otherwise be allowable under paragraph (h)(1) of this section, if the Director, determines that application of the higher rates is necessary to ensure the availability of an adequate number and mix of qualified health care providers in a network in a specific locality. This authority may only be used to ensure adequate networks in those localities designated by the Director, as requiring TRICAR preferred provider networks, not in localities in which preferred provider networks have been suggested or established but are not determined by the Director to be necessary.

Appropriate evidence for determining that higher rates are necessary may include consideration of the number of available primary care and specialist providers in the network locality, availability (including reassignment) of military providers in the location or nearby, the appropriate mix of primary care and specialists needed to satisfy demand and meet appropriate patient access standards (appointment/waiting time, travel distance, etc.), the efforts that have been made to create an adequate network, other cost-effective alternatives, and other relevant factors.

The Director, may establish procedures by which exceptions to applicable CMACs are requested and approved or denied under paragraph (h)(1)(iv)(E) of this section. A decision by the Director, to authorize or deny an exception is not subject to the appeal and hearing procedures of §199.10. When the Director, determines that it is necessary and cost-effective to approve a higher rate or rates in order to ensure the availability of an adequate number of qualified health care providers in a network in a specific locality, the higher rate may not exceed the lesser of the following:

1. The amount equal to the local fee for service charge for the service in the service area in which the service is provided as determined by the Director, based on one or more of the following payment rates:
   (i) Usual, customary, and reasonable;
   (ii) The Health Care Financing Administration’s Resource Based Relative Value Scale;
   (iii) Negotiated fee schedules;
   (iv) Global fees; or
   (v) Sliding scale individual fee allowances.

2. The amount equal to 115 percent of the otherwise allowable charge under paragraph (h)(1) of the section for the service.


L.M. Bynum,
Alternate Federal Register Notice Liaison Officer, Department of Defense.

BILLING CODE 5001–08–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1010–F]

RIN 0938–AK66

Medicare Program; Replacement of Reasonable Charge Methodology by Fee Schedules for Parenteral and Enteral Nutrients, Equipment, and Supplies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements fee schedules for payment of parenteral and enteral nutrition (PEN) items and services furnished under the prosthetic device benefit, defined in section 1861(s)(8) of the Social Security Act. The authority for establishing these fee schedules is provided by the Balanced Budget Act of 1997, which amended the Social Security Act at section 1842(s). Section 1842(s) of the Social Security Act specifies that statewide or other areawide fee schedules may be implemented for the following items and services still subject to the reasonable charge payment methodology: medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrients, equipment, and supplies; electromyogram devices; salivation devices; blood products; and transfusion medicine. This final rule describes changes made to the proposed fee schedule payment methodology for these items and services and provides that the fee schedules for PEN items and services are effective for all covered items and services furnished on or after January 1, 2002. Fee schedules will not be implemented for electromyogram devices and salivation devices at this time since these items are not covered by Medicare. In addition, fee schedules will not be implemented for medical supplies, home dialysis supplies and equipment, therapeutic shoes, blood products, and transfusion medicine at this time since the data required to establish these fee schedules are inadequate.

DATES: These final regulations are effective January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499.

SUPPLEMENTARY INFORMATION: Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. The Website address is http://www.access.gpo.gov/nara/index.html.

I. Background

The provisions of sections 1833 and 1842 of the Social Security Act (the Act) set forth the general payment authority for most physician and other medical and health services furnished under Part B of the Medicare program. Section 1842(s) of the Act, added by section 4315 of the Balanced Budget Act of 1997 (BBA), (Pub. L. 105–33) provides authority for implementing statewide or other areawide fee schedules to be used for payment of the following items and services that are paid on a reasonable charge basis when covered:

- Medical supplies.
- Home dialysis supplies and equipment.
- Therapeutic shoes.
- Parenteral and enteral nutrients, equipment, and supplies.
- Electromyogram devices.
- Salivation devices.
- Blood products.
- Transfusion medicine.

Section 1842(s)(1) of the Act provides that if fee schedules are established for any of the covered items and services listed above, the fee schedules are to be updated on an annual basis by the percentage increase in the consumer price index for all urban consumers (CPI–U) for the 12-month period ending...
II. Summary of Public Comments and Responses

We received comments from five groups representing the industry, two individual suppliers, and one member of the Congress who wrote on behalf of a constituent hospital. We have summarized the comments pertaining to the fee schedules for PEN items and services and present them below along with our responses. We have not included the comments pertaining to those items and services for which we have decided not to implement fee schedules at this time.

Effective Date for Implementation of Fee Schedules

Comment: Several commenters suggested that the fee schedules should not be implemented retroactively based on an effective date of January 1, 1999. One commenter suggested that the fee schedules be implemented no sooner than 60 days after the date of the final rule.

Response: We did not intend to apply this rule retroactively, and are changing the effective date from that proposed in the NPRM to January 1, 2002 to take into account the published date of the final rule. The fee schedules for PEN items and services will apply to items and services furnished on or after January 1, 2002.

III. List of Health Care Financing Common Procedure Coding System (HCPCS) Codes Subject to the Fee Schedules

Comment: One commenter asked which HCPCS codes would be subject to the fee schedules.

Response: The list of HCPCS codes subject to the fee schedules established by this final rule will change as codes are added to and deleted from the HCPCS. The following is the list of HCPCS codes currently subject to the fee schedules established by this final rule:

<table>
<thead>
<tr>
<th>PEN ITEMS AND SERVICES</th>
<th>PEN ITEMS AND SERVICES—Continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>B4034 ............. Enteral Feeding Supply Kit; Syringe, per day</td>
<td>B4150 ............. Enteral Formulae; Category I; semi-synthetic intact Protein/Protein Isolates, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4035 ............. Enteral Feeding Supply Kit; Pump Fed, per day</td>
<td>B4151 ............. Enteral Formulae; category I; Natural Intact Protein/Protein Isolates, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4036 ............. Enteral Feeding Supply Kit; Gravity Fed, per day</td>
<td>B4152 ............. Enteral Formulae; Category II; Intact Protein/Protein Isolates (calorically dense), administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4081 ............. Nasogastric Tubing with Stylet</td>
<td>B4153 ............. Enteral Formulae; Category III; Hydrolized Protein/ Amino Acids, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4082 ............. Nasogastric Tubing without Stylet</td>
<td>B4154 ............. Enteral Formulae; Category IV; Define Formula for Special Metabolic Need, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4083 ............. Stomach Tube—Levine Type</td>
<td>B4155 ............. Enteral Formulae; Category V; Modular Components, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4084 ............. Gastrostomy/Jejunostomy Tubing</td>
<td>B4156 ............. Enteral Formulae; Category VI; Standardized Nutrients, administered through an enteral feeding tube, 100 calories = 1 unit</td>
</tr>
<tr>
<td>B4085 ............. Gastrostomy Tube, Silicone with sliding ring, each</td>
<td>Parenteral Nutrition Solution: Carbohydrates (Dextrose), 50% or less (500 ML = 1 unit)—Homemix</td>
</tr>
<tr>
<td>Parenteral Nutrition Solution: Carbohydrates (Dextrose), 50% or less (500 ML = 1 unit)—Homemix</td>
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</tr>
<tr>
<td>Parenteral Nutrition Solution: Amino Acid, 3.5%, (500 ML = 1 unit)—Homemix</td>
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<tr>
<td>Parenteral Nutrition Solution: Amino Acid, 7%, through 8.5%, (500 ML = 1 unit)—Homemix</td>
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<tr>
<td>Parenteral Nutrition Solution: Amino Acid, greater than 8.5% (500 ML = 1 unit)—Homemix</td>
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<tr>
<td>Parenteral Nutrition Solution: Carbohydrates (Dextrose), greater than 50% (500 ML = 1 unit)—Homemix</td>
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</tr>
<tr>
<td>Parenteral Nutrition Solution: Lipids, 10% with Administration Set (500 ML = 1 unit)—Homemix</td>
<td></td>
</tr>
<tr>
<td>Parenteral Nutrition Solution: Lipids, 20% with Administration Set (500 ML = 1 unit)—Homemix</td>
<td></td>
</tr>
<tr>
<td>Parenteral Nutrition Solution: Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements, and Vitamins, including preparation, any strength, 10 to 51 grams of protein—Premix</td>
<td></td>
</tr>
</tbody>
</table>
PEN ITEMS AND SERVICES—Continued

B4193 .......... Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements, and Vitamins, including preparation, any strength, 52 to 73 grams of protein—Premix

B4197 .......... Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements and Vitamins, including preparation, any strength, 74 to 100 grams of protein—Premix

B4199 .......... Parenteral Nutrition Solution; Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements and Vitamins, including preparation, any strength, 101 to 124 grams of protein—Premix

B4216 .......... Parenteral Nutrition; Additives (Vitamins, Trace Elements, Heparin, Electrolytes) Homemix per day

B4220 .......... Parenteral Nutrition Supply Kit; Premix, per day

B4222 .......... Parenteral Nutrition Supply Kit; Home Mix, per day

B4224 .......... Parenteral Nutrition Administration Kit, per day

B5000 .......... Parenteral Nutrition Solution: Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements, and Vitamins, including preparation, any strength, Renal—Amirroyn RF, Nephramine, Premix

B5100 .......... Parenteral Nutrition Solution: Compounded Amino Acid and Carbohydrates with Electrolytes, Trace Elements, and Vitamins, including preparation, any strength, Hepatic—Fremine HBC, Hepatamine—Premix

B9000 .......... Enteral Nutrition Infusion Pump—without alarm

B9002 .......... Enteral Nutrition Infusion Pump—with alarm

B9004 .......... Parenteral Nutrition Infusion Pump, portable

B9006 .......... Parenteral Nutrition Infusion Pump, stationary

E0776XA .......... IV pole

Calculating Fee Schedule Amounts for Items and Services Where Reasonable Charge Data Is Unavailable

Comment: One commenter questioned how fee schedule amounts were going to be established for items and services for which reasonable charge data were unavailable during the data base period. Response: The compilation of aggregate reasonable charge data for PEN items and services is 100 percent complete.

Payment for Professional Services Associated With Furnishing PEN Items and Services

Comment: Several commenters stated that we ignored the recommendation of the Congress that appeared in the conference agreement on the BBA to "* * * examine carefully the appropriateness of including the costs of professional services * * *" when establishing the fee schedule amounts for PEN items and services.

Response: The Medicare payment to a supplier who furnishes PEN nutrients, equipment, and supplies to a Medicare beneficiary includes payment for providing all services that are medically necessary to furnish the PEN nutrients, equipment, and supplies. The Medicare payment for these services was predicated on the assumption that suppliers included in their charges all medically necessary services directly related to furnishing PEN nutrients, equipment, and supplies. Payment for services of a physician that are related to furnishing PEN, such as the initial evaluation of the patient leading to the prescription for PEN, are paid for separately under the Medicare fee schedule for physicians' services. However, the reasonable charges for PEN items and services included payment for services such as the supplier's assessment of the patient, patient education, and general care provided by registered nurses, and dispensing of nutrition supplies by licensed pharmacists that are part of the overall services furnished by the supplier. Therefore, payment for all medically necessary services directly associated with providing PEN nutrients, equipment, and supplies always has been included in the payment amounts developed under the reasonable charge payment methodology, a methodology that uses suppliers' charges to calculate payment amounts. Because the fee schedule amounts for PEN items and services established by this final rule are based on the payment amounts that were developed under the reasonable charge methodology, payment for any necessary professional services provided by a supplier as part of furnishing PEN nutrients, equipment, and supplies to Medicare beneficiaries is included in the fee schedule amounts.

Moreover, it is important to note that the statute requires that the fee schedule amounts established by this final rule must be budget-neutral. Therefore, additional payment for professional services provided by suppliers furnishing PEN nutrients, equipment, and supplies, would duplicate payment already included in the fee schedule rate and payments for all other PEN items and services would have to be reduced to maintain budget-neutrality. The total payment for PEN items and services would therefore remain the same.

Lump Sum Payment for PEN Items and Services

Comment: One commenter requested clarification regarding the provision in the proposed rule that payment for PEN items and services is to be made on a lump sum basis.

Response: The term "lump sum" generally refers to a one-time payment for the purchase of an item. Since payment for certain PEN items and services is made on a rental basis rather than a purchase basis, the use of the term "lump sum" in relation to payment for these rental PEN items is erroneous. Therefore, we have revised the rule to reflect that the term "lump sum" only applies to purchase transactions.

III. Provisions of the Final Regulations

The provisions of this final rule are the same as the provisions of the July 27, 1999, proposed rule except as noted below. The following changes have been made:

• Fee schedules will only be implemented for PEN items and services. Fee schedules will not be implemented at this time for electromyogram devices, salivation devices, medical supplies, home dialysis supplies and equipment, therapeutic shoes, blood products, and transfusion medicine.

• The initial year that the fee schedules will be in effect will be calendar year 2002 rather than calendar year 1999.

• For PEN items and services, the fee schedule amounts will be based on the reasonable charges that would have been used in determining payment for these items and services in 2002.

• The section regarding payment for PEN items and services has been revised to reflect that payment for these items and services will be on either a rental basis for the equipment or in a lump sum amount for the purchase of the nutrient or supply.

The 2002 fee schedule amounts for all HCPCS codes for PEN items and services are listed below. Section 4551(b) of the BBA specifies that the reasonable charges for PEN items and services for 2002 may not exceed the reasonable charges for these items and services from 1995. Therefore, the fee schedule amounts for PEN items and services, other than codes B4176 and
B4222, are based on the reasonable charges for the items or services during 1995. We have determined that the reasonable charges for codes B4176 and B4222 for 2002 will be less than the reasonable charges from 1995. Therefore, the fee schedule amounts for codes B4176 and B4222 will be based on the amounts that would have been used in calculating the reasonable charges for 2002. A modifier (MOD), if applicable, identifies the service as either: purchase of new equipment (NU); purchase of used equipment (UE); or rental of equipment (RK).

2002 Fee Schedule—Pen Items and Services

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<td>29.15</td>
</tr>
</tbody>
</table>

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.)

V. Regulatory Impact Statement

We have examined the impact of this final rule as required by Executive Order (EO) 12866, the Unfunded Mandates Reform Act (UMRA) (Pub. L. 104–4), the Regulatory Flexibility Act (RFA) of 1995 (Pub. L. 98–566), and the Federalism Executive Order (EO) 13132. 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 safety, and security effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more annually). This rule will not result in a change in expenditures of $100 million or more annually, and is therefore not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of $5 million to $25 million annually. Individuals and states are not included in the definition of a small entity. Based on data from the Small Business Administration (SBA), we estimate that 98 percent of suppliers of the items and services affected by this rule would be defined as small entities for purposes of the RFA. Due to the fact that the statewide fee schedule amounts will be calculated using the average of the payment amounts made in each State under the reasonable charge payment methodology, we expect that the overall impact of this rule on small businesses will be minimal.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

In the proposed rule we certified that this rule would not have a significant impact on a substantial number of small entities and on small rural hospitals. Since we did not receive any comment on our initial regulatory impact statements, we are conforming our initial determination and certifying that this rule will not have a significant impact on a substantial number of small entities including 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 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule would not have an effect on the governments mentioned, and private sector costs would be less than the $110 million threshold.

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

We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does not significantly affect the rights, roles, and responsibilities of State or local governments.

42 CFR part 414 is amended as set forth below:

PART 414—Payment for Part B Medical and Other Health Services

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

2. A new subpart is added to read as follows:

Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§ 414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of:

(1) The actual charge for the item or service; or
(2) The fee schedule amount for the item or service, as determined in accordance with §§414.104.

(b) Payment classification. (1) HCFA or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in §414.104.

(2) HCFA designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year.

§414.104 PEN Items and Services.

(a) Payment Rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) Fee schedule amount. The fee schedule amount for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

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


Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.


Tommy G. Thompson,
Secretary.

[FR Doc. 01–21657 Filed 8–27–01; 8:45 am]
BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[CS Docket No. 98–132; FCC 99–12]

1998 Biennial Review—Multichannel Video and Cable Television Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: This document announces the effective date of the rules published on September 5, 2000. Those rules amended the Commission’s cable television rules pertaining to the public file, notice and recordkeeping requirements. These rules contained information collection requirements that required the approval of the Office of Management and Budget (“OMB”) before they could become effective. These rule sections have been approved by OMB and become effective on August 28, 2001.

DATES: Sections 76.1622, 76.1713, and 76.1800 published at 65 FR 53610 (September 5, 2000) are effective on August 28, 2001.

FOR FURTHER INFORMATION CONTACT:
Sonia Greenaway of the Consumer Protection and Competition Division, Cable Services Bureau at (202) 418–7200 TTY (202) 418–7172.

SUPPLEMENTARY INFORMATION:
A summary of the public file, notice, and recordkeeping requirements set forth in Part 76 of the Commission’s cable television rules in CS Docket No. 98–132, 1998 Biennial Regulatory Review—Streamlining of Cable Television Services Part 76 Public File and Notice Requirements, Report and Order (FCC 99–12, 14 FCC Rcd 4653 (1999)) was published in the Federal Register at 65 FR 53610 (Sept. 5, 2000). The rules revised and streamlined the public file and notice requirements, and reduced the regulatory burden faced by cable operators. Sections 76.1622, 76.1713, and 76.1800 contained information collection requirements that required approval from OMB before they could become effective. OMB approved the information collection requirements on June 7, 2001. See OMB No. 3060–0981. Accordingly, §§76.1622, 76.1713, and 76.1800 become effective on August 28, 2001. This document constitutes publication of the effective date of those sections.

List of Subjects in 47 CFR Part 76

Multichannel video and cable television service.

Federal Communications Commission.

Magalie Roman Salas,
Secretary.

[FR Doc. 01–21626 Filed 8–27–01; 8:45 am]
BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 107, 171, 172, 173, 175, 176, 177, 178, 179, 180

[Docket No. RSPA–01–10374 (HM–1895)]

RIN 2137–AD60

Hazardous Materials Regulations:
Editorial Corrections and Clarifications

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule.

SUMMARY: This final rule corrects editorial errors, makes minor regulatory changes, and, in response to requests for clarification, improves the clarity of certain provisions in the Hazardous Materials Regulations (HMR). The intended effect of this rule is to enhance the accuracy and reduce misunderstandings of the HMR. The amendments contained in this rule are minor editorial changes and do not impose new requirements.


FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background

RSPA (we) annually reviews the HMR to identify and correct errors. Inaccuracies corrected in this final rule include typographical and printing errors, incorrect references to other rules and regulations in the CFR, inconsistent use of terminology, and misstatements of certain regulatory requirements. In response to inquiries RSPA received concerning the clarity of particular requirements specified in the HMR, certain other changes are made to reduce uncertainties.

Because these amendments do not impose new requirements, notice and public procedure are unnecessary. In addition, making these amendments effective without the customary 30-day delay following publication will allow the changes to appear in the next revision of 49 CFR.

The following is a section-by-section summary of the amendments made under this final rule. It does not discuss all minor editorial corrections (e.g., typographical, capitalization and punctuation errors), changes to legal authority citations and certain other