) below the top to the head and within 70 mm of the rear of the head—reduced the likelihood of whiplash by 36 percent in females and 10 percent in males. Figure B shows that an 800 mm (31.5 inches) high head restraint is likely to be high enough to be rated as ''good'' at all backsets within the ''good'' range. NHTSA believes that the proposed requirement for backset, in conjunction with the proposed height requirements, would lead to a significant improvement in safety.

Although the agency tentatively concludes that its proposed 800 mm (31.5 inches) height requirement would offer significant benefits for people taller than 50th percentile males, the agency wishes to know if additional safety benefits could be realized by requiring head restraints to be capable of achieving a somewhat greater height. Therefore, NHTSA requests comments on:

1. The marginal benefits and costs of requiring head restraints to be capable of achieving a height greater than the one proposed in this notice.
2. Other issues that may be raised by a height requirement greater than the proposed one, including those associated with the potential effects on visibility, seat adjustability and compliance with other safety standards, e.g., Standard 201, ''Head Protection in Interior Impact.''

B. Backset Requirement

NHTSA is also proposing to add, for vehicles produced on or after the first occurrence of September 1, three years after publication of the final rule, a backset requirement of no more than 50 mm (2 inches) for front and rear head restraints. The consensus of the biomechanics community is that the backset dimension has an important influence on the forces felt by the neck and the length of time a person is disabled by injury. This judgment is based on testing, computer modeling and real world crash data. As far back as 1967, Mertz and Patrick showed that loading on the head during a rear impact is minimized by reducing the initial separation between the head restraint and head. With the head initially against the head restraint, a volunteer test subject endured a 71 kph (44 mph) rear impact without discomfort. Research presented at the 1990 International Research Council on the Biomechanics of Impact (IRCOBI) examined 25 rear impacts involving 33 occupants of Volvo cars. The study results showed a statistically significant increase in neck injury duration when there was more than 100 mm (4 inches) of backset. A 1994 study conducted by Volvo found additional potential injury reduction as the backset approaches zero, allowing no relative motion between the head and torso upon rear impact. IIHS, in its studies of head restraints, considered a backset of 70 mm (2.8 inches) or less to be ''good.''

NHTSA has tentatively concluded that adding a requirement specifying a limit on backset would result in reduced angular displacement between the head and torso in a crash. One method the agency used to assess the potential benefits of a backset limit was through a computer modeling study in which the backset dimension was defined as the distance between two vertical lateral

planes; one plane passing through the rearmost point on the headform and the other passing through the forwardmost part of the head restraint at its centerline. A seat model intended to represent a 1986–1994 Pontiac Grand Am was used with the head restraint positioned in 21 different configurations with varying heights and backsets. The vehicle seat, as modeled, was relatively stiff in the longitudinal direction in comparison to those currently on the market. Another set of data was generated with the hinge joint kept completely rigid. This was intended to simulate a rear seat that has its seat back structure rigidly attached to the vehicle body, such as is the case for many passenger cars. A model of a Hybrid III 50th percentile male was the seat occupant.

For both seat stiffnesses, no head-to-torso angular rotation was greater than 2 degrees for head restraints above 750 mm (29.5 inches) and backsets 50 mm (2 inches) and closer. At backsets up to 100 mm (4 inches), all head-to-torso angular rotations were less than 21 degrees for head restraints above 750 mm (29.5 inches). At a backset of 150 mm (6 inches), head rotations of 27 and 44 degrees occurred at head restraint heights of 750 mm (29.5) and 800 mm (31.5 inches), respectively.

The computer modeling indicates that the lowest head-to-torso rotation value was seen when the backset was approximately 50 mm (2 inches). NHTSA tentatively concludes that this amount of backset is appropriate for all outboard seating positions.

The agency understands that there are differences in the way occupants adjust and sit in seats and that the backset measurement device being used may not capture this variety completely since it attempts to represent the head position of a 50th percentile male in a seat with a 25 degree inclination from the vertical. A steeper seat back inclination will further reduce the backset.

The agency also believes that physical differences in seat design may contribute to seat performance. In fact, National Automotive Sampling Systems (NASS) crash data indicate that the whiplash rate for rear seat occupants is significantly lower than that of front seat occupants. One explanation may be that many rear seats are often configured differently than front seats and frequently do not have adjustable backs. Adjustable seat backs allow wide variations in location of the head restraint relative to the user as the seatback angle changes through the range of adjustment.

In making the backset proposal, the agency has attempted to balance the need for both occupant safety and comfort while considering potential misadjustment. The agency believes the backset requirement is practicable—the majority of occupants should comfortably fit in seats with a 50 mm (2 inch) backset and it is well within the capability of manufacturers to produce seats with this backset.

The agency measured 14 MY 1999 vehicles and found that the front seats of the Toyota Camry, Chevy C1500, Chevy S10, Saab 9–5, and Chevy Malibu had backsets within the proposed 50 mm (2 inch) limit. Saab 9–5 rear seats also meet that proposal. For the entire fleet of new vehicles, we estimate that front seats are an average of 23 mm (0.9 inches) away from meeting the proposal and rear seats are an average of 47 mm (1.8 inches) away from the proposal. These fleet estimates were derived by using the sales weighted averages of the 14 MY 1999 vehicles measured. More details can be found in the PEA for this proposed rule.

Further, based on IIHS' rating of head restraints in MY 1999 vehicles, it appears that there are at least some models in all classes of vehicles that already meet or come close to meeting the proposed backset limit. As noted above, IIHS rates the backset of a vehicle's head restraints as good if it is not more than 70 mm (2.6 inches). According to IIHS, cars with head restraints rated good overall (i.e., both backset and height) include the BMW Z3 Coupe, Saab 9–3 and 9–5, Volkswagen New Beetle (some seat options), and Volvo C70/S70/V70 and S80 models. Among pickups, the Chevrolet S10 and GMC Sonoma have good restraints. And among utility vehicles, the Chevrolet Blazer (some seat options) and Mitsubishi Montero earn good ratings.

Nonetheless, NHTSA solicits comments on whether this proposed backset limitation is appropriate. In particular, the agency seeks information and comments on:

3. Whether limiting backset to 50 mm (2 inches) is sufficient to prevent excessive relative motion between the occupant's head and torso. Does 50 mm (2 inches) of backset provide sufficient head clearance and comfort for most occupants?

4. Would it be appropriate to allow a greater maximum backset (e.g., 100 mm (4 inches)) while requiring that head restraints with more than 50 mm (2 inches) of backset be adjustable so that backset can be reduced to 50 mm (2 inches)? Please provide data on the amount of safety disbenefit that would be associated with allowing a backset of 75 or 100 mm (3 or 4 inches), instead of 50 mm (2 inches).

NHTSA is proposing that compliance with the backset requirement be measured through use of the ICBC Head Restraint Measuring Device. Under the proposed rule, all outboard seat head restraints must have a backset of not more than 50 mm (2 inches). This 50 mm (2 inches) backset must not be exceeded at any height between 750–800 mm (29.5–31.5 inches). Although no height adjustment beyond 750 mm (29.5 inches) is required for rear seats, if these higher height positions exist, backset must be limited to 50 mm (2 inches). Figure E is a graph of the zones of adjustment for front and rear head restraints relative to the head C.G. of a 50th and 95th percentile male dummy. These positions are based on the assumptions stated in Section IV.A., Height Requirements and shown in Figures C and D.

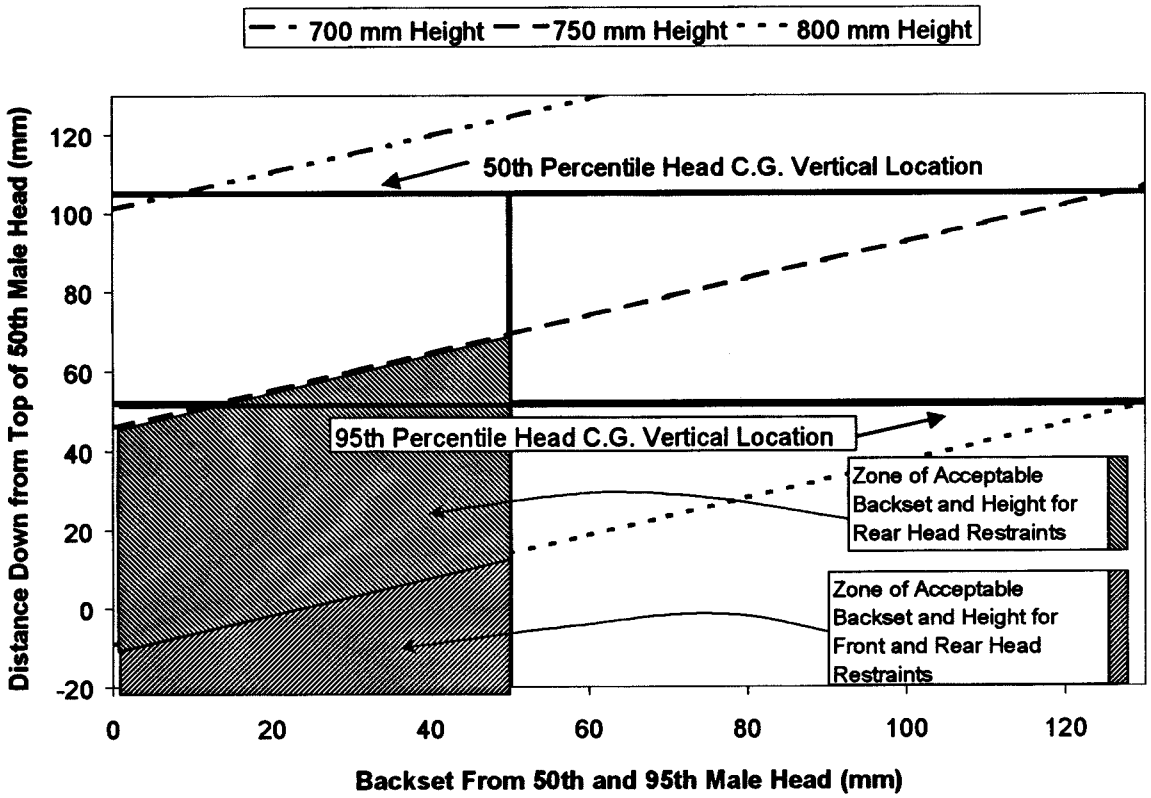

Figure E - Proposed limits on head restraint position for all outboard head restraints relative to 50th and 95th percentile dummy head C.G.

The agency believes that the ICBC measuring device is an appropriate tool for measuring backset. However, the agency solicits comments on:

5. Other devices that may be used to perform the same function as the ICBC device and whether such devices would be more appropriate.

NHTSA observes that the ECE 25 requirements do not include a specification for backset. The agency believes, however, that the proposed backset requirement, which the agency believes offers significant safety benefits, would not prevent manufacturers from producing designs meeting ECE 25.

Both the height and backset measurements are accomplished through the use of the SAE J826 manikin (June 1992) or H-point machine. The positioning procedure for this device is explicitly defined in SAE J826 in order to maximize repeatability. This in turn maximizes the repeatability of the height and backset measurements.

C. Height Adjustment and Backset Limit Retention Requirements

The agency is also proposing, for vehicles produced on or after the first occurrence of September 1, three years after publication of the final rule, that performance requirements for adjustable head restraints be added to Standard 202 which are intended to assure that the front head restraints remain locked in specific positions. A 1982 NHTSA study found that the effectiveness of integral head restraints was greater than adjustable head restraints. The study concluded that this difference in effectiveness was due, in part, to adjustable head restraints not being properly positioned. Although one reason for improper positioning is a lack of understanding on the part of the occupant on where to place the head restraint, it also could be due to the head restraint's moving out of position either during normal vehicle use or in a crash. Adjustment locks can mitigate this problem by helping to retain the adjusted position. IIHS has also been critical of adjustable head restraints, especially when they do not provide locks, in their evaluation of head restraints. This criticism has manifested itself in that IIHS, in its rating of head restraints, automatically gave adjustable restraints a lower rating on the assumption that these restraints would not be properly adjusted. In addition, it only evaluated adjustable head restraints without locks in their lowest position. In comments on the agency's 1996 technical report, Advocates stated that adjustable restraints should be required to lock. Toyota also stated that, at a minimum, head restraints should lock vertically.

The modifications to the existing height requirements and the addition of a backset requirement that are now being proposed are expected to improve the performance of all adjustable head restraints. The performance of adjustable head restraints may be further improved if steps are taken to ensure that a restraint remains in position after it has been set by the user.

In making this proposal, the agency has no desire to require specific methods for adjustment and locking. A typical adjustable head restraint design allows manual adjustment by sliding the head restraint in and out of the seat back on posts attached to the head restraint. Position locking is achieved by notches in the shaft allowing for a detent mechanism. There are also powered adjustable head restraints which are infinitely adjustable within a specific range. When the adjustment mechanism is inactive, the head restraint is, in effect, locked in position. Under the

current proposal, these and other locking methods would be permissible as long as the performance criteria below are met.

Therefore, we are proposing that adjustable head restraints for the front outboard seating positions must maintain their height (i.e., lock) in several height positions under application of a downward force. In addition to locking at a position of not less than 800 mm (31.5 inches), they must also lock at the highest adjustment positions. It may be that, for some designs, the highest position is at 800 mm (31.5 inches). Adjustable head restraints for the rear outboard seating positions must lock at the highest position of adjustment above 750 mm (29.5 inches), if this position exists. In addition to locking at these specified positions of height adjustment, both front and rear head restraints must be capable of retaining the minimum height of 750 mm (29.5 inches) under application of a downward force.

The height position retention requirements must be met at any backset position of adjustment. The agency believes that this is important for designs which adjust vertically as well as rotate for backset adjustment. Although there may be no backset position more than 50 mm (2 inches), a change in the backset position may change the height of the head restraint.

We are also proposing to adopt the following backset retention requirement. Under application of a rearward moment, with the head restraint adjusted to 800 mm (31.5 inches) for front outboard seats and 750 mm (29.5 inches) for rear outboard seats, the head restraint must maintain any position of backset adjustment.

The agency believes that the proposed height and backset position retention requirements are very comprehensive and that requirements for other positions than those mentioned above are unnecessary and would not result in significant additional safety benefits. The agency notes, however, that manufacturers would not be precluded from providing additional lockable positions within the range of the head restraint's adjustment.

The proposed height adjustment retention lock and backset limiter compliance tests begin by applying a small initial load to the head restraint. A headform is used to apply the load and a reference position is recorded. The head form reference position is measured with this load applied to eliminate variability associated with the soft upholstery of the head restraint. A larger load is then applied through the headform to test the locking mechanism. Finally, the load is then reduced to the initial value and the head form is checked against its initial position. In order to comply, the locking and limiter mechanisms must not have allowed the headform to have moved more than 10 mm (0.4 inches) from the initial reference position. First, to test the vertical lock, a load is of 500 N (112 pounds) is applied vertically downward. Then, to test the backset limiter, a force is applied sufficient to generate a 373 Nm moment (3,300 inch-pounds) perpendicular and rearward to the torso reference line about the H-point. A force of approximately 500 N (112 pounds) is required to generate this moment. The agency has reviewed upper neck shear loading from 33 rigid moving barrier, rear impact (48 kph (30 mph)) FMVSS 301 tests and found the average maximum load caused by the head being loaded in the forward direction with respect to the torso is 351 N (78.9 pounds). This direction of shear load is a good indicator of head restraint loading on the head and, therefore, head loading on the head restraint. Thus, the 373 Nm (3,300 inch-pounds) rearward moment and 500 N (112) downward force are representative of the peak loads likely to be encountered in moderate to severe rear impacts.

NHTSA remains concerned, however, that while the addition of the proposed locking and limiter requirements will help ensure that properly adjusted head restraint remain in position, the requirements cannot do anything to ensure that adjustable head restraints are actually put in that position in the first place. The agency requests comments on:

6. The appropriateness of the load values used to assess the position retention capability of head restraints. Should other height and adjustment positions such as a mid-height position be tested and/or required?

7. Do vehicle users understand how to properly adjust head restraints? If not, should manufacturers be required to provide information on this subject to consumers in the vehicle owner's manual or elsewhere?

8. The extent to which misadjustment of head restraints is due to the absence of adjustment retention locks versus intentional misadjustment by occupants.

9. Do vehicle users intentionally misadjust head restraints for reasons related to comfort, visibility, or other factors?

10. Are adjustable head restraints with adjustment retention locks significantly less likely to be misadjusted than ones without such locks?

11. Would equipping restraints with locks discourage misadjustment? If not, should other requirements be adopted to address the problem of misadjustment? The agency has previously addressed issues of misuse, non-use and adjustment in several contexts, including manual seat belts and child seats. Would the measure adopted in these contexts be appropriate with respect to head restraints?

12. What would the costs and benefits be of requiring that the height of front seat head restraints be fixed at 800 mm (31.5 inches) or at some other single height? What would the costs and benefits be of adopting such a fixed head restraint requirement for rear seat head restraints?

D. Rear Outboard Seating Positions

In addition to modifying requirements for head restraints for front outboard seating positions, NHTSA is also proposing to add head restraint requirements for rear outboard seating positions for vehicles produced on or after the first September 1 that occurs three years after publication of the final rule. The agency has tentatively concluded that the addition of head restraints for these seating positions would reduce whiplash injuries to rear seat occupants and harmonize Standard 202 with the ECE 25 head restraint requirements. Data obtained from NASS for non-rollover towaway rear crashes for passenger cars and LTV's for the years 1988 through 1996 shows that there were 5,440 whiplash injuries reported annually for occupants of rear outboard seating positions.

The whiplash rate (number of occupants with whiplash divided by the number in crashes) for these seating positions is less than that for front outboard seating positions, but is still significant. The reasons for a lower rear seat whiplash rate are not clear, but probably cannot be attributed solely to the fact that rear seat occupants are on average shorter than front seat occupants. Occupants may sit differently in rear seats—their posture may place the head closer to the head restraint and reduce or eliminate backset. Although rear seat head restraints are on average 33 mm (1.3 inches) lower than front seat head restraints, the reason for the relatively low occurrence of whiplash in rear seats may be the existing configuration of rear seats and rear seat head restraints.

NHTSA is proposing that rear outboard seat head restraints must have a minimum height of 750 mm (29.5 inches) above the H-point. As noted above in the backset requirement section, the rear outboard head restraints must also meet backset requirements and have a backset of 50 mm (2 inches) or less.

NHTSA sampled the head restraint heights and backsets of 12 1999 MY vehicles which had front and rear head restraints. Three of the vehicles had rear seats of sufficient height and one vehicle met the backset limit proposed

for rear seats. One of the twelve vehicles would meet both the height and backset proposal.

The agency's proposal to require head restraints in the rear outboard seating positions is, in part, based on a philosophy that commonly used seating positions should offer similar levels of protection to their occupants. This philosophy has guided the agency in requiring a test dummy to be placed in the rear seat for the dynamic performance test in FMVSS 214; *Side Impact Protection,* and in the provision of FMVSS 208; *Occupant Crash Protection,* requiring lap/shoulder seat belts to be installed in forward facing rear outboard seating positions. In establishing the FMVSS 208 and 214 requirements for both front and rear seats, we realized that, because of the significantly lower rear seat occupancy rates, the ratio of cost to benefit was inherently higher than similar front seating position requirements. In this case, there are again lesser safety benefits from rear seat head restraint protection because of lower rear seat occupancy rates. However, when people are sitting in the rear seat, they will gain safety benefits from improved head restraints.

Assessment of the relative merits of requiring enhanced protection for rear seats must also reflect the fact that NHTSA has recommended that all children 12 and under sit in the rear. Given that we have provided this advice to parents, NHTSA feels particularly obligated to provide similar levels of protection in the rear. Older children are large enough to benefit from a rear seat head restraint particularly in family vehicles with bench type seats such as minivans and SUVs. Also, rear seat occupancy should rise as more children sit there, thereby increasing the at-risk population and the corresponding benefits of rear seat head restraints. For these reasons, we have decided to propose upgrading whiplash protection in outboard rear seats notwithstanding lower cost-effectiveness for improved head restraints at those positions. NHTSA is especially interested in public comments on this approach.

The agency is not proposing to require front or rear center seat head restraints because of significant costs, much higher cost per equivalent fatality than outboard positions, and visibility concerns. The combined total cost of front and rear center seats head restraints would be $52 million (front) + $94 million (rear) = $146 million. We estimate that this substantial investment would result in reducing the annual number of whiplash injuries in the front center seat by 440 and in the rear center seat by 1,276. The combination of these cost and benefit figures would be a cost per equivalent life saved (at 7 percent discount) of $52 million for front center seat head restraints, based on the effectiveness for increasing the height of head restraints and assuming no benefit for backset. For rear center seat head restraints, the cost would be $33 million. For both front and rear center seats combined, the cost per equivalent life saved would be $38 million. All of those figures are much higher than the cost per equivalent life saved for front outboard seats ($3 million) and that for rear outboard seats ($9 million).

Finally, having center seat head restraints limits to some extent the driver's ability to see following traffic using the inside rearview mirror. When a vehicle is in reverse, front and rear center head restraints limit visibility when the driver turns his/her head to back up. In addition, a front center seat head restraint can limit vision through the right side second seat window when the driver is considering a lane change maneuver to the right. The agency can not quantify these potential losses in visibility, nor the potential impact that this loss in visibility could have on safety.

The agency is aware of rear seat head restraint designs which have the goal of lessening the rearview obstruction. Some designs provide open areas in the head restraint so the driver can see through them. Other head restraints fold out of the way into non-use positions. The agency's current proposal does not contain any requirements to specifically compensate for the potential rearview obstruction. However, the agency is proposing language in S4.3 which will allow for folding or retractable head restraints for rear seats if they meet specific criteria. If such a head restraint is adjusted to a non-use position, i.e., any position in which its minimum height is less than that proposed in this document or in which its backset is more than that proposed in this document, it must give the occupant an unambiguous physical cue that the head restraint is not properly positioned by altering the normal torso angle of the occupant or it must automatically return to a position where it would comply with all provisions of the regulation when the seat is occupied. To determine if the head restraint in a non-use position alters the torso angle of an occupant, the SAE J826 manikin is placed in the seat position. The torso angle of the manikin when the head restraint is in a non-use position must be at least 10 degrees closer to the vertical than when the head restraint is in a normal use position. Alternately, if the head restraint is designed to return automatically from a non-use position to a normal use position, this must occur when a 5th female and 50th male Hybrid III test dummy in placed in the seating position.

The agency would like commenters to address the issues surrounding rear seat head restraints and their impact on rearward visibility. Specifically, the agency would like to know the following:

13. Are data available related to safety risks, if any, associated with decreased visibility caused by rear seat head restraints?

14. Should the agency place specific design requirements on rear seat head restraints to compensate for any potential visibility losses?

15. Should Standard 202 allow rear head restraints to have non-use positions? If so, how should such positions be defined and limited?

16. Are the proposed requirements for non-use positions sufficiently objective? Are they sufficient to alert occupants that the head restraint is not in a normal use position?

17. Given the lesser safety from rear seat head restraint protection because of lower rear seat occupancy rates, and given the visibility issues, should the agency limit the application of any final rule to front seating positions?

An additional concern raised by the required installation of outboard rear seat head restraints is the impact of such restraints on child restraints that use top mounted tether straps. The agency notes that tethered child restraint requirements have just been instituted in the United States and have been required for some time in Canada and Australia—where vehicles with rear head restraints are relatively common. Inquiries to Transport Canada, NHTSA's Canadian counterpart, indicate that interference between rear head restraints and child seat tethers has not posed significant problems. NHTSA also wishes to point out that on March 5, 1999, the agency published the final rule for Standard 225, ''Child Restraint Anchorage System'' (64 FR 10785). The standard requires an independent system which has two lower anchorages, and one upper anchorage. Each lower anchorage includes a rigid round rod or bar onto which a hook, a jaw-like buckle or other connector can be snapped. The bars will be located near the intersection of the vehicle seat cushion and seat back. The upper anchorage will be a ring-like object to which the upper tether of a child restraint system can be attached.

In its examination of the potential for interference between tethers and rear seat head restraints conducted prior to the issuance of that final rule, the agency agreed that compatibility

problems between the tether and rear seat head restraints could occur in some situations but concluded that this did not present an unsurmountable design problem. NHTSA concluded that ''Y'' shaped tether strap designs that encircle the head restraint might be used where the tether could not pass over or under the head restraint. Furthermore, as the final rule amending Standard 213, ''Child Restraint Systems,'' requires the use of a fixture for testing tether strength, manufacturers should be able to identify and correct for potential compatibility problems between the tether system and head restraints.

Nonetheless, the agency solicits comments on the following:

18. Are there potential safety concerns caused by interference between rear seat head restraints and child seat tethers?

19. The existence or significance of test data showing whether passing the top tether over the top of the head restraint or underneath an adjustable head restraint has any effect on head excursion or lateral stability of a child restraint.

E. Removability of Head Restraints

The agency is aware that some current head restraints, both front and rear, can be manually removed solely by hand (*i.e.,* without the assistance of any hand held object). Such a design is not currently prohibited by Standard 202. The agency believes strongly that all occupied outboard seats should have a properly positioned head restraint in place. However, for seats which are often unoccupied, which is usually the case for rear seats, there may be a potential benefit to allow head restraints to be removable for the sake of increasing a driver's field of view towards the rear. The proposed rule would prohibit removable head restraints in the front seats, but would not prohibit removable head restraints in the rear seats. The agency believes that a rear seat which has its head restraint removed gives a strong visual cue to a prospective occupant unlike a head restraint which may be in a subtle non-use position. Front seats must be designed so that they cannot be removed solely by hand.

20. Should Standard 202 continue to allow any head restraints to be removable by hand? If so, should this be limited to rear seat head restraints?

21. Should there be some type of indicator to warn a prospective occupant that the head restraint has been removed, or is the visual cue of a seat without a head restraint sufficient?

F. Head Restraint Configuration Requirements

1. Width

NHTSA has tentatively concluded that the requirements for head restraints on vehicles produced on or after the first occurrence of September 1, three years after publication of the final rule, should maintain the existing width requirements contained in Standard 202. These provisions require that head restraints be at least 170 mm (6.7 inches) wide on single seats and 254 mm (10 inches) wide on bench seats. The agency believes that doing otherwise will degrade the level of safety currently available. Occupants seated on bench seats are freer than occupants of single seats to position themselves so that they are not directly in front of the head restraint. This is especially true if they do not use their seat belts—a concern that is more relevant in the United States than in Europe. Thus, the head restraint needs to be wider to assure that, in the event of a crash, the head restraint will be positioned behind an occupant's head.

This proposal differs from the ECE 25 regulations in specifying a different width requirement for bench seats than for other seats. As noted above, the agency is concerned that because seats other than bucket seats, i.e., bench and split bench seats, are more widely used in the United States than in Europe, Standard 202 should dictate different width requirements than those found in ECE 25.

2. Gaps

NHTSA is proposing the addition of maximum gap requirements for head restraint designs incorporating openings within the perimeter of the restraint. Gaps may be provided to allow for sight through the head restraint. However, gaps which are too large may defeat the purpose of the head restraint by allowing the head to displace too far before contact with the head restraint. The agency used ECE 25 as a model for the gap requirement in the NPRM. The agency proposal for integral restraints allows a maximum 60 mm (2.36 inches) gap in the head restraint and an identical maximum gap between the head restraint and seat. For height adjustable head restraints, 60 mm (2.36 inches) gaps are allowed in the head restraint. When adjustable head restraints are in their lowest position they must have some position of backset adjustment where the gap between the seat and head restraint is less than 25 mm (1 inch). However, this gap cannot be greater than 60 mm (2.36 inches). The agency believes that a 25 mm (1 inch) gap requirement between the seat and head restraint would essentially require the seat back to provide the travel stop for head restraint adjustment downward. This would eliminate significant discontinuities between the seat back and head restraint when the head restraint is in its lowest position, which may be a benefit to short occupants. The maximum 60 mm (2.36 inches) gap between the seat back and head restraint when the head restraint is in the lowest adjustment position is allowed in anticipation of designs that have rotational backset adjustment. It may not be possible for this type of design to meet the 25 mm (1 inch) limit in all rotational positions.

Finally, it should be noted that the gap requirements would place no limit on the size of the gap between the seat back and head restraint that is produced when the head restraint is raised. The establishment of such a limit would eliminate from the market place most existing adjustable head restraints. The agency anticipates that occupants will not adjust their head restraints such that the rear portion of their head would be between the top of the seat and bottom of the head restraint. Nonetheless, the agency would like comments on this issue.

For harmonization purposes, NHTSA notes that the proposed gap requirements are identical to the ECE 25 specifications with two exceptions. First, the proposed NHTSA limit on the distance between the head restraint and the seat when the head restraint is in its lowest position applies only at a single position of backset adjustment. The ECE requirement does not contemplate head restraints that may be adjustable for backset and simply allows no more than a 25 mm (1 inch) gap. Second, the ECE standard allows an alternate compliance option of application of a load to the gap area rather than limiting the gap to 60 mm (2.36 inches). The agency assumes that the concept behind this option is that if pushing on the gap area with a head form does not cause deflection of more than 102 mm (4 inches), the gap is acceptable. The agency sees no need for permitting this alternate method of compliance.

22. The agency requests comments on the need for a requirement limiting the gap between the lower edge of an adjustable head restraint and the seat to 25 mm (1 inch) when the restraint is in its lowest position.

23. NHTSA requests comments on whether 60 mm (2.36 inches) is an appropriate value for the maximum size of the gap between a seat and the lower edge of an integral head restraint and the maximum allowable gap in any head restraint.

24. The agency also requests comments on whether a limit should be placed on the gap

between adjustable head restraints and the seat back when the head restrain is in a raised position.

G. Energy Absorption

For vehicles produced on or after the first occurrence of September 1, three years after publication of the final rule, the agency is also proposing an energy absorption requirement specifying that when the front of the head restraint is impacted by a head form at a velocity of 24.1 kilometers per hour (15 mph), the deceleration of the head form must not exceed 80g continuously for more than 3 milliseconds. The impactor would be a free-motion head form with a 6.8 kg (15 pound) mass. The proposal would require the head restraint to comply in any position of adjustment. The area of the head restraint subject to impact in the compliance test would differ depending on the seat configuration. The proposal limits this area to within 70 mm (2.8 inches) of the head restraint vertical centerline for single seats, but increases the impact area to within 105 mm (4.1 inches) of the centerline for bench seats because of the potential for occupants to be seated farther from the centerline in bench seats. The point of impact must be at least 635 mm (25 inches) above the H-point.

The agency proposal is similar, but not identical, to the requirements of ECE 25. ECE 25 requires the use of a pendulum impactor. The agency's proposal specifies the use of a free-motion head form impactor. NHTSA believes the results from a pendulum or head form impactor would be the same. In order to increase the level of harmonization with ECE 25, the agency is not at this time proposing the use of the free-motion head form in Part 572 Subpart L. This head form is required for upper interior impacts in Standard 201; Occupant Protection in Interior Impacts. The Part 572(L) head form has a 4.5 kg mass (10 pound) rather than a 6.8 kg (15 pound) mass. However the mass and impact speed of the head form in ECE 25 and being proposed here are the same as required by Section 5 of Standard 201.

The agency proposal also differs from ECE 25 in the dimensions of the area of impact. ECE 25 specifies a single size for the impact area regardless of the seat configuration. As bench seating is more common in vehicles produced for the North American market, the agency believes that the variance between the two regulations is justified.

The proposal also contains a minimum radius of curvature requirement for the front surface of the head restraint. In order to protect rear seat occupants from injuries caused by impact with the head restraint in frontal crashes and all occupants in rollovers or similar crashes, any part of the head restraint outside of the impact zone for the energy absorption requirement must not have a radius smaller than 5 mm (0.2 inches) unless it can pass the energy absorption requirement. This requirement is intended to eliminate potential sources of high pressure contacts between occupants and head restraints. NHTSA is not aware of any surfaces on current head restraint designs that have such a small radius of curvature and believes that most, if not all, would be in compliance. Nonetheless, NHTSA is proposing this requirement in the interest of increasing the level of harmonization with ECE 25.

25. The agency requests comment on the need for the requirement for limiting the radius of curvature outside of the impact zone to no less than 5 mm (0.2 inches).

26. NHTSA would also like comments whether the Part 572 Subpart L free-motion head form should be proposed rather than the head form in the current proposal which more closely harmonizes with ECE 25.

H. Test Procedures

1. Displacement Test Procedure

The agency is also proposing changes to the existing displacement test procedure contained in Standard 202. In this procedure, the head restraint's ability to resist deflection is measured by applying a load to the back pan of the seat and applying a load to the head restraint after the load on the back pan of the seat is released. A 102 mm (4 inch) displacement is allowed with a 373 Nm (3,300 inch-pounds) moment applied. The applied load is then increased until the seat or seat back fails or the load reaches 890 N (200 pounds) and the head restraint withstands this load.

The proposal modifies this test procedure to require that the back pan of the seat and the head restraint be subjected to simultaneous loading. The agency proposal also removes the current standard's provision allowing seats or seat backs to fail when the head restraint is subjected to the 890 N (200 pounds) load. Lastly, the proposal modifies the existing test procedure to clarify the direction of the loads placed on the restraint, seat and seat back. The proposal maintains the 4 inch displacement limit. The exact SI conversion to 102 mm is used rather than rounding the value to 100 mm because it is an existing requirement.

Data provided by the AAMA and AIAM indicate that loading the seat back pan and the head restraint at the same time results in a more severe test. These data were contained in a petition submitted to the agency in support of harmonizing the existing Standard 202 test with the ECE 25 test. AAMA/AIAM provided data from one 1998 model year vehicle seat that showed a 64 mm (2.5 inch) displacement for the Standard 202 method and a 89 mm (3.5 inch) displacement for the ECE method. NHTSA's review of the AAMA/AIAM data indicates that the AAMA/AIAM position appears to be correct. Because the back pan position is maintained while the head restraint is loaded, some amount of load may be applied through the back pan to the seat. This load, along with the load applied to the head restraint, results in the total applied seat moment and contributes to head restraint deflection. Thus, the head restraint deflection may be greater than if the back pan load is removed before application of the head restraint load. The agency believes that applying loads to both the back pan and the head restraint simultaneously better reflects the stresses that occur in rear end crashes.

This change, if adopted, will harmonize the Standard 202 displacement test procedure with that contained in the ECE 25 regulation. In both test procedures, the back pan of the SAE J826 test device is used to apply a 373 Nm (3,300 inch-pounds) moment to the seat back. Currently, the difference in the two test procedures is that Standard 202 specifies that the back pan load is removed before application of the moment to the head restraint and ECE 25 specifies that the back pan position is maintained while the head restraint moment is applied.

Additional text has been added to the displacement test procedure to clarify the direction of loading on the head restraint and seat back. The proposal would require that the back pan be constrained so that as pressure is applied, it rotates about the H-point and the moment producing force, which is initially perpendicular to the torso line, rotates with the back pan. However, the proposal also would require that the moment-producing force on the head restraint initially be applied perpendicular to the displaced torso reference line and that the orientation be maintained with respect to the ground throughout the testing.

Finally, the existing displacement procedure allows the seat back to fail without consequence under application of 890 N (200 pounds) to the head restraint. Yet, from the perspective of an occupant, if the head restraint is displaced during loading, the consequences may be equally severe regardless of the reason for the

displacement. Therefore, the NPRM removes the allowance for seat back failure. The head restraint must be able to apply a resistive force of 890 N (200 pounds) to the load applying head form. If the head restraint is displaced out of the path of the head form prior to achievement of the 890 N (200 pounds) load, the head restraint has failed, regardless of whether failure was due to weakness in the seat or the head restraint components.

2. Dynamic Sled Test Procedure

The agency is also proposing changes to the existing Standard 202 dynamic test option. Currently, Standard 202's dynamic compliance option specifies that the seat structure must be accelerated such that the acceleration pulse lies between two half sine waves. The lower boundary half sine wave is represented by the expression $a = 78 \text{ Sin}(\pi t/80)$ and the upper boundary is represented by $a = 94 \text{ Sin}(\pi t/96)$, where t is in milliseconds and a has the units of m/s^2. Figure F shows these sled pulse boundaries along with the target sled pulse between them (represented by $a = 86 \text{ Sin}(\pi t/88)$). It can be seen from this figure that at the beginning of the pulse there is very little area in the corridor. NHTSA believes that as a practical matter the existing corridor cannot be met. For this reason, a new sled pulse corridor has been developed. Its dimensions are derived from a scaled down corridor now used in the FMVSS 208 sled test procedure. The new corridor is wider than the existing corridor until about 40 ms and narrower from about 60 ms on. However, the target sled pulse remains the same.

In addition to modifying the corridor shape, we have revised the test procedure to specify that the vehicle, instead of simply the seat, is mounted on the sled. The agency believes this is necessary because both front and rear seats are now required to have head restraints and could be dynamically tested. This also simplifies the test setup because the dummies are required to be restrained by a Type 2 belt which is often attached to the B-pillar. The agency believes existing sled designs can stay within the specified acceleration corridor with a vehicle mounted to them. Finally, SAE J211/1 (March 1995) has been referenced to indicate the use of channel filter class (CFC) 60 for data processing.

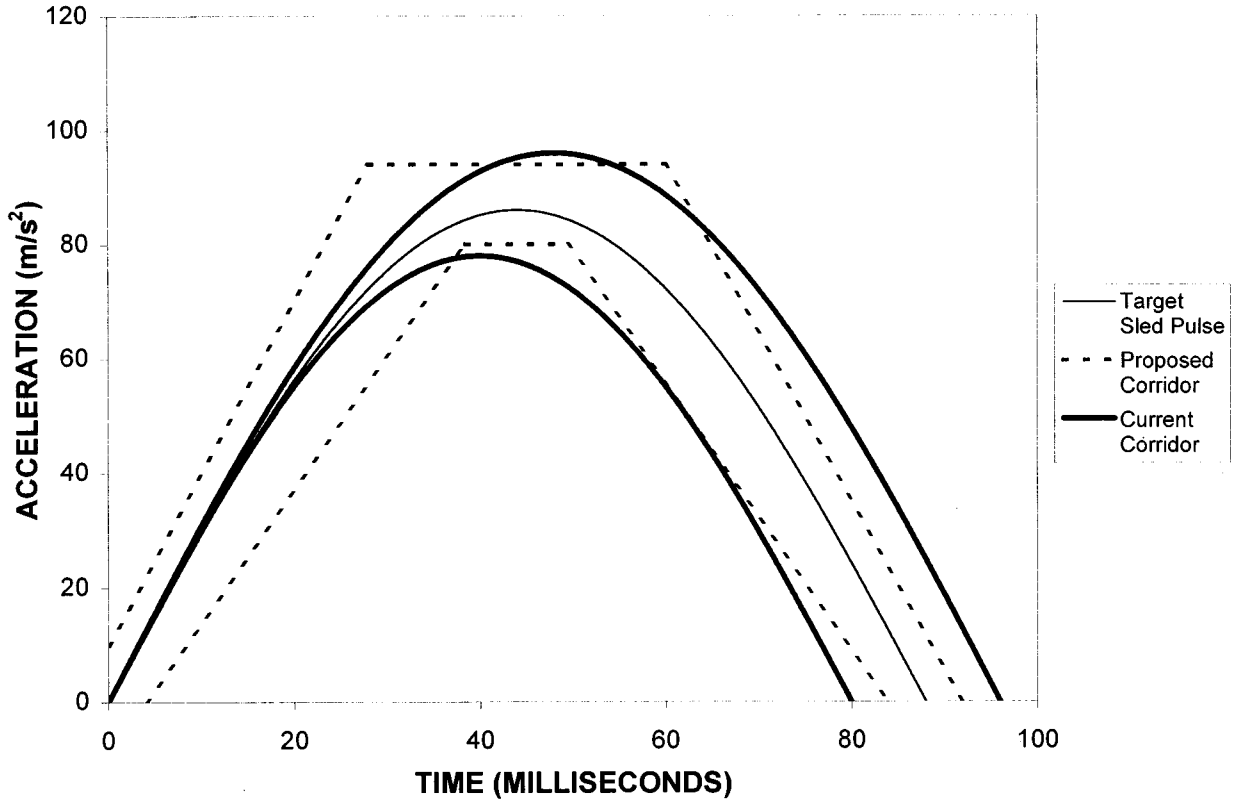

Figure F - Current and proposed sled pulse corridors for the dynamic compliance options of Standard 202.

The agency is also proposing to alter the performance requirements for the dynamic compliance test option due to the proposal's alteration of the existing head restraint height requirements. The current dynamic test accelerates a seat loaded with a 95th percentile dummy to an 8g half sine acceleration pulse over 80 ms. In order to pass this test, the dummy neck must not rotate rearward with respect to the torso more than 45 degrees. The 45 degree performance limit was developed such that a 700 mm (27.5 inch) high head restraint would pass the dynamic test.

The proposal also alters the specifications for one aspect of the seating procedure for the dynamic test. Standard 202 currently specifies that the test device shall be secured by a Type 1 seat belt in the design seating position of each designated seating position with a head restraint. The proposal changes

this requirement by substituting a Type 2 seat belt for a Type 1. This change is being instituted to more accurately reflect current requirements for the installation of Type 2 belts in outboard seating positions.

If the agency's proposal did not alter the dummy head rotation requirement, manufacturers could pass the standard using the dynamic test with 700 mm (27.5 inch) high head restraints even though the new proposed minimum height requirement is 750 mm (29.5 inches). To avoid this, we are proposing to alter the dynamic test procedure and injury criteria for front outboard seating positions so that when the 95th percentile male test dummy is used, only head restraints at least 800 mm (31.5 inches) high with a maximum 50 mm (2 inch) backset could pass. We are also proposing requirements using a 50th percentile male test dummy at all outboard seating positions.

In their comments to the agencies 1996 Technical Report discussed in Section II.B, Volvo favored the elimination of the dynamic test option. It believed that there was insufficient knowledge about injury mechanisms and that test dummies needed to be improved. However, Volvo has developed a seat design to specifically reduce whiplash injuries, indicating that it believes that it has enough knowledge to change the way it designs seats. In their comments to the Technical Report, Chalmers supported a dynamic test using either a BioRID or Hybrid III dummy and suggested that the Neck Injury Criterion (NIC) be used to evaluate performance. Chalmers also believes a dynamic test procedure is needed to measure the performance of active head restraints.

There are several reasons why the agency does not wish to eliminate the dynamic compliance option. Some of these became apparent when NHTSA proposed deleting this option in 1995. In October 1995, under the ''Regulatory Reinvention Initiative,'' the agency published an NPRM which proposed to eliminate the dynamic options because it believed neither manufacturers nor the agency used this option to determine compliance. Comments on the Reinvention NPRM by vehicle manufacturers favored deleting the options, but Advocates and recreational vehicle (RV) manufacturers and a seat supplier opposed the deletion because it would limit compliance options.

IIHS wanted to keep the dynamic test because not having it might limit the development of active head restraint systems designed to deploy upon rear impact. For example, as noted above, the Saab 9–5 is equipped with active head restraints which operate by use of a lever.[14] We measured a head restraint in a MY 1999 model 9–5 to determine its height and backset. It meets the current height requirement by 95 mm (3.8 inches). Therefore, there is no need for the manufacturer to certify to the current dynamic compliance option. However, the current design would not meet the requirements in this proposal by 6 mm (0.3 inches). However, if the proposed requirements were in place, the manufacturer could choose to certify to the dynamic compliance option.

NHTSA believes that the dynamic test option should be retained and upgraded. The dynamic test option provides the means to assess the many seat design parameters which affect whiplash reduction. However, as it is clear that limiting hyperextension alone does not prevent whiplash injury, the agency proposes to modify the dynamic test procedure by adopting new performance values of relative head-to-torso rearward rotation for determining compliance with Standard 202. The proposed performance requirement for front seating positions is a maximum of 12 degrees of relative head-to-torso rotation with the 50th percentile dummy and a maximum of 20 degrees of head-to-torso rotation with a 95th percentile dummy. For rear seating positions no more than 12 degrees of head-to-torso rotation is permissible with a 50th percentile dummy as the measurement device. The current standard allows head-to-torso rotation of 45 degrees with a 95th percentile dummy for the front seating positions and does not regulate the rear seating positions.

The proposed values were selected to be consistent with the height and backset requirements in the proposed static compliance option. The head restraints would need to comply at any position of height and backset adjustment when the 50th percentile dummy is used in the front and rear seats. The manufacturer would have the option of selecting a single height position for the 95th percentile dummy in the front seats. The key testing parameters associated with each seating position are shown in Table 3.

TABLE 3.—PROPOSED TESTING PARAMETERS FOR EACH SEATING POSITION FOR THE DYNAMIC COMPLIANCE OPTION

Seating position	Dummy size	Rotation limit (deg.)	Head restraint adjustment	
			Backset	Height
Front	50th male	12	Any	Any
Front	95th male	20	Any	One*
Rear	50th male	12	Any	Any

*Position selected at the manufacturer's option.

The criteria were developed primarily through sled testing of a modified production vehicle seat. A preliminary report on the experimental results is available in the docket for this notice. The seat used was not optimized to limit head rotation, but was modified to allow positioning of the head restraint to specified locations and stiffened to eliminate seat back rotation with respect to the seat base. Stiffening of the seat back was believed to create a worst case situation for head rotation. Table 4 shows the rearward angular head-to-torso rotation of a 50th and 95th percentile Hybrid III dummy when exposed to a sled acceleration such that the change in velocity was about 20—25 percent greater than that in both the current and proposed regulation. Rotation was not measured beyond 200

[14] The Saab active head restraint is purely mechanical. When the vehicle is struck from the rear (at speeds equivalent to 16 km/h or greater in a crash involving a barrier), the driver and front seat passenger's bodies move rearward into the seat cushion. A padded pressure plate is moved rearward as a result, and through a linkage moves the head restraint upwards and forward to support the head. The precise activation of the system is determined by the force with which the driver or passenger's back is propelled against the backrest, the magnitude of the crash forces and the occupant's weight.

milliseconds because the dummy torso has rebounded away from the seat at that point in time. The backset values listed were as measured by the ICBC device prior to testing.

TABLE 4.—50TH AND 95TH PERCENTILE MALE HYBRID III DUMMY MAXIMUM HEAD-TO-TORSO ROTATION (DEG.) AS A FUNCTION OF HEAD RESTRAINT BACKSET AND HEIGHT

Height	Backset					
	0 mm (0 in.)		50 mm (2 in.)		100 mm (4 in.)	
	50th	95th	50th	95th	50th	95th
750 mm (29.5 in.)	11	*25	18	45	41	61
800 mm (31.5 in.)	*13	*20	23	34	44	56

*Maximum value prior to 200 ms after start of acceleration.

The sled test data for the 50th percentile dummy show that the 750 mm (29.5 inches) high head restraint had lower head rotation than the 800 mm (31.5 inches) high restraint. This may have been because of the shape of the head restraint caused the dummy head to contact the head restraint above the rearmost portion of the head. Thus, the tested head restraint was more optimally fit to the 50th percentile dummy head when positioned at a height of 750 mm (29.5 inches). This phenomenon illustrates why the proposed regulation would also specify the use of a 95th percentile male dummy. If only the 50th dummy were specified, complying head restraints could have heights of no more than 750 mm (29.5 inches). This would be inconsistent with the static height requirement of 800 mm (31.5 inches) for front seats. The agency believes that compliance with performance requirements with both the 50th and 95th percentile dummies is needed to assure that all occupants in the front seating positions up to and including the tallest are protected. To be consistent with the rear seat static requirement, where only a minimum height of 750 mm (29.5 inches) required, only the 50th percentile dummy is specified for rear seat dynamic compliance.

Based on the sled testing, the agency believes that head restraints 800 mm (31.5 inches) high with a backset of 50 mm (2 inches) could restrict head-to-torso rearward rotation of a 95th percentile dummy to 20 degrees in the proposed dynamic test. Similarly, head restraint at least 750 mm (29.5 inch) high with a 50 mm (2 inch) backset could restrict head-to-torso rearward rotation of a 50th percentile dummy to 12 degrees. The proposed performance values are as shown in Table 3.

In selecting performance criteria for the dynamic compliance option, the agency's goal was to provide a level of safety similar to that provided by the static requirements and provide a method of compliance appropriate for both static and active head restraint designs. Although the modified seat tested by the agency had greater head-to-torso rotation than the proposed performance values in some of the head restraint positions that are proposed for the static compliance option, the agency believes these test data provide insight into the worst case head-to-torso rotation at each head restraint position tested. As stated above, this was partially due to the rigid nature of the seat back, which provided very firm restraint to the dummy torso and therefore accentuated the effect of any gap between the dummy head and the head restraint. It was also due to the sled pulse velocity change being 20–25 percent greater than the target of 17.3 kph in about the same time period. Finally, the method used to attach the head restraint to the seat back, which in some situations allowed significant movement of the head restraint when in contact with the dummy head, added to head-to-torso rotation. As an example of this movement, when the 95th male dummy was tested at the 800 mm (31.5 inch) high and 50 mm (2 inch) backset head restraint position, the dummy head rotated an additional 10 degrees after the head restraint began to deform due to contact with the dummy head. A similar situation occurred at the 750 mm (29.5 inch) high and 50 mm (2 inch) backset head restraint position when the 50th percentile dummy was tested. Therefore, the agency believes that it would be practicable for manufacturers to achieve head-to-torso rotations below those proposed when tested within the proposed acceleration corridor.

The agency plans to perform additional sled tests before the publication of the final rule to assure that the head rotation performance values selected are appropriate.

The agency considered performance criteria other than head rotation for the dynamic compliance options. These included N_{ij}, which is a combination of upper neck moments and forces introduced in the Advanced Air Bag Rulemaking (Docket NHTSA–98–4405); NIC, which was developed by Chalmers University and has been used by IIHS in testing active head restraints; and individual values of force, moment and acceleration. In the absence of generally accepted injury criteria specifically applicable to whiplash injuries, the agency must still assume that a head restraint's ability to prevent whiplash is primarily due to its ability to prevent the rearward translation and rotation of the occupant's head with respect to the torso. The sled tests showed that rearward head rotation seemed to correlate to head restraint position. Other biomechnics researchers have found a similar correlation and used head-to-torso rotations for the evaluation of whiplash injury.[15] Such a correlation indicates there are similar safety benefits between the dynamic and static requirements of the proposed regulation. The agency is willing to reconsider the dynamic performance criteria when more advanced whiplash injury criteria become available.

The agency requests comments on:

27. Are the performance criteria and values tentatively selected for the dynamic performance option the most appropriate criteria and values?

28. Should a limit also be placed on forward head rotation or neck loading so that any potential negative effects of active head restraints would be minimized?

In the current standard the dynamic test procedure specifies only a 95th percentile dummy, but not the specific type. This proposal rectifies this ambiguity by proposing the use of the Hybrid III 50th and 95th percentile dummy. The 95th percentile male dummy is not currently incorporated in 49 CFR Part 572, *Anthropomorphic Test*

[15] Geigl *et al.* (1994) The Movement of Head and Cervical Spine During Rear-end Impact. IRCOBI, pp 127–137.

Devices. However, we anticipate issuing an NPRM to incorporate this dummy into 49 CFR Part 572 within 12 to 18 months, which will probably be several years prior to the proposed effective date of the upgraded Standard 202.

The positioning procedure for the 95th Hybrid III dummy is essentially the same as for the 50th Hybrid III except for the positioning of dummy's H-point in reference to the seat H-point. The offset specified is 9 mm (0.35 inches) above and 15 mm (0.60 inches) forward of the seat H-point.

NHTSA is aware of criticism that the 50th percentile Hybrid III neck lacks sufficient biofidelity to be a useful tool for rear impact testing and, since it is likely to be very similar in design, the same criticism could be extended to the 95th percentile dummy neck. NHTSA is also aware of a newly developed test device, BioRID,[16] which purports to more accurately models the human neck, and of a recent paper by Ford (SAE 973342) which argues that the 50th percentile Hybrid III neck is sufficiently biofidelic in the rearward direction. The agency is likely to revisit both the dynamic performance values and the proposed test device as more advanced dummies are developed and as injury criteria based on human studies achieve broader consensus. The agency would like commenters to address the following issues related to the test dummy selected for the dynamic compliance option:

29. Should the agency consider the use of the 5th percentile female in addition to the 50th and 95th percentile male dummies in the dynamic test or is it reasonable to assume that designs which are adequate for the 50th and 95th males will be adequate for the 5th female?

30. Which advanced dummy neck designs should be considered for future use in the dynamic test and are they likely to be available prior to the effective date of the proposal?

Currently, the dynamic compliance test option requires only that the head rotation criteria be met. The agency is now proposing that, in addition to head rotation, a Head Injury Criterion (HIC) (15 ms) limit of 150 must not be exceeded. We are proposing a 15 ms HIC window to be consistent with the new HIC criterion in Standard 208. The HIC level of 150 is associated with a 1.1 to 4.3 percent probability of moderate (MAIS 2+) head injury. It is the agency's view that inclusion of this requirement would serve as an equivalent to the 80g energy absorption limit found in the static test option.

NHTSA has tentatively concluded that the addition of the HIC requirement to the dynamic compliance option would not place an undue burden on manufacturers while ensuring that head restraints certified to this option have adequate impact absorption characteristics. The HIC values measured in sled testing of a modified production vehicle seat are shown in Table 5. The greatest HIC value in Table 5 is for the 50th percentile dummy with a head restraint position of 50 mm (2 inches) of backset and 750 mm (29.5 inches) of height. This HIC of 157 exceeds the proposed limit of 150. However, the sled pulse for this test had a velocity change of 4.3 kph (25 percent) greater than the proposed velocity change of 17.3 kph and, as mentioned previously the head restraint was not optimized in any way. The agency believes that for a more optimally designed head restraint tested within the proposed acceleration corridor the 150 HIC limit can be met without great difficulty and is needed to provide assurance that head restraints will be sufficiently padded.

31. The agency solicits comments on the proposed HIC 15 limit of 150. Should a different upper limit be specified? Should a 36 ms window be used? If so, should the maximum allowable HIC value be increased?

TABLE 5.—50TH AND 95TH PERCENTILE MALE HYBRID III DUMMY MAXIMUM HEAD-TO-TORSO ROTATION (DEG.) AS A FUNCTION OF HEAD RESTRAINT BACKSET AND HEIGHT

Height	Backset					
	0 mm (0 in.)		50 mm (2 in.)		100 mm (4 in.)	
	50th	95th	50th	95th	50th	95th
750 mm (29.5 in.)	11	*25	18	45	41	61
800 mm (31.5 in.)	*13	*20	23	34	44	56

The agency believes that head restraints certified to the dynamic compliance option should also be required to meet the head restraint width provisions proposed for the static test. These provisions require that head restraints be at least 170 mm (6.7 inches) wide on single seats and 254 mm (10 inches) wide on bench seats. The agency notes that because the motion of the sled used in the dynamic test is unimodal—in a single longitudinal direction—the proposed test would not address the performance of head restraints in off-axis impacts.

The proposed width requirements are the only dimensional criteria offered for inclusion in the dynamic test option. The agency believes that the gap limits proposed in the static test option are not necessary, as head rotation limits would be exceeded if gap sizes were excessive. NHTSA is, however, soliciting comments relating to certain aspects of the proposed dynamic test option:

32. Is the head restraint width requirement appropriate for the dynamic compliance option? Should any of the other dimensional requirements used in the static test option be inserted into the dynamic test requirements?

V. Interim Compliance Options Before Upgraded Requirements Become Mandatory

The August 13, 1997 petition submitted by AAMA/AIAM urged NHTSA to consider compliance with European head restraint regulations to be functionally equivalent to compliance with the current Standard 202. There are three European regulations applicable to head restraints—EEC 96/37/EU, promulgated by the European Union, and ECE 17.05, and ECE 25.04, both issued by the Economic Commission for Europe. Of these three regulations, both 96/37/EU

[16] BioRID stands for Biofidelic Rear Impact Dummy. It was developed by a consortium of Chalmers University of Technology in Sweden, Autoliv, Saab and Volvo to help safety engineers evaluate the relative motion of the head and torso in rear crashes. BioRID has a flexible spine with 24 vertebra-like segments, the same number as in the human spine. It has joints that allow for forward and backward movement of the head, and integrates spring-loaded cables that simulate the action of human neck muscles. Its spine is said to interact with vehicle seats in a more humanlike way than the Hybrid III's rigid spine. Further, its neck is capable of producing the S-shape observed in human necks during rear crashes.

and ECE 17.05 are applicable to seats and seat backs, but incorporate the head restraint provisions found in ECE 25. Each establishes a performance requirement for energy absorption which is slightly more stringent than that now in Standard 202. Further, the requirements for height, allowable gaps, rear seat head restraints, energy absorption and the procedure for rearward displacement testing are identical to those now being proposed by NHTSA for incorporation in Standard 202. However, the agency's proposal contains backset requirements and adjustment retention lock provisions not found in the European regulations and retains the existing minimum width provisions currently incorporated into Standard 202. The European regulations also do not contain a separate width requirement for bench seats found in the current version of Standard 202 and specify a slightly smaller minimum width for head restraints for non-bench seats.

NHTSA's policies and procedures for evaluating the functional equivalence of foreign safety standards are contained in Appendix B of 49 CFR Part 553, the agency's rulemaking procedures, published in the **Federal Register** on May 13, 1998 (63 FR 26508). Under the policy and procedures enunciated in that final rule, a determination by this agency that a foreign standard is functionally equivalent to a counterpart U.S. standard is dependent upon this agency's concluding that the functional performance or safety benefits associated with compliance with the foreign standard is at least as great as those associated with the current U.S. standard.

The first step in the procedures is the determination of whether the U.S. regulation and the foreign directive are intended to address the same safety problem. In the instant case, ECE 25 and Standard 202 are intended to address neck and other injuries to occupants in rear impacts. Having identified both standards as addressing the same safety need, the agency then performed further analysis.

Under the agency's procedures, the next step in evaluating functional equivalence is a comparison of the requirements, test conditions and test procedures found in the two standards. If the differences between the two standards are not insignificant, the next step involves the examination of the real world safety data to examine the relative benefits of the two standards. If this safety data show the foreign standard offers greater benefits, the agency will begin rulemaking to upgrade the U.S. standard to the level of the foreign standard or beyond. If the real world data show the performance of the two standards to be equal, the agency may initiate rulemaking to add the foreign standard as an alternative means of compliance.

NHTSA recognizes that the differences in requirements, test conditions, and test procedures between the U.S. regulation and the ECE 25 may have safety consequences. Therefore, the agency must make some effort to compare the relative benefits and effectiveness of each regulation. The preferred means of determining if foreign standard produces at least as much benefit are real world crash data from some vehicles meeting one standard and from other vehicles meeting the other standard.

When an attempt was made to examine crash data to compare the relative benefits of Standard 202 and ECE 25, NHTSA determined that the crash data available relating to the actual performance of ECE 25 was not sufficient to allow the agency to draw any meaningful conclusions. Similarly, the agency has determined that since ECE 25 and Standard 202 compliance data are primarily dimensional in nature, these data are not useful in comparing the relative safety benefits of each.

Completion of this initial phase of data analysis placed NHTSA at a major decision point in the functional equivalence process (i.e., Are there sufficient data to assess the functional equivalency of the two standards? If not, could additional research be conducted to generate data?). Rather than embarking on a research program of its own, the agency surveyed existing biomedical and safety research to determine if this information could be used to assess the relative merits of ECE 25 and the existing provisions of Standard 202.

As noted above, there is a general consensus in the safety and biomedical community that head restraints that are both higher and closer to the head offer increased protection against whiplash injuries in rear impacts. ECE 25 specifies a greater minimum height which is 50 mm (2 inches) greater than the height that must currently be achieved in Standard 202. That difference suggests that compliance with ECE 25 provides greater safety benefits than the existing provisions of Standard 202. Also, the maximum height that must be achieved in ECE 25 is 100 mm (4 inches) greater than that required by Standard 202. ECE 25 differs from the existing version of Standard 202 in ways other than height requirements. Standard 202 currently does not require head restraints for rear seating positions or contain any requirements for energy absorption. ECE 25 contains requirements for energy absorption and applies to head restraints in rear seating positions.

Therefore, the agency has tentatively concluded that ECE 25 offers greater safety benefits than the existing version of Standard 202 under the functional equivalence process defined in Part 553, Appendix B. Therefore, the agency is proposing that in the period between 90 days following the publication of any final rule that is derived from this proposal and the first occurrence of September 1, three years after publication of the final rule (the date on which new cars must meet the upgraded Standard 202 requirements), manufacturers may certify their vehicles using the existing ECE 25 requirements, with one exception. Standard 202 now requires that restraints on vehicles equipped with bench seats must be at least 254 mm (10 inches) wide and other seats must have head restraints that are 171 mm (6.75 inches) wide while ECE 25 specify a 170 mm (6.70 inch) minimum width for all head restraints. The agency has tentatively concluded that the continued use of bench and split bench seats in vehicles manufactured for the U.S. market makes it necessary maintain this portion of FMVSS 202.

The agency is not simply proposing that compliance with ECE 25 be considered to be the equivalent of compliance with the existing version of Standard 202 but is also proposing an upgrade to Standard 202. The proposed upgrade to Standard 202 requires the agency to make a second functional equivalence assessment comparing ECE 25 to the new Standard 202. As outlined above, the agency's functional equivalence assessment in this case has, due to the lack of European crash and compliance test data, focused on existing research regarding the performance of head restraints in reducing whiplash injuries.

The backset, vertical adjustment retention, and existing bench seat head restraint width requirements proposed for the upgrade to Standard 202 do not have counterparts in the European regulations. In performing its functional equivalence assessment, NHTSA found that current research indicates that these requirements are important factors in the safety performance of head restraints. If those new requirements were adopted, ECE 25 could no longer be said to be equivalent to the upgraded Standard. Accordingly, we are not proposing to allow compliance with

ECE 25 as an option after the upgraded requirements go into effect.

VI. Benefits

In support of this rulemaking action, the agency has prepared a Preliminary Economic Assessment (PEA) which contains a thorough analysis of both the benefits and the costs of the changes this document proposes for Standard 202. The analysis contained in the PEA estimates that full implementation of the proposed changes would result in, on an annual basis, 9,575 fewer whiplash injuries for front seat occupants and 4,672 fewer whiplash injuries for rear seat occupants, providing a total of 14,247 fewer whiplash injuries for both front and rear seating positions in rear impacts.

NHTSA estimates from National Automotive Sampling System (NASS) data that, between 1988 and 1996, there were 805,581 occupants with whiplash injuries (non-contact AIS 1 neck injuries) annually in the outboard seating positions of passenger cars (PCs), light trucks, and vans (LTVs) in police reported and unreported towaway and non-towaway nonrollover impacts. However, since the agency believes head restraints will have their greatest effectiveness in rear impacts, the benefits analysis will be restricted to that crash mode only. Based on this same 1988 to 1996 NASS data, the average number of whiplash injuries in rear impacts annually was 272,088. The number of vehicles with head restraints in the rear outboard seats has increased dramatically over the last several years. An estimated 41 percent of the MY 1999 fleet have rear seat head restraints and 20 percent have no rear seat. Because of the increase in the numbers of rear seat head restraints, it is estimated that for the 1999 model year the total population of whiplash injures will be 270,815 (251,035 front seat occupant injuries and 19,780 rear seat occupant injuries).

The average economic cost (excluding property damage) of a whiplash injury in a rear impact, in 1998 dollars, is estimated to be $6,485, resulting in a total annual cost of approximately $1.75 billion for 272,088 whiplash injuries. The $6,485 estimate is based on the assumption that the maximum injury per occupant is an AIS 1 injury. The agency believes that this is a reasonable assumption because very few occupants in the rear impact crashes used to develop our estimate had injuries higher than AIS 1. Further, in such impacts, a whiplash injury is likely to be the most costly AIS 1 injury and the longest lasting one.

The characteristics of adjustable head restraints and their use have changed as well. A 1982 survey of adjustable head restraints indicated that at the lowest position in the range of adjustment, the lowest head restraint was 635 mm (25 inches) high. In a survey conducted for this rulemaking, the agency determined that, at the lowest position of adjustment, the lowest head restraint observed had a height of 712 mm (28 inches). Therefore, the lowest adjustment height for these restraints has increased by three inches. Examination of survey data for the highest position of adjustment indicates that adjustable head restraints are also 40 mm (1.6 inches) higher now at the uppermost range of adjustment than they were in 1982. At the lowest observed position, contemporary adjustable restraints are now 13 mm (.5 inches) lower than integral restraints observed in 1982.

Adjustable restraints are not only higher now than they were in 1982, but they are also more likely to be properly adjusted. While the majority of adjustable head restraints are still not properly adjusted, agency data indicates that 47 percent of current head restraints are properly positioned as opposed to 27 percent in 1982.

The agency believes that about 30 percent of all occupants involved in towaway rear impacts receive a whiplash injury. However, injury rates do not appear to vary significantly between integral and adjustable head restraints. The changes in head restraint configurations and use discussed above may explain why. The data available for front and rear head restraints combined are not sufficient to make statistically valid comparisons between restraint and vehicle types. This data indicated that the average whiplash injury rate for passenger cars with integral head restraints (31.75 per hundred occupants in towaway rear impacts) was higher than the whiplash injury rate (27.99 per hundred) for adjustable head restraints. For LTVs, the data indicated that the average whiplash rate (30.57 per hundred) for adjustable head restraints was slightly higher than the whiplash injury rate (30.53 per hundred) for integral head restraints. Comparing integral restraints by vehicle type shows that the injury rate for cars (31.75 per hundred) exceeds that for trucks (30.53 per hundred) while for adjustable head restraints, the rate for cars is lower (27.99 per hundred) than it is for trucks (30.57 per hundred).

Two sets of data were statistically significant for front occupants only and indicate that integral restraints are performing differently in cars and trucks and in trucks depending on occupant height. For shorter occupants of front outboard seats, the injury rate for trucks with integral restraints was much lower (17.14 per hundred) than the rate for cars (37.94 per hundred). When comparing short drivers with taller drivers in trucks with integral restraints, the taller drivers were injured at a much greater rate (56.71 per hundred) than the shorter (17.14 per hundred). This may indicate that integral head restraints in trucks are better positioned to perform well in preventing injury to short drivers and not as well in protecting tall drivers. Estimates of annual whiplash injury rates by vehicle and restraint type are shown in Table 6.

TABLE 6.—WHIPLASH RATES FOR NONROLLOVER REAR IMPACTS 1988–1996 NASS ANNUALIZED DATA IN TOWAWAY CRASHES

Front and Back Outboard Occupants			
Vehicle Type:		Integral	Adjustable
Car		31.75	27.99
Truck		30.53	30.57
Head Restraint Type:		Car:	Truck:
Integral		31.75	30.53
Adjustable		27.99	30.57
Front Outboard Only			
Vehicle Type:	Occupant Height:	Integral	Adjustable
Car	Short	37.94	31.00

TABLE 6.—WHIPLASH RATES FOR NONROLLOVER REAR IMPACTS 1988–1996 NASS ANNUALIZED DATA IN TOWAWAY CRASHES—Continued

Car	Tall	35.72	28.04
Vehicle Type:	Head Restraint Type:	Short	Tall
Car	Integral	37.94	35.72
Car	Adjustable	31.00	28.04
Vehicle Type:	Occupant Height:	Integral	Adjustable
Truck	Short	17.14	20.65
Truck	Tall	56.71	30.19
Vehicle Type:	Head Restraint Type:	Short:	Tall:
Truck	Integral	17.14	*56.71
Truck	Adjustable	20.65	30.19
Head Restraint Type:	Occupant Height:	Car	Truck
Integral	Short	37.94	*17.14
Integral	Tall	35.72	56.71
Adjustable	Short	31.00	20.65
Adjustable	Tall	28.04	30.19

*Difference is significant at 0.05.

NHTSA estimates that the present fleet of vehicles has an average front seat outboard head restraint maximum height of 768 mm (30.2 inches), which is 32 mm (1.3 inches) less than the proposed minimum height capability of 800 mm (31.5 inches). As outlined in the PEA, the agency believes that raising the height of the front seat outboard head restraint from the present average to 800 mm (31.5 inches) will result in a 1.1 percentage point increase in effectiveness for all rear impact injuries and a 1.83 percentage point increase for whiplash injuries alone.

In examining the effectiveness of the proposed changes, the agency considered the differences between integral and adjustable head restraints. For integral head restraints and those adjustable head restraints properly adjusted in the fully up position (which the agency estimates would be 53 percent of such restraints), the average increase in effectiveness would be a 1.68 percentage points. For the remaining percentage of adjustable head restraints, the 47 percent that would be adjusted in the lowest adjustment position, we estimated that the proposed minimum height of 750 mm (29.5 inches) would result in a 3.50 percentage point increase in effectiveness for all rear impact injuries and 5.83 percentage point increase in effectiveness for whiplash injuries.

Calculating the benefits of the proposed requirements for rear seat head restraints poses several challenges. The baseline heights of rear seats are different than those of front seats. In addition, rear seats are less frequently occupied. When they are occupied, the occupant is often a child. The present fleet also includes vehicles with and without rear seat head restraints.

Agency survey data indicate that, in vehicles with rear seat head restraints, the average lowest head restraint height is 653 mm (25.7 inches), which is 97 mm (3.8 inches) lower than the proposed minimum height of 750 mm (29.5 inches). In models with rear seat adjustable head restraints, the average head restraint height is 655 mm (25.8 inches) and the average seatback height in vehicles without rear seat head restraints is 650 mm (25.6 inches). As outlined in the PEA, an increase in head restraint height from 25.7 inches to the 29.5 inches for front seats would increase effectiveness by 12.35 percentage points. After correcting for the different occupancy rates and occupant heights in rear seats, the average effectiveness for the rear seat would be 13 percent.

Taking into account the differing degrees of effectiveness for each type of head restraint available for front seat occupants, *i.e.,* integral, adjustable in the highest position, and adjustable in the lowest position, the agency estimates that the increase in minimum head restraint height for integral head restraints would result in 1,588 fewer injuries per year. For adjustable head restraints adjusted to the highest position, it is anticipated that the proposed increase in minimum height would result in 1,959 fewer front seat occupant injuries per year. Reductions in injuries for adjustable head restraints in the lowest position would be 6,028 front seat occupant injuries annually. The total reduction in injuries attributable to the proposed front seat head restraint requirements would be 9,575 fewer injuries per year.

For the rear seat, the proposed head restraint requirement, which would require head restraints to be installed at locations where they were not previously required, would result in 4,642 fewer injuries per year.

Adding the benefits from the rear seat requirements to those calculated for the front seat results in rear impact crashes alone a total reduction of 14,247 whiplash injuries each year.

The agency has not prepared an analysis of the potential benefits of two other new requirements contained in this proposal—the backset requirement and the adjustment lock requirement. It should be noted that while there is a general consensus among safety researchers that a smaller backset will result in a reduction of injuries, NHTSA has not yet developed a methodology for quantitatively assessing this benefit. Similarly, the benefits of adding a height locking requirement have also not been calculated. The agency has not determined how many vehicles in the current fleet have height locks for their head restraints. Therefore, a baseline for calculating benefits has not been developed. Further, the benefits of such locks will depend entirely on the rate at which they are employed. As NHTSA does not have access to such data at this time, no estimation of the benefits of the height lock requirement has been prepared.

VII. Costs

In estimating the costs of the proposed requirements, the agency relied on a 1992 NHTSA tear down study of a variety of vehicles. As outlined in the PEA, this study, adjusted to 1998 dollar values, revealed that the sales weighted average cost of integral head restraints is $30.12 per restraint. The same analysis applied to adjustable head restraints indicated an average cost of $29.13 per restraint. The average cost for both adjustable and integral is $29.44 per restraint. As the proposal contains provisions requiring that head restraints be higher than the existing ones in the front and rear seats, we used data from the 1992 study also to calculate the cost per inch of head restraint. Using the same tear-down study and distinguishing between

integral and adjustable head restraints, the agency calculated a cost per inch of $1.40 for integral head restraints and $1.46 per inch for adjustable head restraints. As these calculations indicated little difference in cost between integral and adjustable head restraints, the agency estimated that the sales weighted average cost per inch of head restraints for all restraints, in 1998 dollars, was $1.54. In determining the overall cost of compliance with the proposed regulations both in situations where existing head restraints must be raised or a head restraint must be added to the rear seat, we have tentatively concluded that an average cost of $1.54 per additional inch of head restraint height is appropriate.

To evaluate the cost of the proposed minimum height requirements, NHTSA assumed that the cost increase associated with this new requirement is the cost of increasing the highest head restraint position up to 800 mm (31.5 inches) in the front seat or to 750 mm (29.5 inches) in the rear seat. As we believe that the cost of head restraints would be very similar for adjustable and integral head restraints, we assume that the true cost would be to raise the highest height of the head restraint and that changes in design, at no additional variable cost, could be accomplished to comply with the minimum height requirements.

The agency believes that the backset requirements would not add cost to the vehicle. There would be some redesign costs to both increase the height and reduce the backset, but the agency believes that the backset requirement is a design change that could be implemented at the same time as height is increased, with no increase in head restraint cost.

Light vehicle sales in the U.S. totaled 15.55 million units in 1998. There were 8.14 million car sales and 7.40 million truck sales in the U.S. in 1998. All of these vehicles would be required to have higher front seat head restraints. The cost of raising front seat head restraints would be $4.21 per vehicle, resulting in a fleet cost of $65.5 million. In regard to rear seats without head restraints, raising the seat back to create an integral restraint would cost $12.34 per vehicle, resulting in a fleet cost of $74.8 million. Raising the rear seat head restraints in vehicles already equipped with rear head restraints costs $3.61 per vehicle, resulting in a fleet cost of $19.6 million. There would be a small cost to add locking mechanisms to those head restraints that do not currently have such mechanisms. Our studies indicate that approximately half of the existing fleet with adjustable head restraints has locking mechanisms. Adding locking mechanisms to the rest of the fleet with adjustable head restraints at a cost of $0.15 per vehicle is projected to result in costs of $3.3 million for front seat restraints and $2.6 million for rear seats for a combined total is $5.9 million. The total estimated costs of the vehicle changes that would be required by this proposal would be $160.5 million ($65.5 million for the front seat and $95.0 million for the rear seat).

VIII. Effective Date

As noted above, the agency is proposing two amended versions of Standard 202. The first version would become effective 90 days after issuance of the final rule. It would allow three options for compliance. The first option would be compliance with the requirements of the existing Standard 202. The second option would allow manufacturers to comply with the requirements of ECE 25 as supplemented by the current width requirements. The third option would allow manufacturers to comply with the new upgraded Standard 202 requirements, which would apply to vehicles manufactured on or after the first occurrence of September 1, three years after the publication of the final rule, before that date. Between the effective date of the final rule and August 31, 2004, manufacturers may choose one of the foregoing three options when certifying their vehicles. However, the election of the option used by the manufacturer in certifying the vehicle, including the choice between the static and dynamic test options, must be made at or before the time of certification, and the manufacturer may not thereafter rely on any other test option to establish compliance.

The agency is proposing that compliance with the upgraded version of the standard become mandatory on the first occurrence of September 1, three years after publication of the final rule. NHTSA believes that this date will provide manufacturers with sufficient leadtime to redesign seats and seating systems in production vehicles and to incorporate new elements of head restraint design in new models.

IX. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was reviewed by the Office of Management and Budget under Executive Order 12866, ''Regulatory Planning and Review.'' The rulemaking action has been determined to be economically significant. NHTSA is placing in the public docket a Preliminary Economic Assessment (PEA) describing the costs and benefits of this rulemaking action. The costs and benefits are summarized earlier in this document.

B. Regulatory Flexibility Act

NHTSA has considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) I hereby certify that the proposed amendment would not have a significant economic impact on a substantial number of small entities.

The proposed rule would affect motor vehicle manufacturers, alterers, and seating manufacturers.

NHTSA estimates that there are only about four small passenger car and light truck manufacturers in the United States. These manufacturers serve a niche market. The agency believes that small manufacturers manufacture less than 0.1 percent of total U.S. passenger car and light truck production per year.

There are about 30 seating manufacturers in the U.S. Many of these are small businesses. The proposed rule would affect these small businesses by changing the requirements for head restraints. Raising the height of and integral seat or of an adjustable head restraint is not a new or novel idea. The agency does not believe that this will have a significant impact on these manufacturers.

NHTSA notes that final stage vehicle manufacturers and alterers could also be affected by this proposal. Many final stage manufacturers and alterers install supplier constructed seating systems in vehicles they produce. The proposal would not have any significant effect on final stage manufacturers or alterers, however, since the seats they purchase should be tested and certified by the seat manufacturer.

Small organizations and small governmental units would not be significantly affected since the potential cost impacts associated with this proposed action should only slightly affect the price of new motor vehicles.

For the reasons discussed above, the small entities that would most likely be affected by this proposal are small vehicle manufacturers, seating manufacturers, final stage manufacturers and alterers.

The agency believes, further, that the economic impact on these manufacturers would be small. While the small vehicle manufacturers would face additional compliance costs, the

agency believes that seating manufacturers would likely provide much of the engineering expertise necessary to meet the new requirements. Raising the height of a head restraint is not a new or novel engineering task. However, doing so for many makes and models at the same time could present a challenge. The agency also notes that, in the unlikely event that a small vehicle manufacturer or alterer did face substantial economic hardship, it could apply for a temporary exemption for up to three years. See 49 CFR Part 555. It could subsequently apply for a renewal of such an exemption. However, the agency requests comments concerning:

32. The economic impact of the proposed rule on small vehicle manufacturers, seating manufacturers, final stage manufacturers and vehicle alterers.

Additional information concerning the potential impacts of the proposed requirements on small entities is presented in the PEA.

C. National Environmental Policy Act

NHTSA has analyzed this proposal for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

The agency has analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 and has determined that it does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The final rule has no substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials.

E. Unfunded Mandates Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). This assessment is included in the PEA.

F. Civil Justice Reform

This proposal would not have any retroactive effect. Under 49 U.S.C. 21403, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 21461 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

G. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA)(Public Law 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' This action proposes to modify performance requirements for head restraints to allow, on an interim basis, compliance with either U.S. or ECE requirements. After the end of the interim period, head restraints must comply with the proposed U.S. requirements. Certain technical standards developed by the Society of Automotive Engineers (SAE) and other bodies have been incorporated into this proposal but the overall need for safety precludes, in NHTSA's view, the adoption of such voluntary standards as a substitute for this proposal.

H. Paperwork Reduction Act

This rule does not contain any collection of information requirements requiring review under the Paperwork Reduction Act of 1995 (Public Law 104–13).

X. Submission of Comments

How Can I Influence NHTSA's Thinking on This Proposed Rule?

In developing this proposal, we tried to address the concerns of all our stakeholders. Your comments will help us improve this rule. We invite you to provide different views on options we propose, new approaches we haven't considered, new data, how this proposed rule may affect you, or other relevant information. We welcome your views on all aspects of this proposed rule, but request comments on specific issues throughout this notice. We grouped these specific requests near the end of the sections in which we discuss the relevant issues. Your comments will be most effective if you follow the suggestions below:

- Explain your views and reasoning as clearly as possible.
- Provide solid technical and cost data to support your views.
- If you estimate potential costs, explain how you arrived at the estimate.
- Tell us which parts of the proposal you support, as well as those with which you disagree.
- Provide specific examples to illustrate your concerns.
- Offer specific alternatives.
- Refer your comments to specific sections of the proposal, such as the units or page numbers of the preamble, or the regulatory sections.
- Be sure to include the name, date, and docket number with your comments.

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Comments may also be submitted to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on ''Help & Information'' or ''Help/Info'' to obtain instructions for filing the document electronically.

How Can I Be Sure That My Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, you

should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR Part 512.)

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date. If Docket Management receives a comment too late for us to consider it in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How Can I Read the Comments Submitted by Other People?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Docket Management System (DMS) Web page of the Department of Transportation (*http://dms.dot.gov/*).

(2) On that page, click on ''search.''

(3) On the next page (http://dms.dot.gov/search/), type in the four-digit docket number shown at the beginning of this document. Example: If the docket number were ''NHTSA–1998–1234,'' you would type ''1234.'' After typing the docket number, click on ''search.''

(4) On the next page, which contains docket summary information for the docket you selected, click on the desired comments. You may download the comments. However, since the comments are imaged documents, instead of word processing documents, the downloaded comments are not word searchable.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this proposal.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, it is proposed that 49 CFR part 571 be amended as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

1. The authority citation for part 571 of title 49 would be revised to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50.

2. Section 571.202 would be revised to read as follows:

§ 571.202 Standard No. 202; Head restraints.

S1. *Purpose and scope.* This standard specifies requirements for head restraints to reduce the frequency and severity of neck injury in rear-end and other collisions.

S2. *Application.* This standard applies to passenger cars, and to multipurpose passenger vehicles, trucks and buses with a GVWR of 4,536 kg (10,000 pounds) or less manufactured before [Insert a date which is the first occurrence of September 1, three years after publication of the final rule].

S3. *Definitions.*

Head restraint means a device that limits rearward displacement of a seated occupant's head relative to the occupant's torso.

S4. *Requirements.*

S4.1 Each passenger car must comply with, at the manufacturer's option, either S4.3, S4.4 or S4.5 of this section.

S4.2 Each truck, multipurpose passenger vehicle and bus with a GVWR of 4,536 kg (10,000 pounds) or less must comply with, at the manufacturer's option, either S4.3, S4.4 or S4.5 of this section.

S4.3 Except for school buses, a head restraint that conforms to either S4.3 (a) or (b) of this section must be provided at each outboard front designated seating position. For school buses, a head restraint that conforms to either S4.3 (a) or (b) of this section must be provided for the driver's seating position.

(a) It must, when tested in accordance with S5.1 of this section, limit rearward angular displacement of the head reference line to 45 degrees from the torso reference line; or

(b) It must, when adjusted to its fully extended design position, conform to each of the following—

(1) When measured parallel to torso line, the top of the head restraint must not be less than 700 mm above the seating reference point;

(2) When measured either 64 mm below the top of the head restraint or 635 mm above the seating reference point, the lateral width of the head restraint must be not less than—

(i) 254 mm for use with bench-type seats; and

(ii) 171 mm for use with individual seats;

(3) When tested in accordance with S5.2 of this section, any portion of the head form in contact with the head restraint must not be displaced to more than 102 mm perpendicularly rearward of the displaced extended torso reference line during the application of the load specified in S5.2(c) of this section; and

(4) When tested in accordance with S5.2 of this section, the head restraint must withstand an increasing load until one of the following occurs:

(i) Failure of the seat or seat back; or,

(ii) Application of a load of 890N.

S4.4 Except for school buses, a head restraint that conforms to S4.4 (a) and (b) of this section must be provided at each outboard front designated seating position. For school buses, a head restraint that conforms to S4.4 (a) and (b) of this section must be provided for the driver's seating position.

(a) The head restraint must comply with paragraphs 6.1 through 6.6.3, 6.8 through 6.10, 7, and 8 of the following English language version of the Economic Commission for Europe Regulation 25: E/ECE/324–E/ECE/TRANS/505/Rev.1/Add.24/Rev.1, as amended by E/ECE/324–E/ECE/TRANS/505/Rev.1/Add.24/Rev.1/Corr.1, E/ECE/324–E/ECE/TRANS/505/Rev.1/Add.24/Rev.1/Amend.1, and E/ECE/324–E/ECE/TRANS/505/Rev.1/Add.24/Rev.1/Amend.2. (A copy of paragraphs 2, 6.1 through 6.6.3 and 6.8 through 6.10, 7, and 8 may be reviewed at the DOT Docket Management Facility, U.S. Department of Transportation, Room PL–01, 400 Seventh Street, SW., Washington, DC 20590–0001. Copies of E/ECE/324–E/ECE/TRANS/505, Rev.1/Add.24/Rev.1/Amend.2, 16 April 1997 may be obtained from the ECE Internet site at http://www.unece.org/trans/main/wp29/wp29regs.html or by writing to the United Nations, Conference Services Division, Distribution and Sales Section, Office C.115–1, Palais des Nations, CH–1211, Geneva 10, Switzerland); and

(b) The head restraint must meet the width requirements specified in S4.3(b)(2) of this section.

S4.5 Head restraints that comply with the requirements of § 571.202a of this part, becoming effective on [Insert a date which is the first occurrence of September 1, three years after publication of the final rule], must be provided at each outboard designated seating position.

S4.6 Whenever this standard provides an option for compliance the manufacturer must select the option no later than the time it certifies the vehicle and may not thereafter select a different option for the vehicle.

S5. *Demonstration procedures.*

S5.1 Compliance with S4.3(a) of this section is demonstrated in accordance with the following with the head restraint in its fully extended design position:

(a) On the exterior profile of the head and torso of a dummy having the weight and seated height of a 95th percentile adult male with an approved representation of a human, articulated neck structure, or an approved equivalent test device, establish reference lines by the following method:

(1) Position the dummy's back on a horizontal flat surface with the lumbar joints in a straight line.

(2) Rotate the head of the dummy rearward until the back of the head contacts the same flat horizontal surface in paragraph (a)(1) of S5.1 of this section.

(3) Position the SAE J–826 two-dimensional manikin's back against the flat surface in S5.1(a)(1) of this section, alongside the dummy with the h-point of the manikin aligned with the h-point of the dummy.

(4) Establish the torso line of the manikin as defined in SAE Aerospace-Automotive Drawing Standards, sec. 2.3.6, P.E1.01, September 1963.

(5) Establish the dummy torso reference line by superimposing the torso line of the manikin on the torso of the dummy.

(6) Establish the head reference line by extending the dummy torso reference line onto the head.

(b) At each designated seating position having a head restraint, place the dummy, snugly restrained by a Type 2 seat belt, in the manufacturer's recommended design seated position.

(c) During forward acceleration applied to the structure supporting the seat as described in this paragraph, measure the maximum rearward angular displacement between the dummy torso reference line and head reference line. When graphically depicted, the magnitude of the acceleration curve must not be less than that of a half-sine wave having the amplitude of 78 m/s^2 and a duration of 80 milliseconds and not more than that of a half-sine wave curve having an amplitude of 94 m/s^2 and a duration of 96 milliseconds.

S5.2 Compliance with S4.3(b) of this section is demonstrated in accordance with the following with the head restraint in its fully extended design position:

(a) Place a test device, having the back plan dimensions and torso line (centerline of the head room probe in full back position), of the three dimensional SAE J826 manikin, at the manufacturer's recommended design seated position.

(b) Establish the displaced torso reference line by applying a rearward moment of 373 Nm moment about the seating reference point to the seat back through the test device back pan located in paragraph S5.2(a) of this section.

(c) After removing the back pan, using a 165 mm diameter spherical head form or cylindrical head form having a 165 mm diameter in plan view and a 152 mm height in profile view, apply, perpendicular to the displaced torso reference line, a rearward initial load 64 mm below the top of the head restraint that will produce a 373 Nm moment about the seating reference point.

(d) Gradually increase this initial load to 890 N or until the seat or seat back fails, whichever occurs first.

* * * * *

3. On [Insert a date which is the first occurrence of September 1, three years after publication of the final rule], § 571.202(a) would be added to read as follows:

§ 571.202(a) Standard 202; Head restraints.

S1. *Purpose and scope.* This standard specifies requirements for head restraints to reduce the frequency and severity of neck injury in rear-end and other collisions.

S2. *Application.* This standard applies to passenger cars, and to multipurpose passenger vehicles, trucks and buses with a GVWR of 4526 kg (10,000 pounds) or less.

S3. *Definitions.*

Backset means the minimum horizontal distance between the rear of a representation of the head of a seated 50th percentile male occupant and the head restraint.

Head restraint means a device that limits rearward displacement of a seated occupant's head relative to the occupant's torso.

Height means the distance from the H-point to a point measured parallel to the torso reference line defined by the three dimensional SAE J826 (July 1995) manikin.

Top means the point on the head restraint with the greatest height.

S4. *Requirements.*

S4.1 Except as provided in S4.3 of this section, each vehicle must comply with S4 of this section.

S.4.2 *Performance levels.* In vehicles other than school buses, a head restraint that conforms to either S4.2(a) or (b) of this section must be provided at each outboard designated seating position. In school buses, a head restraint that conforms to either S4.2(a) or (b) of this section must be provided for the driver's seating position.

(a) *Dynamic performance and width.* Each head restraint must conform to the following—

(1) When tested in accordance with S5.1 of this section, during a forward acceleration of the dynamic test platform described in S5.1(a), the head restraint must—

(i) Limit the rearward angular displacement between the dummy's head and torso to 12 degrees for the 50th percentile male dummy in front and rear seating positions and 20 degrees for the 95th percentile male dummy in front seating positions; and

(ii) Limit HIC to 150, when calculated in accordance with the following formula:

$$\mathrm{HIC} = \left[\frac{1}{(t_2 - t_1)} \int_{t_1}^{t_2} a\,dt \right]^{2.5} (t_2 - t_1)$$

Where the term a is the resultant head acceleration expressed as a multiple of g (the acceleration of gravity), and t1 and t2 are any two points in time during the impact which are separated by not more than a 15 millisecond time interval; and

(2) The head restraint must have the lateral width specified in S4.2(b)(3) of this section.

(b) *Dimensional and static performance.* Each head restraint must conform to each of paragraphs S4.2(b)(1) through (12) of this section:

(1) *Minimum height capability.* When measured in accordance with S5.2(a) of this section, the top of head restraints in front seating positions must be capable of being positioned at a height not less than 800 mm (31.5 inches).

(2) *Minimum height limit.* When measured in accordance with S5.2(b) of this section, the top of the head restraint must have a height not less than 750 mm (29.5 inches) in any position of adjustment.

(3) *Width.* When measured 64 ± 3 mm (2.5 ± 0.1 inches) below the top of the head restraint, the lateral width of the head restraint must be not less than—

(i) 254 mm (10 inches), in the case of head restraints on bench-type seats; and

(ii) 171 mm (6.75 inches), in the case of head restraints on individual seats.

(4) *Backset.* When measured in accordance with S5.2(c) of this section, the head restraint backset must be not more than 50 mm (1.97 inches), with the top of adjustable head restraints in any height position of adjustment between 750 mm (29.5 inches) and 800 mm (31.5 inches).

(5) *Gaps.* Except as provided in S4.2(b)(6) of this section, when measured in accordance with S5.3 of this section using the described head form, there must not be any gap greater than 60 mm (2.36 inches) in the front surface of the head restraint or between the front surface of the head restraint and the front surface of the seat.

(6) *Gaps.* For adjustable head restraints, when measured in accordance with S5.3 of this section using the described head form, there must be no gap greater than 25 mm (1 inch) between the front surface of the head restraint and the front surface of the seat.

(7) *Energy absorption.* When the front surface of the head restraint is impacted in accordance with S5.4 of this section by the described head form at any velocity up to and including 24.1 kilometers per hour (15 mph), the deceleration of the head form must not exceed 785 m/s^2 (80g) continuously for more than 3 milliseconds.

(8) *Radius of curvature.* Any portion of the front surface of the seat or head restraint that has a height greater than 635 mm (25 inches) and that is outside of the impact area described in S5.4(c) of this section must either have a radius of curvature of not less than 5 mm (0.2 inches) or meet the requirement of S4.2(b)(7) of this section when tested outside the impact area.

(9) *Height retention.* When tested in accordance with S5.5 of this section, the lowest portion of the described head form must return to within 10 mm (0.4 inches) of its initial reference position after application of at least a 500 N (112 pound) load and reduction of the load to 50 ± 1 N (11.2 ± 0.2 pounds).

(10) *Displacement.* When tested in accordance with S5.6(a) through (f) of this section, the rearmost portion of the described head form must not be displaced to more than 102 mm (4 inches) perpendicularly rearward of the displaced extended torso reference line during the application of a 373 ± 7.5 Nm (3,300 ± 66 inch-pounds) moment about the H-point.

(11) *Backset retention.* When tested in accordance with S5.6 of this section, the rearmost portion of the described head form must return to within 10 mm (0.39 inches) of its initial reference position after application of a 373 ± 7.5 Nm (3,300 ± 66 inch-pounds) moment about the H-point and reduction of the moment to 37 ± 0.7 Nm (327 ± 6.5 inch-pounds).

(12) *Strength.* When tested in accordance with S5.6 of this section, the head restraint must provide a resistance to the test device of at least 890 N (200 pounds).

S4.3 *Folding or retracting head restraints for unoccupied seats.* A rear seat head restraint may be adjustable by folding or retracting to a position in which its minimum height is less than that specified in S4.2(b)(2) of this section or in which its backset is more than that specified in S4.2(b)(4) of this section. In any such position, the head restraint must meet either S4.3(a) or (b) of this section.

(a) The head restraint must automatically return to a position in which its height is not less than that specified in S4.2(b)(2) of this section and its backset is not more than that specified in S4.2(b)(4) of this section when a test dummy representing a 5th percentile female is positioned in the seat and when a test dummy representing 50th percentile male is positioned in the seat and the midsagittal plane of the test dummy is aligned within 15 mm (0.6 inches) of the head restraint centerline; or

(b) The head restraint must, when tested in accordance with S5.7 of this section, cause the torso reference line angle to be at least 10 degrees closer to vertical than when the head restraint is in any position of adjustment in which its height is not less than that specified in S4.2(b)(2) of this section and its backset is not more than that specified in S4.2(b)(4) of this section.

S4.4 *Removability of head restraints.* A front seat head restraint must not be removable from the seat solely by hand. A rear seat head restraint may be removable from the seat solely by hand.

S4.5 *Compliance option selection.* Whenever this standard provides an option for compliance, the manufacturer must select the option not later than the time it certifies the vehicle and may not thereafter select a different option for the vehicle.

S5. *Procedures.* Demonstrate compliance with S4.2 and S4.3 of this section with any adjustable lumbar support adjusted to its rearwardmost nominal design position in forward facing seats and its forwardmost nominal design position in rear facing seats. Except for S5.1 of this section, if the seat back is adjustable, it shall be set at an initial inclination position closest to 25 degrees from the vertical, as measured by the three dimensional SAE J826 manikin (July 1995) equipped with the ICBC Head Restraint Measuring Device (available from the Insurance Corporation of British Columbia, 151 West Esplanade, North Vancouver, BC V7M 3H9, Canada. www.icbc.com). The order of test performance is S5.7 and S5.1 to S5.6 of this section, in numerical order.

S5.1 *Procedures for dynamic performance.* Demonstrate compliance with S4.2(a) of this section in accordance with S5.1(a) though (i) of this section with the head restraints in any backset position of adjustment. For all seating positions demonstrate compliance with a 50th percentile male Hybrid III test dummy specified in 49 CFR part 572, subpart E. For front seating positions demonstrate compliance with a 95th percentile male Hybrid III test dummy specified in 49 CFR part 572. When testing with the 95th percentile dummy demonstrate compliance with the head restraint at one height position of adjustment, at the option of the manufacturer. When testing with the 50th percentile demonstrate compliance with the head restraint at any height position of adjustment.

(a) Mount the vehicle on a dynamic test platform at the vehicle attitude set forth in S13.3 of § 571.208 of this part, so that the longitudinal centerline of the

vehicle is parallel to the direction of the test platform travel and so that movement between the base of the vehicle and the test platform is prevented. Instrument the platform with an accelerometer and data processing system having a frequency response of channel class 60 as specified in the Society of Automotive Engineers (SAE) Recommended Practice J211/1, March 1995. Position the accelerometer sensitive axis parallel to the direction of test platform travel.

(b) Remove the tires, wheels, battery, fluids, and all unsecured components. Remove or rigidly secure the engine, transmission, axles, exhaust, vehicle frame, etc. in order to assure that all points on the acceleration vs. time plot measured by an accelerometer on the floor pan fall within the corridor described in Figure 1 and Table 1.

(c) Place any moveable windows in the fully open position.

(d) At each outboard designated seating position, place the test dummy with the seat adjusted as specified in S8.1.2 through S8.1.3 of § 571.208 of this part. Prior to placing the Type 2 seat belt around the test dummy, exercise the seat belt retractor(s) three times to remove slack.

(e) Dress and adjust each test dummy as specified in S8.1.8.2 through S8.1.8.3 of § 571.208 of this part.

(f) Position each test dummy as specified in S10.1 through S10.3 of § 571.208 of this part and S7.1 through S7.4 of § 571.214 of this part, except for the following:

(1) If it is not possible to position the test dummy so that the midsagittal plane is aligned within 15 mm (0.6 inches) of the head restraint centerline, follow the positioning procedure in S7.1 through S7.4 of § 571.214 of this part.

(2) The H-point of the 95th percentile male test dummy coincides within 13 mm (0.5 inches) in the vertical dimension and 13 mm (0.5 inches) in the horizontal dimension of a point 9 mm (0.4 inches) above and 15 mm (0.6 inches) forward of the H-point of the seat.

(g) Accelerate the dynamic test platform such that it experiences a forward velocity change of 17.3 ± 0.6 kph (10.8 ± 0.37 mph) and all of the points on the acceleration vs. time curve fall within the corridor described in Figure 1 and Table 1. Measure the maximum rearward angular displacement between the head and torso of each dummy.

(h) Calculate the angular displacement from the output of instrumentation placed in the torso and head of the test dummy and an algorithm capable of determining the relative angular displacement to within one degree and conforming to the requirements for a 600 Hz channel class as specified in SAE Recommended Practice J211/1 (March 1995). No data generated after 200 ms from the beginning of the forward acceleration are used in determining angular displacement.

(i) Calculate the HIC from the output of instrumentation placed in the head of the test dummy using the equation in S4.2(a)(1)(ii) of this section and conforming to the requirements for a 1000 Hz channel class as specified in SAE Recommended Practice J211/1 (March 1995). No data generated after 200 ms from the beginning of the forward acceleration are used in determining angular displacement.

S5.2 *Procedures for height and backset.* Demonstrate compliance with S4.2(b)(1), (2), and (4) of this section in accordance with S5.2(a) through (c) of this section.

(a) For adjustable head restraints in front seating positions, adjust the top of the head restraint to its highest position and measure the height. For all other head restraints in front seating positions, measure the height.

(b) For adjustable head restraints, adjust the top of the head restraint to its lowest position and measure the height. For all other head restraints, measure the height.

(c) For adjustable head restraints, adjust the head restraint so that its top is at any height between 750 mm (29.5 inches) and 800 mm (31.5 inches) and to the maximum backset position at that height, and measure the backset. For all other head restraints, measure the backset.

S5.3 *Procedures for measuring gaps.* Demonstrate compliance with S4.2(b)(5) and (6) of this section in accordance with the requirements of S5.3(a) through (c) of this section. For adjustable head restraints, demonstrate compliance with the head restraint adjusted to its minimum height position. Demonstrate compliance with S4.2(b)(5) of this section at any backset position of adjustment. Demonstrate compliance with S4.2(b)(6) of this section at one backset position of adjustment, at the option of the manufacturer.

(a) The area of measurement is anywhere on the front surface of the head restraint or seat with a height greater than 540 mm (21.3 inches) and within a distance of the head restraint vertical centerline of—

(1) 127 mm (5 inches) for bench-type seats; and

(2) 85 mm (3.4 inches) for individual seats.

(b) Place a 165 ± 2 mm (6.5 ± 0.1 inches) diameter spherical head form against any gap such that only two points of contact are made. The surface roughness of the head form is less than 1.6 μm, root mean square.

(c) Determine the gap dimension by measuring the straight line distance between the two contact points, as shown in Figures 2 and 3.

S5.4 *Procedures for energy absorption.* Demonstrate compliance with S4.2(b)(7) of this section in accordance with S5.4(a) through (e) of this section, with the seatback rigidly fixed and adjustable head restraints in any height and backset position of adjustment.

(a) Propel a semispherical head form with a 165 ± 2 mm (6.5 ± 0.1 inches) diameter and a surface roughness of less than 1.6 μm, root mean square, into the head restraint. The head form and associated base have a combined mass of 6.8 ± 0.05 kg (15 ± 0.1 pound).

(b) Instrument the head form with an acceleration sensing device whose output is recorded in a data channel that conforms to the requirements for a 600 Hz channel class as specified in SAE Recommended Practice J211/1 (March 1995). The axis of the acceleration sensing device coincides with the geometric center of the head form and the direction of impact.

(c) At the time of launch, the longitudinal axis of the head form is within 2 degrees of being horizontal and parallel to the vehicle longitudinal axis. The direction of travel is rearward.

(d) The headform travels freely through the air along the path described in S5.4(b) of this section not less than 25 mm (1 inch) before making contact with the head restraint.

(e) Impact the front surface of the seat or head restraint at any point with a height greater than 635 mm (25 inches) and within a distance of the head restraint vertical centerline of—

(1) 105 mm (4.1 inches) for bench-type seats; and

(2) 70 mm (2.8 inches) for individual seats.

S5.5 *Procedures for height retention.* Demonstrate compliance with S4.2(b)(9) of this section in accordance with S5.5 (a) through (d) of this section.

(a) Adjust adjustable head restraints so that the top of the head restraint is at any of the following height positions at any backset position—

(1) For front seating positions—

(i) The highest position;

(ii) Not less than, but closest to 800 mm (31.5 inches);

(iii) Not less than, but closest to 750 mm (29.5 inches); and

(2) For rear seating positions—

(i) The highest position; and

(ii) Not less than, but closest to 750 mm (29.5 inches).

(b) Establish the head form initial reference position by applying a vertical downward load of 50 N ± 1 (11.2 ± 0.2 pounds) to the top of the head restraint at the head restraint centerline using a 165 ± 2 mm (6.5 ± 0.1 inch) diameter spherical head form with a surface roughness of less than 1.6 μm, root mean square.

(c) Increase the load at the rate of 250 ± 50 N/minute (50.6 ± 10 pounds/minute) to at least 500 N (112 pounds) and maintain this load level for not less than 5 seconds.

(d) Reduce the load at the rate of 250 ± 50 N/minute (50.6 ± 11.2 pounds/minute) to 50 ± 1 N (11.2 ± 0.22 pounds) and determine the head form position with respect to its initial reference position.

S5.6 *Procedures for displacement, backset retention and strength.* Demonstrate compliance with S4.2(b)(10) through (12) of this section in accordance with S5.6(a) through (h) of this section. The angular orientation of the load vectors generating the specified moments on the head restraint are initially within 2 degrees of a vertical plane parallel to the vehicle longitudinal centerline and do not deviate more than 2 degrees from their initial orientation.

(a) Adjust adjustable head restraints so that the top of the head restraint is at the height not less than, but closest to—

(1) 800 mm (31.5 inches) for front seating positions; and

(2) 750 mm (29.5 inches) for rear seating positions;

(b) Adjust adjustable head restraints to any backset position;

(c) Place a test device, having the back pan dimensions and torso line (vertical centerline), when viewed laterally, of the head room probe in full back position, of the three dimensional SAE J826 manikin, in the seat;

(d) Establish the displaced torso reference line by creating a rearward moment of 373 ± 7.5 Nm (3,300 ± 66 inch-pounds) about the H-point by applying a force to the seat back through the test device back pan located as specified in S5.6(c) of this section at the rate of 187 ± 37 Nm/minute (1,655 ± 327 inch-pounds/minute). The initial location on the back pan of the moment generating force vector has a height of 290 mm ± 13 mm (11.4 ± 0.5 inches). Apply the force vector normal to the torso line and maintain it within 2 degrees of a vertical plane parallel to the vehicle longitudinal centerline. Constrain the back pan to rotate about the H-point. Rotate the force vector direction with the back pan;

(e) Maintain the position of the test device back pan as established in S5.6(d) of this section. Using a 165 ± 2 mm (6.5 ± 0.1 inch) diameter spherical head form with a surface roughness of less than 1.6 μm, root mean square, establish the head form initial reference position by applying, perpendicular to the displaced torso reference line, a rearward initial load on the head restraint centerline 65 ± 3 mm (2.6 ± 0.1 inches) below the top of the head restraint that will produce a 37 ± 0.7 Nm (327 ± 6.5 inch-pounds) moment about the H-point;

(f) Increase this initial load at the rate of 187 ± 37 Nm/minute (1,655 ± 327 inch-pounds/minute) until a 373 ± 7.5 Nm (3,300 ± 66 inch-pound) moment about the H-point is produced. Maintain the load level producing that moment for not less than 5 seconds and then determine the head form position with respect to the displaced torso reference line;

(g) Reduce the load at the rate of 187 ± 37 Nm/minute (1655 ± 327 inch-pounds/minute) until a 37 ± 0.7 Nm (327 ± 6.5 in-pound) moment about the H-point is produced. While maintaining the load level producing that moment, determine the head form position with respect to its initial reference position; and

(h) Increase the load at the rate of 250 ± 50 N/minute (50.6 ± 10 pounds/minute) to at least 890 N (200 pounds) and maintain this load level for not less than 5 seconds.

S5.7 *Procedures for folding or retracting head restraints for unoccupied rear seats.* Demonstrate compliance with S4.3(b) of this section in accordance with S5.7(a) through (d) of this section:

(a) Place the head restraint into any position meeting the requirements of S4.2 of this section;

(b) Measure the torso reference line angle with the three dimensional SAE J826 manikin;

(c) Fold or retract the head restraint to any position in which its minimum height is less than that specified in S4.2(b)(2) of this section or in which its backset is more than that specified in S4.2(b)(4) of this section; and

(d) Again measure the torso reference line angle.

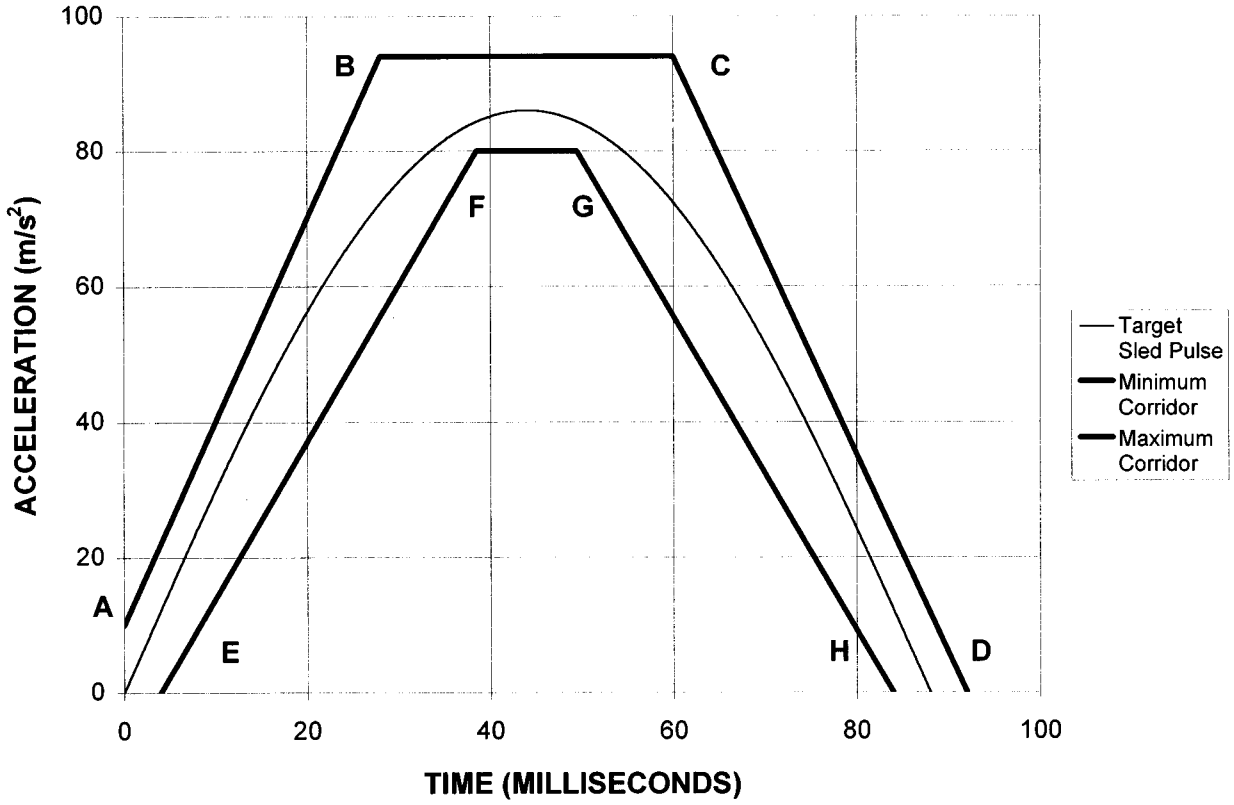

Figure 1 - Sled pulse acceleration corridor. The target acceleration with time expressed in milliseconds is a $= 86 \text{ Sin}(\pi t/88)$ m/s^2, for $\Delta V = 17.3 \pm 0.6$ kph. The time zero for the test is defined by the point when the sled acceleration achieves 2.5 m/s^2 (0.25 G's).

TABLE 1.—SLED PULSE CORRIDOR REFERENCE POINT LOCATIONS

Reference point	time (ms)	Acceleration (m/s^2)
A	0	10
B	28	94
C	60	94
D	92	0
E	4	0
F	38.5	80
G	49.5	80
H	84	0

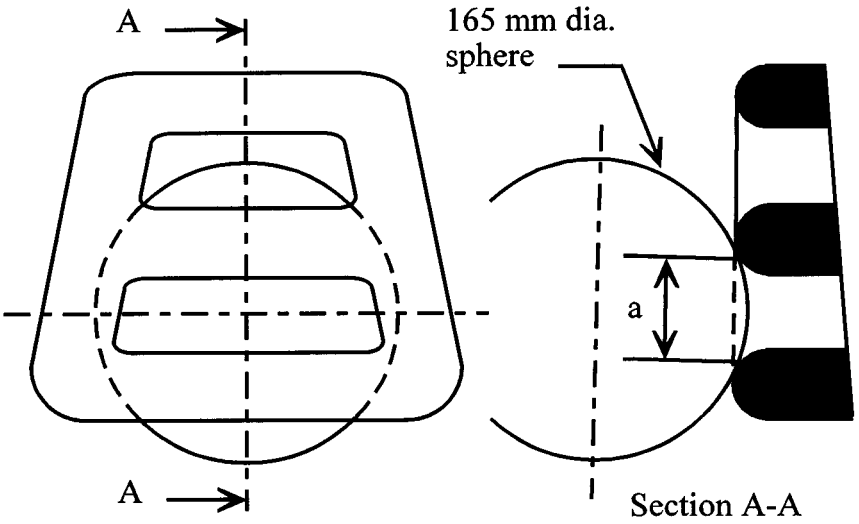

Figure 2 - Measurement of a vertical gap "a".

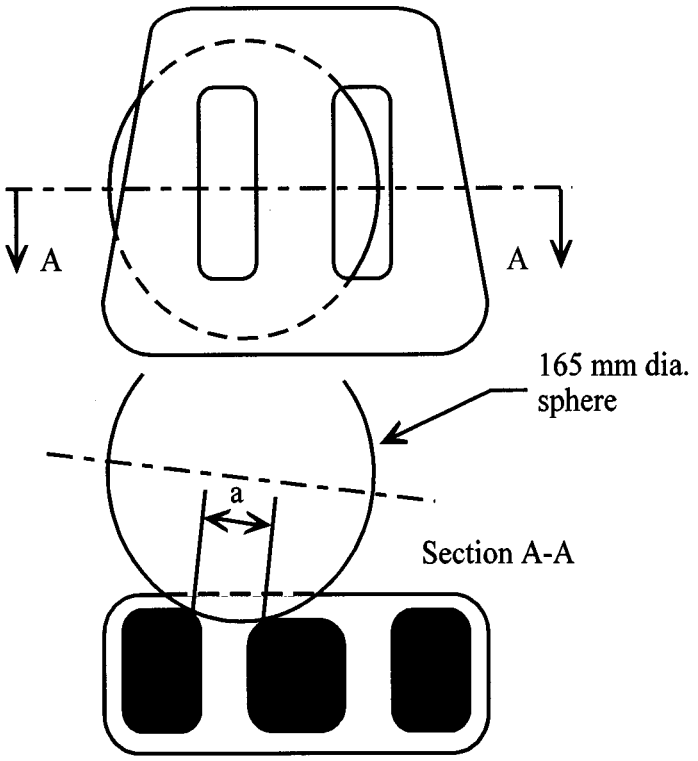

Figure 3 - Measurement of a horizontal gap "a".

Issued on December 22, 2000.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–136 Filed 1–3–01; 8:45 am]

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Federal Register

Thursday,
January 4, 2001

Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Parts 91, 93, 121, 135
Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones; Final Rule
Commercial Routes for the Grand Canyon National Park; Notice

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 93, 121, 135

[Docket No. FAA–1999–5926]

RIN 2120–AG74

Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Delay of effective date.

SUMMARY: On April 4, 2000, the FAA published two final rules for Grand Canyon National Park (GCNP). One rule limited the number of commercial air tour operations in the GCNP Special Flight Rules Area (SFRA); the other modified the airspace of the SFRA. The Commercial Air Tour Limitations final rule was effective on May 4, 2000. The airspace modifications were scheduled to become effective December 1, 2000. On November 20, 2000, the FAA published a final rule delaying the effective date of the Airspace Modification Final Rule until December 28, 2000, so that the FAA could investigate further new safety issues raised by the air tour operators. The FAA has completed its investigation and based on that investigation is delaying the Airspace Modification final rule pending resolution of some safety issues on the east end of the GCNP SFRA. In a companion document in this **Federal Register** the FAA also delays the implementation of the routes in GCNP.

DATES: The final rule Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones, was issued on March 28, 2000, and published in the **Federal Register** on April 4, 2000 (65 FR 17735). It was scheduled to become effective on December 1, 2000. The FAA delayed the effective date of the final rule until December 28, 2000 (65 FR 69846; November 20, 2000). The FAA is now delaying the final rule until April 1, 2001. This action does not affect the Commercial Air Tour Limitations final rule that became effective May 4, 2000.

ADDRESSES: You may view a copy of the final rules, Commercial Air Tour Limitations in the Grand Canyon National Park Special Flight Rules Area and Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones, through the Internet at: *http://dms.dot.gov*, by selecting docket numbers FAA–99–5926 and FAA–99–5927. You may also review the public dockets on these regulations in person in the Docket Office between 9 and 5, Monday through Friday, except Federal holidays. The Docket Office is on the plaza level of the Nassif Building at the Department of Transportation, 400 7th St., SW., Room 401, Washington, DC, 20590.

As an alternative, you may search the **Federal Register**'s Internet site at *http://www.access.gpo.gov/su_docs* for access to the final rules.

You may also request a paper copy of the final rules from the Office of Rulemaking, Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC, 20591, or by calling (202) 267–9680.

FOR FURTHER INFORMATION CONTACT: Howard Nesbitt, Flight Standards Service, (AFS–200), Federal Aviation Administration, Seventh and Maryland Streets, SW., Washington, DC 20591; Telephone: (202) 493–4981.

SUPPLEMENTARY INFORMATION:

Background

On April 4, 2000, the Federal Aviation Administration published two final rules, the Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones (Air Space Modification), and the Commercial Air Tour Limitation in the Grand Canyon National Park Special Flight Rules Area (Commercial Air Tour Limitation). See 65 FR 17736; 65 FR 17708; April 4, 2000. The FAA also simultaneously published a notice of availability of Commercial Routes for the Grand Canyon National Park (Routes Notice). See 65 FR 17698, April 4, 2000. The Commercial Air Tour Limitations final rule became effective on May 4, 2000. The Air Space Modification final rule and the routes set forth in the Routes Notice were scheduled to become effective December 1, 2000. The Final Supplemental Environmental Assessment for Special Flight Rules in the Vicinity of Grand Canyon National Park (SEA) was completed on February 22, 2000, and the Finding of No Significant Impact was issued on February 25, 2000.

On May 8, 2000, The United States Air Tour Association and seven air tour operators (hereinafter collectively referred to as the Air Tour Providers) filed a petition for review of the two final rules before the United States Court of Appeals for the District of Columbia Circuit. The FAA, The Department of Transportation, the Department of Interior, the National Park Service and various federal officials were named as respondents in this action. On May 30, 2000, the Air Tour Providers filed a motion for stay pending review before the Court of Appeals. The federal respondents in this case filed a motion for summary denial on grounds that petitioners had not exhausted their administrative remedies. The Court granted the federal respondents summary denial on July 19, 2000. The Grand Canyon Trust, the National Parks and Conservation Association, the Sierra Club, the Wilderness Society, Friends of the Grand Canyon and Grand Canyon River Guides, Inc. (The Trust) filed a petition for review of the same rules on May 22, 2000. The Court, by motion of the federal respondents, consolidated that case with that of the Air Tour Providers. The Hualapai Indian Tribe of Arizona filed a motion to intervene in the Air Tour Providers petition for review on June 23, 2000. The Court granted that motion on July 19, 2000.

On July 31, 2000, the Air Tour Providers filed a motion for stay before the FAA. Both the Hualapai Indian Tribe and the Trust filed oppositions to the Air Tour Providers' stay motion. On October 11, 2000, (65 FR 60352) the FAA published a disposition of the stay request, denying the stay. On October 25, 2000, the Air Tour Providers filed a Motion for Stay and Emergency Relief Pending Review of an Agency Order with the Court of Appeals. The federal respondents filed their Opposition to Petitioner's Motion for Stay Pending Review and Notification of Administrative Stay of Route and Airspace Rules on November 2, 2000. The FAA issued an administrative stay of the routes and airspace until December 28, 2000, so that it could further investigate some new safety allegations raised by the Air Tour Providers during the course of litigation.

Agency Action

In the Air Tour Providers' motion filed October 25, 2000, the Air Tour Providers raised some specific safety allegations about the routes in the Dragon Corridor (Green Route 2 and 2R), the routes north of the Zuni Point Corridor (Green 1; Black 1) and east of the Desert View Flight Free Zone (Black 2 and Green 3). These safety issues were not previously understood by the FAA. The FAA has investigated the allegations and determined that additional measures need to be taken with regard to the east end of the GCNP SFRA to ensure the safest routes possible. Because of the interrelationship between the routes and the airspace in the GCNP SFRA, it is

necessary to stay the Airspace Modification final rule pending the resolution of the safety issues. The FAA is staying the Airspace Modification final rule until the east end route issues are resolved. In a parallel change, SFAR 50–2 is reinstated and extended until April 1, 2001; it is republished in this **Federal Register**. The FAA intends on having these issues resolved by or before April 1, 2001.

The FAA intends on implementing the entire route system by spring 2001, in time for summer tour season. In the event the FAA cannot resolve the east end routes in a timely manner, it will likely implement some or all of the west end routes (Blue Direct North, Blue Direct South, Green 4, Blue 2 and the Brown routes as shown on the April 4, 2000 map) by spring 2001. Elsewhere in the **Federal Register**, the FAA publishes a notice delaying the effective date of the routes published on April 4, 2000. Additionally, on December 13, 2000, the FAA published a notice of availability of routes so that interested parties may obtain a copy of a map depicting the proposed modifications to the routes.

Immediate Effective Date

The FAA finds that good cause exists under 5 U.S.C. 553(d) for this final rule to become final rule upon issuance. The FAA and NPS must implement new air tour routes, flight-free zones, and flight corridors at the same time in order to transition to a new operating environment in GCNP. The FAA has determined that because new safety concerns have been raised that need to be investigated further, it is paramount that this rule become effective immediately.

Economic Evaluation

In issuing the final rule for the Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zone, the FAA prepared a cost benefit analysis of the rule. A copy of the regulatory evaluation is located in docket Number 99–5926, Amendment No. 93–80. This delay of the effective date for the final rule will not affect that evaluation, although the delay in the implementation of the FFZs may be temporarily cost relieving for air tour operators.

Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended, the FAA completed a final regulatory flexibility analysis of the final rule. This extended delay of the effective date will not affect that supplemental analysis.

Federalism Implications

This amendment will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this amendment would not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104–4 on March 22, 1995, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure of $100 million or more (when adjusted annually for inflation) in any one year by State, local, and tribal governments in the aggregate, or by the private sector. Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed ''significant intergovernmental mandate.'' A ''significant intergovernmental mandate'' under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments in the aggregate of $100 million (adjusted annually for inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that, before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan, which, among other things, must provide for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity for these small governments to provide input in the development of regulatory proposals. The FAA has determined that this rule will not impose any unfunded mandates.

List of Subjects

14 CFR Part 91, 121, 135

Aircraft, Airmen, Aviation safety

14 CFR Part 93

Air traffic control, Airports, Navigation (Air)

Adoption of Amendments

Accordingly, the Federal Aviation Administration (FAA) amends 14 CFR parts 91, 93, 121, and 135 as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40109, 40113, 44502, 44514, 44701, 44719, 46301.

PART 121—[AMENDED]

1a. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44901, 44903–44904, 44912, 46105.

PART 135—[AMENDED]

1b. The authority citation for Part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44915–44717, 44722.

2. In Parts 91, 121, and 135, SFAR 50–2 is reinstated and republished, and section 9 is revised. The map that accompanied SFAR 50–2 is not reinstated, but a note regarding its availability is added. The republished, revised, and added text reads as follows:

Special Federal Aviation Regulations

SFAR No. 50–2—Special Flight Rules in the Vicinity of the Grand Canyon National Park, AZ

Section 1. Applicability. This rule prescribes special operating rules for all persons operating aircraft in the following airspace, designated as the Grand Canyon National Park Special Flight Rules Area:

That airspace extending upward from the surface up to but not including 14,500 feet MSL within an area bounded by a line beginning at lat. 36°09′30″ N., long. 114°03′00″ W.; northeast to lat. 36°14′00″ N., long. 113°09′50″ W.; thence northeast along the boundary of the Grand Canyon National Park to lat. 36°24′47″ N., long. 112°52′00″ W.; to lat. 36°30′30″ N., long. 112°36′15″ W. to lat. 36°21′30″ N., long. 112°00′00″ W. to lat. 36°35′30″ N., long. 111°53′10″ W., to lat. 36°53′00″ N., long. 111°36′45″ W. to lat. 36°53′00″ N., long. 111°33′00″ W.; to lat. 36°19′00″ N., long. 111°50′50″ W.; to lat. 36°17′00″ N., long. 111°42′00″ W.; to lat. 35°59′30″ N., long. 111°42′00″ W.; to lat. 35°57′30″ N., long. 112°03′55″ W.; thence counterclockwise via the 5 statute mile radius of the Grand Canyon Airport airport reference point (lat. 35°57′09″ N., long. 112°08′47″ W.) to lat. 35°57′30″ N., long. 112°14′00″ W.; to lat. 35°57′30″ N., long. 113°11′00″ W.; to lat. 35°42′30″ N., long. 113°11′00″ W.; to 35°38′30″ N.; long. 113°27′30″ W.; thence counterclockwise via

the 5 statute mile radius of the Peach Springs VORTAC to lat. 35°41′20″ N., long. 113°36′00″ W.; to lat. 35°55′25″ N., long. 113°49′10″ W.; to lat. 35°57′45″ N., 113°45′20″ W.; thence northwest along the park boundary to lat. 36°02′20″ N., long. 113°50′15″ W.; to 36°00′10″ N., long. 113°53′45″ W.; thence to the point of beginning.

Section 3. Aircraft operations: general. Except in an emergency, no person may operate an aircraft in the Special Flight Rules, Area under VFR on or after September 22, 1988, or under IFR on or after April 6, 1989, unless the operation—(a) Is conducted in accordance with the following procedures:

Note: The following procedures do not relieve the pilot from see-and-avoid responsibility or compliance with FAR 91.119.

(1) Unless necessary to maintain a safe distance from other aircraft or terrain—

(i) Remain clear of the areas described in Section 4; and

(ii) Remain at or above the following altitudes in each sector of the canyon:

Eastern section from Lees Ferry to North Canyon and North Canyon to Boundary Ridge: as prescribed in Section 5.

Boundary Ridge to Supai Point (Yumtheska Point): 10,000 feet MSL.

Western section from Diamond Creek to the Grant Wash Cliffs: 8,000 feet MSL.

(2) Proceed through the four flight corridors describe in Section 4 at the following altitudes unless otherwise authorized in writing by the Flight Standards District Office:

Northbound

11,500 or
13,500 feet MSL

Southbound

>10,500 or
>12,500 feet MSL

(b) Is authorized in writing by the Flight Standards District Office and is conducted in compliance with the conditions contained in that authorization. Normally authorization will be granted for operation in the areas described in Section 4 or below the altitudes listed in Section 5 only for operations of aircraft necessary for law enforcement, firefighting, emergency medical treatment/evacuation of persons in the vicinity of the Park; for support of Park maintenance or activities; or for aerial access to and maintenance of other property located within the Special Flight Rules Area. Authorization may be issued on a continuing basis. (c)(1) Prior to November 1, 1988, is conducted in accordance with a specific authorization to operate in that airspace incorporated in the operator's part 135 operations specifications in accordance with the provisions of SFAR 50–1, notwithstanding the provisions of Sections 4 and 5; and

(2) On or after November 1, 1988, is conducted in accordance with a specific authorization to operate in that airspace incorporated in the operated in the operator's operations specifications and approved by the Flight Standards District Office in accordance with the provisions of SFAR 50–2.

(d) Is a search and rescue mission directed by the U.S. Air Force Rescue Coordination Center.

(e) Is conducted within 3 nautical miles of Whitmore Airstrip, Pearce Ferry Airstrip, North Rim Airstrip, Cliff Dwellers Airstrip, or Marble Canyon Airstrip at an altitudes less than 3,000 feet above airport elevation, for the purpose of landing at or taking off from that facility. Or

(f) Is conducted under an IFR clearance and the pilot is acting in accordance with ATC instructions. An IFR flight plan may not be filed on a route or at an altitude that would require operation in an area described in Section 4.

Section 4. Flight-free zones. Except in an emergency or if otherwise necessary for safety of flight, or unless otherwise authorized by the Flight Standards District Office for a purpose listed in Section 3(b), no person may operate an aircraft in the Special Flight Rules Area within the following areas:

(a) Desert View Flight-Free Zone. Within an area bounded by a line beginning at Lat. 35°59′30″ N., Long. 111°46′20″ W. to 35°59′30″ N., Long. 111°52′45″ W.; to Lat. 36°04′50″ N., Long. 111°52′00″ W.; to Lat. 36°06′00″ N., Long. 111°46′20″ W.; to the point of origin; but not including the airspace at and above 10,500 feet MSL within 1 mile of the western boundary of the zone. The area between the Desert View and Bright Angel Flight-Free Zones is designated the ''Zuni Point Corridor.''

(b) Bright Angel Flight-Free Zone. Within an area bounded by a line beginning at Lat. 35°59′30″ N., Long. 111°55′30″ W.; to Lat. 35°59′30″ N., Long. 112°04′00″ W.; thence counterclockwise via the 5 statute mile radius of the Grand Canyon Airport point (Lat. 35°57′09″ N., Long. 112°08′47″ W.) to Lat. 36°01′30″ N., Long. 112°11′00″ W.; to Lat. 36°06′15″ N., Long. 112°12′50″ W.; to Lat. 36°14′40″ N., Long. 112°08′50″ W.; to Lat. 36°14′40″ N., Long. 111°57′30″ W.; to Lat. 36°12′30″ N., Long. 111°53′50″ W.; to the point of origin; but not including the airspace at and above 10,500 feet MSL within 1 mile of the eastern boundary between the southern boundary and Lat. 36°04′50″ N. or the airspace at and above 10,500 feet MSL within 2 miles of the northwest boundary. The area bounded by the Bright Angel and Shinumo Flight-Free Zones is designated the ''Dragon Corridor.''

(c) Shinumo Flight-Free Zone. Within an area bounded by a line beginning at Lat. 36°04′00″ N., Long. 112°16′40″ W.; northwest along the park boundary to a point at Lat. 36°12′47″ N., Long. 112°30′53″ W.; to Lat. 36°21′15″ N., Long. 112°20′20″ W.; east along the park boundary to Lat. 36°21′15″ N., Long. 112°13′55″ W.; to Lat. 36°14′40″ N., Long. 112°11′25″ W.; to the point of origin. The area between the Thunder River/Toroweap and Shinumo Flight Free Zones is designated the ''Fossil Canyon Corridor.''

(d) Toroweap/Thunder River Flight-Free Zone. Within an area bounded by a line beginning at Lat. 36°22′45″ N., Long. 112°20′35″ W.; thence northwest along the boundary of the Grand Canyon National Park to Lat. 36°17′48″ N., Long. 113°03′15″ W.; to Lat. 36°15′00″ N., Long. 113°07′10″ W.; to Lat. 36°10′30″ N., Long. 113°07′10″ W.; thence east along the Colorado River to the confluence of Havasu Canyon (Lat. 36°18′40″ N., Long. 112°45′45″ W.;) including that area within a 1.5 nautical mile radius of Toroweap Overlook (Lat. 36°12′45″ N., Long. 113°03′30″ W.); to the point of origin; but not including the following airspace designated as the ''Tuckup Corridor'': at or above 10,500 feet MSL within 2 nautical miles either side of a line extending between Lat. 36°24′47″ N., Long. 112°48′50″ W. and Lat. 36°17′10″ N., Long. 112°48′50″ W.; to the point of origin.

Section 5. Minimum flight altitudes. Except in an emergency or if otherwise necessary for safety of flight, or unless otherwise authorized by the Flight Standards District Office for a purpose listed in Section 3(b), no person may operate an aircraft in the Special Flight Rules Area at an altitude lower than the following:

(a) Eastern section from Lees Ferry to North Canyon: 5,000 feet MSL.

(b) Eastern section from North Canyon to Boundary Ridge: 6,000 feet MSL.

(c) Boundary Ridge to Supai (Yumtheska) Point: 7,500 feet MSL.

(d) Supai Point to Diamond Creek: 6,500 feet MSL.

(e) Western section from Diamond Creek to the Grand Wash Cliffs: 5,000 feet MSL.

Section 9. Termination date. Sections 1. Applicability, Section 4, Flight-free zones, and Section 5. Minimum flight altitudes, expire on 0901 UTC, April 1, 2001.

Note: An informational map of the special flight rules areas defined by SFAR 50–2 is available on the Office of Rulemaking's website at *http://www.faa.gov/avr/armhome.htm.* A paper copy is available from the Office of Rulemaking by calling Linda Williams at (202) 267–9685.

PART 93—SPECIAL AIR TRAFFIC RULES AND AIRPORT TRAFFIC PATTERNS

3. The authority citation for part 93 continues to read as follows:

Authority: 49 USC 106(g), 40103, 40113, 40120, 44101,44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46502, 46504, 46506–46507, 47122, 47508, 47528–47531.

§§ 93.305, 93.307 [Delayed]

4. Sections 93.305 and 93.307 published on December 31, 1996 (61 FR 69330), corrected at 62 FR 2445 (January 16, 1997), and delayed at 65 FR 5397 (February 3, 2000) and made effective December 1, 2000 in a rule published on April 4, 2000 (65 FR 17736) and delayed until December 28, 2000 (65 FR 69846, November 20, 2000) are further delayed until April 1, 2001.

§§ 93.301, 93.305, 93.307, 93.309 [Delayed]

5. The amendments to Section 93.301, 93.305, 93.307 and 93.309 published on April 4, 2000 (65 FR 17736) and delayed until December 28, 2000 (65 FR 69846, November 20, 2000) are further delayed until April 1, 2001.

Issued in Washington DC, on December 28, 2000.

Jane F. Garvey,

Administrator.

[FR Doc. 00–33457 Filed 12–28–00; 4:08 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Routes for the Grand Canyon National Park

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice; delay of effective date.

SUMMARY: On April 4, 2000, the FAA issued a Notice of Availability of commercial routes in the Grand Canyon National Park (GCNP) Special Flight Rules Area (SFRA) setting forth new routes available for GCNP. Additionally, on that same day, the FAA published a final rule modifying the airspace of the SFRA. The new routes and the Airspace Modification final rule are interrelated. Based on safety concerns for air tours in the east end of the GCNPSFRA expressed by air tour operators, the FAA delays the effective date of the route system until the issues in the east end of the GCNP SFRA are resolved. The FAA also publishes in this **Federal Register** a companion document delaying the effective date for the Airspace Modification final rule.

DATES: The Notice of availability for Commercial Routes for the Grand Canyon National Park was issued on March 28, 2000, and published in the **Federal Register** on April 4, 2000 (65 FR 17698). It was scheduled to become effective on December 1, 2000 and delayed until December 28, 2000. The FAA is further delaying implementation of the routes until the issues are resolved.

FOR FURTHER INFORMATION CONTACT: Howard Nesbitt, Flight Standards Service, (AFS–200), Federal Aviation Administration, Seventh and Maryland Streets, SW., Washington, DC 20591; Telephone: (202) 493–4981.

SUPPLEMENTARY INFORMATION:

Background

On April 4, 2000, the Federal Aviation Administration published two final rules, the Modification of the Dimensions of the Grand Canyon National Park Special Flight Rules Area and Flight Free Zones (Air Space Modification), and the Commercial Air Tour Limitation in the Grand Canyon National Park Special Flight Rules Area (Commercial Air Tour Limitation). See 65 FR 17736; 65 FR 17708; April 4, 2000. The FAA also simultaneously published a notice of availability of Commercial Routes for the Grand Canyon National Park (Routes Notice). See 65 FR 17698, April 4, 2000. The Commercial Air Tour Limitations final rule became effective on May 4, 2000. The Air Space Modification final rule and the routes set forth in the Routes Notice were scheduled to become effective December 1, 2000. The effective date of the Air Space Modification final rule and the new routes was delayed to provide the air tour operators ample opportunity to train on the new route system during the non-tour season. The Final Supplemental Environmental Assessment for Special Flight Rules in the Vicinity of Grand Canyon National Park (SEA) was completed on February 22, 2000, and the Finding of No Significant Impact was issued on February 25, 2000.

On May 8, 2000, The United States Air Tour Association and seven air tour operators (hereinafter collectively referred to as the Air Tour Providers) filed a petition for review of the two final rules before the United States Court of Appeals for the District of Columbia Circuit. This petition did not cover the Routes Notice. The FAA, The Department of Transportation, the Department of Interior, the National Park Service and various federal officials were named as respondents in this action. On May 30, 2000, the Air Tour Providers filed a motion for stay pending review before the Court of Appeals. The federal respondents in this case filed a motion for summary denial on grounds that petitioners had not exhausted their administrative remedies. The Court granted the federal respondents summary denial on July 19, 2000. The Grand Canyon Trust, the National Parks and Conservation Association, the Sierra Club, the Wilderness Society, Friends of the Grand Canyon and Grand Canyon River Guides, Inc. (The Trust) filed a petition for review of the same rules on May 22, 2000. The Court, by motion of the federal respondents, consolidated that case with that of the Air Tour Providers. The Hualapai Indian Tribe of Arizona filed a motion to intervene in the Air Tour Providers petition for review on June 23, 2000. The Court granted that motion on July 19, 2000.

On July 31, 2000, the Air Tour Providers filed a motion for stay before the FAA. Both the Hualapai Indian Tribe and the Trust filed oppositions to the Air Tour Providers' stay motion. On October 11, 2000, (65 FR 60352) the FAA published a disposition of the stay request, denying the stay. On October 25, 2000, the Air Tour Providers filed a Motion for Stay and Emergency Relief Pending Review of an Agency Order with the Court of Appeals. The federal respondents filed their Opposition to Petitioner's Motion for Stay Pending Review and Notification of Administrative Stay of Route and Airspace Rules on November 2, 2000. The FAA stayed the routes and airspace until December 28, 2000 so that it could investigate further some new safety allegations raised by the Air Tour Providers during the course of the litigation. The FAA has analyzed these safety issues and has determined that further modifications are necessary in order to address some safety problems identified by the Air Tour Providers.

Agency Action

The Air Tour Providers' Motion, filed October 25, 2000, raised some specific safety allegations about the routes in the Dragon Corridor (Green Route 2 and 2R), Zuni Point Corridor (Green 1; Black 1) and east of the Desert View Flight Free Zone (Black 2 and Green 3). These safety issues were not previously understood by the FAA. The FAA has now had the opportunity to conduct an initial investigation of the east end route structure and has determined that there likely are some improvements that can be made to address concerns raised by the Air Tour Operators. Thus, the FAA is delaying the effective date of the new routes until the issues on the east end of the GCNP SFRA are resolved. The FAA intends the routes to be implemented by or before April 1, 2001. Elsewhere in this **Federal Register,** the FAA also is delaying the effective date of the airspace changes adopted in the April 4, 2000 final rule.

The FAA notes that if the issues on the east end cannot be resolved by April 1, 2001, the FAA may implement the routes on the west end of the GCNP SFRA (Blue Direct North, Blue Direct South, Green 4, Blue 2 and Brown routes) while maintaining the SFAR 50–2 route structure on the east end. The goal for a partial implementation also is spring 2001.

Dated: Issued in Washington, DC on December 22, 2000.

Jane F. Garvey,

Administrator.

[FR Doc. 00–33291 Filed 12–28–00; 4:08 pm]

BILLING CODE 4910–13–M

Federal Register

Thursday,
January 4, 2001

Part V

Department of Housing and Urban Development

24 CFR Part 941
Public Housing Total Development Cost; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 941

[Docket No. FR–4489–P–01]

RIN 2577–AC05

Public Housing Total Development Cost

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend HUD's regulations governing Total Development Cost (TDC) for the development of public housing. The amendments would implement statutory changes made to the statutory TDC requirements. Among other changes, this proposed rule would limit the amount of public housing funds that a public housing agency may use to pay for housing construction costs. The rule would also provide that demolition and environmental hazard remediation costs are included in TDC only to the extent that such costs are associated with the replacement of public housing units on the project site.

DATES: *Comments Due Date:* March 5, 2001.

ADDRESSES: Interested persons are invited to submit written comments regarding this proposed rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Comments should refer to the above docket number and title. A copy of each comment submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address. Facsimile (FAX) comments will not be accepted.

FOR FURTHER INFORMATION CONTACT: William Flood, Office of Public and Indian Housing, Room 4134, U.S. Department of Housing and Urban Development, 451 Seventh St., SW., Washington, DC 20410; telephone (202) 708–1640 (this is not a toll-free telephone number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

The United States Housing Act (42 U.S.C. 1437 *et seq.*) (the 1937 Act) establishes the statutory framework for HUD's public and assisted housing programs. The 1937 Act authorizes HUD to assist public housing agencies (PHAs) with the development and operation of public housing projects, and sets forth several requirements regarding public housing development. Two such statutory requirements regarding the development of public housing are found in sections 3(c)(1) and 6(b) of the 1937 Act.

Section 3(c)(1) of the 1937 Act (42 U.S.C. 1437a(c)(1)) defines the terms ''development'' and ''development cost.'' Specifically, section 3(c)(1) defines development to mean ''any and all undertakings necessary for planning, land acquisition, demolition, construction, or equipment, in connection with a'' public housing project. Further, section 3(c)(1) specifies that development cost ''comprises the costs incurred by a [PHA] in such undertakings and their necessary financing (including the payment of carrying charges), and in otherwise carrying out the development of'' the public housing project.

Section 6(b)(1) of the 1937 Act (42 U.S.C. 1437d(b)(1)) limits the amount of public housing funds provided by HUD that a PHA may use to pay for the costs of developing a public housing project, unless HUD provides otherwise. (For purposes of this preamble, the term ''public housing funds'' includes public housing Capital Funds, public housing development funds, modernization funds converted to development purposes, and HOPE VI program funds.)

Section 6(b)(2) of the 1937 Act (42 U.S.C. 1437d(b)(2)) directs HUD to determine total development cost by multiplying the ''construction cost guideline'' for the project ''by averaging the current construction costs, as listed in not less than two nationally recognized residential construction cost indices, for publicly bid construction of a good and sound quality.'' The construction cost guideline is then multiplied by 1.6 for elevator type structures and by 1.75 for non-elevator construction. The statutory total development cost (TDC) limit is calculated by adding the resulting amounts for all units in the public housing project.

II. Public Housing Reform

On October 21, 1998, President Clinton signed into law HUD's fiscal year (FY) 1999 Appropriations Act, which includes the Quality Housing and Work Responsibility Act of 1998 (title V of the FY 1999 HUD Appropriations Act; Public Law 105–276; 112 Stat. 2461) (referred to in this preamble as the ''Public Housing Reform Act''). The Public Housing Reform Act constitutes a substantial overhaul of HUD's public housing and Section 8 assistance programs. The Public Housing Reform Act enacts into law many of the reforms originally proposed in Secretary Andrew Cuomo's HUD 2020 Management Reform Plan, HUD's public housing bill and Congressional bills that are directed at revitalizing and improving HUD's public housing and Section 8 tenant-based programs.

Section 520 of the Public Housing Reform Act (entitled ''Total Development Costs'') makes three revisions to the public housing development requirements set forth in the 1937 Act. First, section 520(a) amends the statutory definition of ''development cost'' to specify that such cost ''does not include the costs associated with demolition of or remediation of environmental hazards associated with public housing units that will not be replaced on the project site, or other extraordinary site costs as determined by the Secretary'' of HUD.

Section 520(b) of the Public Housing Reform Act amends section 6(b) of the 1937 Act to provide that the statutory TDC limit applies only to public housing funds provided by HUD for use in the development of public housing, and does not apply to other funding—such as funding under the HOME Investment Partnerships Program or funding under the Community Development Block Grants (CDBG) Program.

Section 520(b) also provides that HUD may limit the amount of public housing funds that a PHA may use to pay for housing construction costs, including ''the actual hard costs for the construction of units, builder's overhead and profit, utilities from the street, and finish landscaping.''

III. This Proposed Rule

HUD's regulations implementing the public housing development requirements of the 1937 Act are located at 24 CFR part 941. This proposed rule would update part 941 and incorporate the statutory amendments made by section 520 of the Public Housing Reform Act. The following summarizes the major amendments that would be made to part 941 by this proposed rule:

A. Amendments to the Definition of TDC (§ 941.103)

1. *TDC sub-allocations.* In order to better understand and control the actual costs involved in the development of a project, the proposed rule would amend the definition of TDC in § 941.103 to provide that the maximum TDC allocation consists of two sub-

allocations: housing construction costs and community renewal costs. This will enable HUD to identify the actual costs associated with the different aspects of the whole development program.

Housing construction costs are the costs allocated to construct the dwelling units. The proposed rule would define the TDC housing construction sub-allocation to include costs attributable to:

- Dwelling unit hard costs (including construction and equipment);
- Builder's overhead and profit;
- On site streets and utilities from the street;
- Finish landscaping; and
- Davis-Bacon wage rates, as applicable.

Community renewal costs are the balance of the development costs remaining within the TDC limit after the housing construction cost allocation is subtracted from the TDC limit. Community renewal costs include the costs allocated to renewal of the community, as well as certain other costs associated with the development of the public housing project. The proposed rule would define the community renewal sub-allocation to include costs attributable to:

- Planning (including proposal preparation);
- Administration;
- Site acquisition;
- Relocation;
- Demolition and site remediation of environmental hazards associated with public housing units that will be replaced on the project site;
- Interest and carrying charges;
- Off-site facilities;
- Community buildings and other HUD-approved non-dwelling facilities;
- A contingency allowance;
- Insurance premiums; and
- Any initial operating deficit.

2. *Demolition and site remediation costs.* The proposed rule would revise the definition of TDC to provide that demolition and site remediation costs are included in TDC only to the extent that such costs are associated with the development of public housing units on the project site.

3. *Extraordinary site costs.* In accordance with section 520 of the Public Housing Reform Act, the proposed rule would also specify that extraordinary site costs as approved by HUD are not included in TDC. The proposed rule provides that extraordinary site costs may include, but are not limited to: (1) removal or replacement of extensive underground utility systems; (2) extensive rock and/or soil removal and replacement; (3) construction of extensive street and other public improvements; and (4) dealing with unusual site conditions such as slopes, terraces, water catchments, and lakes. The proposed rule would require that extraordinary site costs be verified by an independent certified engineer and approved by HUD.

4. *TDC limit for purposes of the Annual Contributions Contract.* Currently, the definition of TDC in § 941.103 contains the following provision:

> The total development cost in the proposal, when reviewed and approved by HUD, becomes the maximum total development cost stated in the ACC. Upon completion of the project, the actual development cost is determined, and this becomes the maximum total development cost of the project for purposes of the ACC.

For purposes of clarity, this proposed rule would relocate this provision to § 941.306, which sets forth the maximum development cost requirements for public housing development.

B. Amendments to Maximum Development Cost Requirements (§ 941.306)

The proposed rule would entirely revise § 941.306, which establishes the maximum development cost requirements. The following summarizes the major changes that would be made to § 941.306 by this proposed rule:

1. *Exceptions to TDC limit.* Section 6(b) of the 1937 Act permits the Secretary of HUD to approve development costs higher than the TDC for a public housing project. Section 941.306(a) describes the conditions under which the Secretary would approve an exception to the TDC. HUD has recently undertaken an intensive process of analysis and consultation to establish appropriate cost limits and, therefore, does not foresee circumstances under which an exception would be warranted. Accordingly, this proposed rule would remove the regulatory language regarding exceptions to the TDC limits.

2. *Elaboration of TDC calculation procedures.* Currently, § 941.306(b) provides that ''HUD will determine the maximum * * * TDC in accordance with section 6 of the'' 1937 Act. For the convenience of readers, this proposed rule would revise § 941.306(b) to provide greater detail regarding the procedures used by HUD in determining the TDC for a public housing project.

In Senate colloquy before passage of the Public Housing Reform Act, Senator Mack noted that HUD ''should interpret [section 6(b)(2) of the 1937 Act] as requiring the use of indices such as the R.S. Means cost index for construction of 'average' quality and the Marshal & Swift cost index for construction of 'good' quality'' (Congressional Record of October 8, 1998, S. 11840). Accordingly, the proposed rule would also specify that HUD will be using these two indices to calculate TDC. HUD has the discretion to change the cost indices to other such indices which reflect comparable housing construction quality.

3. *Limit on housing construction costs.* In accordance with section 520 of the Public Housing Reform Act, HUD has decided to limit the amount of public housing funds that a PHA may use to pay for housing construction costs.

HUD will determine the limit on housing construction costs by averaging the housing construction costs listed in at least two nationally recognized residential housing construction cost indices for specific bedroom sizes and structure types. This formula is the same as that used in determining the project TDC, with the exception that the multipliers (for elevator type structures and non-elevator type structures) are not applied to the average of the two construction indices. HUD will use the R.S. Means cost index for construction of ''average'' quality and the Marshall & Swift cost index for construction of ''good'' quality to calculate the limit on housing construction costs (HUD has the discretion to change the cost indices to other such indices which reflect comparable housing construction quality). The balance of the public housing funds provided by HUD for the development of the project (up to the maximum TDC allocation) may be used to pay for community renewal costs.

4. *TDC applicability to public housing funds.* The proposed rule clarifies that the TDC limit applies only to costs paid from public housing funds provided by HUD to a PHA for use in the development of public housing. As provided in section 520 of the Public Housing Reform Act, the TDC limit does not apply to other funding provided by HUD to a PHA. A PHA may use funding sources not subject to the maximum TDC limitation (such as CDBG funds, HOME funds, low-income tax credits, private donations, and private financing) to cover project costs that exceed the housing cost cap or the maximum TDC amount.

IV. Findings and Certifications

Regulatory Planning and Review

The Office of Management and Budget (OMB) reviewed this rule under

Executive Order 12866, *Regulatory Planning and Review.* OMB determined that this rule is a ''significant regulatory action'' as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to this rule as a result of that review are identified in the docket file, which is available for public inspection in the office of the Department's Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410–0500.

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). The Finding is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC.

Federalism Impact

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) (the RFA), has reviewed and approved this proposed rule and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. The reasons for HUD's determination are as follows:

(1) *A Substantial Number of Small Entities Will Not Be Affected.* The proposed rule is exclusively concerned with public housing agencies that receive capital assistance provided by HUD for the development of public housing. The proposed rule would update HUD's public housing development regulations at 24 CFR part 941 to incorporate the statutory amendments made by section 520 of the Public Housing Reform Act. Under the definition of ''Small governmental jurisdiction'' in section 601(5) of the RFA, the provisions of the RFA are applicable only to those few public housing agencies that are part of a political jurisdiction with a population of under 50,000 persons. The number of entities potentially affected by this rule is therefore not substantial.

(2) *No Significant Economic Impact.* The proposed regulatory amendments will not change the amount of capital funding available to public housing agencies for the development of public housing. Accordingly, the economic impact of this rule will not be significant, and it will not affect a substantial number of small entities. Notwithstanding HUD's determination that this rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule does not impose any Federal mandates on any State, local, or tribal governments or the private sector within the meaning of Unfunded Mandates Reform Act of 1995.

List of Subjects in 24 CFR Part 941

Grant programs—housing and community development, Loan programs—housing and community development, Public housing, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD proposes to amend 24 CFR part 941 as follows:

PART 941—PUBLIC HOUSING DEVELOPMENT

1. The authority citation for 24 CFR part 941 continues to read as follows:

Authority: 42 U.S.C. 1437b, 1437c, 1437g, and 3535(d).

2. Revise § 941.102(b)(3) to read as follows:

§ 941.102 Development methods and funding.

* * * * *

(b) * * *

(3) Funds available to it from any other source, consistent with § 941.306(e), or as may be otherwise approved by HUD.

* * * * *

3. In § 941.103 revise the definition of ''*Total development cost (TDC)*'' to read as follows:

§ 941.103 Definitions.

* * * * *

Total Development Cost (TDC). (1) The sum of all HUD-approved:

(i) Housing construction costs (as defined in paragraph (2) of this definition); and

(ii) Community renewal costs (as defined in paragraph (3) of this definition).

(2) Housing construction costs are the development costs attributable to:

(i) The dwelling unit hard costs (including construction and equipment);

(ii) Builder's overhead and profit;

(iii) On-site streets and utilities from the street;

(iv) Finish landscaping;

(v) Davis-Bacon wage rates, as applicable.

(3) Community renewal costs are the development costs attributable to:

(i) Planning (including proposal preparation);

(ii) Administration;

(iii) Site acquisition;

(iv) Relocation;

(v) Demolition and site remediation of environmental hazards associated with public housing units that will be replaced on the project site;

(vi) Interest and carrying charges;

(vii) Off-site facilities;

(viii) Community buildings and non-dwelling facilities;

(ix) A contingency allowance;

(x) Insurance premiums; and

(xi) Any initial operating deficit.

(4) TDC does not include extraordinary site costs, or demolition or environmental remediation costs associated with public housing units that will not be replaced on the site. Extraordinary site costs must be verified by an independent certified engineer and approved by HUD. Examples of extraordinary site costs include, but are not limited to:

(i) Removal or replacement of extensive underground utility systems;

(ii) Extensive rock and/or soil removal and replacement;

(iii) Construction of extensive street and other public improvements; and

(iv) Dealing with unusual site conditions such as slopes, terraces, water catchments, lakes, etc.

* * * * *

4. Revise § 941.306 to read as follows:

§ 941.306 Maximum development cost.

(a) *Limit on approved HUD funds to TDC.* (1) No funds provided by HUD

under the Act or the HOPE VI program may be used to pay development costs in excess of the TDC.

(2) The total development cost in the proposal, when reviewed and approved by HUD, becomes the maximum TDC stated in the ACC. Upon completion of the project, the actual development cost is determined, and this becomes the maximum TDC of the project for purposes of the ACC.

(b) *Determination of maximum TDC.* HUD will determine the maximum TDC for a public housing project as follows:

(1) *Step 1: Unit construction cost guideline.* HUD will first determine the ''construction cost guideline'' for the project by averaging the current construction costs as listed in two nationally recognized residential construction cost indices for publicly bid construction of a good and sound quality for specific bedroom sizes and structure types. The two indices HUD will use for this purpose are the R.S. Means cost index for construction of ''average'' quality and the Marshal & Swift cost index for construction of ''good'' quality. HUD has the discretion to change the cost indices to other such indices which reflect comparable housing construction quality.

(2) *Step 2: Bedroom size and structure types.* The construction cost guideline is then multiplied by the number of units for each bedroom size and structure type.

(3) *Step 3: Elevator and non-elevator type structures.* HUD will then multiply the resulting amounts from step 2 by 1.6 for elevator type structures and by 1.75 for non-elevator type structures.

(4) *Step 4: Maximum TDC.* The maximum TDC for a project is calculated by adding the resulting amounts from step 3 for all units in the project.

(c) *Limit on housing construction costs.* (1) *General.* As described in the definition of TDC in § 941.103, the maximum TDC allocation is composed of two sub-allocations: housing construction costs and community renewal costs. A PHA may not use funds provided by HUD under the Act to pay housing construction costs in excess of the ''housing cost cap'' established by HUD.

(2) *Determination of housing cost cap.* HUD will determine the housing cost cap by averaging the housing construction costs listed in at least two nationally recognized residential housing construction cost indices for specific bedroom sizes and structure types. The two indices HUD will use for this purpose are the R.S. Means cost index for construction of ''average'' quality and the Marshal & Swift cost index for construction of ''good'' quality. HUD has the discretion to change the cost indices to other such indices which reflect comparable housing construction quality.

(3) *Balance of TDC allocation.* The balance of the funds provided by HUD under the Act for the development of the project (up to the maximum TDC allocation) may be used to pay for community renewal costs.

(d) *Funds not subject to TDC limit.* (1) As noted in paragraph (a) of this section, the maximum TDC limit applies only to funds provided by HUD under the Act or the HOPE VI program to a PHA and used for the development of public housing.

(2) A PHA may use funding sources not subject to the maximum TDC limitation (such as CDBG funds, HOME funds, low-income tax credits, private donations, and private financing) to cover project costs that exceed the housing cost cap or the maximum TDC amount. The added funding, however, may not be used for items that would result in substantially increased operating, maintenance or replacement costs, and must meet the requirements of section 102 of the HUD Reform Act (42 U.S.C. 3545).

(3) Although certain funding sources are not subject to the TDC limitations or housing cost cap described in paragraphs (a) and (c) of this section, these funds must be included in the project development cost budget, and legally acceptable written commitments for such funds must be provided by the PHA for HUD approval.

Dated: December 8, 2000.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

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Federal Register

Vol. 66, No. 3

Thursday, January 4, 2001

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–226..... 2
227–704..... 3
705–1012..... 4

CFR PARTS AFFECTED DURING JANUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
13184.....697
13185.....701
Proclamations:
7389.....703
Administrative Orders
Presidential Determinations:
No. 2001–05 of December 15, 2000.....223
No. 2001–06 of December 15, 2000.....225

5 CFR

792.....705

7 CFR

905.....227
930.....229, 232
944.....227
989.....705

8 CFR

212.....235

9 CFR

2.....236
3.....239

10 CFR

5.....708

12 CFR

225.....257, 400
1501.....257
1780.....709
Proposed Rules:
225.....307
1501.....307

14 CFR

25.....261
39.....1, 2, 5, 7, 263, 264, 265, 267
91.....1002
93.....1002
121.....1002
135.....1002
Proposed Rules:
39.....57, 59, 61, 64

20 CFR

Proposed Rules:
369.....314

21 CFR

522.....711
524.....712

24 CFR

888.....162
Proposed Rules:
941.....1008

26 CFR

1.....268, 279, 280, 713, 715, 723
301.....725
602.....280
Proposed Rules:
1.....66, 76, 315, 319, 747, 748
301.....77, 749

30 CFR

Proposed Rules:
948.....335

33 CFR

66.....8

40 CFR

52.....8, 586, 634, 666, 730
70.....16
180.....296, 298
271.....22, 23, 28, 33, 733
Proposed Rules:
70.....84, 85
271.....85, 86
413.....424
433.....424
438.....424
463.....424
464.....424
467.....424
471.....424

42 CFR

411.....856
424.....856

47 CFR

1.....33
73.....737
90.....33

Proposed Rules:

1.....86, 341
2.....341
90.....86

49 CFR

Proposed Rules:

229.....136
567.....90
571.....968
591.....90
592.....90
594.....90

50 CFR

20.....737
635.....55
679.....742

Proposed Rules:

17.....345
648.....91

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JANUARY 4, 2001

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Cherries (tart) grown in—

Michigan et al.; published 1-3-01

Oranges, grapefruit, tangerines, and tangelos grown in—

Florida and imported; published 1-3-01

ENVIRONMENTAL PROTECTION AGENCY

Acquisition regulations:

Business ownership representation; published 12-5-00

Hazardous waste program authorizations:

Indiana; published 1-4-01

FEDERAL DEPOSIT INSURANCE CORPORATION

Risk-based capital:

Market risk measure; securities borrowing transactions; published 12-5-00

FEDERAL RESERVE SYSTEM

Risk-based capital:

Market risk measure; securities borrowing transactions; published 12-5-00

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Animal drugs, feeds, and related products:

Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension; published 1-4-01

Sponsor name and address changes—

Phoenix Scientific, Inc.; published 1-4-01

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Federal Housing Enterprise Oversight Office

Practice and procedure:

Civil money penalties; inflation adjustment; published 1-4-01

INTERIOR DEPARTMENT

Fish and Wildlife Service

Migratory bird hunting:

Tungsten-nickel-iron shot approval as nontoxic for waterfowl and coots hunting; published 1-4-01

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Learjet; published 11-30-00

TREASURY DEPARTMENT

Comptroller of the Currency

Risk-based capital:

Market risk measure; securities borrowing transactions; published 12-5-00

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Corporations; liability assumptions in certain corporate transactions; published 1-4-01

Partnership mergers and divisions; tax consequences; published 1-4-01

Tentative carryback adjustment in consolidated return context; filing application guidance; published 1-4-01

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

Exportation and importation of animals and animal products:

Horses, ruminants, swine, and dogs; inspection and treatment for screwworm; comments due by 1-12-01; published 11-13-00

User fees:

Veterinary services—

Permit applications; comments due by 1-12-01; published 11-13-00

AGRICULTURE DEPARTMENT

Food and Nutrition Service

Child nutrition programs:

National school lunch and child and adult care food programs, State administrative expense funds, and free and reduced price meals and free milk in schools-

Afterschool care programs; snacks reimbursement; comments due by 1-9-01; published 10-11-00

COMMERCE DEPARTMENT

National Institute of Standards and Technology

National Voluntary Laboratory Accreditation Program; operating procedures; comments due by 1-8-01; published 11-7-00

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

Atlantic coastal fisheries—

American lobster; comments due by 1-9-01; published 11-28-00

Atlantic highly migratory species—

Pelagic longline fishery; sea turtle protection measures; comments due by 1-8-01; published 10-13-00

Northeastern United States fisheries—

Atlantic herring; comments due by 1-10-01; published 12-11-00

Ocean and coastal resource management:

Marine sanctuaries—

Florida Keys National Marine Sanctuary, FL; boundary expansion; comments due by 1-8-01; published 11-22-00

DEFENSE DEPARTMENT

Federal Acquisition Regulation (FAR):

Preference for U.S.-flag vessels; comments due by 1-8-01; published 11-7-00

ENVIRONMENTAL PROTECTION AGENCY

Air pollutants, hazardous; national emission standards:

Municipal solid waste landfills; comments due by 1-8-01; published 11-7-00

Air programs:

Outer Continental Shelf regulations—

California; consistency update; comments due by 1-10-01; published 12-11-00

Air quality implementation plans; approval and promulgation; various States:

Alabama; comments due by 1-8-01; published 12-8-00

Superfund program:

National oil and hazardous substances contingency plan—

National priorities list update; comments due by 1-8-01; published 12-8-00

Superrfund program:

National oil and hazardous substances contingency plan—

National priorities list update; comments due by 1-8-01; published 12-8-00

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:

Access charges—

Competitive local exchange carriers; tariff charge reform; comments due by 1-11-01; published 12-27-00

Satellite communications—

Fixed-Satellite Service (FSS) earth stations and terrestrial fixed service stations; efficient use and sharing of radio spectrum; comments due by 1-8-01; published 11-24-00

Telecommunications service quality reporting requirements; biennial regulatory review; comments due by 1-12-01; published 12-4-00

Radio stations; table of assignments:

Arizona; comments due by 1-8-01; published 11-29-00

Colorado; comments due by 1-8-01; published 12-18-00

Oregon; comments due by 1-8-01; published 11-29-00

Wisconsin; comments due by 1-8-01; published 11-30-00

GENERAL SERVICES ADMINISTRATION

Federal Acquisition Regulation (FAR):

Preference for U.S.-flag vessels; comments due by 1-8-01; published 11-7-00

HEALTH AND HUMAN SERVICES DEPARTMENT

Health Care Financing Administration

Medicare:

Hospital outpatient services; prospective payment

system; comments due by 1-12-01; published 11-13-00

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Fair housing:

Fair Housing Act violations; sexual harassment cases; comments due by 1-12-01; published 11-13-00

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species

Critical habitat designations—

Various plants from Kauai and Niihau, HI; comments due by 1-8-01; published 11-7-00

Various plants from Kauai and Niihau, HI; correction; comments due by 1-8-01; published 11-13-00

Endangered and threatened species:

Scotts Valley polygonum; comments due by 1-8-01; published 11-9-00

INTERIOR DEPARTMENT

Minerals Management Service

Royalty management:

Rate relief or reduction; deep water royalty relief for post-2000 OCS oil and gas leases; comments due by 1-9-01; published 12-15-00

JUSTICE DEPARTMENT

Prisons Bureau

Inmate control, custody, care, etc.:

Suicide prevention program; comments due by 1-12-01; published 11-13-00

LEGAL SERVICES CORPORATION

Regulations review; comment request; comments due by 1-8-01; published 11-24-00

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Federal Acquisition Regulation (FAR):

Preference for U.S.-flag vessels; comments due by 1-8-01; published 11-7-00

NUCLEAR REGULATORY COMMISSION

Spent nuclear fuel and high-level radioactive waste; independent storage; licensing requirements:

Approved spent fuel storage casks; list; comments due by 1-8-01; published 12-7-00

SMALL BUSINESS ADMINISTRATION

Small business size standards:

8(a) business development/ small disadvantaged business status determinations; comments due by 1-8-01; published 11-8-00

TRANSPORTATION DEPARTMENT

Coast Guard

Drawbridge operations:

Massachussetts; comments due by 1-8-01; published 11-8-00

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Boeing; comments due by 1-8-01; published 11-7-00

Empresa Brasileira de Aeronautica S.A.; comments due by 1-8-01; published 12-8-00

Fairchild; comments due by 1-11-01; published 12-5-00

McDonnell Douglas; comments due by 1-11-01; published 11-27-00

Robinson Helicopter Co.; comments due by 1-8-01; published 11-7-00

Special conditions—

Sikorsky Aircraft Corp. Model S-92 helicopters; comments due by 1-12-01; published 11-28-00

Airworthiness standards:

Special conditions—

Eurocopter France Model EC-155 helicopters; comments due by 1-12-01; published 11-28-00

Class D airspace; comments due by 1-12-01; published 11-28-00

Class D and Class E airspace; comments due by 1-12-01; published 11-28-00

TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

Motor vehicle safety standards:

Fuel system integrity; comments due by 1-12-01; published 11-13-00

TREASURY DEPARTMENT

Alcohol, Tobacco and Firearms Bureau

Firearms:

Commerce in explosives—

Imported explosive materials; identification markings; comments due by 1-12-01; published 11-13-00

TREASURY DEPARTMENT

Fiscal Service

Financial management services:

Federal-State funds transfers; rules and procedures; comments due by 1-10-01; published 10-12-00

TREASURY DEPARTMENT

Internal Revenue Service

Income Taxes:

Corporations; liability assumptions in certain corporate transactions; hearing; comments due by 1-10-01; published 1-4-01

Income taxes:

Principal residence sale or exchange; exclusion of gain; comments due by 1-8-01; published 10-10-00

Procedure and administration:

Pension and employee benefit trusts, and other trusts; classification; comments due by 1-10-01; published 10-12-00

LIST OF PUBLIC LAWS

This completes the listing of public laws enacted during the second session of the 106th Congress. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

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H.R. 5528/P.L. 106–568
Omnibus Indian Advancement Act (Dec. 27, 2000; 114 Stat. 2868)

H.R. 5640/P.L. 106–569
American Homeownership and Economic Opportunity Act of 2000 (Dec. 27, 2000; 114 Stat. 2944)

S. 2943/P.L. 106–570
Assistance for International Malaria Control Act (Dec. 27, 2000; 114 Stat. 3038)

H.R. 207/P.L. 106–571
Federal Physicians Comparability Allowance Amendments of 2000 (Dec. 28, 2000; 114 Stat. 3054)

H.R. 2816/P.L. 106–572
Computer Crime Enforcement Act (Dec. 28, 2000; 114 Stat. 3058)

H.R. 3594/P.L. 106–573
Installment Tax Correction Act of 2000 (Dec. 28, 2000; 114 Stat. 3061)

H.R. 4020/P.L. 106–574
To authorize the addition of land to Sequoia National Park, and for other purposes. (Dec. 28, 2000; 114 Stat. 3062)

H.R. 4656/P.L. 106–575
To authorize the Forest Service to convey certain lands in the Lake Tahoe Basin to the Washoe County School District for use as an elementary school site. (Dec. 28, 2000; 114 Stat. 3063)

S. 1761/P.L. 106–576
Lower Rio Grande Valley Water Resources Conservation and Improvement Act of 2000 (Dec. 28, 2000; 114 Stat. 3065)

S. 2749/P.L. 106–577
To establish the California Trail Interpretive Center in Elko, Nevada, to facilitate the interpretation of the history of development and use of trails in the settling of the western portion of the United States, and for other purposes. (Dec. 28, 2000; 114 Stat. 3068)

S. 2924/P.L. 106–578
Internet False Identification Prevention Act of 2000 (Dec. 28, 2000; 114 Stat. 3075)

S. 3181/P.L. 106–579
National Moment of Remembrance Act (Dec. 28, 2000; 114 Stat. 3078)

H.R. 1795/P.L. 106–580
National Institute of Biomedical Imaging and Bioengineering Establishment Act (Dec. 29, 2000; 114 Stat. 3088)

Last List December 29, 2000

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