ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 262, 263, 271

[FR 2939-7]

Hazardous Waste Management System; Exports of Hazardous Waste

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for comment.

SUMMARY: On November 8, 1984, the President signed into law the Hazardous and Solid Waste Amendments of 1984 (HSWA). These amendments to the Resource Conservation and Recovery Act of 1976 (RCRA) require EPA to promulgate rules to implement new section 3017 regarding exports of hazardous waste. Accordingly, to implement section 3017 and improve upon its existing program, EPA is today proposing and requesting public comment on revisions to its current regulations governing exports of hazardous waste. Consistent with HSWA, the regulations proposed today would prohibit the export of hazardous waste unless certain requirements are met. These requirements include advance written notification to EPA of the plan to export hazardous waste, prior written consent to such plan by the receiving country, attachment of a copy of the receiving country's written consent to the manifest accompanying each waste shipment, and conformance of the shipment to such consent. These requirements would apply except to the extent EPA promulgates any different requirements set forth in any international agreement the United States may enter into with a receiving country which establishes different notice, export and enforcement procedures for the transportation, storage and disposal of such waste. In addition to provisions concerning the preceding requirements, today's proposal includes provisions governing special manifest requirements, exception reporting, annual reporting, recordkeeping, transporter responsibilities, confidentiality, and State authorization.

DATE: Comment on this proposal will be accepted until April 28, 1986. The proposed Parts 260, 262, 263 and 271 standards applicable to exports of hazardous waste will be effective 30 days after the date of publication in the Federal Register of the final rules.

ADDRESSES: Comments on this proposal should be submitted to Carolyn K. Barley at the address cited below. The official record for this rulemaking is located in Room S-212A, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, and is available for review from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: Carolyn K. Barley, (202) 382-2217, Office of Solid Waste, Room S-257 (WH-563), 401 M Street SW., Washington, D.C. 20460 or the toll-free RCRA Hotline: 800/424-9346 (in Washington, D.C., call 202/382-3000).

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

I. Authority

These regulations are being proposed under the authority of sections 2002(a), 3002, 3003, 3006, 3007, 3008 and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6912(a), 6922, 6923, 6926, 6927, and 6937.

II. Background

A. Existing Export Regulations

On February 26, 1980 EPA promulgated regulations under the Resource Conservation and Recovery Act of 1976 (RCRA) governing exports of hazardous waste. 45 FR 12732, 12743-12744 (codified at 40 CFR Parts 262 and 263). These regulations place certain requirements on generators and transporters regarding exports of hazardous waste in light of the special circumstances involved in international shipments. Since RCRA did not expressly address exports of hazardous waste, these provisions were promulgated primarily under sections 3002 (Standards Applicable to Generators of Hazardous Waste) and 3003 (Standards Applicable to Transporters of Hazardous Waste) of RCRA and are limited in scope.

Essentially, current Subpart E of Part 262 requires any person exporting hazardous waste to comply with the requirements generally applicable to generators such as initiating the manifest, using proper labels and containers, offering placards, and complying with the recordkeeping and reporting requirements of RCRA. A generator must also notify EPA before the initial shipment of hazardous waste to each foreign country in a calendar year. This notification requirement was established to allow EPA to inform a foreign country or an intended export and to assist EPA in tracking exports of hazardous waste. The content of this notification, however, is minimal: A generator must only identify the waste and consignee. Notification of the quantities of waste, frequency of shipment, or the manner in which such waste will be transported to, treated, stored or disposed in the receiving country is not required. Current regulations also do not require prior written consent of the receiving country prior to shipment. Accordingly, under current regulations, EPA has no authority to prohibit the export of hazardous waste if the foreign country objects to its receipt; any action to stop the shipment must be taken by the receiving country. As a further means of tracking the waste, Subpart E regulations also require that the generator require the consignee to confirm delivery of the waste. Special manifest and exception reporting requirements are also included in Subpart E.

In addition to the export provisions set forth in Subpart E and elsewhere in Part 262 (Standards Applicable to Generators), certain requirements regarding exports of hazardous waste are also included in Part 263 (Standards Applicable to Transporters of Hazardous Waste). These include a requirement that the transporter note on the manifest the date the waste left the United States, sign and retain one copy

of the manifest, and return a signed copy to the generator. Transporters must also deliver the entire quantity of waste to the place outside the United States designated by the generator unless the generator directs otherwise and the manifest is revised. These requirements were established to further enable EPA to track exports of hazardous waste.

B. The Hazardous and Solid Waste Amendments of 1984

On November 8, 1984, the President signed into law a set of comprehensive amendments to RCRA, entitled the Hazardous and Solid Waste Amendments of 1984 (HSWA). These comprehensive amendments will have far-reaching ramifications for EPA's hazardous waste regulatory program. Among other things, they add a new section 3017 to RCRA specifically addressing hazardous waste exports. In enacting this provision, Congress was concerned that EPA's existing notification system was inadequate to address the present and potential environmental, health, and foreign policy problems which occur when wastes are exported to nations which do not wish to receive them or lack sufficient information to manage them properly. *See, e.g.*, S. Rep. No. 98–284, 98th Cong., 1st Sess. 47 (1983). Congress also expressed concern that the failure to effectively regulate exports may be creating a major loophole for circumvention of U.S. hazardous waste laws. 129 Cong. Rec. H8163–H8164 (daily ed. Oct. 6, 1983) (Statements of Rep. Mikulski and Rep. Florio). Thus, Section 3017 expands current notification requirements and requires prior written consent by the receiving country before the shipment can take place.

Generally, subsection (a) of section 3017 provides that, beginning 24 months after enactment of HSWA, the export of hazardous waste is prohibited unless the person exporting such waste: (1) Provides notification to the Administrator; (2) the government of the receiving country has consented to accept the waste; (3) a copy of the receiving country's written consent is attached to the manifest which accompanies each waste shipment; and, (4) the shipment conforms to the terms of such consent. In lieu of meeting the above requirements, a person may export hazardous waste if the United States and the government of the receiving country have entered into an international agreement establishing notice, export, and enforcement procedures for the transportation, treatment, storage, and disposal of hazardous waste and the shipment conforms to the terms of the agreement.

Subsection (c) of section 3017 sets forth the requirement to notify the Administrator before the shipment leaves the United States and specifies the information to be included in such notification. Subsections (d) and (e) establish procedures for obtaining the receiving country's consent to accept the waste. Subsection (f) addresses the effect of an international agreement on the requirements of section 3017. Subsection (b) requires the Administrator to promulgate regulations necessary to implement section 3017. Subsection (h) authorizes the Administrator to establish other standards for the export of hazardous waste under sections 3002 and 3003 of RCRA. Finally, Congress also amended section 3008 of RCRA to provide criminal penalties for knowingly exporting hazardous waste without the consent of the receiving country or in violation of an existing international agreement between the United States and the receiving country.

Section 3017 of HSWA contains one additional requirement with which exporters must comply immediately: Subsection (g) requires any person exporting hazardous waste to file with the Administrator, no later than March 1, of each year, a report summarizing the types, quantities, frequency, and ultimate destination of all hazardous waste exported during the previous year. EPA recently codified this statutory requirement in its export regulations. 50 FR 28702, 28746 (July 15, 1985).

C. Proposed Regulations

Today EPA is proposing amendments to its hazardous waste export regulations to implement section 3017 and improve upon its current program governing exports. New Subpart E of 40 CFR Part 262 would address only exports of hazardous waste and replace existing regulations governing such exports now contained in that Subpart. Since Subpart E currently also includes special requirements governing imports of hazardous waste and the disposition of waste pesticides by farmers, these provisions would be moved to new Subparts F and G respectively with no substantive changes. Amendments are also proposed to 40 CFR Parts 260 regarding confidentiality, 263 pertaining to transporters of hazardous waste, and 271 with respect to State authorization.

III. Detailed Discussion of Proposed Regulation

The following is a detailed section-by-section discussion of the proposed changes to the export regulations.

A. Applicability [§ 262.50]

This section describes the applicability of Subpart E. Subpart E requirements would be applicable to exports of hazardous waste. As discussed more fully below, the term "exporter" is proposed to be defined as the person required to prepare the manifest for a shipment of hazardous waste, in accordance with 40 CFR Part 262, Subpart B, or equivalent State provision, which specifies a treatment, storage or disposal facility in a foreign country as the facility to which the waste will be sent. As such, exporters would be required to comply not only with the special requirements of Subpart E but also with Part 262 requirements applicable to generators (except to the extent Subpart E specifically provides otherwise).

This section also provides that the requirements of Subpart E apply to all exports of hazardous waste unless an international agreement is entered into between the United States and a receiving country which provides for different requirements. As the U.S. government has yet to enter into any such agreements, § 262.58 is proposed to be reserved to set forth any requirements placed on private parties by international agreements which are different from those required by the proposed regulations.

B. Definitions [§ 262.51]

Current regulations do not include a definitional section. This section has been added to provide definitions of new terms used in implementing section 3017 and for purposes of clarity.

1. "Receiving Country"

Congress did not define the term "receiving" country in enacting section 3017. Accordingly, EPA has the discretion to define that term to best effectuate Congressional intent. EPA's interpretation of this term is important because section 3017 requires prior consent of the "receiving country" to accept a hazardous waste; otherwise the export cannot take place. This prior consent requirement is the key element of new section 3017.

EPA believes that under most circumstances there will be only one foreign country involved in an export transaction: The country actually accepting the waste for purposes of its ultimate disposition in that country. However, circumstances may arise where a hazardous waste is transported through or temporarily stored for a short period (for example, at a loading dock or transfer facility) in another country en route to its final destination. Under the

latter circumstances, the question arises as to what constitutes the "receiving country" for purposes of obtaining consent to accept the shipment.

The term "receiving country" could be limited to the first country through which the waste travels or in which a waste may be temporarily held in the course of transportation even if ultimately destined for another country. Under this theory, once the waste enters the initial foreign country, it would then be the responsibility of that country to regulate any further export of such waste. Thus, consent would only be required from the initial country the waste enters. On the other hand, the term "receiving country" could include both transit countries and the country ultimately receiving the waste thus requiring consent from all countries involved. Finally, the term "receiving country" could be limited to the country of ultimate destination of the waste.

After considering the preceding alternatives, EPA proposes to define the term "receiving country" to mean only the foreign country of ultimate destination of the waste. Thus, consent must be obtained from the country in which the hazardous waste ultimately will be treated, stored or disposed. Consent would not be required from countries through which a shipment is transported or in which a shipment is temporarily held in the course of transportation to its ultimate destination. EPA realizes, however, that there may be limits to an exporter's knowledge of the ultimate destination of the waste. Accordingly, if the exporter does not know and cannot reasonably ascertain the country of ultimate destination, the receiving country would be the last country to which the waste will be sent that is known to the exporter.

EPA believes this proposed definition best reflects Congressional intent. It does not appear as though Congress contemplated that consent be obtained from both transit countries and the country ultimately handling the waste. The statutory language itself refers to "receiving country" not "receiving countries." Furthermore, section 3017 specifically requires exporters to notify EPA of the name and address of the "ultimate" treatment, storage or disposal facility. This requirement is indicative of Congressional concern with the "ultimate" destination of the waste. Moreover, Congressional discussions leading up to the enactment of section 3017 focus on the "dumping" or "disposal" of hazardous waste in unsuspecting foreign countries as the activity of primary concern, not the transportation through or temporary storage in a foreign country en route to its final destination.[1] *See, e. g.*, 129 Cong. Rec. H8163–8164 (daily ed. October 6, 1983) (Remarks of Rep. Mikulski and Rep. Florio). EPA believes that requiring consent only from the country actually accepting the waste for purposes of its ultimate disposition also best serves Congressional intent to impose a minimum of additional regulatory burdens on U.S. generators and administrative burdens on EPA while establishing a more comprehensive and responsible export policy. *See* 130 Cong. Rec. S9152 (daily ed. July 25, 1984) (Statement of Sen. Mitchell).

EPA also rejected the alternative of limiting the meaning of the term "receiving country" to the first foreign country the waste may enter or in which it may be temporarily held in the course of transportation to its final destination. Again, Congress specifically requires notification of the "ultimate" treatment, storage or disposal facility thereby indicating an intent to ensure consent by the country handling the "ultimate" disposition of the waste. And, as noted above, Congressional discussions leading up to HSWA also focused on the actual "disposal" of the waste. Moreover, EPA does not believe it appropriate to relinquish authority over the export of such waste at the point it simply enters another country in the course of transportation where it is known that such waste will ultimately be disposed of elsewhere. Were "receiving country" defined in such a limited manner, exporters could avoid consent requirements of countries to which the waste is ultimately being sent simply by rerouting the waste through another country. EPA especially requests comments on its definition of the term "receiving country."

2. "Consignee"

EPA has chosen to use the term "consignee" to refer to the "ultimate" treatment, storage or disposal facility to which the hazardous waste will be sent in the receiving country. The place of ultimate destination of the waste is to be distinguished from a facility at which any short term storage of the waste might occur incidental to transportation (e.g., at transfer facilities, loading docks). Thus, for example, if a waste is being exported to London via Portsmouth and the waste may be held temporarily in Portsmouth awaiting transportation to London, the consignee would be the facility to which the waste is being sent in London. The type of storage incidental to transportation which EPA tends to distinguish from the "ultimate" destination of the waste is similar to that type of storage discussed in the preamble to the rule clarifying when a transporter handling shipments of hazardous waste is required to obtain a storage facility permit. *See* 45 FR 86966 (Dec. 31, 1980). However, for purposes of determining who is the consignee, as between a temporary storage facility at which the waste may be stored incidential to transportation and the ultimate destination of the waste, no time limit on the length of such storage is being proposed as is the case in the rule referenced above. EPA believes it would be extremely difficult, if not impossible, due to unforeseen events occurring in transit abroad, for an exporter to know prospectively whether a shipment might be stored, for example, for more than ten days at a storage facility in the course of transportation and would thus become the "consignee." Accordingly, the consignee is the facility of ultimate destination of the waste and is not a temporary storage facility where a waste may be stored for a short period of time incidental to transportation.

3. "Transit country"

A definition of transit country is included in light of EPA's proposal, discussed in detail below, to provide notification to transit countries. A transit country is any foreign country through which a hazardous waste passes en route to a receiving country.

4. "EPA Acknowledgment of Consent"

The "EPA Acknowledgment of Consent" is defined as the cable prepared by the U.S. Embassy in the receiving country that acknowledges the written consent of the receiving country to accept the hazardous waste and describes the terms and conditions of the receiving country's consent. This cable will be transmitted to EPA via the Department of State in Washington and hence to the exporter for attachment to the manifest (or shipping paper for exports by rail or water (bulk shipment)) accompanying each waste shipment. As explained more fully below, EPA proposes to use this document to constitute the "consent" of the receiving country for purposes of section 3017, as opposed to a reproduction of the actual communication from the receiving country, for purposes of uniformity, to

[1] As discussed in detail below, however, EPA is proposing that the United States notify transit countries pursuant to the authority of section 3017(h), although consent will not be required. EPA believes that such notification is important from a foreign policy perspective and that, in light of the nature of the activity occurring in transit countries, notification alone is appropriate and sufficient.

provide an English translation to the exporter of the terms and conditions of consent, and to allow expeditious transmission of consent telegraphically to expedite communication and meet the statutory time frames for transmitting consent to the exporter.

5. "Exporter"

Section 3017 requires "any person" who exports hazardous waste to comply with the notification, consent, and reporting requirements of that section. EPA believes that several persons could be involved in a single export transaction (e.g., a generator, transporter, and a broker). The statutory language, however, does not specify which of such parties should, for example, provide the notification information to EPA, receive the EPA Acknowledgment of Consent, and attach a copy of such document to the manifest (or shipping paper for exports by rail or water (bulk shipment)) accompanying each waste shipment. In order to avoid confusion as to which party is responsible for specific export requirements and avoid duplicative notification, EPA proposes to place the primary statutory responsibilities for exports on a single party in each transaction.

EPA thus proposes to define the term "exporter" to be the person who is required to prepare the manifest in accordance with 40 CFR Part 262, Subpart B for a shipment of hazardous waste which specifies a treatment, storage, or disposal facility in the receiving country as the facility to which the waste will be sent. EPA believes that the person preparing the manifest for such shipments is in the best position to provide EPA with the notification information, receive the EPA Acknowledgment of Consent, attach such document to the manifest (or shipping paper for exports by rail or water (bulk shipment)), and ensure that the shipment initially conforms with the terms and conditions of the receiving country's consent. Such party is often in the best position to know the types and quantities of the waste to be exported. Generally, such party will have contracted with the consignee for receipt of the waste and will know the name of the consignee and be most able to obtain information on the manner in which the waste will be handled. Because such party will be preparing the manifest (or shipping paper for exports by rail or water (bulk shipment)), he should also know the details of transportation to the receiving country. And, because he will be initiating the shipment, he should also be in the best position to receive and attach the EPA Acknowledgment of Consent to the manifest accompanying the waste shipment, and ensure initial compliance with the terms of the EPA Acknowledgment of Consent.

Under the proposed definition, an "exporter" could be a generator as defined in 40 CFR 260.10 or other person required to assume generator responsibilities, i.e., a transporter who mixes hazardous wastes of different DOT shipping descriptions by placing them into a single container pursuant to 40 CFR 263.10(c) or the owner or operator of a treatment, storage or disposal facility who initiates a shipment of hazardous waste pursuant to 40 CFR 264.71(c) or 265.71(c). Current regulations for exports place notification requirements on generators. The proposed regulations simply clarifies that an exporter is a generator or other person required to assume generator responsibilities such as provided in 40 CFR 263.10(c), 264.71(c), and 265.71(c).

EPA considered the alternative of defining "exporter" to be "any person" who intends to export a hazardous waste. Under such a definition, all parties involved in the export, the generator (or person assuming generator responsibilities), transporter, and any export broker would be required to comply with the exporter requirements and could be held liable for failure to comply with such requirements. Similar treatment has been afforded generators where several parties meet the definition of generator. *See* 45 FR 72024, 72026 (Oct. 30, 1980). Under such a definition, EPA would expect one party, however, to assume and perform particular duties on behalf of all the parties. Guidance on who the agency would prefer to assume such responsibilities would be provided in the preamble. Enforcement actions, could, however, be taken against all parties for any violation where equitable and in the public interest.

This option was rejected because EPA believes that it would be difficult to define the point at which the "intent to export" would occur. The most tangible evidence of such "intent" is the point at which a manifest is prepared specifying a treatment, storage or disposal facility in a foreign country as the facility to which the waste will be sent. Only at that point does it become clear that an export will occur. Moreover, EPA believes that unlike in the situation governed by the rule noted above, a particular party, the generator (or person required to assume generator responsibilities) stands out as the predominant party in all cases. In addition, in the case of exports, EPA believes its proposed definition would cause less confusion and delay and that certain parties, such as transporters, shoud not be ostensibly subject to liability for responsibilities more appropriately placed on generators or persons required to assume generator responsibilities. Transporter responsibilities should include such matters as refusing to accept waste for export unless an EPA Acknowledgment of Consent is attached to the manifest, ensuring that the EPA Acknowledgment of Consent accompanies each waste shipment in transit, and that the shipment is not altered in transit contrary to the terms of the receiving country's consent. Generators (or persons required to assume generator responsibilities) are, on the other hand, in a better position to supply the notification and ensure initial compliance of the shipment with the receiving country's consent. Thus, the liability of such parties should relate to those duties for which such parties are in the best position to assume. As far as export brokers are concerned, such parties woud be acting on behalf of a generator (or person assuming generator responsibilities) as an agent. Under the definition of exporter as proposed, the generator (or person required to assume generator responsibilities) would remain liable for any violations of the duties imposed upon him when performed by a broker on his behalf. Of course, if a broker engages in activities which make him a generator or other person required to assume generator responsibilities under EPA regulations, the exporter requirements would apply to such party under the definition as proposed.

EPA particularly requests information on the nature of the export industry and comments on the appropriate liabilities and responsibilities which should be placed on brokers, transporters, and generators.

Under EPA's proposed definition of "exporter," Subpart E requirements would not be applicable to exports of hazardous waste initiated by persons not required to prepare a manifest under 40 CFR Part 262 Subpart B or an equivalent provision in an authorized State program. Thus, exports of hazardous wastes that are exempt from the manifest requirements of 262 Subpart B would not be subject to Subpart E requirements (see discussion later in this Preamble). EPA recognizes that section 3017 requires notification and consent for exports of "any hazardous waste identified or listed under this subtitle." However, it is not clear whether in using this language Congress intended to regulate wastes

exported more stringently than domestic wastes or to expand existing export requirements to cover exports not currently covered (e.g., some recycled wastes). EPA requests comments on the proposed continuation of an exemption of such exports from regulations especially whether there are any strong policy reasons to extend coverage of Subpart E to such exports.

C. General Requirements [§ 262.52]

This section sets forth the general requirements applicable to exports of hazardous waste. It provides that exports of hazardous waste are prohibited except in compliance with the applicable requirements of Subpart E and summarizes the general statutory prohibitions on exports set forth in section 3017(a) as implemented by proposed Subpart E.

D. Notification of Intent to Export [§ 262.53]

Subsection (c) of Section 3017 requires that any person who intends to export a hazardous waste shall, before such waste is scheduled to leave the United States, provide notification to the Administrator. This subsection also sets forth the minimum information which must be included in such notification. The primary purpose of this notification requirement is to provide sufficient information to a receiving country to allow it to make an informed decision on whether to accept the waste and, if so, to manage it in an environmentally sound manner. S. Rept. No. 98–284, 98th Cong., 1st Sess. 47 (1983). Coupled with the prohibition on exports in the absence of the consent of the receiving country, this provision is also intended to ensure that environmental, public health, and U.S. foreign policy interests are safeguarded. *Id.; see also* 130 Cong. Rec. S9152 (daily ed. July 25, 1984) (Statement of Senator Mitchell). This notification requirement is further intended to assist EPA in determining the amounts and ultimate destination of exports of U.S. generated hazardous waste so as to enable EPA and Congress to gauge whether the right to export is being abused. 130 Cong. Rec. S9152, *supra.*

The notification requirements proposed today are intended to implement the broad statutory requirements for notification set forth in section 3017(c) and ensure that sufficient information is obtained to satisfy Congressional intent. Accordingly, proposed § 262.53(a) requires an exporter to notify EPA of an intended export before the waste leaves the United States. Such notifications should be submitted sixty days prior to the intended date of the initial shipment. This sixty-day advance time is included in order to allow a reasonable amount of time for transmission of the notification to the receiving country, receipt of the receiving country's consent or objection to the export, and transmission of an EPA Acknowledgment of Consent to the exporter. In this respect, it should be noted that the statute itself sets forth the time frame (30 days) within which a complete notification must be transmitted to the receiving country after receipt by EPA and the time frame (30 days) within which the consent or objection must be transmitted to the exporter after receipt by the Secretary of State. Since EPA believes the information can be transmitted in less time than statutorily required (see discussion in Part III E), this 60-day advance time allows approximately thirty days for the receiving country to provide its consent or objection to the Department of State. Of course, EPA cannot require a receiving country to respond within a specific number of days. And, since an export is prohibited in the absence of consent, the shipment cannot take place until such consent has been obtained even though the notification may have been submitted sixty days prior to shipment. Thus, exporters are encouraged to submit notifications at the earliest possible date.

The regulation would also require such notification to be in writing and signed by the exporter. This requirement is intended to ensure the accurate transmission of the required information to EPA and the usefulness of the document in enforcement actions. A single notification may cover more than one shipment; a separate piece of paper providing notification for each shipment is not necessary. This appears consistent with legislative intent since the statute itself specifies that a notification include information on the "frequency of shipment." Comments are specifically requested, however, on whether a separate notification should be required for each shipment. The proposal limits a notification to shipments occurring over a maximum period of twenty-four months. The agency considered allowing a notification to cover a twelve month period but rejected this option in favor of the 24-month period as a better balance between concerns for currency and accuracy of information and imposition of administrative burdens on exporters. However, EPA specifically requests comments on whether it would be appropriate to restrict this period of time to twelve months.

Regarding the content of a notification, the statute itself requires that a notification include the following information:

(1) The name and address of the exporter;

(2) The types and estimated quantities of hazardous waste to be exported;

(3) The estimated frequency or rate at which such waste is to be exported; and the period of time over which such waste is to be exported;

(4) The ports of entry;

(5) A description of the manner in which such hazardous waste will be transported to and treated, stored, or disposed in the receiving country; and

(6) The name and address of the ultimate treatment, storage or disposal facility.

To implement these broad informational requirements, the proposed regulation identifies certain specific information which would be required. Accordingly, notification would be required to contain the following:

(1) Name, mailing address, telephone number and EPA ID number of the exporter;

(2) By consignee, for each hazardous waste type:

(i) A description of the hazardous waste and the EPA hazardous waste number (from 40 CFR Part 261, Subpart C and D), U.S. DOT proper shipping name, hazard class and ID number (UN/NA) for each hazardous waste as identified in 49 CFR Part 171–177;

(ii) The estimated number of shipments of the hazardous waste and approximate date of each shipment;

(iii) The estimated total quantity of the hazardous waste in units as specified in the instructions to the Uniform Hazardous Waste Manifest Form (8700–22);

(iv) All points of entry to and departure from each foreign country through which the hazardous waste will pass;

(v) A description of the means by which each shipment of the hazardous waste will be transported (e.g., mode of transportation vehicle (air, highway, rail, water, etc.), type(s) of container (drums, boxes, tanks, etc.));

(v) A description of the manner in which the waste will be treated, stored or disposed of in the receiving country (e.g., land or ocean incineration, other land disposal, ocean dumping, recycling); and

(vii) The name and site address of the consignee and any alternate consignee.

As discussed in detail below, the United States intends to provide notification to transit countries as well as receiving

countries. Conset from transit countries, however, would not be required. Accordingly, the proposal also requires, pursuant to the authority of section 3017(h), designation of any transit countries through which the waste will pass and information on its handling while there.

Paragraph (b) of proposed § 262.53 specifies the place to which notification must be sent. Paragraph (c) requires renotification, consent from the receiving country, and EPA Acknowledgement of Consent for changes in the conditions specified in the original notification. This would include changes in the amount of waste to be exported in excess of the estimate originally provided since EPA believes a foreign country would not consent to receiving more waste than contemplated when consent was given. EPA believes this section is necessary since "consent" arguably has not been received for any shipment differing from the shipment of which the receiving country was notified. Since this provision is likely to be used when unforeseen circumstances arise necessitating a change in the export close to the date of the intended initial shipment, EPA will act expeditiously to obtain consent to such changes. However, exporters should keep in mind that an export deviating from the description in the original notification has not been consented to and, therefore, cannot take place until consent to the changes has been obtained and a new EPA Acknowledgement of Consent has been received.

Paragraph (d) would allow EPA to obtain any additional information from an exporter in the event the receiving country requests further information in order to respond to a notification of intent to export.

Paragraph (e) provides that EPA will forward a complete notification to the receiving country and any transit countries. A notification would be complete when EPA receives all information EPA determines is necessary to satisfy the requirements of § 262.53(a). This paragraph also provides that, if a claim of confidentiality is asserted with respect to any of the required notification information, EPA may find a notification not "complete" until any such claims are resolved in accordance with § 260.2. For a discussion of the basis for and purpose of this provision, see the section below on confidentiality.

Paragraph (f) provides that exporters will be notified of any responses by receiving and transit countries. Where the receiving country consents to the shipment, an EPA Acknowledgement of Consent will be provided the exporter for attachment to the manifest (or shipping paper for exports by rail or water (bulk shipments)) accompanying each waste shipment.

EPA specifically requests comments on the proposed notification requirements especially regarding whether any additional information would be appropriate to satisfy Congressional intent.

E. Procedures for the Transmission of Notification, Consent and Objection

Subsections (d) and (e) of section 3017 set forth the procedures involving EPA and the Department of State for notifying the receiving country on an intended export, obtaining the receiving country's response to the notification, and notifying the exporter of such response. These statutory provisions require the Department of State to transmit notification of the intended export to the government of the receiving country within thirty days of receipt by EPA of a complete notification from the exporter. EPA must then notify the exporter of the receiving country's consent or objection to the intended export within thirty days of receipt by the Department of State of the receiving country's response.

EPA is not proposing any specific regulations regarding procedures for the exchange of information among EPA, the Department of State, receiving countries and transit countries because these actions are administrative in nature and impose no requirements on the public. For informational purposes, however, a discussion of such procedures follows.

In order both to meet the statutory time frames noted above and expedite transmission of information, EPA anticipates notifying the Department of State within five days of receipt of the exporter notification. The Department of State anticipates notifying the receiving country within ten days of receipt of the information from EPA. The Department of State anticipates notifying EPA of the receiving country's response within ten days of receipt of such response, and EPA anticipates notifying the exporter of such response within five days of receipt of the response from the Department of State. This amounts to a total of thirty days transmission time for notification and consent. Thus, as previously discussed, EPA has proposed that exporters notify EPA at least sixty days prior to the intended first shipment to allow time for the receiving country to respond. Thirty days remain for the receiving country to provide its consent to the export. Exporters are reminded, however, that an export cannot take place without consent of the receiving country and, therefore, the shipment could be delayed if the receiving country does not respond within that time period.

The Department of State will use its telegraphic system to notify the receiving country of an intended export and to transmit the response back from the U.S. Embassy in the receiving country to the Department of State in Washington. Thus, EPA will draft a cable incorporating the details of the exporter notification which the Department of State will transmit to the U.S. Embassy in the receiving country. The U.S. Embassy will then pass the information on to the appropriate authorities in the receiving country with a request to respond expeditiously to the notification by providing the U.S. Embassy with a written consent or objection to the intended export. Upon receipt of the written response of the receiving country, the Embassy will then translate this response into English, if necessary, and cable it to the Department of State in Washington. This cable would then be forwarded to EPA. Where the receiving country fully consents to the shipment or consents with specified modifications, this cable will constitute the EPA Acknowledgment of Consent and would then be forwarded to the exporter for attachment to the manifest (or shipping paper for exports by rail or water (bulk shipments)) accompanying each waste shipment. Where the foreign country rejects the shipment, EPA will so notify the exporter in writing. Meanwhile, the original written communication from the receiving country would be sent to the Department of State in the diplomatic pouch used by the Department of State to transmit documents from foreign posts to the Department of State. This document would then be forwarded to EPA for retention. A copy will also be forwarded to the exporter. EPA will work closely with the State Department to establish procedures to ensure that cables prepared by the U.S. Embassy in the receiving country include all of the relevant information contained in the exporter's original notification, as well as an exact reiteration or translation of the receiving country's written consent to the notification. This will provide U.S. Customs officials with the information necessary to check the shipment against the receiving country's consent to the notification.

Telegraphic transmission of information between the United States and receiving countries is necessary to expeditiously transmit notification and consent information. Mailing actual reproductions of such documents would

take considerably longer, making it difficult to meet the statutory deadlines for transmission of such information and necessitating earlier notification by the exporter than that proposed. In light of the use of cables, a copy of the exporter's actual notification letter will not be transmitted to receiving countries. Similarly, a copy of the receiving country's actual consent document does not need to be attached to the manifest (or shipping paper for exports by rail or water (bulk shipments)). As stated earlier, the cable received from the U.S. Embassy in the receiving country will constitute the EPA Acknowledgment of Consent document and will be used to transmit the receiving country's consent to the exporter for attachment to the manifest (or shipping paper for exports by rail or water (bulk shipment)). Use of such a document not only allows the exporter to be notified expeditiously of the cabled response of the receiving country but also makes possible the inclusion of an English translation of the terms and conditions of the receiving country's response where such response is in a foreign language. Without such a translation, it would be difficult for the exporter to ensure conformance with such consent.

Thus, EPA interprets the statutory language of subsection (d) of section 3017 which requires that "a copy of the notification" be forwarded to the receiving country to mean forwarding the information contained in the notification from the exporter to the receiving country. And, EPA interprets the statutory language of subsection (a) requiring attachment of a "copy of the receiving country's written consent" to the manifest accompanying each waste shipment to mean attachment of the EPA Acknowledgment of Consent incorporating the terms and conditions of such consent. Similarly, EPA interprets the statutory language of subsection (e) which references the written consent, objection, or other communication from the receiving country and provides that "such a consent, objection or other communication" be forwarded to the exporter to mean forwarding the information contained in the foreign country's response to the notification. EPA believes the means it proposes to transmit information is consistent with Congressional intent to ensure notification, consent, attachment of such consent to the manifest, and conformance of the shipment to the consent while ensuring that the statutory time frames for transmission are met.

EPA considered developing a standard form to incorporate all of the relevant information contained in the exporter's notification. This form would provide a concise transmission (in consistent format) of the information relevant to the export. In preparing this form, EPA would include only that information needed by U.S. Customs to determine whether the shipment was in conformance with the receiving country's consent. Copies of the receiving country's consent or an exact translation of that consent would be sent directly to the exporter in order to inform the company of all of the receiving country's conditions of acceptance. However, EPA rejected this option in favor of the proposed one for the following reasons: (1) The amount of time required to prepare the form would add a few days to the process of notification; and (2) by working closely with the U.S. Department of State to ensure that the cable prepared by the U.S. Embassy in the receiving country includes all of the relevant information, the cable will provide Customs officials with the information necessary to monitor shipments at the border. EPA requests comments on whether a form rather than a copy of the cable which includes a reiteration of all of the receiving country's conditions of acceptance should be prepared.

As required by section 3017, in notifying receiving countries of intended shipments, the government of the receiving country will be advised that United States law prohibits the export of hazardous waste unless the receiving country consents to accept the waste. The notification will include a request to provide the Department of State with a response to the notification which either consents to the full terms of the notification, consents to the notification with specified modifications, or rejects receipt of the hazardous waste. Also, in accordance with statutory requirements, a description of the Federal regulations which would apply to the treatment, storage and disposal of hazardous waste in the United States will be provided the receiving country.

F. Notification of Transit Countries

EPA has been a full and regular partner in extensive international consultations concerning the international shipment of hazardous waste under the auspices of the Organization for Economic Cooperation and Development (OECD). U.S. experts along with those of other OECD member countries have worked to develop agreed-upon principles governing international shipments of hazardous waste. In February of 1984, the United States, along with other OECD member countries, voted to adopt a formal decision and recommendations for implementing such decision regarding the control of international shipments of hazardous waste. The OECD decision provides:

> . . . Member countries shall control the transfrontier movements of hazardous waste and, for this purpose, shall ensure that the competent authorities of the countries concerned are provided with adequate and timely information concerning such movements.

The term "countries concerned" is defined to include exporting, importing and transit countries. To implement this decision, the OECD Council recommended that countries apply certain principles concerning transfrontier movements including the following:

> . . . [C]ountries should take the measures necessary to ensure that the entities within their jurisdiction provide, directly or indirectly, the authorities of the exporting, importing and transit countries with adequate and timely information.

Accordingly, EPA has exercised its authority pursuant to section 3017(h) to require exporters to notify EPA of any countries through which a hazardous waste will pass en route to the receiving country. The requirement to provide information regarding the approximate length of time the waste will remain in a transit country and the nature of its handling while there is proposed in order to provide sufficient information to a transit country regarding the nature of the transit of the waste through such country. EPA, in conjunction with the Department of State, plans to provide such countries with the information contained in the exporter's notification and will inform the exporter of any response by such countries.

EPA, however, does not propose to require consent from transit countries. Section 3017 requires consent only of receiving countries and EPA's proposed regulation defines "receiving country" to mean the country in which the waste will be ultimately treated, stored or disposed. Exporters should keep in mind, however, that the transit country may take action to prohibit entry of the waste into that country. Accordingly, EPA recommends that exporters make every effort to reroute the waste should a transit country object to the entry of such waste into that country.

EPA's plan to notify transit countries is intended to implement the OECD Decision and Recommendations and is also intended to respond to the legitimate interests of transit countries

in light of the nature of the activity which would occur in such countries, i.e., transit through or temporary storage in such countries. In EPA's view, it is important for protection of human health and the environment as well as foreign relations to provide notification to transit countries. This will enable transit countries to stop shipments which are unwelcome, to ensure safe handling during transit and be prepared to deal with any incidents (such as spills) which may occur during transit. EPA specifically requests comments on its proposed treatment of transit countries. Related to this issue is the alternative considered by EPA (and discussed above) to define "receiving country" to include both the ultimate country receiving the waste and transit countries. Were this alternative adopted, consent from transit countries would also be required before the shipment could take place.

G. Special Manifest Requirements [§ 262.54]

This section sets forth special manifest requirements pertaining to exports of hazardous waste in light of the special circumstances relative to such shipments. Accordingly, as specified in the proposed rule, some of the proposed requirements are in lieu of the provisions applicable to generators in Part 262 while others are in addition to such Part 262 requirements.

Paragraph (a) of proposed § 262.54 retains the current requirement that an exporter enter on the manifest the name and address of the consignee in place of the designated permitted facility. Paragraph (b) is added to make clear that the exporter may enter the name of any alternate consignee for which consent has been obtained in lieu of a permitted alternate facility in the United States.

Paragraph (c) retains the current requirement of § 262.50(b)(3)(ii) to identify the point of departure of the waste from the United States. This requirement was originally included in the regulations in order to provide additional information on the movement of an international waste shipment. Paragraph (d) requires an exporter to add to the certification on the manifest in Item 16 that the shipment conforms to the EPA Acknowledgment of Consent. This certification is included for purposes of enforcement. Paragraph (e) retains the current § 262.50(b)(4) requirement which specifies where the exporter should obtain the manifest form. This requirement deviates slightly from the requirement set forth in § 262.21 pertaining to domestic shipments since the waste is being sent outside the United States. Paragraph (f) essentially retains current § 262.50(b)(2) that requires the exporter to require the consignee to confirm delivery as a condition of their business agreement. A copy of the manifest signed by the foreign consignee may be used for this purpose. EPA proposes to add the requirement that the exporter require the consignee to describe any significant discrepancies as defined in 40 CFR 264.72(a) between the manifest and the shipment. This requirement is for enforcement purposes and is similar to current manifest discrepancy requirements for domestic shipments.

Paragraph (g) applies in lieu of § 262.20(d). This section is intended to place the responsibility on the exporter for hazardous waste that cannot be delivered to a facility to which the foreign country has consented pursuant to the original notification. Thus, an exporter has three choices in such a situation: (a) He can obtain new consent; (b) he can have the waste returned to himself; or (c) he can designate another facility in the United States. EPA realizes that new consent may be difficult to obtain expeditiously which could result in practical problems regarding what should be done with the waste in the meantime. However, it is provided as an option even though EPA believes that the other options noted above are preferable. The proposed regulation also requires the exporter to instruct the transporter to revise the manifest in accordance with the exporter's instructions regarding where the waste should be taken. This ensures that an accurate record of the hazardous waste will be maintained.

Paragraph (h) is proposed to ensure attachment of the EPA Acknowledgment of Consent to the manifest (or shipping paper for exports by rail or water (bulk shipments)) as required by RCRA section 3017. EPA regulations allow a shipping paper to accompany shipments by rail and water (bulk shipments) in lieu of a manifest (*see* 40 CFR 263.20). Accordingly, the EPA Acknowledgment of Consent would accompany the shipping paper under such circumstances. In EPA's view, Congress provided that consent be attached to the manifest to ensure that consent traveled with the document identifying the waste. Accordingly, attachment of the EPA Acknowledgment of Consent to the shipping paper under these circumstances would satisfy this intent.

EPA considered requiring an additional copy of the manifest which the transporter would give to a U.S. Customs official at the border. Customs officials would periodically forward the copies it collected to EPA. Upon receipt EPA would compare these copies with the agreed-upon terms of export to determine compliance. The Agency decided not to propose this requirement, however, because there is no evidence that exporters are violating current notification requirements under § 262.50. Further, the receiving country could request such a review if there was concern about violations of exporter notifications. EPA specifically requests comment on whether such a monitoring system is necessary.

H. Exception Reports

Proposed pragraphs (a) and (b) retain current requirements for exception reporting which deviate somewhat from exception reporting for domestic shipments in light of the special circumstances involved in international shipments. For domestic shipments, exception reports are required where a copy of the manifest is not returned to the generator by the designated facility. Since EPA has no jurisdiction over a foreign facility to require it to return a copy of the manifest, EPA regulations require the exporter to require the consignee to confirm delivery of the waste. As a back-up to tracking the waste in light of EPA's lack of jurisdiction over foreign facilities, EPA regulations also require the transporter to sign a copy of the manifest, enter the date the waste left the United States and return a copy to the generator (40 CFR 263.20(g)). Thus, the proposed exception reporting requirements hinge upon the lack of receipt of the transporter's copy of the manifest and the failure to receive confirmation from the consignee that the waste was received.

Exception reporting is an important tracking and enforcement tool for exports of hazardous waste. It allows notification to EPA that a waste has not left the United States or has left the United States but has not been received by the consignee. Thus, EPA can determine whether the waste remains in the United States or has reached the foreign country but not reached the consignee. The proposed regulation also requires submission of an Exception Report where the waste is returned to the United States. This requirement is proposed to be added because EPA believes that it is in the interest of U.S. foreign policy to know that a hazardous waste shipment was rejected when consent by the foreign country was provided.

I. Annual Reports [§ 262.56]

As discussed above, section 3017(g) of RCRA imposes a new annual reporting

requirement for exports of hazardous waste.

On July 15, 1985 (50 FR 28702), EPA codified the language of section 3017(g) due to the immediate effectiveness of this requirement. Today's proposal would amend this annual reporting requirement to require specific reporting information to implement the broad statutory reporting requirements to summarize the types, quantities, frequency, and ultimate destination of all exported waste. Thus, EPA proposes to require annual reporting of: (1) The EPA ID number, name, and mailing and site address of the exporter; (2) the calendar year covered by the report; (3) the name and site address of each consignee; (4) a description of each waste exported including the EPA hazardous waste number and DOT hazard class; (5) the name and U.S. EPA ID number (where applicable) for each transporter used; (6) the total amount of waste shipped pursuant to each notification; and (7) the number of shipments pursuant to each notification. Items (4) through (7) would be provided by consignee for each hazardous waste exported. As with the biennial reporting requirements for domestic shipments, a certification requirement is included. The address of the place reports would be sent is also specified. These reporting requirements would assist EPA in using the annual report as an enforcement tool and aid Congress and EPA in determining whether the export right is being abused and additional controls are necessary or desirable.

Because the annual report provides the agency with information on exports of hazardous waste, today's proposal would eliminate the requirement of § 262.41 which requires generators to include in the biennial report information relative to exports.

EPA plans to change the instructions to the form in future printings of the biennial report form to clarify this reporting requirement. Exporters should note, however, that authorized States may continue to require generators to include information on exports in the biennial report and may also require exporters to send a copy of the annual report to the States.

The agency considered retaining the requirement for generators to include in the biennial report information on exports and eliminating the requirement to file an annual report during those years in which a biennial report was required. This option was not selected, however, because the agency believes eliminating export information from the biennial report would not place a greater workload on generators since most generator retain separate records on domestic and exported shipments and, thus, are in a position to file separate reports on those activities. Further, copies of the reports must be submitted to different addressees, i.e., the annual report must be submitted to EPA Headquarters and the biennial report to EPA Regional Administrators. In addition, it is administratively less burdensome for the agency to receive two separate reports, because EPA will not then have to pull out information on exports from the biennial report to keep Congress informed on the issue of exports. Furthermore, it appears that Congress intended that reporting of exports be separated out from information on other shipments by enacting section 3017(g). The agency requests comments on this requirement.

J. Recordkeeping [§ 262.57]

The recordkeeping provisions proposed today are consistent with current recordkeeping requirements of § 262.40 which require generators to retain for a period of three years copies of manifest and biennial and exception reports. For enforcement purposes, the proposed regulation includes requirements to retain for a period of three years those special documents relative to exports: (a) The notification of intent to export; (b) the EPA Acknowledgment of Consent; (c) the confirmation of delivery (if not the manifest); and (d) the annual report. Also consistent with § 262.40, the proposal includes a requirement that the specified periods of retention are extended automatically during the course of any unresolved enforcement action or as requested by the Administrator.

There are several reasons for requiring the exporter to retain copies of notifications, Acknowledgments of Consent, and annual reports. Primary among these is that EPA considers the burden of proof, in general, to be on the generator/exporter. Generators, on the whole, are required to keep copies of biennial reports and manifests (40 CFR 262.40, 262.40(b)). Copies of notifications of intent to export and Acknowledgments of Consent are similarly necessary for the exporter to show compliance with the export standards. In addition, unique to exports, notifications, Acknowledgments of Consent, and annual reports pass between the exporter and EPA Headquarters. The Regions and State Directors are not directly part of the paperwork flow or approval process. They are, however, in the direct line of enforcement. For this reason, Regional and State enforcement personnel should have access to those documents when they visit or inspect an exporter's site which is best accomplished if these records are required to be retained by the exporter.

K. International Agreements [§ 262.58]

This section has been reserved for future regulatory provisions which would set forth different requirements established in any international agreements the United States may enter into with a foreign country regarding exports of hazardous waste. In this respect, section 3017 of HSWA provides that where such an agreement exists, only the requirements of subsections (a)(2) and (g) apply. Subsection (a)(2) provides that no person shall export a hazardous waste from the United States to a receiving country where an international agreement pursuant to subsection (f) has been entered into unless the shipment conforms with the terms of such agreement. Subsection (g) requires annual reporting. Section 3008(d)(6) of HSWA provides for criminal enforcement action for exports not in conformance with such agreements.

L. Transporter Responsibilities [§ 263.20]

To implement section 3017(a)(1)(c) and for purposes of enforcement, EPA proposes to amend § 263.20 to prohibit a transporter from accepting waste from an exporter unless, in addition to a manifest, an EPA Acknowledgment of Consent is attached to the manifest. This section would also be amended to require transporters to ensure that an EPA Acknowledgment of Consent accompanies the hazardous waste en route. Current §263.20(g) also requires the transporter to send a copy back to the generator. This provision would not be changed.

M. Small Quantity Generators

EPA proposes to define an exporter as the person required to prepare a manifest pursuant to 40 CFR Part 262, Subpart B, or equivalent State provision, which specifies a treatment, storage, or disposal facility in a foreign country as the facility to which the waste will be sent.

Under the existing rules, generators of less than 1,000 kg of non-acutely hazardous waste in a calendar month (i.e., small quantity generators) are not subject to Subpart B of Part 262 (or any other Part 262–266 or 270 regulations), provided the small quantity generator complies with § 262.11 (hazardous waste determination) and ensures delivery of his waste to an on-site facility or off-site facility which is:

1. Permitted under Part 270;
2. In interim status under Part 270 and 265;
3. Authorized to manage hazardous waste by a State with a hazardous waste management program approved under Part 271;
4. Permitted, licensed, or registered by a State to manage municipal or industrial solid waste; or
5. A facility which beneficially uses, reuses, or legitimately recycles or reclaims its waste or treats its waste prior to beneficial use, reuse, or legitimate recycling or reclamation.

A small quantity generator who exports his waste would be unable to comply with any of the above requirements since (1) through (4) require approval by a government entity while item 5 would require that the generator somehow "assure" that his waste is "legitimately" recycled by a foreign facility, a difficult requirement with which to comply when a foreign facility is involved. Consequently, the existing § 261.5 rules require that all small quantity generators comply with the manifesting provisions of Part 262. These generators would, therefore, qualify as exporters under today's proposal. The effect of this situation is to subject small quantity generators who export their wastes to full Part 262 requirements including the proposed export requirements while the small quantity generators who ship to any of the five kinds of domestic facilities identified above are currently excluded from the Part 262 requirements.[2]

Based upon the notifications which EPA has been receiving since 1980, the agency is not aware of any exports by small quantity generators. Accordingly, EPA does not propose to change the existing applicability of Part 262 (which would also require compliance with the proposed export requirements if finally promulgated) to all such small quantity generators.

However, EPA requests comments from generators of less than 1,000 kg/month on whether they intend to export hazardous wastes. In addition, EPA requests comments (with supportive explanation) from generators intending to export such wastes on whether they should be subject to full Part 262 requirements in addition to the export requirements, some of Part 262 requirements in addition to the export requirements, only the export requirements or none of Part 262 requirements and none of the export requirements. The agency will consider these alternatives in issuing any final rule.

On the one hand, it is arguable that generators of 100 kg/mo or less exporting hazardous waste should be exempt from Part 262 requirements and the export requirements on the grounds that EPA should not be more concerned about exports from such generators than domestic shipments by such generators. By the same token, however, foreign policy concerns (including human health and the environment concerns) may indicate that such generators at least comply with the export requirements [3] especially since the regulations exempting such generators from Part 262 requirements require shipment to appropriate facilities in order to obtain the benefit of the exemption. This evidences some concern for such waste handled domestically which may indicate that foreign countries would have some concern and therefore should be accorded notification, etc.

Nevertheless, the increased burdens on such generators of compliance with the exporter requirements may outweigh the degree of concern involved.

For generators generating between 100–1,000 kg/mo of hazardous waste, current regulations subject such generators to certain manifest requirements which are imposed pursuant to 40 CFR 261.5 but which are similar to some Part 262 requirements. Accordingly, again, these generators arguably also should not be regulated more stringently for exports than for domestic shipments and therefore should not be subject to full Part 262 requirements. It may be better to require these generators to comply with partial Part 262 requirements such as those currently imposed pursuant to 40 CFR 261.5. In other words, apply general Part 262 requirements only to the extent they are required for domestic off-site shipment for such generators. Foreign policy concerns for requiring such generators to at least comply with the export requirements are stronger than for generators of 100 kg/mo or less since generators of between 100 and 1,000 kg/mo are regulated more stringently domestically than generators of 100 kg/mo or less. This evidences more domestic concern with such waste which indicates that a foreign country would have increased concerns and therefore should be notified, etc. Again, on the other hand, the increased burdens on such generators of compliance with the exporter requirements may outweigh the degree of concern involved.

Thus, EPA will consider these options for handling small quantity generators in light of any comments received. In addition, EPA points out that it recently proposed new requirements generally for small quantity generators on August 1, 1985 at 50 FR 31278. Any decision EPA makes in its final rulemaking regarding exports will take into consideration any decisions EPA makes in issuing a final rule regarding that proposal.[4]

N. State Authority

1. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization EPA retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State. When new, more stringent Federal requirements were promulgated or enacted, the State was obliged to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under newly enacted section 3006(g) of RCRA, new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. EPA is directed to carry out those requirements and prohibitions in authorized States

[2] Generators of between 100 and 1,000 kg of hazardous waste in a calendar month are currently subject to certain manifest provisions mandated by section 3001(d) of the HSWA. However these manifest requirements are not imposed pursuant to Part 262, Subpart B and thus do not subject these generators to the exporter definition.

[3] If this option were selected, since such generators are not required to prepare a manifest, the EPA Acknowledgment of Consent would only be required to travel with any other shipping document accompanying the shipment as opposed to the requirement that the EPA Acknowledgment of Consent be attached to the manifest.

[4] It should be noted that the proposed amendments to the small quantity generator rules would remove generators of between 100 kg and 1,000 kg of hazardous waste in a calendar month from the conditional exclusion provisions of § 261.5 and subject them instead to regulation under Part 262. As a result, if the August 1, 1985, amendments are finalized, generators of 100–1,000 kg/mo would fall within the definition of exporter and would be subject to the export requirements and portions of Part 262.

until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, HSWA applies in authorized States in the interim.

Today's announcement proposes standards that would be effective in all States since the requirements are imposed pursuant to section 3017 of the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. 6937. The rule setting forth these standards would be added to Table 1 in § 271.1(j) which identifies the Federal program requirements that are promulgated pursuant to HSWA and that take effect simultaneously in all States regardless of their authorization status.

2. Effect on State Authorizations

Under current regulations (40 CFR 271.10(e)), States are required to include provisions respecting international shipments which are equivalent to those at 40 CFR 262.50, except that advance notification of international shipments, as required by 40 CFR 262.50(b)(1) must be filed with the Admininstrator of EPA. Upon receipt of the notification, EPA then forwards the information, in conjunction with the Department of State, to the receiving country. Thus, unlike other provisions of Part 262, States were not authorized to carry out § 262.50 in its entirety.

Consistent with existing procedures, EPA does not propose to allow States to assume the authority to receive notifications of intent to export. In addition, States would not be authorized to transmit such information to foreign countries through the Department of State or to transmit Acknowledgments of Consent to the exporter. In EPA's view, foreign policy interests and exporters' interests in expeditious processing are better served by EPA's retaining these functions. This will provide the Department of State with a single point of contact in administering the export program which will better allow for uniformity and expeditious transmission of information between the United States and foreign countries. Accordingly, States would be required to include requirements equivalent to those proposed today with the exceptions noted above. EPA requests comments on the alternative of allowing States to assume the functions covered by the exceptions. The rule proposed today also would require that annual reports and exception reports be provided the Administrator. Of course, States can also require that such documents be submitted to State Directors. This requirement is necessary in light of EPA's participation in the export scheme and in light of foreign policy interests.

EPA also proposes to amend § 271.11 to require State programs to include the requirements that transporters also carry a copy of the EPA Acknowledgment of Consent.

3. Schedule for Receiving Authorization

A State may apply to receive either interim or final authorization under section 3006(g)(2) or 3006(b), respectively, on the basis of requirements that are substantially equivalent or equivalent to 40 CFR 271.10(e). The procedures and schedule for State program modifications under Section 3006(b) are described in 40 CFR 271.21. The same procedures should be followed for Section 3006(g)(2).

Applying § 271.21(e)(2), States that have final authorization must modify their programs within a year of promulgation of EPA's regulations if only regulatory changes are necessary, or within two years of promulgation if statutory changes are necessary. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)).

States that submit official applications for final authorization less than 12 months after promulgation of EPA's regulations may be approved without satisfying § 271.10(e) as amended. However, once authorized, a State must modify its program to include standards substantially equivalent or equivalent to those in § 271.10(e) within the time periods discussed above.

4. "Hazardous Waste" in Authorized States

EPA intends that where a State obtains authorization, "hazardous waste" for purposes of export requirements would be those hazardous wastes identified or listed by the State as part of its authorized program plus any hazardous wastes which EPA identifies or lists pursuant to HSWA. This is consistent with EPA's usual interpretation of "identified or listed under this subtitle" as referring to an authorized State's universe of hazardous waste plus HSWA wastes. This approach allows an exporter to function on the basis of the State universe of hazardous waste, with which he is already familiar, expanded by those wastes EPA adds pursuant to the HSWA. One drawback to this approach is that notification would be required for waste "A" exported from a State which considers it to be hazardous but would not be required in another State where waste "A" is not considered hazardous. This might be confusing to foreign countries.

Alternatively, EPA could base implementation on only the Federal universe of hazardous wastes. While this approach would be easier for foreign countries to understand and perhaps better from a foreign policy perspective, it would require that exporters become familiar with the entire Federal universe in addition to the State universe under which the exporters otherwise function. EPA requests comments on which universe of hazardous wastes should apply in authorized States.

O. Confidentiality [§§ 260.2, 262.53(e)]

Title 40 CFR 260.2 provides that information submitted to EPA under Parts 260 through 265[5] of 40 CFR will be made available to the public to the extent authorized by, among other statutory provisions, Section 3007(b) of RCRA as implemented by the regulations of Part 2, Subpart B of 40 CFR. Section 260.2 also provides that a person submitting such information to EPA may submit a claim of confidentiality covering all or part of such information by following the procedures set forth in 40 CFR 2.203(b). Under such circumstances EPA will disclose such information only in accordance with Part 2, Subpart B, of 40 CFR. Part 2, Subpart B, sets forth the standards for determining the validity of a claim of confidentiality and the procedures for processing such claims and disclosing such information determined not to be entitled to confidential treatment.

EPA proposes to amend § 260.2 to provide that information for which a claim of confidentiality is made will be disclosed by EPA only to the extent and by means of the procedures set forth in 40 CFR Part 2, Subpart B, except that information contained in a notification of intent to export a hazardous waste pursuant to proposed § 262.53(a) will be provided to appropriate authorities in receiving countries and the Department of State regardless of such a claim. Information will otherwise be disclosed to the public and transit countries in accordance with 40 CFR Part 2.

This approach to the confidentiality of Section 3017 notices is based upon EPA's interpretation of RCRA. There is an apparent conflict on the face of the statute between section 3007(b) and section 3017. Section 3007(b) could be read as prohibiting *all* disclosure of any

[5] This reference to Part 265 has been changed in the proposed regulation to Part 266 so as to include new Part 266 (50 FR 666, January 4, 1985) consistent with the intent of 40 CFR 260.2 to cover all the hazardous waste regulations.

confidential business information contained in a notice of intent to export. However, this reading would contradict section 3017. Because the statute must be interpreted to give the fullest possible effect to both section 3007(b) and section 3017, EPA interprets section 3017 to require provision of the notification information to a receiving country through the Department of State even if the information in the notice is confidential but to prohibit disclosure by EPA of such confidential business information to other persons. The purpose of the notification is to allow receiving countries to make an informed decision as to whether to accept the waste and, if so, how to deal with that waste. Moreover, section 3017 prohibits the export of hazardous waste in the absence of consent by the receiving country. Thus, unless such information can be divulged to the Department of State and receiving countries, informed consent could not be obtained and the export would be prohibited.

There is no statutory purpose for EPA to receive notices under section 3017 unless EPA can give such notices to the receiving country. Nor could EPA implement the requirement to obtain the consent of such governments unless such notice can be provided. Accordingly, EPA must divulge such information to the Department of State and receiving countries to implement section 3017.

The disclosure of additional information to the Department of State and receiving countries pursuant to a request from a receiving country for further information beyond that required by § 262.53 will be governed by section 3007(b) and implementing regulations at 40 CFR Part 2. In EPA's view, Congress specifically delineated in section 3017(c) the information minimally necessary to allow a foreign country to take appropriate action in response to a notification of intent to export and authorized EPA to impose any additional requirements if deemed necessary. The proposed notification provision accomplishes this and any further information which a receiving country may request should be treated in the same manner as other Subtitle C information. However, exporters should keep in mind that if such information is not disclosed to a receiving country, consent may not be forthcoming and the export could not take place.

As previously discussed, EPA also plans to notify transit countries. Since EPA proposed to define "receiving countries" not to include transit countries, section 3007(b) would govern provision of notification information to transit countries. Accordingly, any claims of confidentiality will be processed in accordance with 40 CFR Part 2 with respect to transit countries. However, as provided in proposed § 262.53(e), a notification may be deemed not to be complete until any claims of confidentiality made with respect to the information required by § 262.53(a) are resolved.

Under this proposal, EPA would have the discretion to determine whether the information claimed confidential in a notification is information which must be provided a transit country unless determined by EPA to be entitled to confidential treatment. Thus, the time frame set forth in section 3017(d) for submission of a "complete" notification to a receiving country will not begin to run until a determination by EPA of the validity of any such claims has been made. Only upon EPA's completion of such processing of confidentiality claims will the notification information be provided to receiving countries and any nonconfidential information provided to transit countries. Since an export cannot take place in the absence of the consent of the receiving country, exporters should be aware that claims of confidentiality could therefore significantly delay shipment.

If an exporter claims only portions of the notification information confidential and EPA determines that the information not claimed confidential is sufficient to provide necessary infromation to a transit country, EPA may find the notification complete and proceed to notify the receiving country of all notification information and transit countries of that information not claimed confidential, thereby avoiding delay. For example, if an exporter claims only the name of the consignee confidential, EPA could reasonably conclude that this information is not significant with respect to transit countries and that the remaining information is sufficient to provide necessary information to the transit country. Thus, EPA may find the notification complete, and proceed with notification.

EPA believes that notification of transit countries is important to protect human health and the environment as well as important from a foreign policy standpoint. Therefore, EPA wishes to inform transit countries of as much information as possible. This policy, however, is constrained by the need to maintain the confidentiality of validity confidential business information. In order to satisfy both these policies, EPA's proposal would allow EPA to delay transmission of notification information until such confidentiality claims are resolved where it determines such action to be necessary. Once resolved, EPA will proceed with providing receiving countries with all notification information and transit countries with all information determined not to be entitled to confidential treatment in accordance with 40 CFR Part 2, Subpart B. This provision is proposed under the authority of section 3017(h).

EPA puts exporters on notice, however, that EPA does not believe that notification information generally is entitled to treatment as confidential business information. This belief is supported by EPA's experience that existing notifications, which consist of identification of the exporter, waste and consignee, have not been claimed by exporters to be confidential. Furthermore, EPA believes that exporters will not be able to demonstrate that the availability of such information is likely to cause substantial harm to the business's competitive position or that this information is not otherwise obtainable without the business's consent. For example, much of this information is required on manifests which may be available from State authorities. Moreover, if a situation arises where confidentiality may be a valid concern, EPA believes that it would generally be sufficient to assert a claim as to only a single piece of information, such as the consignee, to ensure protection. EPA requests comments on its proposed treatment of confidentiality claims.

IV. Enforcement

A. EPA

Noncompliance with RCRA section 3017 or regulations promulgated thereunder is subject to enforcement actions under section 3008. As the legislative history of section 3017 states:

> The requirements of this section should be vigorously enforced using all the tools of section 3008. To accomplish this, the Agency should work with the U.S. Customs Service to establish an effective program to monitor and spotcheck international shipments of hazardous waste to assure compliance with the requirements of the section. Violations should then be vigorously pursued. S. Rep. No. 98–284, 98th Cong., 1st sess. 48.

Most importantly, the HSWA amendments include an amendment to section 3008(d) of RCRA authorizing criminal penalties for knowingly exporting a hazardous waste without the consent of the receiving country or in nonconformance with an international agreement between the U.S. and a receiving country. Section 3008

establishes a penalty of $50,000 per day for knowingly exporting a hazardous waste without a consent or in violation of a bilateral agreement. Prison terms may be up to two years. Penalties and prison terms may be doubled for second offenses. EPA intends to prosecute violators of the export rule to the fullest extent.

B. Customs

The new HSWA provision on the export of hazardous waste raises issues concerning cooperation between EPA and the U.S. Customs Service on enforcement matters. As noted above, Congress intended that EPA "should work with the U.S. Customs Service to establish an effective program to monitor and spotcheck international shipments of hazardous waste to assure compliance with the requirements of [Section 3017]." To further this legislative intent, EPA is presently consulting with the U.S. Customs Service in order to develop an effective program to monitor and spotcheck hazardous waste exports.

The United States Customs Service has independent authority to stop, inspect, search, seize, and detain suspected illegal exports of hazardous wastes under the Export Administration Act, 50 U.S.C. App. 2411, as amended by the Export Administration Amendments Act of 1985, Pub. L. No. 99-64, 99 Stat. 120 (1985), case law, and U.S. Customs Service regulations (e.g., 19 CFR Part 162). Exporters who violate the Export Administration Act or U.S. Customs Service regulations may also be subject to enforcement actions under those authorities.

C. Other Agencies

Exporters of hazardous waste also may be required to comply with pertinent export control laws and regulations issued by other agencies. For example, regulations promgulated by the Bureau of the Census, Department of Commerce, require exporters to file Shipper's Export Declarations for shipments valued over $1,000. 15 CFR Part 30. It may very well be possible that hazardous waste exported for purposes of recycling would have a value over $1,000. The "Schedule B—Statistical Classification of Domestic and Foreign Commodities exported from the United States" contains a statistical reporting number for certain waste and scrap. This number (793.0000) must be used in preparing Shipper's Export Declarations, as required by 13 U.S.C. 301 and 15 CFR Part 301. EPA is consulting with the Bureau of the Census about the advisability of adding a reporting number for hazardous waste to "Schedule B."

Failure to file a Shipper's Export Declaration is subject to civil penalties as authorized by 13 U.S.C. 305. It is also unlawful to knowingly make false or misleading representations in such documents. This constitutes a violation of the Export Administration Act. To knowingly make false or misleading statements relating to information on the Shipper's Export Declaration is a criminal offense subject to penalties as provided for in 18 U.S.C. 1001.

V. Effective Date of Final Regulations

EPA proposes that any final regulatory provisions issued pursuant to section 3017(c) setting forth export notification requirements shall become effective 30 days after promulgation.

Section 3010(b) provides that regulations promulgated under Subtitle C shall have an effective date six months after the date of promulgation. That section also allows the Administrator to provide for a shorter period prior to the effective date under specified conditions. Section 3017(b) also sets forth the requirement that regulations be effective six months (180 days) after promulgation. It does not mention specifically, however, the Administrator's discretion to allow a shorter time. Thus, the question arises as to whether section 3010(b) or section 3017(b) is controlling. It is EPA's view that section 3010(b) is controlling. Where Congress intended that the Administrator have no discretion to shorten the period prior to the effective date, Congress used specific language to that effect. Thus, section 3001(d)(9) provides that "the last sentence of § 3010(b) shall not apply to regulations promulgated under this Section." Accordingly, since Congress did not specifically provide otherwise under section 3017, the Administrator retains the authority to shorten this period.

EPA believes a shorter effective date is appropriate with respect to the export rules since the regulated community does not need six months to come into compliance with these rules. These rules are not complex and simply involve the exchange of general information. In addition, at this point in time, it is unlikely that these regulation can be effectuated by November 8, 1986,[6] and still allow for a 180 day period prior to the effective date. Yet, EPA believes it important to have rules in effect to properly implement section 3017 by that date.

[6] Section 3017(a) provides compliance with that section 24 months after enactment of HSWA (November 8, 1986).

Assuming, however, that section 3010(b) is not controlling, EPA believes that its scheme for effectuation of these rules is also authorized by section 3017 itself. This scheme comports with Congressional intend that this section go into effect by November 8, 1986, and that regulations be in place by that time. Although section 3017 also provides that regulations promulgated under that section take effect 180 days after promulgation, it is unlikely that, at this point in time, final regulations will be promulgated sufficiently in advance of November 8, 1986, to allow for effectuation by that date as well as a 180-day period between promulgation and effectuation. Under such circumstances, and because regulatory provisions interpreting section 3017 are important to the proper implementation of that section, it is EPA's view that the November 8, 1986 date must control for purposes of the effective date of the export regulations. Where EPA is unable to satisfy both of these statutory time frames, surely the November 8, 1986 deadline for implementing section 3017 is more important than the number of days between promulgation and effectuation.

VI. Economic, Environmental and Regulatory Impacts

A. Impact on Small Quantity Generators

Because of the small number of Small Quantity Generators EPA expects will export hazardous waste, the impact on Small Quantity Generators should be minimal.

B. Executive Order 12291—Regulatory Impact

Under Executive Order 12291 (46 FR 12193, February 19, 1981), EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis.

This proposed regulation is not major because it will not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) cause significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Therefore, under Executive Order 12291, today's action is not "major." This proposed regulation has been submitted to the Office of Management and Budget (OMB) for review.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA and a copy may be obtained from: Nanette Liepman: Information Management Branch; EPA; 401 M. Street, SW. (PM–223); Washington, D.C. 20460 or by calling 202–382–2742. Submit comments on these requirements to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for EPA, 726 Jackson Place NW., Washington, D.C. 20503. The final rule will respond to OMB or public comments on the information collection requirements.

D. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, a regulatory flexibility analysis must be performed if the regulatory requirements have a significant impact on a substantial number of small entities. No regulatory flexibility analysis is required where the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Since 1980, generators exporting hazardous waste have been required by EPA to notify the Administrator four weeks before the initial shipment of hazardous waste to each country in each calendar year. Based upon an analysis of those notifications received, the Agency has determined that no small entities have filed notifications of intent to export. EPA does not anticipate that the universe of generators exporting hazardous waste will significantly change in the future. Therefore, this rule is not expected to have a significant economic impact on a substantial number of small entities and does not require a regulatory flexibility analysis. Therefore, pursuant to 5 U.S.C. 601(b), I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

VII. List of Subjects

40 CFR Part 260

Administrative practice and procedure, Confidential business information, Hazardous Waste, Liquids in Landfills.

40 CFR Part 262

Hazardous material transportation, Hazardous waste, Imports, Exports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Waste minimization.

40 CFR Part 263

Hazardous materials transportation, Waste treatment and disposal.

40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Lee M. Thomas,

Administrator.

March 4, 1986.

For the reasons set out in the Preamble, Title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The authority citation for Part 260 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3001, through 3007, 3010, 3014, 3015, 3017, 3018, 3019 and 7004, Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974).

2. Section 260.2 is proposed to be amended by revising paragraph (b) to read as follows:

§ 260.2 Availability of information; confidentiality of information.

* * * * *

(b) Any person who submits information to EPA in accordance with Parts 260 through 266 of this chapter may assert a claim of business confidentiality covering part or all of that information by following the procedures set forth in § 2.203(b) of this chapter. Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in Part 2, Subpart B, of this chapter except that information required by §262.53(a) which is submitted in a notification of intent to export a hazardous waste will be provided to the Department of State and the appropriate authorities in a receiving country regardless of any claims of confidentiality. However, if no such claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the person submitting it.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

3. The authority citation for Part 262 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3002, 3003, 3004, 3005, and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6906, 6912(a), 6922, 6923, 6924, 6925, and 6937).

4. Section 262.41 is proposed to be amended by revising the introductory text of paragraph (a) and paragraphs (a)(3), (a)(4) and (a)(5) and adding two sentences to the end of paragraph (b) to read as follows:

§ 262.41 Biennial Report.

(a) A generator who ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States must prepare and submit a single copy of a Biennial Report to the Regional Administrator by March 1 of each even numbered year. The Biennial Report must be submitted on EPA Form 8700–13A, must cover generator activities during the previous year, and must include the following information:

* * * * *

(3) The EPA identification number, name, and address for each off-site treatment, storage, or disposal facility in the United States to which waste was shipped during the year;

(4) The name and EPA identification number of each transporter used during the reporting year for shipments to a treatment, storage or disposal facility within the United States;

(5) A description, EPA hazardous waste number (from 40 CFR Part 261, Subpart C or D), DOT hazard class, and quantity of each hazardous waste shipped off-site for shipments to a treatment, storage or disposal facility within the United States. This information must be listed by EPA identification number of each off-site facility to which waste was shipped.

* * * * *

(b) * * *

Reporting for exports of hazardous waste is not required on the Biennial Report form. A separate annual report requirement is set forth at 40 CFR 262.56.

5. Subpart E consisting of §§ 262.50–262.58 of 40 CFR Part 262 is proposed to be by revised to read as follows:

Subpart E—Exports of Hazardous Waste

Sec.

Sec.

Subpart E—Exports of Hazardous Waste

§ 262.50 Applicability.

This subpart establishes requirements applicable to exports of hazardous waste. An exporter of hazardous waste must comply with the special requirements of this subpart except to the extent § 262.58 provides otherwise. Section 262.58 sets forth the requirements of international agreements between the United States and receiving countries which establish different notice, export, and enforcement procedures for the transportation, treatment, storage and disposal of hazardous waste for shipments between the United States and those countries.

§ 262.51 Definitions.

In addition to the definitions set forth at 40 CFR 260.10, the following definitions apply to this subpart:

"Consignee" means the ultimate treatment, storage or disposal facility in the receiving country to which the hazardous waste will be sent.

"EPA Acknowledgment of Consent" means the cable sent to EPA from the U.S. Embassy in the receiving country that acknowledges the written consent of the receiving country to accept the hazardous waste and describes the terms and conditions of the receiving country's consent to the shipment.

"Exporter" is the person who is required to prepare the manifest for a shipment of hazardous waste, in accordance with 40 CFR Part 262, Subpart B, or equivalent State provision, which specifies a treatment, storage or disposal facility in the receiving country as the facility to which the hazardous waste will be sent.

"Receiving country" means the foreign country of ultimate destination of the hazardous waste.

"Transit country" means any foreign country through which a hazardous waste passes en route to a receiving country.

§ 262.52 General Requirements.

Exports of hazardous waste are prohibited except in compliance with the applicable requirements of this subpart. No person shall export any hazardous waste unless:

(a) Notification in accordance with § 262.53 has been provided;

(b) The receiving country has consented to accept the hazardous waste;

(c) A copy of the EPA Acknowledgment of Consent to the shipment is attached to the manifest (or shipping paper for exports by rail or water (bulk shipment)) accompanying each hazardous waste shipment; and

(d) The hazardous waste shipment conforms to the terms of the receiving country's written consent as reflected in the EPA Acknowledgment of Consent.

§ 262.53 Notification of intent to export.

(a) An exporter of hazardous waste must notify EPA of an intended export before such waste is scheduled to leave the United States. A complete notification should be submitted sixty (60) days before the initial shipment is intended to be shipped off site. This notification may cover export activities extending over a twenty-four (24) month or lesser period. The notification must be in writing, signed by the exporter and include the following information:

(1) Name, mailing address, telephone number and EPA ID number of the exporter;

(2) By consignee, for each hazardous waste type:

(i) A description of the hazardous waste and the EPA hazardous waste number (from 40 CFR Part 261, Subparts C and D), U.S. DOT proper shipping name, hazard class and ID number (UN/NA) for each hazardous waste as identified in 49 CFR Parts 171–177;

(ii) The estimated number of shipments of the hazardous waste and approximate date of each shipment;

(iii) The estimated total quantity of the hazardous waste in units as specified in the instructions to the Uniform Hazardous Waste Manifest Form (8700–22);

(iv) All points of entry to and departure from each foreign country through which the hazardous waste will pass;

(v) A description of the means by which each shipment of the hazardous waste will be transported (e.g., mode of transportation vehicle (air, highway, rail, water, etc.), type(s) of container (drums, boxes, tanks, etc.));

(vi) A description of the manner in which the hazardous waste will be treated, stored or disposed of in the receiving country (e.g., land or ocean incineration, other land disposal, ocean dumping, recycling);

(vii) The name and site address of the consignee and any alternate consignee; and

(viii) The name of any transit countries through which the hazardous waste will be sent and a description of the approximate length of time the hazardous waste will remain in such country and the nature of its handling while there;

(b) Notification shall be sent to the Office of International Activities (A–106), EPA, 401 M Street SW., Washington, D.C. 20460.

(c) When the conditions specified on the original notification change (including any exceedance of the estimate of the quantity of hazardous waste specified in the original notification), the exporter must provide EPA with a written renotification of the change. The shipment cannot take place until consent of the receiving country to the changes has been obtained and the exporter receives an EPA Acknowledgment of Consent reflecting the receiving country's consent to the changes.

(d) Upon request by EPA, an exporter shall furnish to EPA any additional information which a receiving country requests in order to respond to a notification.

(e) In conjunction with the Department of State, EPA will provide a complete notification to the receiving country and any transit countries. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of paragraph (a) of this section. Where a claim of confidentiality is asserted with respect to any notification information required by paragraph (a) of this section, EPA may find the notification not complete until any such claim is resolved in accordance with 40 CFR 260.2.

(f) Where the receiving country consents to the receipt of the hazardous waste, EPA will forward an EPA Acknowledgment of Consent to the exporter for attachment to the manifest (or shipping paper for exports by rail or water (bulk shipment)) accompanying each waste shipment. Where the receiving country objects to receipt of the hazardous waste or withdraws a prior consent, EPA will notify the exporter in writing. EPA will also notify the exporter of any responses from transit countries.

§ 262.54 Special manifest requirements.

An exporter must comply with the manifest requirements of 40 CFR 262.20–262.23 except that:

(a) In lieu of the name, site address and EPA ID number of the designated permitted facility, the exporter must enter the name and site address of the consignee;

(b) In lieu of the name, site address and EPA ID number of a permitted

alternate facility, the exporter may enter the name and site address of any alternate consignee.

(c) In Special Handling Instructions and Additional Information, the exporter must identify the point of departure from the United States;

(d) The following statement must be added to the end of the first sentence of the certification set forth in Item 16 of the Uniform Hazardous Waste Manifest Form: "and conforms to the terms of the attached EPA Acknowledgment of Consent";

(e) In lieu of the requirements of § 262.21, the exporter must obtain the manifest form from the exporter's State if that State supplies the manifest form and requires its use. If the exporter's State does not supply the manifest form, the exporter may obtain a manifest form from any source.

(f) The exporter must require the consignee to confirm in writing the delivery of the hazardous waste to that facility and to describe any significant discrepancies (as defined in 40 CFR 264.72(a)) between the manifest and the shipment. A copy of the manifest signed by such facility may be used to confirm delivery of the hazardous waste.

(g) In lieu of the requirements of § 262.20(d), where a shipment cannot be delivered for any reason to the designated or alternate consignee, the exporter must:

(1) Renotify EPA of a change in the conditions of the original notification to allow shipment to a new consignee in accordance with § 262.53(c) and obtain an EPA Acknowledgment of Consent prior to delivery; or

(2) Instruct the transporter to return the waste to the exporter in the United States or designate another facility within the United States; and

(3) Instruct the transporter to revise the manifest in accordance with the exporter's instructions.

(h) The exporter must attach a copy of the EPA Acknowledgment of Consent to the shipment to the manifest (or shipping paper for exports by rail or water (bulk shipment)) which must accompany the hazardous waste shipment.

§ 262.55 Exception Reports.

In lieu of the requirements of § 262.42, an exporter must file an exception report with the Administrator if:

(a) He has not received a copy of the manifest signed by the transporter stating the date and place of departure from the United States within forty-five (45) days from the date it was accepted by the initial transporter;

(b) Within ninety (90) days from the date the waste was accepted by the initial transporter, the exporter has not received written confirmation from the consignee that the hazardous waste was received;

(c) The waste is returned to the United States.

§ 262.56 Annual Reports.

(a) Exporters of hazardous waste shall file with the Administrator no later than March 1 of each year, a report summarizing the types, quantities, frequency, and ultimate destination of all such harardous waste exported during the previous calendar year. Such reports shall include the following:

(1) The EPA identification number, name, and mailing and site address of the exporter;

(2) The calendar year covered by the report;

(3) The name and site address of each consignee;

(4) By consignee for each hazardous waste exported, a description of the hazardous waste, the EPA hazardous waste number (from 40 CFR Part 261, Subpart C or D), DOT hazard class, the name and US EPA ID number (where applicable) for each transporter used, the total amount of waste shipped and number of shipments pursuant to each notification; and

(5) A certification signed by the exporter which states:

"I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment."

(b) Reports shall be sent to the following address: Office of International Activities (A-106), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

§ 262.57 Recordkeeping.

(a) For all exports an exporter must:

(1) Keep a copy of each notification of intent to export for a period of at least three years from the date the hazardous waste was accepted by the initial transporter;

(2) Keep a copy of each EPA Acknowledgment of Consent for a period of at least three years from the date the hazardous waste was accepted by the initial transporter;

(3) Keep a copy of each confirmation of delivery of the hazardous waste from the consignee for at least three years from the date the hazardous waste was accepted by the initial transporter;

(4) Keep a copy of each annual report for a period of at least three years from the due date of the report.

(b) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

§ 262.58 International Agreements [Reserved].

6. Title 40 CFR Part 262 is proposed to be amended by adding new Subpart F consisting of § 262.60 to read as follows:

Subpart F—Imports of Hazardous Waste

§ 262.60 Imports of Hazardous Waste.

(a) Any person who imports hazardous waste from a foreign country into the United States must comply with the requirements of this part and the special requirements of this subpart.

(b) When importing hazardous waste, a person must meet all the requirements of § 262.20(a) for the manifest except that:

(1) In place of the generator's name, and address and EPA identification number, the name address of the foreign generator and the importer's name, address and EPA identification number must be used.

(2) In place of the generator's signature on the certification statement, the U.S. Importer or his agent must sign and date the certification and obtain the signature of the initial transporter.

(c) A person who imports hazardous waste must obtain the manifest form from the consignment State if that State supplies the manifest and requires its use. If the consignment State does not supply the manifest form, then the manifest form may be obtained from any source.

7. Title 40 CFR Part 262 is proposed to be amended by adding a new Subpart G consisting of § 262.70 to read as follows:

Subpart G—Farmers

§ 262.70 Farmers.

A farmer disposing of waste pesticides from his own use which are hazardous wastes is not required to comply with the standards in this part or other standards in 40 CFR Parts 270, 264 or 265 for those wastes provided he triple rinses each emptied pesticide container in accordance with § 261.7(b)(3) and disposes of the pesticide residues on his own farm in a

manner consistent with the disposal instructions on the pesticide label.

Appendix—Uniform Hazardous Waste Manifest and Instructions (EPA Forms 8700–22 and 8700–22A and Their Instructions)

8. The instructions to the Uniform Hazardous Waste Manifest form in the Appendix to Part 262 is amended to add under Item 16 a new paragraph after the first paragraph as follows:

* * * * *

Exporters shipping hazardous wastes to a facility located outside of the United States must add to the end of the first sentence of the certification the following words "and conforms to the terms of the attached Acknowledgment of Consent."

* * * * *

PART 263—STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

9. The authority citation for Part 263 is proposed to be revised to read as follows:

Authority: Secs. 2002(a), 3002, 3003, 3004, 3005 and 3017 of the Solid Waste Disposal Act as amended by the Resource Conservation and Recovery Act of 1976 and as amended by the Quiet Communities Act of 1978 (42 U.S.C. 6912, 6922, 6923, 6924, 6925, and 6937).

10. Section 263.20 is proposed to be amended by revising paragraphs (a), (c), (e)(2), and (f)(2) to read as follows:

§ 263.20 The Manifest System.

(a) A transporter may not accept hazardous waste from a generator unless it is accompanied by a manifest signed in accordance with the provisions of 40 CFR 262.20. In the case of exports, a transporter may not accept such waste from an exporter or other person unless, in addition to a manifest signed in accordance with the provisions of 40 CFR 262.20, such waste is also accompanied by an EPA Acknowledgment of Consent attached to the manifest.

* * * * *

(c) The transporter must ensure that the manifest accompanies the hazardous waste. In the case of exports, the transporter must ensure that a copy of the EPA Acknowledgment of Consent also accompanies hazardous waste for export.

* * * * *

(e) * * *

(2) A shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator certification, and signatures) and, for exports, an EPA Acknowledgment of Consent accompanies the hazardous waste; and

* * * * *

(f) * * *

(2) Rail transporters must ensure that a shipping paper containing all the information required on the manifest (excluding the EPA identification numbers, generator certification, and signatures) and, for exports an EPA Acknowledgment of Consent accompanies the hazardous waste at all times.

* * * * *

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

11. The authority citation for Part 271 continues to read as follows:

Authority: Sec. 1006, 2002(a), and 3006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), and 6926).

§ 271.1 [Amended]

12. Section 271.1(j) is proposed to be amended by adding the following entry to Table 1 in chronological order:

TABLE 1.—REGULATIONS IMPLEMENTING THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Date	Title of regulation
• •	• •
March 13, 1986	Exports of Hazardous Waste.

13. Section 271.10 is proposed to be amended by revising paragraphs (e) introductory text and (e)(1) and (e)(2) to read as follows. The note remains unchanged.

§ 271.10 Requirements for generators of hazardous wastes.

* * * * *

(e) The State program shall provide requirements respecting international shipments which are equivalent to those at 40 CFR Part 262 Subparts E and F, except that:

(1) Advance notification, annual reports and exception reports in accordance with 40 CFR 262.53, 262.55 and 262.56 shall be filed with the Administrator; States may require that copies of the documents referenced also be filed with the State Director); and

(2) The Administrator will notify foreign countries of intended exports in conjunction with the Department of State and exporters of foreign countries' responses in accordance with 40 CFR 262.53.

14. Section 271.11 is proposed to be amended by revising paragraph (c) to read as follows:

§ 271.11 Requirements for transporters of hazardous wastes.

* * * * *

(c) The State must require the transporter to carry the manifest during transport, except in the case of shipments by rail or water specified in 40 CFR 263.20 (e) and (f) and to deliver waste only to the facility designated on the manifest. The State program shall provide requirements for shipments by rail or water equivalent to those under 40 CFR 263.20 (e) and (f). For exports of hazardous waste, the State must require the transporter to also carry a copy of the EPA Acknowledgment of Consent to the shipment.

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federal register

Thursday
March 13, 1986

Part III

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Changes to the Diagnosis-Related Group (DRG) Classification System; Proposed Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BERC-357-PN]

Medicare Program; Changes to the DRG Classification System

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

ACTION: Proposed notice.

SUMMARY: In the final rule published September 3, 1985 on the prospective payment system for inpatient hospital services (50 FR 35646), we stated that we would publish a later notice addressing issues related to the Diagnosis-Related Group (DRG) classification system. This is that notice. In this proposed notice, we respond to comments received on the DRG classification system, discuss Medicare coverage changes affecting the DRG system, list procedures for which new identifying codes (in the coding system of the International Classification of Diseases on which DRG assignments are based) have been proposed, and propose certain changes in the DRG classification system to resolve some of the problems identified by comments and analysis to date.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on April 14, 1986.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-357-PN, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC; or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-357-PN. Comments will be available for public inspection as they are received, beginning approximately three weeks after today, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone 202-245-7890).

FOR FURTHER INFORMATION, CONTACT: Linda Magno (301) 594-9343.

SUPPLEMENTARY INFORMATION:

I. Background

A. Prospective Payment System—General

Under section 1886(d) of the Social Security Act (the Act), enacted by the Social Security Amendments of 1983 (Pub. L. 98-21) on April 20, 1983, a prospective payment system for Medicare payment for inpatient hospital services was established effective with hospital cost reporting periods beginning on or after October 1, 1983. Under this system, Medicare payment is made at a predetermined, specific rate for each discharge; that payment varies by the diagnosis-related group (DRG) to which a beneficiary's stay is assigned. The list of DRGs currently contains 471 specific categories. All but 3 DRGs are categorized into 23 major diagnostic categories (MCDs).

The formula used to calculate payment for a specific case takes a hospital's payment rate per case and multiplies it by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG relative to the national average resources consumed per case by the average hospital. Thus, cases in a DRG with a weight of 2.0 would, on average, require twice as many resources as the average case for the average hospital.

B. Basic DRG Classification System

The method of classifying cases into DRGs for payment under the prospective payment system involves a number of steps. First, the physician enters into a patient's medical record the principal diagnosis, any additional diagnoses, and any procedures performed during the stay. This information is expressed by the hospital using codes from the International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM). The principal diagnosis, as many as four additional diagnoses, the principal procedure, and as many as two additional procedures are reported, along with a patient's age, sex, and discharge status, to the hospital's fiscal intermediary on the hospital request for payment.

The intermediary then enters the information into its claims system and subjects it to a series of automated screens called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before classification into a DRG can be accomplished. During this process, cases such as the following are selected for further development:

- Cases that are obviously improperly coded (for example, diagnoses are shown that are inappropriate given the sex of the patient).
- Cases that include surgical procedures not covered under Medicare (for example, electromagnetic hearing aid implants).
- Cases that require more information (for example, certain biopsies are identified so that the intermediary can determine through development whether the case actually involved an open biopsy (a procedure warranting assignment to a surgical DRG) or a closed biopsy (a procedure warranting assignment to a nonsurgical DRG)).
- Cases with principal diagnoses that do not usually justify admission to the hospital (for example, benign hypertension).

After screening through the Medicare Code Editor and any further development of the claims, cases are classified by the GROUPER computer program into the appropriate DRG. The GROUPER program was developed as a means of classifying each case into a DRG on the basis of the diagnosis and procedure codes and demographic information (that is, sex, age, and discharge status). It is used to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights, and to classify current cases for purposes of determining payment.

Principal diagnosis determines MDC assignment. Within most MDCs, cases are then divided into surgical DRGs (based on a surgical hierarchy that orders procedures by resource intensity) and medical DRGs. Medical DRGs are differentiated on the basis of diagnosis only. Generally, GROUPER does not look at other procedures; that is, those not surgical or those minor surgical procedures generally not done in an operating room and therefore not recognized as surgical by GROUPER.

C. Changes to the DRG Classifications and Weighting Factors

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. In addition, Congress provided the Secretary with authority to reclassify diagnoses and procedures within the DRG system to take into account changes in medical technology and treatment patterns. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and weighting factors effective for discharges occurring in FY 1986 and at least every four fiscal years thereafter. These adjustments are made to reflect changes in resource consumption,

treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The intention of Congress was that we would make changes as often as needed to achieve the objectives of the prospective payment system, including the need to keep current with developments in the areas of coverage and medical technology.

D. Implementation of the DRG System

1. General

During the initial operating period of the prospective payment system, we learned that the DRG method of classification is dynamic rather than static and that the need to maintain and improve it posed some operational challenges that we needed to address further. Operational experience and technological advances have led us to identify situations that require positive actions to resolve. These cases include the following:

- Cases that can be classified more accurately with revisions to GROUPER.
- Cases in which we discover that there are unintended omissions or inequities in the classification system (for example, mechanical or conceptual flaws).
- Cases in which an addition to Medicare coverage requires assignment of a new item, service, or procedure to an existing or new DRG.

2. Publication of Proposed and Final Rules—1985

On June 10, 1985, we published a notice of proposed rulemaking (NPRM or proposed rule) in the **Federal Register** (50 FR 24366) to update the prospective payment system in general. As part of that NPRM, and as required by section 1886(d)(4)(C) of the Act, we proposed to adjust the DRG classifications and weighting factors for discharges beginning with Federal fiscal year (FY) 1986. The classification changes were described in Table 6 of the addendum to the NPRM. We proposed to use these new groupings in a revised GROUPER program that was used to classify cases prior to recalibrating the DRG weights published in Table 5 of the addendum to the NPRM.

On September 3, 1985, we published a final rule in the **Federal Register** (50 FR 35646) concerning the prospective payment system. We included in that rule the classification changes proposed in the June 10 proposed rule as we had modified them in response to comments and suggestions we received on the NPRM. We also included some additional changes that followed the principles discussed in the proposed rule or that were similar to them. (As a result of the Emergency Extension Act of 1985 (Pub. L. 99-107) and subsequent extensions of that Act (Pub. L. 99-181, 99-189, and 99-201), the classifications and weights established by the September 3, 1985 final rule will not go into effect until March 15, 1986.)

We indicated in the final rule that we could not address certain classification issues that were raised in the NPRM comment period for various reasons; we also noted that those comments would be analyzed and reviewed during the several months after publication of the final rule and that actions on them would be published in a notice early in 1986. Also, in keeping with our commitment to review classification changes on an ongoing basis, we solicited comments on any other proposed classification changes, and provided an address for such comments.

II. Public Comments

In keeping with our commitment to publish proposed reclassification changes prior to the annual notice of proposed changes to the prospective payment rates, we have prepared this document. We have included in this proposed notice responses to comments that were raised in the NPRM comment period which, as just mentioned, we were unable to respond to in the September 3 final rule, and others that we have received on the DRG weights and the classification process since publication of the September 3 final rule. We expect these proposed changes to represent the major portion of reclassifications for Federal fiscal year 1987. However, we are continuing to study several issues, such as thoracoabdominal aortic aneurysm repairs, major head and neck procedures, hand and upper extremity procedures, and burn cases. Therefore, it is possible that a few additional classification changes may be proposed in the June notice of proposed prospective payment system changes. These comments and our reponses follow and are generally set forth in MDC order.

A. Comments on MDC 1: Diseases and Disorders of the Nervous System

Comment: One commenter believes that it is inappropriate to classify cases of myasthenia gravis (ICD-9-CM codes 3580 and 3581) that involve plasmapheresis into DRG 34 (Other Disorders of the Nervous System, Age over 69 and/or complications or comorbidities [1]).

Response: Myasthenia gravis is not classified in DRG 34. The GROUPER classifies all cases with a principal diagnosis of myasthenia gravis into DRG 12 (Degenerative Nervous System Disorders), regardless of whether plasmapheresis is or is not used as a treatment. While we recognize that plasmapheresis is a costly procedure, it is not a surgical procedure. Accordingly, cases involving plasmapheresis are necessarily assigned to medical DRGs, which are differentiated by principal diagnosis, not by treatment procedures. To the extent that plasmapheresis is used to treat myasthenia gravis, the resources associated with such treatments would be reflected in the weight for DRG 12.

In addition, we note for general reference that since DRG 34 is specific to patients over age 69 or those with complications or comorbidities, a given diagnosis would never be assigned exclusively to that DRG, but would also be assigned to DRG 35 (Other Disorders of Nervous Systems, Age Under 70 without C.C.). Whenever a DRG is split on age and/or complications or comorbidities, it is identical to one or two other DRGs except for the age range of patients assigned to it and the presence or absence of complications/comorbidities. That is, all diagnoses and/or procedures assigned to one DRG specific to a particular age group are assigned to the DRG(s) specific to all other age groups.

B. Comments on MDC 2: Diseases and Disorders of the Eye

Comment: One commenter disagrees with HCFA's decision to classify lens extractions involving anterior chamber injections (procedure code 1292) into DRG 39 (Lens Procedures With or Without Vitrectomy), as was set forth in the September 3, 1985 **Federal Register** publication. Rather, the commenter believes such cases should be classified into DRG 42 (Intraocular Procedures Except Retina, Iris, and Lens).

Response: While the average standardized charges for lens procedures with anterior chamber injections are slightly higher (less than 5 percent) than for lens procedures without such injections, we believe that this differential is minimal. Moreover, we note that anterior chamber injections occurred in less than one percent of the more than 400,000 cases in DRG 39. We believe this confirms our position that anterior chamber injections are incidental to lens procedures classified in DRG 39.

Comment: One commenter was concerned that DRG 42 (Intraocular

[1] Complications or comorbidities is henceforth, where appropriate, abbreviated C.C.

Procedures Except Retina, Iris, and Lens), with an average length of stay of 3.7 days, did not reflect lengths of stay or adequately pay for costs associated with mechanical vitrectomy (procedure code 1474) for cases of acute endophthalmitis (diagnosis codes 36001 through 36019).

Response: We have reviewed these concerns and examined the charges associated with endophthalmitis in DRG 42, with and without mechanical vitrectomy. Our review of the cases within this DRG in fact indicates that average standardized charges for endophthalmitis cases involving procedure code 1474 are slightly lower than the average standardized charges for endophthalmitis cases not involving the procedure. Therefore, we have not accepted this comment. We would also note, however, that the length of stay data in the tables of weights published in the September 3, 1985 final rule, as well as in previous **Federal Register** documents pertaining to the prospective payment system, are for illustrative purposes only. They are not intended to be prescriptive treatment goals. Rather, each entry merely reflects the averages (arithmetic and geometric) of all cases assigned to that DRG. Moreover, unless all cases assigned to a given DRG had an identical length of stay, there will always be both cases with shorter lengths of stay and cases with longer lengths of stay than the average.

Comment: One commenter expressed concern that the average length of stay and weight for DRG 36 (Retinal Procedures) do not adequately compensate for cases involving insertion of a radioactive plaque (procedure code 1427) to treat malignant tumors of the choroid (diagnosis code 1906). The commenter also believes it is inappropriate to group such cases to DRG 36, since they are not retinal procedures, but instead involve the choroid.

Response: That this DRG encompasses both choroid and retinal procedures is not surprising, given that a number of procedures, including procedure code 1427, are specifically defined as chorioretinal procedures by ICD–9–CM. Our data indicate that while the average standardized charges for DRG 36 cases involving procedure code 1427 are somewhat higher than for the DRG as a whole, implantation of a radioactive plaque is a relatively rare procedure (65 Medicare cases out of more than 19,000 in this DRG during FY 1984). Moreover, such a distribution of cases around the mean is common to all DRGs; we find that neither the disparity in average standardized charges nor the volume of cases is sufficient to warrant a classification change. In that regard, we note that the comment included no specific recommendation as to a more appropriate classification of these cases.

C. Comments on MDC 4: Diseases and Disorders of the Respiratory System

Comment: A comment was received stating that several bacterial-specific pneumonias are included within DRGs 79, 80 and 81 (Respiratory Infections and Inflammations; Age over 69 and/or C.C., Age 18–69 without C.C., and Age 0–17, respectively), while others are included in DRGs 89, 90 and 91 (Simple Pneumonia and Pleurisy; Age over 69 and/or C.C., Age 18–69 without C.C., and Age 0–17, respectively). In the September 3 final rule, DRGs 79, 80 and 81 are assigned relative weights of 1.9546, 1.4403, and .8652, respectively, while the weights for DRGs 89, 90 and 91 are relatively lower at 1.1768, .8900, and .8216 respectively. It has been recommended that all gram-negative pneumonias contained within DRGs 89, 90, and 91, with the exception of Hemophilus influenzae (diagnosis code 8422), be classified into DRGs 79, 80, and 81, since these gram-negative pneumonias tend to be as serious and resource-intensive as those pneumonias currently found in the higher-weighted DRGs 79, 80, and 81.

Response: We have conducted an analysis reviewing all of the bacterial-specific pneumonias contained within DRGs 79, 80, 89 and 90 with respect to the number of stays, the average length of stay, and the average standardized charge for each principal diagnosis in FY 1984. We did not review data for DRGs 81 and 91 since one of these (DRG 81) is a low-volume DRG with a weight based on data from Maryland and Michigan. Based on the data that we used in our review, principal diagnosis 4828 (Bacterial pneumonia NEC), which includes E. Coli and Proteus pneumonias, is the only diagnosis code contained within DRGs 89 and 90 that warrants placement into DRGs 79 and 80, which have higher relative weights. Our analysis indicates there is a significant difference between the average length of stay and average standardized charge for this principal diagnosis (4828) as compared to the remaining simple pneumonias contained within DRGs 89 and 90. Both the average length of stay and average standardized charges of cases with principal diagnosis 4828 are more comparable to those found for the bacterial-specific pneumonias already contained within DRGs 79 and 80.

Therefore, based on this analysis, we propose removing diagnosis code 4828 (Bacterial pneumonia NEC) from DRGs 89, 90, and 91 and placing this code into DRGs 79, 80, and 81. Due to the low volume of cases having this principal diagnosis, as compared to the total volume of cases in DRGs 79, 80, 89, and 90, the total impact of this proposed change on the relative weights of the affected DRGs is expected to be minimal. Although our analysis was limited to DRGs 79, 80, 89 and 90, we believe it is appropriate to propose to remove code 4828 from DRG 91 and to place it into DRG 81, to maintain the existing parallels among the respiratory infection DRGs (79, 80, and 81) and the pneumonia DRGs (89, 90, and 91), since they are identical except for age and complications/comorbidities.

D. Comments on MDC 5: Diseases and Disorders of the Circulatory System

Comment: We received several comments concerning Percutaneous Transluminal Coronary Angioplasty (PTCA). The commenters were concerned with our move in the September 3 final rule, of procedure code 360 (Removal of Coronary Artery Obstruction), which includes PTCA as well as other angioplasty procedures, from DRG 108 (Other Cardiovascular or Thoracic Procedures, with Pump) to DRG 112 (Vascular Procedures Except Major Reconstruction, without Pump). The commenters, including the Prospective Payment Assessment Commission (ProPAC), recommended that PTCA be assigned a separate procedure code, that data on cost and price should be collected, and that the final decision as to DRG assignment (either to an existing DRG or the creation of a new DRG) be based on the data collected. (However, in the interim, ProPAC recommended that PTCA be assigned to DRG 112.) It was also pointed out that by not having a separate procedure code for PTCA, any changes made to the DRG assignment of the procedure code affects a number of other procedures that fall within that procedure code.

Response: These comments suggest that this classification change was made in the absence of data. We would note that we based our decision on the change in the classification of cases involving code 360 on an analysis of all claims with this procedure code for discharges in FY 1984. Although there is not currently a separate code for PTCA, we can infer that the vast majority of the cases with procedure code 360 represent PTCA because our medical consultants advise us that it is relatively rare to remove a coronary artery obstruction using an open thoracic procedure

without use of a pump (code 3961). Moreover, while the nearly 7600 discharges with code 360 without pump may include a few of the more complex angioplasty procedures, it is significant to note that the average standardized charges for all discharges with code 360 without pump are somewhat less than the average standardized charges for all other cases in DRG 112. Since the recalibrated weights are based on charges, the large number of cases coded 360 without pump now in DRG 112, with relatively low charges, would have dominated the relatively high charges for the 900 cases now in DRG 108 and thus reduced the recalibrated weight of DRG 108 by more than 50 percent—from about 4.8 to about 2.3—if PTCA had been left in DRG 108, while leaving the weight of DRG 112 virtually unchanged. This would have resulted in significant under-reimbursement of virtually all cases in DRG 108 except angioplasty.

We have, however, taken steps to obtain, through the Federal inter-agency committee mentioned later in section III.C. of this notice, a discrete code for PTCA to allow us to distinguish this procedure from other procedures coded 360 without pump. If approval for a discrete code is obtained, the coding system would permit such differentiation, and it would then be possible to evaluate resource use for removal of coronary artery obstructions via open thoracic procedures versus PTCA, and to modify the classification further should the resource use warrant such a change.

Comment: We received two comments concerning reimbursement for DRG 117 (Cardiac Pacemaker Replacement and Revision Except Pulse Generator Replacement Only). Both commenters expressed concern with an apparent lack of homogeneity and believed that the DRG encompassed too wide a spectrum of pacemaker procedures, ranging from the replacement of the whole pacemaker system (pulse generator plus leads) to procedures requiring no pacemaker hardware. Both commenters suggested the procedures involving replacement of both leads and pulse generators be moved to DRG 116 (Permanent Cardiac Pacemaker Implant, without AMI, Heart Failure or Shock). It was suggested that this revision would result in reimbursement more closely related to the resource intensity of the procedure.

Response: It appears that the difficulty experienced by the commenters is a result of inconsistencies in the use of ICD–9–CM codes rather than problems with the DRG classification system. The operating room procedures for DRG 117 include replacement or removal of electrodes or revisions to the system (i.e., repositioning of an electrode). When a new (replacement) total pacemaker system is implanted, other procedure coding is required. None of the procedure codes for DRG 117 is appropriate.

The use of any code for insertion of a permanent pacemaker is appropriate whenever a total pacemaker system is inserted and would result in such cases being grouped to DRG 115 (Permanent Cardiac Pacemaker Implant, with AMI, Heart Failure or Shock) or DRG 116. We believe that careful coding will alleviate some of the difficulties the two commenters encountered.

Comment: A number of comments were received regarding the level and/or the "logic" of the recalibrated DRG weights which were contained in our September 3 final rule. One commenter specifically noted the reduction in the weights for DRGs 124 and 125 (Circulatory Disorders Except AMI with Cardiac Catheterization; with and without Complex Diagnosis, respectively); while another commenter observed that the weight differential between DRGs 132 (Atherosclerosis Age over 69 and/or C.C.) and 140 (Angina Pectoris) was not logical; neither accounting for considerable variation in complexity among these cases nor the commenter's belief that atherosclerosis was a chronic condition that, by itself, would not require hospitalization. Another commenter expressed concern about payment for DRG 128 (Deep Vein Thrombophlebitis), noting that such cases were more complex than cases in DRG 130 (Peripheral Vascular Disorders Age over 69 and/or C.C.) to a degree not reflected by the slight difference in their weights.

Response: The weights for the DRGs of concern were based on the following numbers of Medicare discharges from FY 1984 (before elimination of statistical outliers):

	Number of cases
DRG 124	24,086
DRG 125	55,237
DRG 128	42,184
DRG 130	98,199
DRG 132	124,184
DRG 140	312,386

Since none of these commenters identified specific problems with the types of cases being classified into each of these DRGs, we can only express our confidence that the recalibrated weights for these as for all the DRGs reflect the relative resource intensity of all cases assigned to them.

E. Comments on MDC 6: Diseases and Disorders of the Digestive System

Comment: One commenter noted that the GROUPER program does not recognize a partial pancreatectomy as an O.R. procedure in MDC 6, the MDC to which a principal diagnosis of suppurative peritonitis is assigned.

Response: Partial pancreatectomies are not recognized in MDC 6, which includes the diagnosis code for suppurative peritonitis; hence, cases of suppurative peritonitis with this procedure cannot be classified according to the surgical hierarchy that applies within MDC 6. Diseases involving the pancreas fall into MDC 7 (Diseases and Disorders of the Hepatobiliary System). Therefore, when the principal diagnosis is suppurative peritonitis and partial pancreatectomy is the only procedure performed, the GROUPER must assign the case to DRG 468 (Unrelated Operating Room (O.R.) Procedures). We note that such procedures are rare. Also, if the suppurative peritonitis is due to a pancreatic disorder, the pancreatic disorder should be coded as the principal diagnosis, and the case would group to MSC 7.

Comment: One commenter believes that procedure code 5499 (Other Operations of Abdominal Region) should be recognized as an O.R. procedure because it includes the removal and subsequent modification of a peritoneal-vascular shunt.

Response: Our medical consultants do not agree that procedure code 5499 should be classified as an O.R. procedure. The code is very broad in scope, covering a number of procedures. Some require the use of an operating room while others may be done in a less resource-intensive setting.

F. Comments on MDC 7: Diseases and Disorders of the Hepatobiliary System

Comment: Two commenters expressed concern about the accuracy of the relative weights for DRG 199 (Hepatobiliary Diagnostic Procedure for Malignancy) and DRG 200 (Hepatobiliary Diagnostic Procedure for Non-Malignancy).

Response: In examining these commenters' concerns, we compared the relative weights for DRGs 199 and 200 that were published in the September 1, 1983 **Federal Register** (2.3378 and 2.6286, respectively) with the relative weights for DRGs 199 and 200 that were published in the September 3, 1985

Federal Register (2.4574 and 2.5818, respectively). For both sets of relative weights, DRG 199 has a lower relative weight than DRG 200, even though DRG 199 includes what is often perceived as the more severe cases (that is, the malignancies). Based on the data we have available, we believe the relative weights for DRG 199 and DRG 200 are correct as published in the September 3, 1985 final rule.

Our medical consultants note that clinical practice and experience would suggest no inconsistency in the weights for these two DRGs. First, in order to make a final diagnosis of other than a malignancy, resource consumption could be greater in that a physician frequently requires more time, orders more tests, and uses additional medical resources. In addition, certain non-malignant diseases, such as cirrhosis, abscess, and pancreatitis, are often more difficult to treat than malignancies. Finally, when a patient has a malignancy that may be responsive to treatment, an additional procedure may be performed during the same stay. When this occurs and the procedure is higher in the surgical hierarchy, the discharge is assigned to an entirely different DRG.

G. Comments on MDC 8: Diseases and Disorders of the Musculoskeletal System and Connective Tissue

1. Major Joint Procedures—DRG 471

Twelve comments were received concerning DRG 471 (Bilateral or Multiple Major Joint Procedures of the Lower Extremity), which was established in our September 3, 1985 final rule. This DRG was established to distinguish multiple joint procedures that were included in DRG 209 (Major Joint and Limb Reattachment Procedures) from single joint procedures that were also contained in DRG 209. Three commenters expressed unconditional support for the new DRG. One commenter expressed concern over the precedent set by this decision. We addressed this comment in the September 3 final rule (50 FR 35652). The remaining 8 comments are discussed below.

Comment: One commenter expressed concern that the parameters for DRG 471 do not adequately reflect the services required by patients undergoing multiple joint replacements. It was suggested that the new DRG 471 not be implemented until further study of the issue is completed.

Response: In establishing the relative weighting factor for DRG 471, we utilized actual billing information from our FY 1984 Part A Tape Bill (PATBILL) file for the Medicare patients who underwent multiple major joint replacements of the lower extremity during that year. We did not, as was suggested by the commenter, increase the weight of the DRG by the cost of an additional prosthesis to distinguish a multiple joint procedure from a single joint procedure. Rather, the charges for all services provided, including additional inpatient days, the prosthesis, and other ancillary services, were considered. The methodology employed in computing a weighting factor for the new DRG 471 was identical to the one that is generally used, and is thus identical to the methodology used to weight DRG 209 as it existed before DRG 471 was created.

The universe of cases used to establish the weighting factor for DRG 471 may not have included every multiple major joint procedure performed during FY 1984, due to the inability to identify every multiple joint procedure case as such from the billed information for cases included in DRG 209. However, the number of cases identified and used to establish the weight is large enough to produce an accurate measure of relative resource use. In fact, we believe only a very small percentage of the universe of the major multiple joint procedures furnished to Medicare beneficiaries was omitted. We believe postponing implementation of this new DRG 471 while we gather more refined data would only compound the potential problem of inadequate payment for the procedure during this time of continued data analysis.

As we expressed in the September 3 final rule, we intend to monitor payments in this area. However, the Emergency Extension Act, and its extensions, have so far delayed implementation of this DRG, along with all the other DRG classification changes made in the September 3 final rule, thus delaying our effort to gather more refined data and performing further data analysis. If we find further adjustments are necessary, they will be made during the future recalibrations.

Comment: One commenter expressed the desire that more multiple major diagnoses/procedure DRGs be developed, without citing what those specific conditions might be.

Response: We developed DRG 471 out of a recognition that the clinical and resource use issues associated with multiple major joint procedures of the lower extremity warranted a distinction from single joint procedures. We believe that the situation presented in multiple major joint procedures of the lower extremity was unique from a clinical perspective, insofar as performing multiple major joint procedures during a single admission is the approach preferred by some physicians, while performing multiple procedures over two admissions is the course preferred by other physicians. We did not want the payment system to affect the exercise of clinical judgment. This situation is unlike those cases in which a patient has multiple diagnoses or requires more than one surgical procedure which, for clinical, social and/or emotional reasons, are better done in a single admission than in multiple admissions. While the DRG classification system does not always differentiate these cases, we believe that when such a case is substantially more resource intensive than the average case assigned to the DRG, it is likely to become an outlier. Additional payment under the prospective payment system may be made for these situations.

If we discover other specific situations in which specific multiple procedures generally result in inadequate payment, we will consider further changes in the classification methodology. However, such changes will be considered only to the extent that they comport with the basic goals of the DRG system.

Comment: Three commenters expressed concern that the development of DRG 471, which was created to distinguish multiple joint procedures from single, may lead to pressure to perform multiple major joint replacements in one admission when separate admissions may be more medically appropriate for the patient.

Response: Our intent in developing DRG 471 was specifically to establish a mechanism for adequate Medicare payment when performance of multiple major joint procedures during a single inpatient stay is medically appropriate. DRG 209 continues to exist and reflects the relative resource use associated with single major joint replacements. Physicians may freely choose the most appropriate course of treatment for these cases. Therefore, we do not anticipate that problems will arise when physicians determine that a subsequent admission for a second major joint procedure is medically necessary. However, we will monitor actions by the Utilization and Quality Control Peer Review Organizations (PROs) in this regard and will issue clarifying instructions if necessary.

Comment: Three commenters believe that there is a problem with acceptance of duplicate procedure codes by the Medicare Code Editor (MCE). These commenters believe bilateral major joint procedures would continue to group to DRG 209 rather than DRG 471. One commenter pointed out that even if this

problem were corrected, the weighting factor for DRG 209 would remain inappropriately high due to inclusion of such bilateral procedures in the data used to calculate the weight for DRG 209.

Response: While the MCE does prohibit the inclusion of duplicate diagnosis codes, it does not edit for duplicate major joint procedure codes. Thus, when bilateral procedures are appropriately coded by listing the procedure twice, the case will not be edited out by the MCE but will be classified by GROUPER into DRG 471.

We acknowledge that there are no explicit instructions or guidelines on coding bilateral procedures where a single code has not been established to identify bilateral procedures. However, we have found that most hospitals have reported such cases by duplicating the single procedure code on the bills. In this regard, we note that approximately 600 of the nearly 1,700 cases used in computing the weighting factor for DRG 471 were classified to that DRG due to the presence of duplicate major joint procedure codes.

With respect to the concern that the weighting factor for DRG 209 continues to reflect bilateral procedures, we recognize that some bilateral procedures may not have been duplicatively coded and, therefore, were included in the computation of the DRG 209 weighting factor. However, due to the inability to specifically identify such cases as multiple joint procedures, we had no reasonable alternative but to include the charges for such cases in the DRG 209 data base. We believe that the additional payment available in DRG 471 will provide sufficient incentive to ensure that all future bilateral joint procedures of the same site are accurately coded to reflect the multiple procedures. Thus, any resulting current upward distortion in the weighting factor for DRG 209 should be corrected in future recalibrations. Again, as we expressed in the September 3 final rule, we intend to monitor payment in this area.

2. Surgical Hierarchy

Comment: One commenter suggested that wound debridement (procedure code 8622) assigned to DRG 217 (Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders) be placed above amputations assigned to DRG 213 (Amputations for Musculoskeletal and Connective Tissue Disorders) in the MDC 8 surgical hierarchy. This change was made in the September 3 final rule (50 FR 35742). Another commenter believes that wound debridement often is not done in the operating room. Thus, its place in the MDC 8 hierarchy obscures other procedures done during the same admission.

Response: It is true that there is some variability in the resources associated with procedure code 8622 (wound debridement). Sometimes the procedure may not require the use of an operating room. However, we have found the vast majority of such cases are very resource intensive, as is evidenced by the weighting factor assigned to DRG 217. The relative weight for this DRG is the third highest in the MDC. We also note that the arithmetic average length of stay for cases in this DRG is the second highest in MDC 8. We believe these facts substantiate that our decision as to the placement of wound debridement in the hierarchy of surgical procedures for MDC 8 is appropriate, despite the fact that on occasion wound debridement may not be very resource intensive.

3. Movement of Specific Codes between MDCs

Four commenters suggested reclassification of specific codes currently assigned to MDC 8. One of the comments, recommending reclassification of code 7248 (Other Back Symptoms) to DRG 243 (Medical Back Problems) was accepted and included in the September 3 final rule (50 FR 35740). The remaining comments are as follows:

Comment: One commenter believes diagnosis codes 99691 through 99699, which relate exclusively to complications of a reattached extremity or body part, should be reassigned from DRG 249 (Aftercare Musculoskeletal System and Connective Tissue) to DRG 468 (Unrelated O.R. Procedure). The commenter noted that these diagnosis codes indicate complications of transplant organs.

Response: We are not able to accept this commenter's suggestions for a number of reasons. First, DRG 468 is a classification reserved for cases where none of the surgical procedures performed is related to the principal diagnosis. There are no specific diagnoses or procedure codes assigned to this DRG.

Second, DRG 468 is a surgical DRG; that is, all cases assigned to this DRG involve surgical procedures. DRG 249 is a medical DRG and cases assigned to this DRG do not involve surgical procedures. Therefore, it would be inappropriate to combine such non-surgical cases with the cases in DRG 468, all of which involve operating room procedures.

Finally, diagnosis codes 99691 through 99696 are specific to a particular organ system, the musculoskeletal system and connective tissues. That is, such codes relate exclusively to complications of a reattached extremity or body part. Unlike the codes for complications of transplanted organ, such as 9968, which can be used for numerous organ systems, codes 99691 through 99696 and 99699 may be used only for diseases and disorders of the musculoskeletal system and connective tissue. If cases with these principal diagnoses are treated non-surgically, they are appropriately classified into DRG 249. If treated surgically, (i.e., if a reattached limb must again be reattached), they are assigned to DRG 209 (Major Joint and Limb Reattachment). In this regard, we note that there are procedure codes distinct from these diagnosis codes identifying the limb and extremity reattachment procedures. Finally, if surgery is performed and all the surgical procedures are unrelated to these principal diagnoses, the case would then group to DRG 468.

Comment: One commenter stated that replacing or repairing a major joint prosthesis was as resource intensive as the initial major joint procedure and, therefore, should be assigned to DRG 209 (Major Joint and Limb Reattachment) in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) rather than DRGs 442 and 443 (Other O.R. Procedures for Injuries; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) in (Injuries, Poisonings and Toxic Effects of Drugs).

Response: This commenter's concern goes beyond the simple reclassification of a single procedure. Indeed, a similar argument could be made about any number of such revisions. The root of this problem lies in the fact that the ICD-9-CM coding system does not generally differentiate infections and complications of procedures by major organ system. Thus, under the current coding system, a large proportion of such infections and complications, when cited as the principal diagnosis, group to MDC 21 (Injury, Poisoning and Toxic Effects of Drugs). Because the principal diagnosis dictates the MDC to which a case is assigned, principal diagnoses that are non-specific as to organ system must necessarily be assigned to an MDC that is similarly not specific to a single organ system. They cannot appear in all the MDCs for which they might be appropriate. Unlike procedures, which can appear in several MDCs, diagnoses are confined to a single MDC.

We recognize that it would be advantageous to further refine the ICD-9-CM coding system for such indications. However, it would be

inappropriate for HCFA to unilaterally and independently implement revisions in the ICD–9–CM coding system without cooperation and consultation with other programs and consideration of the effects on the users of ICD–9–CM data. In addition, ICD–9–CM coding system is structured to coincide with the ICD codes developed by the World Health Organization for international use. We will, however, keep this comment in mind as we continue to evaluate improvements in the ICD–9–CM codes.

Finally, we would point out that revision of a major joint procedure to correct a malfunction of a prosthesis is currently classified into DRG 209 (Major Joint and Limb Reattachment Procedures). Thus, should future modification of the International Classification of Diseases allow for precise organ system identification of other complications and/or infections, it is reasonable to assume that such new diagnosis codes would be assigned to the same MDC and DRG as the diagnoses necessitating the original procedure.

Comment: One commenter objected to the addition of procedure code 031 (Division Intraspinal Nerve Root) to DRGs 214 and 215 (Back and Neck Procedures; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) contained in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). The commenter noted that the procedure was already included in MDC 1 (Diseases and Disorders of the Nervous System). Noting that resources associated with the procedure would be similar regardless of the diagnosis, the commenter recommended that code 031 be retained in MDC 1.

Response: We do not believe the addition of procedure code 031 to DRGs 214 and 215 in MDC 8 is inappropriate. This procedure is commonly performed on patients with diseases and disorders of the musculoskeletal system as well as those with diseases and disorders of nervous system. In fact, we found the procedure occurring more than twice as frequently in musculoskeletal diagnoses (379 cases) as in nervous system diagnoses (181 cases).

The current DRG classification system is based on diagnosis rather than procedures. There are a number of procedures that are classified into two or more major diagnostic categories, depending upon the principal diagnosis of the patient. We believe it is appropriate, therefore, to classify a given procedure code in as many MDCs as medically appropriate in order to prevent a large number of cases from grouping inappropriately to DRG 468 (Unrelated O.R. Procedures). In this regard, we would point out that procedure code 031 has been included not only in MDC 1 but also in MDC 17 (DRGs 400 (Lymphoma or Leukemia with Major O.R. Procedure), 406 (Myeloproliferative Disorder or Poorly Differentiated Neoplasms with Major O.R. Procedures and C.C.), and 407 (Myeloproliferative Disorder or Poorly Differentiated Neoplasms with Major O.R. Procedures without C.C.), and MDC 21 (DRGs 442 and 443—Other O.R. Procedures for Injuries; Age over 69 and /or C.C., and Age under 70 without C.C., respectively), since the initial implementation of the DRG classification system.

Finally, we note that the weighting factors assigned to DRGs 214 and 215 reasonably approximate the cost of treating cases in which division of intraspinal nerve root (procedure code 031) was reported. The average standardized charges for all 25,000 cases in DRG 214 were about 17 percent higher than the average standardized charges for the 195 cases within the DRG showing procedure code 031. Similarly, the average standardized charges for the nearly 16,000 cases in DRG 215 are about 32 percent higher than those for the 184 cases showing procedure code 031 in DRG 215. Thus, we find no reason to reconsider the appropriateness of our addition in the September final rule of this code to MDC 8. Finally, adding this procedure to MDC 8 does not mean it was moved out of any of the other MDCs to which it is assigned.

H. Comments on MDC 9: Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast

Comment: One commenter objected to our addition of 10 procedure codes to DRGs 269 and 270 (Other Skin, Subcutaneous Tissue and Breast O.R. Procedures; Age over 69 and/or C.C., and Age under 70 without C.C., respectively), in the September 3 final rule (50 FR 35745), citing that this change reduced the clinical homogeneity of the DRGs.

Response: We addressed this comment in our September 3 final rule (50 FR 35649), where we indicated that most of the procedures added were relatively minor and were omitted from the original DRG system through oversight. We continue to believe that the 10 procedure codes are clinically suited to the DRG, in which they are now grouped.

Comment: Another commenter recommended that the surgical hierarchy of MDC 9 be modified to place skin grafts above breast procedures.

Response: Although not specifically addressed in the preamble to the September 3 final rule, this recommended change was accepted and appeared in Table 6, Item D.3, page 35742 of the September 3 rule.

Comment: The GROUPER logic was modified in our September 3 final rule to search out any diagnosis of breast malignancy rather than only a principal diagnosis of malignancy. One commenter believes the initial search on open breast biopsy cases should be limited to breast malignancy rather than any malignancy.

Response: Although the description of the DRG logic change uses the term "any malignancy," GROUPER does recognize only breast malignancies in this search. We believe the explanation of this change in table 6, Item A.2. (page 35736 of the September 3, 1985 **Federal Register**) makes this point clear.

Comment: One commenter expressed concern that a patient initially admitted to a hospital with a skin disorder included in MDC 9, who ultimately undergoes a mastectomy due to carcinoma, would be classified into DRG 261 (Breast Procedure for Non-Malignancy Except Biopsy and Local Excision). The commenter believes such cases should be classified in DRG 468 (Unrelated O.R. Procedures).

Response: We note that MDC 9 recognizes breast malignancy diagnoses as either the principal or secondary diagnosis and mastectomy as an operating room procedure. Such cases are grouped into one of DRGs 257 and 258 (Total Mastectomy for Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) or DRGs 259 and 260 (Subtotal Mastectomy for Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively). As long as the claim identified breast malignancy as one of the diagnoses, the GROUPER would classify such cases into one of DRGs 257 through 260. Generally, cases only group to DRG 468 when all of the surgical procedures are not related to the principal diagnosis. In most MDCs, the GROUPER logic is such that a coupling of any of the principal diagnoses within an MDC and an operating room procedure associated with that MDC will result in classification to a specific surgical DRG within that MDC. While admittedly in some cases the surgical procedure may not be directly related to the principal diagnosis but to a secondary diagnosis in the same MDC, we believe payment in the specific surgical DRG is more appropriate than the result that would obtain if we

structured the DRG logic to "force" cases into DRG 468.

I. Comments on MDC 11: Diseases and Disorders of the Kidney and Urinary Tract

Comment: One comment concerned the DRG classification and reimbursement for implantation of the artificial urinary sphincter (AUS). This procedure is currently being coded under 5799 (other bladder procedures) and is grouped to DRGs 308 and 309 (Minor Bladder Procedures; Age over 69 and/or C.C., and Age under 70 without C.C., respectively), which have relative weights of 1.1490 and .8665, respectively. The commenter suggested that reimbursement was inadequate and that this procedure should be grouped to DRGs 304 or 305 (Kidney, Ureter and Major Bladder Procedures for Non-Neoplasm; Age over 69 and/or C.C., and Age under 70 without C.C., respectively), which have relative weights of 2.0323 and 1.4894, respectively.

Response: Procedure code 5799 is used for a range of bladder procedures not elsewhere classified, some of which may be very simple and others relatively complex. There currently is not a unique ICD–9–CM code to identify AUS as distinct from the other procedures. (See section III.C.6. for proposed changes.) Therefore, we are unable to analyze data specific to AUS cases to determine whether classification in DRGs 304 and 305 is appropriate, and we cannot effect a GROUPER change that moves only the AUS cases and no other cases coded 5799. Moreover, we note that, on average, cases involving procedure code 5799 are not the most resource intensive in DRGs 308 and 309.

Recognizing the inadequacy of the coding system to permit specific identification of AUS cases, we nevertheless reviewed Medicare discharge data for all cases in DRGs 308 and 309 for which procedure code 5799 was present.

In DRG 308, the average standardized charge for cases with procedure 5799 was 96 percent of the average standardized charge for all other cases in the DRG, and those cases represented less than 2 percent of the 14,000 cases assigned to DRG 308. In DRG 309, while the average standardized charges for cases involving procedure 5799 were somewhat higher than the average standardized charges of all other cases in the DRG, there were only 63 cases, or just over 2 percent of the total in DRG 309. Moreover, the average standardized charges for DRGs 304 and 305 are 81 percent and 35 percent higher, respectively, than the average standardized charges for cases involving procedure 5799 in DRGs 308 and 309, respectively.

In light of these disparities in average standardized charges, we do not believe the commenter's concern is fully borne out by the Medicare discharge data. Since we cannot at this time effect a classification change that moves only AUS cases coded 5799, we have not proposed to adopt this commenters recommendation.

Comment: We received a number of comments on reimbursement for extracorporeal shock wave lithotripsy (ESWL). All commenters expressed concern that this procedure was not appropriately grouped and that reimbursement was inadequate.

Response: As we indicated in the September 3, 1985 **Federal Register**, we will monitor the classification of ESWL to assess its appropriateness. However, since this procedure was only recently covered under Medicare, very little Medicare data are available for analysis at this time. (We have also proposed a new ICD–9–CM code for ESWL (see section III.C.5. of this notice)). As these data become available, we will evaluate the relative resource intensity of this procedure to determine what, if any, changes should be made.

J. Comments on MDC 12: Diseases and Disorders of the Male Reproductive System

Four comments were received regarding MDC 12 issues. After publication of the June 10, 1985, proposed rule (50 FR 24366), containing proposed DRG classifications and weighting factors, one commenter recommended that the surgical hierarchy of MDC 12 be revised to order penis procedures above transurethral prostatic resections. This change was made and included in the September 3, 1985 **Federal Register** (50 FR 35742). Even though the average length of stay is greater in transurethral resection cases, the charge data indicate that penis procedures are more resource intensive than transurethral prostatic resections.

Comment: After final publication of the change just discussed, we received a comment objecting to the above-mentioned revision. This commenter stated that many patients diagnosed for benign prostatic hypertrophy undergo both transurethral prostatectomy and internal urethrotomy (a penis procedure). The revised surgical hierarchy assigns such cases based on urethrotomy; therefore, such cases are assigned to DRG 341 (Penis Procedures) rather than to DRGs 336 or 337 (Transurethral Prostatectomy; Age over 69 and/or C.C., or Age under 70 without C.C., respectively). The commenter further noted that physicians practicing at this hospital were objecting to the new DRG assignment.

Response: The commenter seems to believe mistakenly that this results in lower payment levels. In fact, the weighting factor for DRG 341 is slightly higher (.9974) than that for DRG 336 (.9871) or that for DRG 337 (.7788). We find no reason to believe the surgical hierarchy of MDC 12 needs further revision. Patients undergoing both penis procedures and prostate procedures should be assigned to the more resource intensive DRG. While admittedly an internal urethrotomy itself may not be as resource intensive as a transurethral prostatectomy, we continue to believe that penis procedures in general tend to be more resource intensive than prostate procedures.

If, as the commuter further alleged, physicians are complaining about this assignment, we can merely speculate that such complaints are prompted by the trend in many hospitals to place inappropriate emphasis on the average length of stay of DRGs. Since the average length of stay for DRG 341 is less than that of DRG 336, it would be quite reasonable for a physician to complain if he or she were being pressured to discharge prostectomy patients in order to meet the average length of stay of patients classified into DRG 341. As we have noted in the prospective payment update notices, the mean lengths of stay in the DRG tables are furnished only for purposes of illustration, for establishing the day outlier thresholds, and for computing payments to transferring hospitals. Although they are based on the actual length of stay distribution of cases within each DRG, they are not intended to reflect treatment norms. We believe that the physician is the appropriate individual to decide the proper length-of-stay for a particular patient.

Comment. Two commenters expressed concern that the payment for insertion of penile prostheses under DRG 341 is inadequate. One of these commenters particularly noted that there are two distinct types of prostheses commony utilized—inflatable and semi-rigid—with significant cost difference. This commenter recommended the creation of a new DRG to correct this problem.

Response: In analyzing the cases assigned to DRG 341 (Penis Procedures), we find little reason to believe reclassification is necessary. We cannot, at present, differentiate inflatable penile prosthesis from semi-rigid prosthesis

under the procedure codes presently in use; therefore, we cannot fully analyze the merits of adopting the commenters' suggestion of establishing a separate DRG for more costly penile procedures.

The adoption of a unique procedure code for this prosthesis, if finalized by the ICD-9-CM Coordination and Maintenance Committee (see Section III.C.7 of this notice), should significantly increase the quality of data in this regard. We will continue to monitor payments in this area and may consider changes in the future if analyses and data indicate they are necessary.

K. Comments on MDC 13: Diseases and Disorders of the Female Reproduction System

Comment: Several commenters wrote in identifying surgical hierarchy and logic problems in MDC 13. Specifically, two commenters noted that ovarian cancers, among the most common gynecological malignancies, involve extensive treatment of patients who are frequently malnourished and acquire a wide range of resources. In this regard, the commenters expressed concern that an ovarian malignancy, treated surgically with the uterine and adenexa procedures, was classified appropriately in DRG 357 (Uterus and Adenexa Procedures, for Malignancy) with a weight of 2.1101, but that when a hysterectomy was also performed, the case would group to DRGs 354 or 355 (Non-Radical Hysterectomy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) with weights of 1.2335 and .9767, respectively. A similar comment was made with respect to procedures further down in the hierarchy of MDC 13, where a uterine or adenexa procedure for non-malignancies is classified into DRG 358 (Uterus and Adenexa Procedures, for Non-Malignancy Except Tubal Interruption), with a weight of 1.1185. If an incisional tubal interruption is performed during the same admission, the GROUPER classifies the case into DRG 359 (Incisional Tubal Interruption for Non-Malignancy), with a weight of .5044.

Response: We began our analysis by comparing three groups of cases assigned to each of DRGs 354 and 355: those with a principal diagnosis of malignancy, where both a hysterectomy and uterine/adenexa procedures were performed; cases of malignancy where a hysterectomy was performed without uterine/adenexa procedures; and cases of hysterectomy for principal diagnoses other than malignancy. We compared the average standardized charges across the groups, and found a significant difference among the hysterectomy cases in both DRGs 354 and 355, depending on whether the principal diagnosis was malignancy or not. In DRG 354, the average standardized charge for malignancy cases was 38 percent higher than that for non-malignancies. In DRG 355, the malignancies had an average standardized charge 15 percent higher than that of the non-malignancies.

In addition to the differences between average standardized charges, the relative frequencies of cases—11,000 malignancies versus 19,000 non-malignancies in DRG 354, 4,000 malignancies versus nearly 12,000 non-malignancies in DRG 355—were such that the less expensive non-malignancies were dominating the data used to construct the weights for DRGs 354 and 355.

While these findings suggested that malignancies and non-malignancies should be classified in different DRGs, there were even greater differences between these malignancies and those that grouped to DRG 357 (that is, those without hysterectomy). The average standardized charge for DRG 357 is 35 percent and 91 percent higher than those for DRGs 354 and 355, respectively.

Upon further review, we found that ovarian and adenexa cancers make up more than 70 percent of the cases in DRG 357 and are the most resource intensive of the malignancies in this DRG. In addition, when we examined the ovarian and adenexa malignancies in DRGs 354 and 355 (with hysterectomy), we found that the average standardized charges for ovarian and adenexa cancers are fairly comparable regardless of what procedures are performed. Hence, among the cases examined in these three DRGs, diagnosis had consistently greater explanatory power with respect to resource intensity than did the procedure performed.

With respect to the comment that incisional tubal interruptions changed the assignment of non-malignancies with uterine/adenexa procedures from DRG 358 to DRG 359, we conducted a similar analysis and found that incisional tubal interruptions were more comparable in resource use to DRG 361 (Laparoscopy and Endoscopy (Female) Except Tubal Interruption) than to the uterine/adenexa procedure with which it is currently combined in the surgical hierarchy.

In light of all these findings, we are proposing to restructure DRGs 354, 355, 357, 358, and 359 (except for incisional tubal interruption) as follows:

1. Uterus and adenexa procedures (except for incisional tubal interruption: procedure codes 6631, 6632, 6639 and 6663) will be moved into the same section of the surgical hierarchy for MDC 13 as non-radical hysterectomies are currently in, above reconstructive procedures.

2. Cases involving all these surgical procedures (that is, non-radical hysterectomies, uterus and adenexa procedures) will be divided into those with a principal diagnosis of malignancy and those without.

3. Cases with a principal diagnosis of malignancy will be further subdivided.

a. Those with ovarian and adenexal malignancies (diagnosis codes 1830, 1832, 1833, 1834, 1835, 1838, 1839, 1986 and 2362) will become the proposed new DRG 357 (Non-Radical Hysterectomy, Uterus and Adenexa Procedures, for Ovarian and Adenexal Malignancy).

b. Those cases with a principal diagnosis of malignancy except ovarian and adenexal malignancy will be split on age and complications/comorbidities, and will become the proposed new DRGs 354 and 355 (Non-Radical Hysterectomy, Uterus and Adenexa Procedures for Malignancy Except Ovarian/Adenexal Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C., respectively).

4. Cases with a principal diagnosis of other than malignancy will also be divided on age and complications/comorbidities. They will comprise the proposed new DRGs 358 and 359 (Non-Radical Hysterectomy, Uterus and Adenexa Procedures for Non-Malignancy; Age over 69 and/or C.C., and Age under 70 without C.C, respectively).

We also propose to modify DRGs 361 and 362 as follows:

1. The procedure codes for incisional tubal interruption (6631, 6632, 6639 and 6663) will be moved from DRG 359 and the uterine and adenexa part of the hierarchy to the laparoscopy and endoscopy section of the hierarchy.

2. Cases involving these surgical procedures (that is, laparoscopy, endoscopy, and incisional tubal interruption) will be divided into two groups.

a. If an endoscopic tubal interruption (procedure codes 6621, 6622, and 6629) is the only procedure performed from this section of the hierarchy, the case will be classified into proposed new DRG 362 (Endoscopic Tubal Interruption Only).

b. If, in addition to or instead of endoscopic tubal interruption, another procedure is performed, the case will be classified into proposed new DRG 361

(Laparoscopy, Incisional Tubal Interruption).

Comment: We received one comment concerning the relative weight of DRG 353 (Pelvic Evisceration, Radical Hysterectomy and Vulvectomy). The commenter believed that the relative weight did not reflect the resource intensity of the extensive surgery and post-operative care of the extremely ill patients for whom these radical procedures are indicated. Noting that pelvic evisceration frequently entails bladder and rectal resection, the commenter compared the weight of DRG 353 (1.8818) to that of DRG 147 (Rectal Resection) (2.2737).

Response: Because the weight for DRG 353 was, despite its place in the hierarchy, lower than that for DRG 357, we analyzed the average standardized charges for each procedure in DRG 353. We discovered that there was a bimodal distribution of cases by average standardized charge of procedure.

Moreover, the two lowest-priced procedures—Unilateral vulvectomy (code 7161) and Bilateral vulvectomy (code 7162)—are the only non-radical procedures in this DRG but rank third and fourth by frequency of procedure. The weighted average charges for these two procedures is barely 40 percent of the average standardized charge for all other procedures in DRG 353, but is comparable to the average standardized charge for DRG 360 (Vagina, Cervix and Vulva Procedures). In addition, non-radical vulvectomies are clinically more similar to the other procedures in DRG 360 than to the radical procedures in DRG 353. Accordingly, we are proposing to remove procedure codes 7161 and 7162 from DRG 353 and to place them into DRG 360.

L. Comments on MDC 14: Pregnancy, Childbirth, and the Puerperium

Comment: One commenter believes there is a problem with DRGs 378 (Ectopic Pregnancy), 379 (Threatened Abortion), 380 (Abortion Without D&C), 381 (Abortion With D&C, Aspiration, Currettage, or Hysterotomy), 382 (False Labor), 383 (Other Antepartum Diagnoses Without Medical Complications), and 384 (Other Antepartum Diagnoses With Medical Complications) because the GROUPER program will not assign a discharge to DRG 468 (Unrelated O.R. Procedures) when an operating room procedure is performed.

Response: The development of MDC 14, in which DRGs 378 to 384 are located, was somewhat different from the other MDCs. The basic consideration behind the development of the DRGs in MDC 14 was whether the patient delivered or did not deliver a baby. For DRGs 379, 380, 382, 383, and 384, it was so rare to have an operating room procedure associated with the principal diagnoses that group to these DRGs that the decision was made to define the DRG classification based exclusively on principal diagnosis without regard to surgical procedures. Elective surgery is rarely performed on pregnant women, and when a medical emergency necessitates such surgery, it would most likely be for a principal diagnosis other than the pregnancy, such that the case would not be classified in MDC 14. In certain diagnoses a surgical procedure must virtually always be performed as part of the treatment, so the DRG again was defined only in terms of principal diagnosis. For example, in DRG 378 (Ectopic Pregnancy), there are no procedures listed, only principal diagnoses, since the ectopic pregnancy will have to be treated surgically. Similarly, a surgical procedure must be performed in order for a case to be classified into DRG 381.

The commenters gave no specific example of the type of coding problems that had been encountered, so it is impossible to determine if a problem exists in assigning cases to the DRGs in MDC 14. Since we have neither evidence of specific problems with cases assigned to this MDC, not examples of unrelated surgery performed when the principal diagnosis is pregnancy, we do not see a necessity to redefine these DRGs.

M. Comments on MDC 15: Newborns and Other Neonates With Conditions Originating in the Perinatal Period

Comment: Several commenters objected to including diagnosis code 7746 (fetal/neonatal jaundice, NOS) in DRG 391 (Normal Newborns), believing this represented a change to DRG 391.

Response: The commenters are incorrect in stating that this is a change to DRG 391. DRG 391 has always included 7746 as a diagnosis code. A discharge with a principal diagnosis of 7746 would be assigned to DRG 391. A discharge could also be assigned to DRG 391 if the only secondary diagnosis was 7746, and the principal diagnosis was any one of the other principal diagnoses listed under DRG 391.

The change that we made in our September 3 final rule (50 FR 35737) was to remove 7746 from the list of complications and comorbidities. We believe the diagnosis code 7746 reflects a transient physiologic condition and as such belongs only in DRG 391.

Comment: We received a comment that disagreed with our transferring, in the September 3, 1985 final rule ICD-9-CM codes 7584 (Balanced Autosomal Translocation in Normal Individuals) and 7585 (Other Conditions Due to Autosomal Anomalies) from DRG 390 (Neonates with other Significant Problems) to DRG 467 (Other Factors Influencing Health Status); code 7583 (Autosomal Deletion Syndrome) from DRG 390 to DRG 429 (Organic Disturbances and Mental Retardation); and code 7586 (Gonadal Dysgenesis) from DRG 390 to DRG 352 (Other Male Reproductive System Diagnoses) and to DRG 369 (Menstrual and Other Female Reproductive System Disorders). Although the changes appeared to be logically correct, because of the large differences in relative weights between DRG 390 and the other DRGs (.3486 for DRG 390 versus .7223 for DRG 467, .8424 for DRG 429, .5388 for DRG 352, and .5498 for DRG 369), the commenter does not believe the transfers should be implemented.

Response: Our rationale for the transfer of these four ICD-9-CM codes was presented on page 35736 of our September 3 final rule. The commenter has not presented any evidence to support the belief that the transfer of these codes is inappropriate, and we continue to believe that our rationale is valid. In addition, we would note that this classification change entailed the movement of fewer than 20 cases involving a principal diagnosis of either ICD-9-CM code 7583, 7584, 7585 or 7586 from a DRG in which Medicare cases would rarely be classified (that is, DRG 390, which has been deemed a low-volume DRG) to DRGs 429 (with more than 50,000 Medicare discharges), 467 (with more than 17,000 Medicare cases), 352 (with more than 2,500 Medicare cases), and 369 (with more than 8,000 Medicare cases). Moreover, the average standardized charges for the cases involving a principal diagnosis of 7583, 7584, 7585 or 7586 are similar to or somewhat higher than the average standardized charges for each of the DRGs to which these cases were transferred. Because of the volume of total Medicare cases in the receiving DRGs, we are confident in the weights established for them.

N. Comments on MDC 17: Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms

Comment: One commenter objected to the change, made in the September 3 **Federal Register**, whereby cases in MDC 17 involving other than major surgical procedures group to DRGs 401 (Lymphoma or Leukemia with Other O.R. procedures, Age over 69 and/or C.C.), 402 (Lymphoma or Leukemia with

O.R. procedure, Age less than 70 without C.C.) and 408 (Myeloproliferative Disorder or Poorly Differentiated Neoplasm with Other O.R. procedure). Formerly, if the O.R. procedure was not a major procedure (which groups to DRGs 400 (Lymphoma or Leukemia with Major O.R. Procedure), 406 and 407 (Myeloproliferative Disorder or Poorly Differentiated Neoplasm with Major O.R. procedures, with C.C. and without C.C., respectively), such cases were classified as medical rather than surgical. The commenter believes it would be more appropriate to permit these cases to group to DRG 468 where the O.R. procedure is unrelated.

Response: The nature of the diagnosis in DRGs 401, 402 and 408 either involve multiple organ systems or are non-specific as to organ system. Consequently, it is possible that almost any surgical procedure may be performed in relation to the principal diagnosis.

Accordingly, we believe it is more appropriate to recognize that such cases are surgical, not medical, rather than to classify all cases involving procedures other than the major surgical procedures associated with DRGs 400, 406 and 407 into DRG 468, since the nature of the principal diagnoses lends itself to treatment by a vast range of surgical procedures.

O. Comments on MDC 20: Substance Use and Substance Induced Organic Mental Disorders

Comment: A comment was received concerning the use of the term "substance abuse" for DRGs 434 (Substance Abuse, Intoxification, Induced Mental Syndrome Except Dependency and/or Other Symptomatic Treatments), 435 (Substance Dependence, Detoxification, and/or Other Symptomatic Treatment), 436 (Substance Dependence with Rehabilitation Therapy), and 437 (Substance Dependence, Combined Rehabilitation and Detoxification Therapy), as reconfigured in our September 3 final rule. Previously, the titles of these DRGs had signified drug dependence or alcohol use or dependence. The commenter felt that the new titles could diminish the recognition of alcohol and drug abuse and dependence as specific disease entities and could adversely impact public education efforts regarding treatment and prevention.

Response: Based on the concerns raised, we are changing the titles of DRGs 434 through 437. The term "alcohol/drug" will be substituted for the term "substance." For consistency, we are also making this change in the title of DRG 433 (Substance Use and Induced Organic Mental Disorders, Left Against Medical Advice (AMA)):

P. Comments on MDC 21: Injuries, Poisonings and Toxic Effect of Drugs

Comment: Two commenters were concerned with the weighting factors for DRGs 409 (Radiotherapy) and 410 (Chemotherapy). The commenters noted that, depending on the specific types of carcinoma and the patient's condition, the appropriate course of treatment may result in expensive services and require long lengths of stay. The commenters contend that some hospitals are reporting considerable losses on these cases and recommended reexamination of the weights.

Response: The weighting factors for DRGs 409 and 410 have been calculated, as those for all other DRGs, from the charge information submitted on Medicare inpatient bills for cases within those DRGs. We note that the weighting factors for both of these DRGs procedures have increased by about 20 percent since the weighting factors were initially determined. That is, the weighting factors for DRGs 409 and 410 in the September 1, 1983 **Federal Register** were .8134 and .3527, respectively, while the weights published in the September 3, 1985 **Federal Register** were .9856 and .4285, respectively. Since the weight differential between the two DRGs has remained consistent throughout the updating and recalibration, we find no reason to believe these DRGs are inappropriately weighted.

Comment: Two commenters noted what appears to them to be an illogical differential in the weighting factor of two companion DRGs. The commenters believed that, since DRG 412 (History of Malignancy with Endoscopy) requires a procedure not present in its companion, DRG 411 (History of Malignancy without Endoscopy), the weighting factor for the former should be higher.

Response: We do not believe the presence endoscopy necessarily would indicate a more costly hospital admission. In this regard, we note that a single endoscopy may perform essentially the same diagnostic function as numerous x-rays, scans, and laboratory tests. Thus, total resources expended using endoscopy could reasonably be substantially less than total resources for cases without endoscopy. In addition, we note that our bill data indicate that Medicare patients with a history of malignancy receiving an endoscopy, on average, spent considerably less time hospitalized than those who did not receive the procedure. Given the additional room and board charges for added inpatient days, it is not surprising that the weighting factor for DRG 411 is higher than DRG 412.

Q. Comments on MDC 23: Factors Influencing Health Status and Other Contacts With Health Services

Comment: One commenter stated that the relative weight for DRG 465 (Aftercare with a History of Malignancy as a Secondary Diagnosis) should logically be higher than the relative weight for DRG 466 (Aftercare without a History of Malignancy as a Secondary Diagnosis). The commenter states that patients with a history of cancer appear to require more resources than a patient without such a history.

Response: We do not agree with the commenter's rationale. There are many other medical conditions which, as secondary diagnoses, may be more resource intensive than cancer. In addition, DRG 465 deals with only a limited population of patients—only those with a history of malignancy as a secondary diagnosis, whereas DRG 466 encompasses all other patients. We believe our data and relative weights are accurate for DRGs 465 and 466. The commenter did not present any concrete data to support an opposite position.

R. Comments on DRG 468: Unrelated O.R. Procedures

During the public comment period on the June 10 NPRM, 14 commenters raised questions concerning DRG 468 (Unrelated O.R. Procedure).

Comment: One commenter noted the need for a mechanism within the DRG system to take into account implementation of new technology and new treatment regimens. The commenter recommended the development of a new DRG similar to 468 for assignment of cases involving new technology regardless of the patient's diagnosis. It was suggested that cases would be temporarily assigned to the new technology DRG until sufficient information becomes available to classify the procedure to an appropriate DRG.

Response: We do not believe the creation of a new technology DRG is appropriate or necessary. As we stated in the September 3, 1985 final rule, when Medicare covers a new technology, we believe it is most appropriate to make a decision as to the "best fit" DRG that is within the existing classification system. Should subsequent data indicate the initial classification is inappropriate, a reclassification to a more appropriate DRG would be made.

Also, the commenter's suggestion that a new general type of DRG such as DRG

468 be established indicates a basic misunderstanding of the classification system. The basic framework of the DRG system has been built around 23 MDCs. Cases are assigned to a DRG within the MDC indicated by the patient's principal diagnosis. The creation of a new technology DRG would violate the basic principle of the DRG system in that the classification would no longer be based on diagnosis. Rather, such a system would rely chiefly on procedures for classification.

It is our view that DRG 468 does not present such a violation. Instead, this DRG is reserved specifically for those cases where none of the surgical procedures furnished to a patient is related to the principal diagnosis. Thus, DRG 468 is intended to established a classification cell for those cases in which the patient develops pressing medical-surgical needs related to a secondary diagnosis or complication.

We emphasize that this DRG is not a catch-all for cases that do not fit elsewhere, nor does it violate the basic principle of diagnosis-related classifications. Therefore, we do not find the commenter's suggestion concerning a new technology DRG analogous to the basis for establishing DRG 468.

Comment: Two commenters noted the excessive payment made for many cases involving fairly simple surgical procedures assigned to DRG 468. One commenter recommended payment for DRG 468 on a per diem basis. The other commenter recommended PRO denial of surgical procedures that could be done on an outpatient basis.

Response: We, too, are somewhat concerned with the possibility of excessive payments for cases involving simple surgical procedures assigned to DRG 468. In fact, that is the reason we continue to review the procedures on the O.R. list and have added some procedures to MDCs for which they are appropriate, thus precluding assignment of cases involving such procedures to DRG 468. However, as discussed in our September 3 final rule (50 FR 35658), we are not adopting either of the changes recommended by the above two commenters. We do not believe it is appropriate to implement a special payment mechanism for a specific DRG. In addition, payment on a per diem basis for discharges assigned to DRG 468 would present administrative complexities in reconciling interim payments.

It has also been suggested that a significant number of cases assigned to DRG 468 are the result of patients undergoing elective surgical procedures that could have been done on an outpatient basis, while hospitalized for some reason unrelated to the cause of the surgery. It was suggested that such elective procedure be denied upon review by the PRO.

We do not believe there is authority under the current statute to instruct PROs to deny such medically necessary procedures when performed during an unrelated medically necessary hospital stay. We are satisfied, for the present, that the current PRO review procedure of DRG 468 cases is adequate and supported by the law and regulations. We will, however, continue to monitor DRG 468 cases. If the data indicate any further action is necessary, we may modify review procedures in the future.

Comment: One commenter recommended that procedure code 4029 (Excision of the Lymphatic Structures) be included in MDC 5 (Diseases and Disorders of the Circulatory System) to match with diagnosis code 2281 (Lymphangioma) to avoid DRG 468 assignment.

Response: We had already noted that diagnosis code 2281 and procedure code 4029, which often occur in the same admission, had not been classified in the same MDCs, and made a change to resolve this problem in the September 3, 1985 final rule (50 FR 35740, Table 6, Item A.22). However, we determined the more appropriate classification to be to MDC 16 (Diseases and Disorders of Blood and Blood Forming Organs and Immunological Disorders), rather than to MDC 5 (Diseases and Disorders of the Circulatory System). Therefore, rather than moving the procedure code, we moved diagnosis code 2281 from MDC 5 to DRGs within MDC 16. When treated by excision of the lymphatic structures, the case is grouped to DRG 394 (Other O.R. Procedures of the Blood and Blood Forming Organs); where no surgery is performed, the cases fall into DRGs 398 and 399 (Reticuloendothelial and Immunity Disorders; Age over 69 and/or C.C., and Age under 70 without C.C., respectively).

Comment: One commenter recommended that an exception to the GROUPER be made for patients receiving a cardiac pacemaker. Since pacemakers are relatively expensive, the commenter believes all cases involving pacemakers furnished to patients with a principal diagnosis that is not classified into MDC 5 (Diseases and Disorders of the Circulatory System) should be assigned to DRG 115 (Permanent Cardiac Pacemaker Implant with AMI, Heart Failure or Shock) and DRG 116 (Permanent Cardiac Pacemaker Implant without AMI, Heart Failure or Shock) rather than DRG 468.

Response: In order to operate a classification system successfully, we must maintain some working guidelines for categorizing cases. The most basic working guideline of the DRG system is that classification is based on principal diagnosis. In evaluating requests for changes in the classification system, we made it clear that we would only consider such requests that would not violate the basic principles of the DRG system.

What the commenter is suggesting is for us to make an exception to the basic principle of classification based on principal diagnosis. We continue to believe that classification of cases based on principal diagnoses, age, sex, complications and surgical procedures, is appropriate. To classify all pacemaker cases to DRGs 115 and 116 when the principal diagnosis is not related to diseases and disorders of the circulatory system would in effect result in classification based on primary diagnosis or procedure, rather than principal diagnosis.

We have already responded to the issue of classification based on primary diagnosis in the January 3, 1984 final rule (49 FR 248). The problems associated with classification based on primary diagnosis that are set forth in that response would be further complicated were we to consider such classification only for one specific type of procedure. Such inconsistencies in the classification mechanism would significantly disrupt the GROUPER system.

In addition, the DRG-based prospective payment system is designed to recognize hospital differences related to patient characteristics in preference to hospital differences related to characteristics over which the hospital has control. We believe that classification based on principal diagnosis is more consistent with this goal than classification based on procedure, which establishes incentives to perform more resource-intensive procedures than might be medically appropriate. Further, we believe that the resultant categories, based on principal diagnoses and surgical versus non-surgical treatment, are reasonably homogeneous and promote the goal of encouraging efficiency and prudent hospital management.

Comment: In the September 3 final rule (Item A.10 of Table 6, page 35738), we removed procedure codes 5051 (Ancillary Liver Transplant) and 5059 (Liver Transplant) from DRGs 442 and 443 (Other O.R. Procedures for Injuries; Age over 69 and/or C.C., and Age under 70 without C.C., respectively) so that

cases involving retransplants due to complications would group to DRG 468. One commenter believes this is inappropriate. The commenter recommends such cases be assigned to DRG 191 (Major Pancreas, Liver and Shunt Procedures).

Response: Like the immediately preceding comment, this suggestion violates the basic principle of the DRG system, that is, that classification be based on principal diagnosis. DRG 191 may only be assigned when a patient's principal diagnosis is for diseases and disorders of the hepatobiliary system and pancreas. Most complication and infection diagnosis codes, such as 996.8, which is used for liver transplant rejection, are not organ-specific. Consequently, they cannot be assigned to an organ-system-specific MDC. Rather, they are assigned to MDC 21 (Injury, Poisoning and Toxic Effects of Drugs.)

We noted that other organ transplant procedures codes, such as kidney and cornea transplants, were not included in MDC 21. Therefore, in order to promote consistency in the treatment of such transplants, we removed procedure codes 5051 and 5059 from these DRGs, causing the cases to group to the higher weighted DRG 468. (Alternatively, we could have included the procedure codes for cornea and kidney transplants in DRGs 442 and 443 but, given the constraints of the current coding system, we decided to follow the direction taken in setting up the DRGs and eliminate the liver transplant procedure codes from MDC 21.)

We should point out that we are evaluating the impact on the DRG system of the current coding systems for complications. However, as mentioned elsewhere, coding revisions cut across many aspects of the health care industry; therefore, we must proceed cautiously. If coding revisions in the future permit identification of specific organ system involvement in complications, the DRG classification system may be modified accordingly to reflect such specificity.

Comment: One commenter stated that in DRGs 256 (Other Musculoskeletal System and Connective Tissue Diagnoses) in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), 280 and 281 (Trauma to the Skin, Subcutaneous Tissue and Breast; Age Over 69 and/or C.C., and Age 18–69 without C.C., respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), 445 and 446 (Multiple Trauma; Age 18–69 without C.C., and Age 0–17, respectively), in MDC 21 (Injury, Poisoning and Toxic Effects of Drugs), cases showing procedure code 8010 through 8019 (arthrotomy for removal of foreign body) occurring in conjuction with diagnosis codes with the first three digits 890 through 897 and 880 through 887 are assigned to DRG 468. The commenter believes all such procedures should be assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

Response: It is difficult to respond to this comment because it appears to stem from some basic misconceptions of DRG classifications. All of the specific DRGs cited in either MDC 8 or MDC 21 are medical DRGs to which cases involving a surgical procedure could not be assigned. If the principal diagnosis is an acceptable diagnosis for either of these MDCs (and numerous diagnostic codes within the ranges specified by the commenter are in these MDCs), the case would be assigned to a surgical DRG within those MDCs, rather than to DRGs 256, 445, 446 or 468.

With regard to DRGs 280 and 281 within MDC 9, the arthrotomy procedure code is not considered in DRG assignment. Should arthrotomy be necessary in such cases, the claim would be appropriately assigned to DRG 468 because the surgical procedure is not related to the principal diagnosis.

Comment: One commenter believes that the scattering of injury codes among the various DRGs has resulted in inappropriate assignment to DRG 468. The commenter recommended further study be given to this issue.

Response: The handling of injury codes by the program is a complicated issue. We agree that further study in this area would be valuable. We will be looking into this issue in the future.

Comment: One commenter noted that extra-intracranial vascular bypass procedures involving the anastomosis of the temporal artery to an intracerebral artery, or the subclavian to an intracerebral artery, to bypass the obstructed carotic arteries is coded with two procedure codes (0124 for burr hole and 3929 for vascular shunt procedures). The commenter believes this results in assignment to DRG 468 rather than to DRG 1 (Craniotomy Age over 17 Except for Trauma), as appropriate.

Response: We do not agree with the commenter as to the appropriate codes for the extra-intracranial vascular bypass procedure. The burr hole in this case is an approach to enter the cranium. ICD–9–CM coding rules specifically exclude use of this code as an operative approach. Thus, the appropriate procedure code for the procedure is 3929 only.

Prior to last year's reclassification of the DRGs, procedure code 3929 was not included in the DRGs under MDC 1 (Diseases and Disorders of the Nervous System). Thus, appropriate coding of the procedure using only 3929 with an MDC 1 diagnosis code would have resulted in DRG 468 assignment. However, the addition of procedure code 3929 to MDC 1, DRG 5 (Extracranial Vascular Procedures) was proposed and adopted during the FY 1986 reclassification. Thus, an appropriately coded extra-intracranial vascular bypass would now be assigned to DRG 5. We recognize that the payment for DRG 5 may understate the cost of such procedures in some cases, but the weighting factor reflects the average resource use of all cases grouped in DRG 5, including that associated with procedure 3929. In addition, we do not believe it is appropriate to violate coding guidelines in allowing an approach to be coded in this instance in order to increase Medicare payment. We will continue to evaluate claims data in this area and will consider further reclassification in the future if the data indicate significant problems exist.

Comment: One commenter suggested that procedure codes 0681 (total parathyroidectomy) and 5299 (urinary implants) be assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) to avoid inappropriate DRG 468 assignment.

Response: Procedure code 5299 is not appropriate for urinary implants, but is for other operations on the pancreas. Both procedure codes 0681 and 5799 (the correct code for urinary implants) are presently included in MDC 11, with 0681 assigned to DRG 315 (Other Kidney and Urinary Tract O.R. Procedures) and 5799 grouping to DRGs 308 and 309 (Minor Bladder Procedures, Age over 69 and/or C.C., and Age under 70 without C.C., respectively). We find no reason to believe such cases group to DRG 468.

Comment: One commenter recommended procedure code 5733 (transurethral biopsy of bladder) be considered a valid code for MDC 12 (Diseases and Disorders of the Male Reproductive System) to prevent inappropriate classification to DRG 468.

Response: Procedure code 5733 is currently included in MDC 12, DRGs 344 and 345 (Other Male Reproductive System O.R. Procedures; for Malignancy, and Except for Malignancy, respectively).

Comment: One commenter suggested that procedure codes 8609 (other incision of skin and subcutaneous tissue) and 8699 (other operations on skin and subcutaneous tissue) be added

to the list of acceptable operating room procedures. The commenter believes that code 8609 should be recognized for unspecified surgical DRGs. The commenter also believes code 8699 should be an acceptable operating room procedure for DRG 217 (Wound Debridement and Skin Graft for Musculoskeletal and Connective Tissue Disorders), DRGs 263–266 (Skin Graft and/or Debridement), and DRGs 452 and 453 (Complications of Treatment; Age over 69 and/or C.C., and Age under 70 without C.C., respectively).

Response: Procedure code 8609 is an acceptable operating room procedure under the DRG classification system. It is included in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) under DRGs 269 and 270 (Other Skin, Subcutaneous Tissue, and Breast O.R. Procedures; Age over 69 and/or C.C., and Age under 70 without C.C., respectively), in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) under DRG 292 and 293 (Other Endocrine, Nutritional and Metabolic O.R. Procedures; Age over 69 and/or C.C., and Age under 70 without C.C., respectively), in MDC 16 (Blood, Blood Forming Organs and Immunological Diseases and Disorders) under DRG 394 (Other O.R. Procedures of the Blood and Blood Forming Organs), and MCD 21 (Injury, Poisoning and Toxic Effects of Drugs) under DRGs 442 and 443 (Other O.R. Procedures for Injuries; Age over 69 and/or C.C., and Age under 70 without C.C., respectively). However, without additional specific information on the additional DRGs in which it is recommended that this procedure be considered, we cannot respond to the commenter's concerns.

Our medical consultants have noted that, due to the general nature of procedure code 8699, there can be a good deal of variability in procedures coded under this item. Some of the procedures identified by this code (such as insertion of skin expander in treatment of postburn cases and release of pedicle or flap graft) may require the use of a dedicated operating room. However, other procedures identified by this code, such as removal of sutures from a limb, may be done in less intensive settings, including at the patient's bedside, without use of anesthesia or other operating room resources. We do not have data available indicating the frequency of such procedures by setting to analyze the merits of the recommendation. We do note, however, that DRGs 452 and 453 are medical DRGs. Thus, even if code 8699 were recognized as an O.R. procedure, cases involving this procedure could not be assigned to these DRGs but would be classified in one or a pair of surgical DRGs.

Comment: Three commenters expressed general concern over the list of procedures assigned in our final rule (pages 35743ff) to the different MDCs to reduce DRG 468 assignment. The commenters believe the added procedures may reduce the clinical homogeneity of the DRGs and reduce payment levels to hospitals.

Response: We do not agree with the commenters that the addition of procedure codes to specific DRGs significantly disrupts the clinical homogeneity of the DRGs. All such additions were made only after careful clinical review and concurrence by physicians. In fact, our reassignment of procedures previously found in DRG 468 was specifically supported by a comment from one of the physicians who was involved in the physician panel that established the original Yale DRGs.

With regard to the allegation that the number of DRG 468 cases will decrease and be spread to DRGs with lower weights, we do not believe this to be an obstacle to more appropriate reclassifications. DRG 468 is intended to reflect only those cases in which none of the surgical procedures is related to the principal diagnosis. When data indicate that a specific procedure is commonly associated with a particular diagnosis, we would be remiss in our statutory duty were we not to reclassify the procedures. This decision must be made independent of payment levels.

We should point out, however, that reclassification changes were made prior to recalibration. That is, all the claims from FY 1984 were regrouped using the revised GROUPER before we recalibrated the DRG weights. Thus, the new weighting factors adequately reflect the charges for the cases assigned to each DRG. To the extent we moved expensive cases out of DRG 468 and into a lower weighted DRG, the reclassified cases would increase the weighting factor for the newly assigned DRG.

S. Other Issues

Comment: One commenter believes that procedure code 8623 (Removal of fingernail, toenail, or nail-fold) should be included on the list of O.R. procedures when there is a secondary diagnosis of insulin-dependent diabetes.

Response: Our medical consultants do not agree that procedure code 8623 should be classified as an O.R. procedure. In the great majority of cases, the procedure is handled in a non-O.R. setting. Moreover, to recognize a specific procedure in conjunction with secondary diagnoses would create unwarranted logic and hierarchy problems confounding the classification of cases into the DRGs.

III. Provisions of This Notice

A. Changes Resulting From Comment Process

Based on the comments, and our responses, just presented in section II of this notice, we are proposing the following changes:

1. MDC 4: Diseases and Disorders of the Respiratory System

We would remove diagnosis code 4828 (Bacterial pneumonia not elsewhere classified) from DRGs 89 (Simple Pneumonia and Pleurisy, Age over 69 and/or CC), 90 (Simple Pneumonia and Pleurisy; Age 18–69 without CC) and 91 (Simple Pneumonia and Pleurisy; Age 0–17). We would place this code into DRGs 79 (Respiratory Infections and Inflammations Age over 69 and/or CC), 80 (Respiratory Infections and Inflammations, Age 18–69 without C.C.), and 81 (Respiratory Infections and Inflammations, Age 0–17).

2. MDC 13: Diseases and Disorders of the Female Reproductive System

We would reconfigure DRGs 353, 354, 355, 357, 358, 359, 360, 361, and 362 to increase homogeneity and thus more accurately reflect resource intensity of cases assigned to these DRGs. (See section II.K of this notice for a thorough discussion of each modification.)

3. MDC 20: Substance Use and Substance Induced Organic Mental Disorders

We would change the titles of DRGs 433 through 437 in MDC 20. Wherever the term "substance" appears in those DRGs we would substitute the term "alcohol/drug".

We recognize that we have not adopted changes in response to most of the comments received. In this regard we should point out that a very large proportion of the comments concerned either appropriateness of weighting factors (which is not generally a DRG classification issue) or were too broad or non-specific to indicate exactly where a classification problem arose. In addition, in several other areas of concern, there are coding problems that must be resolved before we can identify the cases at issue and gather the necessary data to evaluate proposed changes. Finally, we received a few comments that required so much evaluation that we are continuing our analysis. The areas of our ongoing review include major head and neck

procedures, hand and upper extremity procedures, complex aortic aneurysms, injuries, and the burn DRGs. We will continue to evaluate these issues and report our additional findings at least annually.

B. New Coverage Decisions

Under § 412.10(c) of the regulations, we may make interim changes in the DRG classifications to reflect new additions to coverage made by the Medicare program. Such classification changes are to be included in the next annual notice of DRG classification changes and be subject to public comment.

Effective for procedures performed on or after January 24, 1986, Medicare coverage has been extended to implantation of cardiac defibrillators under certain circumstances. The data on the cost of this procedure available at this time is very limited. We have evaluated these data and the clinical similarity of this procedure to others in MDC 5 (Diseases and Disorders of the Circulatory System).

Initially, we decided it would be appropriate, on an interim basis, to pay for this procedure at the relative weight for DRG 104 (Cardiac Valve Procedure with Pump and with Cardiac Catheter). However, this is the highest weighted DRG and available data are not sufficient to assure us that such classification would not result in excessive payments. It may be more reasonable, clinically, to include this procedure in one of several other DRGs in MDC 5. Therefore, although we will pay for this procedure using the weight for DRG 104 for the time being, this may not be our final decision, and we are soliciting comments as to whether it may be more appropriate to use another DRG, such as DRG 109 (Cardiothoracic Procedures without Pump) or DRGs 115 and 116 (Permanent Cardiac Pacemaker Implant; with AMI, Heart Failure or Shock, and Without AMI, Heart Failure or Shock, respectively).

Discrete ICD-9-CM procedure codes for this new technology have not yet been adopted. Consequently, for the present, payment may be made for such claims only on a manual basis when accomplished by appropriate documentation. The ICD-9-CM Coordination and Maintenance Committee is proposing new ICD-9-CM procedure codes for the implantation of cardiac defibrillators. (See section III.C. of this notice.) If these proposed new codes are adopted, we are proposing to add the new procedure codes to the appropriate DRG.

C. New Coding Changes

A Federal inter-agency committee has been formed to evaluate the International Classification of Diseases (ICD) and its modification, updating and use for Federal programs. This group, called the ICD-9-CM Coordination and Maintenance Committee, holds public meetings quarterly for discussion on educational issues and proposed coding changes. The Committee then formulates recommendations, which must be approved by the co-chair agency heads, (that is, the Administrator of HCFA and the Director of the National Center for Health Statistics) before adoption for general use.

Many of the proposed coding changes will result in one or more specific codes to identify discretely those diagnoses or procedures that are currently being coded under a more general diagnosis or procedure.

In order to prevent the unwarranted delay of recognition of new codes by the Medicare program, we are proposing to modify the GROUPER program, to the extent feasible, to recognize any new ICD-9-CM codes adopted in the future by the ICD-9-CM Coordination and Maintenance Committee and, in most cases, to classify discharges with such codes initially in the same DRG as the previous coding assignment. That is, any coding changes adopted prior to July 1, 1986 will be included in the GROUPER program for Federal fiscal year 1987, (October 1986 through September 1987), but will not necessarily result in changes to the classification of cases using these new codes. In addition, we will consider interim revisions of the GROUPER to recognize new ICD-9-CM codes, should the volume of cases indicate it is appropriate. Because the use of most new ICD-9-CM codes will not result in DRG classification changes initially, the new codes will not be published for public comment. Of course, should reclassification become necessary, we will follow the procedures set forth at § 412.10 of the regulations.

New ICD-9-CM codes have been proposed to identify the following:

1. Cochlear Prosthetic Device Implant

2. Percutaneous Transluminal Coronary Angioplasty

3. Cardioverter/Defibrillator

As discussed in section III.B. of this notice, Medicare coverage has been extended to the implantation of cardioverter/defibrillators under certain circumstances effective for procedures performed on or after January 24, 1986. Mid-year DRG assignment for the implant has been DRG 104. We are proposing to modify GROUPER to assign proposed procedure codes to DRG 104.

4. Thoracoabdominal Aortic Aneurysm Repair

Major new advancements have been made in aortic aneurysm repair. The proposed codes have been refined to reflect these advancements. We are still evaluting alternatives for appropriate classification of thoracoabdominal aortic aneurysm repair. We are attempting to acquire data that would allow us to propose a classification change in the procedure as part of the proposed prospective payment system regulation to be published by June 1, 1986.

5. Lithotripsy

Unique codes have been proposed to identify the use of fragmentation of kidney stones (lithotripsy). New codes have also been proposed with respect to percutaneous nephrostomy and extracorporeal shockwave lithotripsy (ESWL).

6. Artificial Urinary Sphincter Implant (AUS)

Increased utilization of artificial urinary sphincters has prompted the proposed creation of a unique ICD-9-CM code for the procedure.

7. Penile Prosthesis—Inflatable and Non-Inflatable

A new code has been proposed to distinguish the types of penile prostheses.

8. Chemonucleolysis

9. Magnetic Resonance Imaging (MRI) and Intraoperative Ventricular Mapping

D. Effective Dates

The changes in DRG classification and adoption of new ICD-9-CM codes proposed in this notice would become effective for discharges occurring on or after October 1, 1986. The impact of these proposed changes on the DRG weighting factors will be discussed in the June notice of proposed changes to the prospective payment rates.

IV. Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 requires us to prepare and publish an initial regulatory impact analysis for proposed notices such as this if the implementation of the notice would meet the criteria of a "major rule". A notice would be considered a major rule if its implementation would be likely to result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The changes to the DRG classification system and GROUPER program that we are proposing to make would not meet any of these criteria. Therefore, an initial regulatory impact analysis is not required.

B. Regulatory Flexibility Act

We prepare and publish an initial regulatory flexibility analysis, consistent with the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 through 612), for proposed notices such as this unless the Secretary certifies that implementation of the notice would not have a significant economic impact on a substantial number of small entities. We treat all hospitals under the prospective payment system as small entities for purposes of the RFA. Therefore, this notice clearly would affect a substantial number of small entities. However, it is our practice not to consider an economic impact on small entities to be significant unless their annual total costs or revenues would be increased or decreased by at least 3 percent. The changes we are proposing to the DRG classification system and the GROUPER program would not have results meeting this threshold. Therefore, we have determined and the Secretary certifies that a regulatory flexibility analysis is unnecessary. Accordingly, we have not prepared an initial regulatory flexibility analysis.

V. Information Collection Requirements

This proposed rule contains no information collection requirements. Consequently, it does not need to be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

VI. Response to Public Comments

Because of the large number of comments we receive, we cannot acknowledge or respond to them individually. However, in preparing the final notice, we will consider all comments received timely and respond to the major issues in that notice.

(Secs. 1102, 1871, and 1886(d)(4) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395ww(d)(4)); 42 CFR 412.10)

(Catalog of Federal Domestic Assistance Program No. 13.774, Medicare-Supplementary Medical Insurance)

Dated: February 20, 1986.

Henry R. Desmarais,

Acting Administrator, Health Care Financing Administration.

Approved: March 4, 1986.

Otis R. Bowen, M.D.,

Secretary.

[FR Doc. 86-5539 Filed 3-13-86; 8:45 am]

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Federal Register

Thursday
March 13, 1986

Part IV

Department of Agriculture

Agricultural Stabilization and Conservation Service

7 CFR Part 704

Conservation Reserve Program; Interim Rule

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

7 CFR Part 704

Conservation Reserve Program (CRP)

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Interim rule.

SUMMARY: The purpose of this interim rule is to set forth the terms and conditions of the Conservation Reserve Program (CRP) authorized by Title XII of the Food Security Act of 1985 (Pub. L. 99–198). Under the CRP, the Secretary of Agriculture is authorized to enter into long-term contracts with owners and operators of highly erodible cropland to assist such owners and operators in conserving and improving the Nation's soil and water resources. By entering into a contract, the owner or operator agrees to implement a conservation plan approved by the local Conservation District for converting highly erodible cropland normally devoted to the production of an agricultural commodity to a less intensive use. The Secretary will provide technical assistance, share some of the costs of establishing the conservation practices required by the conservation plan, and make an annual land rental payment to compensate the owner or operator for taking the cropland out of production.

DATE: This interim rule shall become effective on March 3, 1986. Comments must be received on or before May 12, 1986 in order to be assured of consideration.

ADDRESS: Comments may be mailed to the Director, Conservation and Environmental Protection Division, ASCS, P.O. Box 2415, Washington, DC 20013.

FOR FURTHER INFORMATION CONTACT: Mr. Gordell A. Brown, Director, Conservation and Environmental Protection Division, ASCS, P.O. Box 2415, Washington, D.C. 20013, (202) 447–6221.

SUPPPLEMENTARY INFORMATION: This interim rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and provisions of Departmental Regulation 1512–1 and has been classified as "major." It has been determined that these provisions will result in an annual effect on the national economy of $100 million or more. However, no major increase in costs or prices for consumers, individual industries, State, or local government agencies, or geographic regions, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets will result upon implementation of these provisions. A preliminary regulatory impact analysis has been prepared and is available upon request.

It has been determined that the Regulatory Flexibility Act is not applicable to this rule since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 533 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

It has been determined by an environmental assessment that this action will have no significant adverse impacts on the quality of the human environment.

Therefore, an environmental impact statement is not needed. Copies of the environmental assessment are available upon written request.

The information collection requirements contained in this rule will not become effective until they have been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Such approval has been requested and is under consideration. Comments concerning the information collection requirements contained in this rule may be addressed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer, ASCS/USDA, Washington, D.C. 20503, telephone number (202) 395–7340.

The titles and numbers of the Federal Assistance Program to which this rule applies are: Title: Conservation Reserve Program; Number 10.069, as found in the catalog of Federal Domestic Assistance.

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

Section 1231 of Title XII of the Food Security Act of 1985 (the "Act") directs the Secretary to formulate and carry out a conservation reserve program during the 1986 through 1990 crop years. The Secretary is authorized to enter into contracts with eligible owners and operators of highly erodible cropland to assist them in conserving and improving the soil and water resources of their farms and ranches by converting such land to permanent vegetative cover. The Secretary is authorized to place in the CRP up to 45 million acres of highly erodible cropland during the 1986 through 1990 crop years.

This interim rule implements the Conservation Reserve Program (CRP) established by the Act.

In order to enter into the CRP, a person who owns or operates highly erodible land must meet the eligibility requirements as set forth in these interim regulations at 7 CFR 704.6 and 704.7. First, a person must have owned the highly erodible land for not less than 3 years prior to the close of the applicable signup period for the program or before January 1, 1985, unless the land was acquired by will or succession or the Commodity Credit Corporation (CCC) determines that ownership was not acquired for the purpose of placing the land in the conservation reserve, or a person must have been an operator of the cropland for the period beginning 3 years prior to the close of the applicable signup period, or January 1, 1985, whichever is later.

Second, the highly erodible land must be cropland, i.e., such land must have been planted or considered planted to produce an agricultural commodity (as defined in the Act) in 2 of the 5 crop years, 1981 through 1985, and it must be physically possible for the land to be planted to an agricultural commodity other than orchards, vineyards, or ornamental plantings.

Third, the highly erodible land must be in a field which has been determined to predominantly consist of land classified by the Soil Conservation Service (SCS) as being Class II, III, IV, and V with an average annual erosion rate of 2 times the soil loss tolerance ("T") or greater as announced by the Secretary, or land classified by the SCS as being Class I VI, VII, or VIII. In order to ensure that program participants place under CRP Contracts the most excessively eroding cropland and cropland subject to the most serious deterioration of productivity, the Secretary has determined that only land which is so classified or has such average annual erosion rates is eligible for the CRP.

Section 1234 of the Act provides that the Secretary may, in accepting contract bid offers, take into consideration the extent of erosion and the productivity of the acreage to be diverted. To provide greater assurance that program participants will first place the most excessively eroding cropland under CRP Contact, the Secretary has announced the average annual rate of erosion must be greater than 3T for land classes II through V offered for contract during the 1986 crop year signup.

The Secretary will, in determining which bid offers to accept for the 1987 through 1990 crop year CRP signup periods, apply a formula which considers the extent of erosion and production on the cropland for which a bid has been offered. This formula is intended to optimize erosion reduction and production adjustment at various bid rates.

Land is considered to have been planted if the cropland base or allotment history has been preserved for land because the land was set-aside or diverted from the production of a commodity in the crop years 1981 through 1985 in order to meet the requirements of production adjustment programs or if the producer was prevented from planting such land to a commodity as a result of a natural disaster. The term "agricultural commodity" means any crop planted and produced by annual tilling of the soil or on an annual basis by one-trip planters or sugar cane planted and produced in a state. This definition is more inclusive of the various commodities produced on farms and ranches than has been traditionally included in Federal commodity production adjustment programs, because the CRP is not limited to those commodities for which acreage bases, allotments, and quotas have been established.

Section 704.11 of the interim rule describes the obligations of participants under the CRP. All participants in the CRP must: (1) Enter into and carry out the terms and conditions of the CRP Contract; (2) implement the conservation plan developed for the eligible cropland as approved by the local conservation district; (3) reduce the aggregate total of acreage bases, allotments, and quotas for the contract period as designated by the participant for each farm which contains land which is subject to a CRP Contract by an amount based upon the ratio between the total cropland acreage on such farm and the total acreage on such farm subject to the CRP Contract; (4) not produce any agricultural commodity on highly erodible land or converted wetland as defined in Section 1201 of the Act and regulations implementing the Act (unless such land is exempted under Sections 1212 and 1222 of the Act); (5) not allow grazing, harvesting, or other commercial use of any crop grown on the land subject to the CRP Contract; (6) maintain the vegetative cover and other conservation practices specified in the conservation plan for the contract period and take other action that may be required by CCC to achieve the reduction in soil erosion necessary to maintain the production capability of the land throughout the CRP Contract period; (7) comply with the noxious weed laws of the applicable State on land subject to the CRP Contract; and (8) not undertake any action which would tend to defeat the purposes of the CRP.

The conservation plan developed for the eligible cropland will specify the conservation practices which must be established on the eligible cropland in order for adequate erosion control to be achieved and will include a time schedule for establishment of the necessary conservation practices.

In exchange for participation in the CRP, CCC shall: (1) Make an annual rental payment to the program participant; (2) share the cost of establishing the required conservation practices; and (3) provide needed technical assistance to the participant. The annual rental payment shall be determined by the submission of a bid by the owner or operator and is designed to compensate the participant for taking the land out of crop production and devoting it to a less intensive use. The maximum amount of annual rental payments which a person may receive for each year may not exceed $50,000. The annual rental payments received by a person shall be in addition to, and not affected by, the total amount of payments that a person may receive under other provisions of the Act or the Agricultural Act of 1949, as amended.

The cost-share assistance which shall be paid to a participant will not exceed 50 percent of the actual or average cost of establishing the required conservation practices as determined by the CCC. Cost-share payments shall be made available upon a determination that the conservation practice has been correctly established.

An owner or operator of eligible cropland desiring to place such cropland under a CRP Contract with CCC must submit an offer on Form CRP-1 to the local Agricultural Stabilization and Conservation Service (ASCS) office that serves the area in which the farm or ranch is located during the announced sign-up period.

The offer shall be irrevocable for a period of 30 days subsequent to the close of the sign-up period. Once the offer has been received by CCC, it is reviewed and evaluated. The revocation of offers during the 30-day review and evaluation period would require a re-evaluation of bids received and would result in additional administrative expenditures by CCC, as well as increased annual rental payments. It is impossible to compute in advance the actual damages CCC may suffer. Therefore, the applicant shall be assessed liquidated damages if the applicant withdraws the offer during such 30-day period.

CCC will notify persons whose offers are accepted as soon as is practicable after the close of the signup period. CCC will consult with persons whose offer must be modified before CCC will enter into a CRP Contract. CCC will enter into a CRP Contract with such persons if there is an agreement as to the revised terms and conditions of the contract.

It is intended in subsequent years that a conservation plan for the land to be placed into the CRP be completed prior to the submission of an offer. However, due to the need to implement the CRP as quickly as possible and due to staffing constraints, it is probable that conservation plans will not be completed prior to the submission of offers to place land in the CRP during the signup period for the 1986 crop year.

Section 704.19 of the interim rule provides that the CRP Contract may be modified by mutual agreement between CCC and the participant. The interim rule allows CRP Contracts to be modified to: (1) Decrease the acreage under the CRP Contract where the participant desires to devote the land to uses other than agricultural production; (2) permit the production of an agricultural commodity during a crop year to grant relief to a participant in cases of hardship or when the Secretary determines that such production is necessary to meet domestic and foreign needs; and (3) facilitate the practical administration of the CRP.

Contracts may also be modified to add, delete, or substitute conservation practices in the conservation plan if practices fail, through no fault of the participant, to achieve adequate erosion control or it is determined that another conservation practice will achieve adequate erosion control.

Section 704.20 of this interim rule provides that if the right and interest in or the right to occupancy of the land which is the subject of a CRP Contract is transferred to another party, and the new owner or operator does not become a party to the CRP Contract, the participant shall forfeit all rights to future payments with respect to the transferred land and may be forced to refund any payments received in accordance with the CRP Contract.

Section 704.21 of this interim rule sets forth the penalities for violations of the terms and conditions of the CRP Contract. Upon a violation of the terms and conditions of a CRP Contract, CCC

may: (1) Terminate the contract and the participant must forfeit all rights to future payment under the CRP Contract and must either refund all payments received under the CRP Contract together with interest as determined by CCC, or pay liquidated damages if no payments have been received, or (2) require a refund of payments received and make such payment adjustments as are determined to be appropriate.

Section 704.24 of this interim rule provides that representatives of the Department shall have the right of access to land which is the subject of an offer to enter into a CRP Contract or land under a CRP contract and shall have the right to examine any other cropland under the participant or applicant's control to ascertain erosion and cropland classification determinations and program compliance.

Section 704.26 of the interim rule sets forth the administrative appeal procedures which are available to program participants for review of any decision rendered by the Department. All requests for reconsideration or appeal of an administrative determination rendered by the county committee or other ASCS officials shall be conducted in accordance with the administrative appeal regulations found at 7 CFR Part 780. Determinations of land classification or erosion rates may be reviewed in accordance with procedures established by the SCS.

Other Program Provisions

The following regulations are incorporated by reference as a part of the CRP:

(a) 7 CFR Part 713, Feed Grain, Rice, Upland and Extra Long Staple Cotton, and Wheat, specifically §§ 713.109 and 713.150 concerning the fair and equitable division of payments among participants of the CRP Contract and the rights of tenants and sharecroppers;

(b) 7 CFR Part 796, Denial of Program Eligibility for Controlled Substance Violation, concerns the withholding of payments where the participant harvested or allowed harvesting of drug producing plants or is convicted of planting, growing, or harvesting of any controlled substance during any crop year; and

(c) 7 CFR Part 707, Payments Due Persons Who Have Died, Disappeared, or Have Been Determined Incompetent, concerning the payment procedures to be followed in case of death, or competency, or disappearance of any participant.

Section 1231(b)(1) of the Act provides that the Secretary shall enter into CRP Contracts covering not less than 5 million acres during the 1986 crop year. Since owners and operators are already making crop planting decisions for the 1986 crop year, it has been determined that this interim rule shall become effective on March 3, 1986, in order to achieve the goal of placing 5 million acres of cropland in the reserve during the 1986 crop year. However, comments from interested persons are requested. Specifically requested are comments and recommendations on how the CRP could be best used to meet environmental concerns while continuing to satisfy all basic program requirements. In addition to the erosion control benefits of the CRP, it should provide significant contributions to reducing off-farm environmental impacts particularly related to water quality problems. Comments must be received by (60 days after the date of publication in the **Federal Register**) in order to be assured of consideration. After the comments have been received and reviewed, a final rule will be published setting forth any changes to these regulations which are determined to be necessary.

Accordingly, the provisions of this interim rule amend Chapter VII of the Code of Federal Regulations to implement the CRP as authorized by Title XII of the Food Security Act of 1985.

Lists of Subjects in 7 CFR Part 704

Administrative practices and procedures, Conservation plan, Contracts, Technical assistance, Natural resources, Wildlife.

Interim Rule

Accordingly, Chapter VII of the Code of Federal Regulations is amended by adding the following new Part 704—Conservation Reserve Program:

PART 704—CONSERVATION RESERVE PROGRAM

Sec.

Authority: Secs. 1201, 1231–1244. Public Law 99–198, 99 Stat. 1354.

§ 704.1 General description of the program.

(a) The regulations in this part set forth the terms and conditions for the Conservation Reserve Program (CRP) authorized by Title XII of the Food Security Act of 1985 (Pub. L. 99–198). The Secretary of Agriculture is authorized to enter into contracts and make payments to eligible owners and operators of eligible cropland to assist them in conserving and improving the soil and water resources of their farms and ranches by converting such land to permanent vegetative cover in accordance with an approved conservation plan. A conservation plan for specified highly erodible croplands shall be developed in cooperation with the Conservation District (CD) in which the lands are located.

(b) The objectives of the CRP are to: (1) Reduce water and wind erosion, (2) protect our long-term capability to produce food and fiber, (3) reduce sedimentation, (4) improve water quality, (5) create better habitat for fish and wildlife through improved food and cover, (6) curb production of surplus commodities, and (7) provide needed income support for farmers.

§ 704.2 Definitions.

(a) The following definitions shall be applicable for the purposes of this part:

(1) "Agricultural commodity" means any crop planted and produced by annual tilling of the soil or on an annual basis by one-trip planters or sugar cane planted or produced in a State;

(2) "Annual rental payment" means the annual payment specified in the CRP Contract which is made to a participant to compensate such participant for placing eligible cropland in the CRP;

(3) "Applicant" means a person who submits an offer to CCC to enter into a CRP Contract;

(4) "Bid" means the per acre rental payment requested by the owner or operator in such owner or operator's offer to participate in the CRP.

(5) "Conservation District (CD)" means a subdivision of a State organized pursuant to the applicable State Soil Conservation District Law or, in instances where a conservation district does not exist, this term shall mean the State Conservationist of the Soil Conservation Service;

(6) "Conservation plan" means the plan describing the conservation practices which must be established on eligible cropland placed in the CRP in order for erosion on such land to be adequately controlled. The conservation plan shall include the approved vegetative cover and other required conservation practices necessary for the establishment and maintenance of vegetative cover;

(7) "Commodity Credit Corporation (CCC)" means a wholly-owned government corporation within the U.S. Department of Agriculture;

(8) "CRP Contract" means the approved agreement, including the conservation plan, entered into in writing between CCC and the participant which sets forth the terms and conditions for participation in the CRP established under this part;

(9) "Cost-share payment" means the payment made by CCC to assist program participants in establishing the conservation practices eligible for cost-share assistance and required in the CRP Contract;

(10) "Department" means the United States Department of Agriculture and includes CCC;

(11) "Eligible cropland" means highly erodible land which meets the requirements of § 704.7;

(12) "Field" means a part of a farm which separated from the balance of the farm by permanent boundaries such as fences, roads, permanent waterways, woodlands, or cropline in cases where the predominantly eligible cropland and farming practices make it a manageable unit and probable that such cropline is not subject to change during the duration of the contract, or other similar features;

(13) "Field windbreak" means a vegetative barrier with a linear configuration composed of trees or shrubs planted for the purpose of wind erosion control;

(14) "Local ASCS office" means the county office of the Agricultural Stabilization and Conservation Service serving the county or a combination of counties in the area in which the landowner's farm or ranch is located;

(15) "Manageable unit" means a part of a field that can be farmed in a normal manner;

(16) "Operator" means a person who is in general control of the farming operations on the farm;

(17) "Owner" means a person who has legal ownership of farmland including a person who is buying farmland under a purchase agreement;

(18) "Participant" means an owner or operator who has entered into a CRP Contract;

(19) "Person" means an individual, partnership, association, corporation, estate or trust, or other business enterprise or other legal entity and, whenever applicable, a State, a political subdivision of a State, or any agency thereof;

(20) "Secretary" means the Secretary of the U. S. Department of Agriculture;

(21) "Soil Loss Tolerance (T)" means the maximum average annual soil loss specified for a soil in the Soil Conservation Service (SCS) technical guide available in local SCS offices and is basically the level of soil loss that may occur and still permit a high level of crop productivity to be obtained economically and indefinitely;

(22) "Technical assistance" means the assistance provided to owners or operators by a representative of the Department in classifying cropland, developing conservation plans, inspecting eligibility of a designated area, and implementing and certifying conservation practices;

(23) "Tree planting plan" means the plan that sets forth the silvicultural treatment necessary for planting trees, in order to obtain adequate erosion control on eligible cropland. The plan shall include site location, number of acres, requirements for site preparation, tree species and specifications, planting dates, pre- and post-care of nursery stock, and maintenance to ensure survival; and

(24) "Vegetative cover" means perennial or permanent grasses, legumes, forbs, and shrubs with a life span of 5 or more years, or trees.

(b) In the regulations in this part and in all instructions, forms, and documents in connection therewith, all other words and phrases specifically relating to ASCS operations shall, unless the context of subject matter otherwise requires, have the meanings assigned to them in the regulations governing reconstitutions of farms, allotments and bases, 7 CFR Part 719.

§ 704.3 Administration.

(a) The program will be administered on behalf of CCC under the general supervision of the Administrator of the Agricultural Stabilization and Conservation Service (ASCS) and shall be carried out in the field by State ASC Committees (STC) and County ASC Committees (COC).

(b)(1) The land capability class, rate of erosion, suitability of land for permanent vegetative cover, and the adequacy of the planned conservation practice to achieve the necessary erosion control shall be determined by the Soil Conservation Service (SCS).

(2) The SCS will provide such other technical assistance in the implementation of the CRP as is determined to be necessary.

(c) The Forest Service (FS) or the State Forestry Agency shall provide such assistance as is determined to be necessary for developing and implementing conservation plans which include tree planting as the appropriate conservation practice.

(d) The Extension Service (ES) shall coordinate the related information and education program concerning implementation of the CRP.

(e) Except as provided in paragraph (b) of this section, the Deputy Administrator, State and County Operations, ASCS (Deputy Administrator), may determine any question arising under the CRP, may reverse or modify any determination made by an STC or COC in connection with the CRP, and may administer any or all phases of the CRP delegated to the COC, STC, or any employee(s) where the COC, STC, or any employee fails to perform a function required in these regulations. In exercising this authority the Deputy Administrator may authorize a person or persons to carry out the CRP or other function(s) for such period of time as is deemed necessary by the Deputy Administrator.

§ 704.4 Applicability.

(a) The CRP is applicable in the 50 States, the Commonwealth of Puerto Rico, and the Virgin Islands of the United States.

(b) The CRP is applicable to private croplands, Indian tribal croplands, and State or local government croplands that otherwise meet the requirements of eligibility set forth in § 704.7.

§ 704.5 Maximum county acreage.

The maximum acreage which may be placed in the CRP may not exceed 25 percent of the total cropland in the county unless CCC determines that such action would not adversely affect the local economy of the county.

§ 704.6 Eligible person.

In order to be eligible to enter into a CRP Contract in accordance with this part, a person must be an owner or operator of eligible cropland and—

(a) If an operator of eligible cropland, must have operated such cropland for the period beginning not less than 3 years prior to the close of the applicable signup period or January 1, 1985, whichever is later, and must provide satisfactory evidence that such person will be the operator of such cropland for the CRP Contract period; or

(b) If an owner of eligible cropland, must have owned such cropland for not less than 3 years prior to the close of the applicable signup period, unless:

(1) The new owner acquired such cropland by will or succession as a result of the death of the previous owner;

(2) The new owner acquired such cropland prior to January 1, 1985; or

(3) It is determined that the new owner of such cropland did not acquire such cropland for the purpose of placing it in the CRP.

§ 704.7 Eligible cropland.

(a) In order to be eligible to be placed in the CRP, land must—

(1) Have been annually planted or considered planted to produce an agricultural commodity other than orchards, vineyards, or ornamental plantings in 2 of the 5 crop years, 1981 through 1985;

(2) Be physically possible to be planted to produce an agricultural commodity other than orchards, vineyards, or ornamental plantings; and

(3) Be either:

(i) In a field which is classified by SCS as being predominantly Land Capability Classes II, III, IV, and V with an average annual erosion rate 2T or greater, as announced by the Secretary; or

(ii) In a field which is classified by SCS as being predominantly Land Capability Classes VI, VII, or VIII; and

(4) If a redefined field, be a manageable unit which meets the minimum acreage requirements as established by CCC for the county.

(b) Land subject to a contract under the Great Plains Conservation Program, Agricultural Conservation Program, Forestry Incentives Program, Rural Clean Water Program, or similar program contract or land currently under an annual program with maintenance or lifespan requirements may be eligible to be placed in the CRP if the eligible cropland meets the requirements of paragraph (a) of this section and the conservation practices required unde the CRP are consistent with the requirements of the existing contracts.

(c) A field shall be considered to be predominantly highly erodible if 66⅔ percent of the land in such field meets the requirements of paragraph (a)(3).

§ 704.8 Conservation plan.

(a) The applicant, in consultation with the SCS, shall develop the conservation plan.

(b) The SCS ensure that the conservation practices included in the conservation plan and agreed to by the applicant will achieve the reduction in erosion necessary to maintain the production capability of the soil.

(c) If applicable, a tree planting plan shall be developed by the State Forester and shall be included with the conservation plan.

(d) The CD shall approve all conservation plans.

§ 704.9 Eligible conservation practices.

(a) Eligible conservation practices are those practices specified in the conservation plan that meet all quantity and quality standards needed to establish permanent vegetative cover, including introduced or native species of grasses and legumes, forest trees, permanent wildlife habitat, field windbreaks, and shallow water areas for wildlife that will provide adequate erosion control for the contract period.

(b) Other conservation practices may be determined to be eligible if such practices are required in the conservation plan to assure establishment of permanent vegetative cover.

§ 704.10 CRP Contract.

(a) In order to enter into the CRP, the owner or operator must enter into a CRP Contract with CCC.

(b) The CRP Contract will be comprised of: (1) The terms and conditions for participation in the CRP, (2) the offer to the applicant, and (3) the conservation plan.

(c) In order to enter into a CRP Contract, the applicant must submit an offer to participate on a Form CRP–1 at the local county ASCS office during the announced signup period for the applicable crop year.

(1) The offer shall be irrevocable for a period of 30 days subsequent to the close of the applicable signup period.

(2) The applicant shall be assessed liquidated damages in an amount provided in the CRP Contract if the applicant revokes an offer prior to 30 days after the close of the applicable signup period. Once an offer has been received by CCC, it shall be reviewed and evaluated. The revocation of offers during this 30-day review and evaluation period would require a re-evaluation of bids reviewed and would result in additional administrative expenditures by CCC as well as increased annual rental payments; however, it would be impossible to compute the actual damages suffered by CCC.

(3) CCC may waive payment of liquidated damages if CCC determines that the assessment of such damages in a particular case is not in the best interest of the CRP.

(d) The CRP Contract must be signed within the dates established by the COC by: (1) The applicant, and (2) the owners of the cropland to be placed in the CRP.

(e) The COC or its designee is authorized to approve CRP Contracts on behalf of CCC in accordance with instructions issued by the Deputy Administrator.

§ 704.11 Obligations of the participant.

(a) All participants in the CRP must:

(1) Carry out the terms and conditions of the CRP Contract for a period of 10 crop years from the date the CRP Contract is entered into by the participant and CCC;

(2) Implement the conservation plan:

(i) The participant shall implement the conservation plan in accordance with the schedule of completion dates included in such plan unless an extension of time is granted by the COC for the participant to implement the plan. Such an extension shall be granted only if the participant cannot fully implement the plan for reasons beyond the participant's control; and

(ii) The participant shall establish temporary vegetative cover when required by the conservation plan or the COC to control soil erosion until permanent vegetative cover can be adequately established;

(3) Reduce the aggregate total of crop acreage bases, allotments, and quotas for the contract period for each farm which contains land which is the subject of the CRP Contract by an amount based upon the ratio between the total cropland acreage on such farm and the total acreage on such farm subject to the CRP Contract;

(4) Not undertake any action on other land under the participant's control during the contract period that tends to defeat the purpose of the CRP, including the production of any agricultural commodity on land subject to subtitles B and C of Title XII the Food Security Act of 1985, Pub. L. 99–198;

(5) Not knowingly or willingly allow grazing, harvesting, or other commercial use of any crop from the cropland

subject to the CRP Contract except for those periods of time in accordance with instructions issued by the Secretary in response to drought or similar emergency;

(6) Maintain the vegetative cover and the required conservation practices on the land subject to the CRP Contract and take other actions that may be required by CCC to achieve the reduction in soil erosion necessary to maintain the production capability of the soil throughout the CRP Contract period; and

(7) Comply with the noxious weed laws of the applicable State on land subject to the CRP Contract.

(b) The participant and each other person signing the CRP Contract shall be jointly and severally responsible for compliance with the CRP Contract and the provisions of this part and for any refunds or payment adjustments which may be required for violation of any of the terms and conditions of the CRP Contract and the provisions of this part.

§ 704.12 Obligations of the Commodity Credit Corporation.

CCC shall, subject to the availability of funds:

(a) Share the cost with participants of establishing eligible conservation practices specified in the conservation plan at the levels and rates of cost-sharing determined in accordance with the provisions of § 704.14;

(b) Pay to the participant for a period of years not in excess of the contract period an annual rental payment in such amounts as may be specified in the CRP Contract; and

(c) Provide such technical assistance as may be necessary to assist the participant in carrying out the CRP Contract.

§ 704.13 Availability of cost-share payments.

(a) Cost-share payments shall be made available upon a determination by CCC that the eligible conservation practice, or an identifiable unit thereof, has been established in compliance with the appropriate standards and specifications.

(b) Cost-share payments may be made under the CRP only for the establishment or installation of an eligible conservation practice.

(c) Except as provided in paragraph (d) of this section, cost-share payments shall not be made to the same owner or operator on the same acreage for any eligible conservation practices which have been previously established, and for which such owner or operator has received cost-share assistance from the Department.

(d) Cost-share payments may be authorized for the replacement or restoration of conservation practices for which cost-share assistance has been previously allowed under the CRP only if:

(1) Replacement or restoration of the practice is needed to achieve adequate erosion control; and

(2) The failure of the original practice was not due to the lack of proper maintenance by the participant.

(e) The cost-share payment made to a participant shall not exceed the participant's actual contribution to the cost of establishing the conservation practice.

§ 704.14 Levels and rates for cost-share payments.

(a) CCC will share not more than 50 percent of the actual or average cost of establishing the eligible conservation practices specified in the conservation plan.

(b) The average cost of performing a conservation practice shall be determined by the STC or COC, based upon the recommendation of the State and county Conservation Review Groups as identified in 7 CFR 701.2 (a) and (f), and may be the average cost in a State, a county, or a part of a county or counties.

§ 704.15 Annual rental payments.

(a) Annual rental payments shall be made in such amount and in accordance with such time schedule as may be agreed upon and specified in the CRP Contract.

(b) The annual rental payment shall be divided among the participants in the manner agreed upon in the CRP Contract.

(c) The maximum amount of rental payments which a person may receive under the CRP for any fiscal year shall not exceed $50,000. The regulations set forth at 7 CFR Part 795 shall be applicable in determining whether certain persons as individuals or other entities are to be considered as a separate person for payment limitation purposes.

§ 704.16 Method of payment.

Payments made by the Department under this part may be made in cash, in-kind, or in commodity certificates or in any combination of such methods of payments in accordance with 7 CFR Part 770.

§ 704.17 Assignments.

Any participant who may be entitled to any cash payment under this program may assign the right to receive such cash payment, in whole or in part, as provided in the regulations at 7 CFR Part 709, Assignment of Payment.

§ 704.18 Payments not subject to claims.

Subject to the regulations found at 7 CFR Part 13, any cost-share or annual payment or portion thereof due any person shall be allowed without regard to questions of title under State law, and without regard to any claim or lien in favor of any creditor, except agencies of the U.S. Government.

§ 704.19 Contract modifications.

(a) CCC, by mutual agreement with the participant, may modify the CRP Contract in order to:

(1) Decrease acreage placed in the CRP;

(2) Permit the production of an agricultural commodity during a crop year on all or part of the land subject to the CRP Contract; and

(3) Facilitate the practical administration of the CRP.

(b) The concurrence of the SCS and the CD are necessary when modifications to a CRP Contract involve a technical aspect of the participant's conservation plan.

(c) CCC may modify CRP Contracts to add, delete, or substitute conservation practices when:

(1) The installed conservation practice failed to adequately control erosion through no fault of the participant;

(2) The installed measure deteriorated because of conditions beyond the control of the participant; or

(3) Another conservation practice will achieve at least the same level of erosion control.

§ 704.20 Transfer of land.

(a)(1) If a new owner or operator purchases or obtains the right and interest in, or right to occupancy of, the land subject to CRP Contract, such new owner or operator, upon the approval of the COC, may become a participant to the existing contract with the same terms and conditions or may offer to enter into a new CRP Contract with CCC covering such transferred land.

(2) If the new owner or operator becomes a participant to the existing CRP Contract, the new owner or operator shall assume all obligations under the CRP Contract of the previous participant with respect to the transferred land.

(3) The following provisions shall be applicable if the new owner or operator becomes a participant to the existing CRP Contract or enters into a new CRP Contract with CCC:

(i) Cost-share payments shall be made to the participant who established the

conservation practice as specified in the contract; and

(ii) Annual rental payments to be paid during the fiscal year when the land was transferred shall be divided: (A) Between the new participant and the previous participant based upon the period of time during the fiscal year during which such participants had control of the land or (B) as agreed upon the participants and approved by the COC.

(b) If a participant transfers all or part of the right and interest in, or right to occupancy of, the land subject to CRP Contract and the new owner or operator does not become a participant to the existing CRP Contract or a new CRP Contract in accordance with the provisions of this section, the CRP Contract shall be terminated on the affected portion of the land subject to the CRP Contract, and the participant:

(1) Must forfeit all rights to any future annual rental or cost-share payments with respect to the transferred acreage; and

(2) Must refund all or part of the payments plus interest thereon, as determined by CCC, that have been made on the transferred land, except a portion of the payments may be retained to the extent CCC determines, after consultation with the technical agency and the CD, that the established conservation practices have achieved desired conservation benefits for an acceptable period.

§ 704.21 Violations.

(a) (1) If the participants fails to carry out the terms and conditions of the CRP Contract, CCC may, after considering the recommendations of the CD and SCS, terminate the CRP Contract.

(2) If the CRP Contract is terminated by CCC in accordance with this subsection, the participant shall:

(i) Forfeit all rights to further payments under the CRP Contract and refund all payments received together with interest thereon as determined by CCC; or

(ii) Forfeit all rights to payments under the CRP Contract and pay liquidated damages to CCC in an amount specified in the CRP Contract if no payments have been received by the participant under the CRP Contract.

(3) The purpose of the CRP is to control erosion on highly erodible lands thereby protecting the Nation's soil and water resources for succeeding generations. Once a CRP Contract has been entered into between CCC and the owner or operator, CCC and other segments of the agricultural community will act based on the assumption that the CRP Contract will be fulfilled and the reduction in erosion and production will be obtained. CCC's action includes budgeting and planning for the CRP in subsequent crop years. A participant's failure to carry out the terms and conditions of the CRP Contract undermines the basis for these actions, damages the credibility of CCC's programs with other segments of the agricultural community, and requires additional expenditures in subsequent crop years in order for the required levels of acreage to be placed in the CRP and in order for an adequate reduction in erosion to be obtained. While the adverse effects on CCC of the participant's failure to comply with the CRP Contract is obvious, it would be impossible to compute the actual damage suffered by CCC. Therefore, participants shall be required to refund all payments received, plus interest, upon the termination of the CRP Contract in accordance with this subsection, or to pay liquidated damages in an amount specified in the CRP Contract if no payments under CRP have been received prior to termination.

(b) CCC may terminate a CRP Contract if the participant agrees to such termination and CCC determines that termination would be in the public interest.

(c) If the participant fails to carry out the terms and conditions of the CRP Contract but CCC determines that such failure does not warrant termination of the CRP Contract, CCC may require such participant to refund payments received under the CRP Contract or to accept such adjustments in the payment as are determined to be appropriate by CCC.

§ 704.22 CRP Contracts not in conformity with regulations.

If, after a CRP Contract is approved by the COC on behalf of CCC, it is discovered that such CRP Contract is not in conformity with the provisions of this part as the result of a misunderstanding of the program procedures by a signatory to the contract, a modification of the contract may be made by mutual agreement. If the parties to the CRP Contract cannot reach agreement with respect to such modification, the CRP Contract shall be terminated and all payments paid or payable under the contract shall be forfeited or refunded to CCC, except as may otherwise be allowed by CCC in accordance with the provisions of § 704.23.

§ 704.23 Performance based upon advice or action of Department.

The provisions of Part 790 of this chapter, as amended, relating to performance based upon the action or advice of a COC or STC shall be applicable to the CRP.

§ 704.24 Access to land.

Any representative of the Department, or designate thereof, shall have the right of access to land which is the subject of an application for a CRP Contract, or land which is the subject of a CRP Contract and shall have the right to examine any other cropland under the applicant's or participant's control for the purpose of determining land classification and erosion rates and for the purpose of determining whether there is compliance with the terms and conditions of the CRP.

§ 704.25 Division of program payments and provisions relating to tenants and sharecroppers.

Payments received under a CRP Contract shall be divided fairly and equitably among all participants to the contract and producers who would have shared in the risk of producing crops on the land to be placed in the CRP shall receive equitable treatment in accordance with the regulations set forth in 7 CFR 713.109 and 713.150 which relate to division of payments and the rights of tenants and sharecroppers.

§ 704.26 Appeals.

(a) Except as provided in paragraph (b) of this section, the participant may obtain a review in accordance with the administrative appeal regulations (7 CFR Part 780) of any administrative determination rendered under this program.

(b) Determinations concerning land classification or erosion rates may be reviewed in accordance with procedures established by SCS.

§ 704.27 Depriving others of payments.

If it is determined by CCC that any participant has employed any scheme or device to deprive any other person of cost-share assistance or land rental payments, any part of any program payment otherwise due or paid such participant during the CRP Contract period may be withheld or required to be refunded with interest thereon as determined by CCC. A scheme or device includes, but is not limited to, coercion, fraud, or misrepresentation.

§ 704.28 Filing of false claims.

If it is determined by CCC that any participant has knowingly supplied false information or has knowingly filed a false claim, such participant shall be ineligible for payments under the CRP with respect to the crop year in which the false information or claim was filed.

False information or false claims include a claim for payment for a conservation practice which is not carried out or a claim for payment for conservation practices which do not meet the specifications of the applicable conservation plan. Any amounts paid under these circumstances shall be refunded, together with interest as determined by CCC, and any amounts otherwise due such participant shall be withheld. The withholding or refunding of such payments will be in addition to any other penalty or liability otherwise imposed by law.

§ 704.29 Miscellaneous.

(a) In accordance with the regulations set forth at 7 CFR Part 796:

(1) No payment shall be made to any participant who harvests or knowingly permits to be harvested for illegal use, marihuana or other such prohibited drug-producing plants on any part of the lands owned or controlled by such participant; and

(2) Any participant who is convicted under Federal or State law of planting, cultivating, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for any payments under this part during that crop year and the four (4) succeeding crop years.

(b) In case of death, incompetency, or disappearance of any participant, any payment due shall be paid to the participant's successor in accordance with the provisions of 7 CFR Part 707.

Signed at Washington, DC, on March 6, 1986.

Frank W. Naylor, Jr.,

Acting Secretary of Agriculture.

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