Authority: 21 U.S.C. 346a and 371.

2. Section 180.1182 is added to subpart D to read as follows:

§ 180.1182 Coat Protein of Potato Virus Y and the genetic material necessary for its production; exemption from the requirement of a tolerance.

An exemption fron the requirement of a tolerance is established for residues of the biological plant pesticide Coat Protein of Potato Virus Y and the genetic material necessary for its production in or on all food commodities.

[FR Doc. 97–21690 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412, 413, and 414

[BPD–763–F]

RIN 0938–AG20

Medicare Program; End-Stage Renal Disease (ESRD) Payment Exception Requests and Organ Procurement Costs

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

ACTION: Final rule.

SUMMARY: These final regulations specify the criteria HCFA uses to determine if a facility that furnishes dialysis services to Medicare patients with end-stage renal disease (ESRD) qualifies for a higher payment under an exception to its prospectively determined payment rate and the procedures HCFA uses to evaluate ESRD payment exception requests. These regulations also revise the way HCFA computes acquisition costs for organs that are transplanted into Medicare beneficiaries.

EFFECTIVE DATE: September 15, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Powell, (410) 786–4557.

SUPPLEMENTARY INFORMATION:

I. Background

Under sections 1881(b)(2) and (b)(7) of the Social Security Act (the Act), a facility that furnishes dialysis services to Medicare patients with ESRD is paid a prospectively determined rate for each dialysis treatment furnished. This rate is a composite that includes all costs associated with furnishing dialysis services except for the costs of physician services and certain laboratory tests and drugs that are billed separately. The composite rate may be adjusted periodically to reflect actual facility costs.

When a facility's costs are higher than the prospectively determined rate, we may, under certain conditions, grant the facility an exception to its composite rate and set a higher prospective rate. The facility must show, on the basis of projected cost and utilization trends, that it will have an allowable cost per treatment higher than its prospective payment rate and that the excess costs are attributable to one or more specific circumstances. These conditions are specified in existing regulations at 42 CFR 413.170 and are discussed in greater detail in Chapter 27 of the Medicare Provider Reimbursement Manual (PRM) (HCFA Pub. 15–1).

A facility may incur excess costs when it furnishes dialysis services to a patient population with a greater than average number of pediatric patients or patients with other medical conditions, such as those with heart disease or unstable medical conditions, who require special equipment, procedures, supplies, or staff trained in treating these patients. This is referred to as ''atypical'' service intensity (or patient mix). A facility may also incur increased costs when it is the only supplier of dialysis services in its geographical area and its patients are unable to obtain dialysis services elsewhere without considerable hardship (an isolated essential facility).

Increased training costs may also be associated with a facility's self-dialysis training program. A facility may train patients to perform self-dialysis with little or no professional assistance in the facility or at home. It may also train other individuals to assist patients in performing self-dialysis or home dialysis. A facility that has training costs greater than its composite training rate may apply for an exception, but must prove that the costs are reasonable and allowable.

Typically, a patient undergoes dialysis three times a week. A facility may furnish a substantial number of treatments to patients who dialyze less frequently than three times a week. As a result, the facility typically has higher per treatment costs because the treatments involve increased labor or supplies. When this occurs, a facility may apply for an exception to the composite rate.

On several occasions, we have denied exception requests based on application of the criteria contained in the PRM, and the facilities have appealed the denials. Subsequently, some denials have been overturned by the Provider Reimbursement Review Board (PRRB) because the PRRB is not bound by the guidelines in the PRM. Therefore, we believe it is necessary to codify in regulations the specific requirements for determining exceptions.

II. Provisions of the Proposed Rule

On August 26, 1994, we published in the **Federal Register** (59 FR 44097) a proposed rule that specified the conditions (previously contained in the PRM) that a facility furnishing dialysis services to patients with ESRD must meet in order to qualify for a higher payment under an exception to the prospectively determined payment rate. The proposed rule also contained the criteria that we would use to evaluate whether the facility meets the conditions.

We also proposed to revise 42 CFR Part 413, Subpart H, Payment for ESRD Services. Currently, all of the Medicare payment rules for covered outpatient maintenance dialysis treatments can be found in § 413.170. We proposed to reorganize the content of Subpart H and divide existing § 413.170 into several smaller sections so that readers can more easily locate specific topics. The table outlining this change is shown below.

New section		Old section
413.170	Scope	413.170(a)
413.172	Principles of prospective payment	413.170(b)
413.174	Prospective rates for hospital-based and independent ESRD facilities	413.170(c)
413.176	Amount of payments	413.170(d)
413.178	Bad debts	413.170(e)
413.180	Procedures for requesting exceptions to payment rates	413.170(f)
413.182	Criteria for approval of exception requests	413.170(g)
413.184	Payment exception: Atypical service intensity (patient mix)	413.170(g)(1)
413.186	Payment exception: Isolated essential facility	413.170(g)(2)

New section	Old section
413.188 Payment exception: Extraordinary circumstances	413.170(g)(4)
413.190 Payment exception: Self-dialysis training costs	413.170(g)(5)
413.192 Payment exception: Frequency of dialysis	413.170(g)(6)
413.194 Appeals	413.170(h)
413.196 Notification of changes in rate-setting methodologies and payment rates	413.170(i)
413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis	413.174
413.200 Payment of independent organ procurement organizations and histocompatibility laboratories	413.178
413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.	413.179

III. Analysis of and Responses to Public Comments

In response to the August 26, 1994 proposed rule, we received nine timely items of correspondence. The specific comments and our responses are set forth below following each section describing the specific provisions of the proposed rule. The sections generally follow the order of the discussed topics in the proposed rule, with the exception of the section entitled *Bad debts* that appears last.

A. General

Comment: One commenter suggested that we update the composite rate on a regularly scheduled basis, as is done for the hospital inpatient prospective payment system rates, home health agency rates, hospice rates, and resource-based relative value scale rates.

Response: Under section 4201 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, from January 1, 1991, onward, Congress has set the composite rates for payment for ESRD services furnished to Medicare beneficiaries. Any change would require legislative action. Thus, we have no discretion in this regard.

B. Procedures for Requesting Exceptions to Payment Rates (§ 413.180)

We proposed to redesignate the content of § 413.170(f), Procedures for requesting exceptions to payment rates, as new § 413.180. In § 413.180(d), we proposed to specify that a facility requesting an exception to its payment rate must do so within 180 days of:

- The effective date of its new composite payment rate(s);
- The effective date that HCFA opens the exceptions process; or
- The date on which an extraordinary cost-increasing event, as described in proposed §§ 413.182(c) and 413.188.

In § 413.180(f)(5), we proposed to require that the facility applying for an exception request compare its most recently completed cost report with those of prior years. Such comparisons may reveal significant changes that may indicate errors or problems with the cost or statistical data and, thus, the need for us to more intensively review the applicable area. Any changes to cost or statistical data (for example, number of treatments) must be explained and the explanation included with the documentation supporting the exception request.

We also proposed in § 413.180(f) and § 413.182 to require that ESRD facilities provide documentation showing that their excessive costs are specifically or directly attributable to one or more of the exception criteria. As an example, for an atypical service intensity request, the facility should be able to document the excessive costs of furnishing care to patients with severe medical conditions. After submitting evidence that it treats these patients, the facility should submit records to show that a more experienced and better trained nursing staff is required to treat these patients and/or additional nursing staff time is needed. An example of the type of records that a provider should submit to document its higher nursing costs could consist of staffing schedules indicating staff and patients per shift. The facility could indicate (on the schedules) the patients with other medical conditions that were treated and the more experienced or additional staff needed to treat them. The monthly staffing schedules should represent 12 months and coincide with the actual cost reporting period of the cost report submitted with the exception request.

In § 413.180 (g) and (h), we proposed to codify in regulations the requirement under section 1881(b)(7) of the Act that specifies that unless we disapprove a composite rate exception request within 60 working days after it is filed with an intermediary, the exception is deemed approved. We require that intermediaries review and process all exception requests within 15 working days, and we process the exceptions within 45 working days.

Comment: One commenter suggested that we set three levels of documentation for exception requests in order to reduce the amount of work involved in both the preparation and review of an exception request. These three levels of documentation would include new requests, renewal of an existing request with significant changes, and renewal of an existing request with no significant changes, respectively. The first level (new requests) would incorporate the standard currently required for all exception requests. The second level (renewal of an existing request) would require sufficient documentation to justify any additional amounts over the amount previously granted by HCFA but would not require documentation for previously justified exceptions. The third level (renewal of an existing request with no significant changes) would require only the submission of basic data and a facility certification to demonstrate that the situation has not changed.

Response: We do not agree with the commenter that the exceptions process should be established at three different levels. Given the limited timeframe allowed by the Act to approve or deny an exception (60 working days), we do not believe it would be feasible to sort through three levels of requests and address the specific issues associated with each level. Moreover, because of the volume of exceptions we receive during each exception window, we are unable to maintain exception documentation on past windows in-house, but must store these files at the Federal Records Center. Retrieving records could significantly lengthen the time we would need to review a request.

However, we agree with the commenter that requiring facilities to file new exception requests each time a cycle is opened may be overly burdensome for those facilities where no significant changes have occurred from the previous exception cycle. Therefore, we are providing (at § 413.180(e)) a mechanism for a facility to request retention of its current exception rate. This option is only available to those facilities that can demonstrate that the circumstances under which their current exception rates were granted still apply.

Historically, these providers have been required to prepare new exception request submissions for each exception

cycle. Almost all pediatric hospitals furnishing dialysis services that apply for exceptions are granted them, and the same is true for many isolated essential facilities. To ease the repetitive filing burden (and cost) for these types of facilities, we are providing for the continuation of prior exception amounts for qualifying facilities. Also, this provision would eliminate uncertainties concerning future payment rates.

We note that during an earlier exception cycle that opened March 1, 1991 and closed August 27, 1991, we allowed renal facilities a similar option of continuing to receive the exception payment rates approved during the preceding exception cycle (December 1, 1989 to May 29, 1990).

For each exception cycle, servicing intermediaries will inform all facilities by letter, 30 days prior to the effective date of a new exception cycle, that they can request exception payment rates approved during the preceding exception cycle. The facilities must then file a request with their servicing intermediary during the 30 days prior to the opening of the next exception cycle. This request should consist of a letter to the facility's servicing intermediary requesting the continuation of its previously approved exception amount. While no specific documentation is required with this request, the facility should provide enough information to adequately demonstrate that the circumstances under which the previous exception was granted have not changed. For example, for all exception requests facilities should document that its cost per treatment is higher than its composite payment rate, or if a facility is an isolated essential facility, it should specify that no new facilities have been established nearby. This request must be filed with the intermediary before the beginning of the exception cycle. The document must be delivered during the intermediary's regular business hours. Delivery of the request must be accomplished through a method that documents the time and date of receipt. A postmark or other similar mark does not serve as documentation of the time and date of receipt.

The intermediary will determine whether the renal facility still meets the exception criteria, that is, that the circumstances under which the exception was granted still exist. The intermediary will be required to make a determination on these requests within 10 working days and notify the provider and HCFA. If the intermediary determines that the renal facility meets the exception criteria, the approved exception amount would be equal to the previously approved rate, and payment at this approved rate would continue. In cases where an exception cycle is opened because a rate increase has been approved by Congress, a facility that chooses to retain its exception rate would do so *in lieu of* any update to its composite payment rate(s).

If the facility does not continue to meet the exception criteria, the intermediary will notify the facility that, effective with the opening of the new exception cycle, the currently approved exception rate will expire and the current composite rate will go into effect. If this facility still believes it is entitled to an exception during this exception cycle, it can file a complete exception request during the remainder of the 180-day cycle.

If a renal facility does not request retention of its previously approved exception rate but still wishes an exception, the facility would be required to submit a new request during the new exception cycle. However, the approval of an exception does not assure that the amount would be equal to or higher than the currently approved exception amount. Furthermore, if the facility fails to adequately justify its exception request in accordance with the regulations and program instructions, its exception request could be denied.

Comment: One commenter suggested that we add an inflation factor to the approved rate in the second and third year during which an exception has been granted.

Response: A facility requesting approval of an exception to its composite rate must request a higher payment rate based on its projected budget estimate(s). Therefore, an approved exception rate based on projected costs would already include the inflation factor. The projected budget estimate(s) should cover the period to which the exception rate is to apply.

Comment: Several commenters suggested that we should establish regularly scheduled intervals or effective dates for the opening of the exceptions process to avoid placing an administrative burden on the provider, the intermediary, and HCFA.

Response: Currently, the exceptions process is opened each time there is a legislative change in the composite payment rate. In addition, because of the lack of any updates to the composite rates in recent years, we have opened the exceptions process three times without issuing new rates, most recently from November 1, 1993 through April 29, 1994. Only Congress has the authority to issue new rates. Deciding whether to issue new rates has been driven by several factors, such as: (a) A review of updated ESRD audited cost and statistical data; (b) an analysis of the general growth and mix of the ESRD population in renal dialysis facilities, and (c) Congressional concerns with payment rates. Therefore, if new prospective payment rates are not issued by Congress, we will continue to determine when to open the exceptions process.

Comment: One commenter suggested that when we open the exceptions process all facilities should be eligible to apply for an exception, rather than the limited group of facilities specified in the proposed rule.

Response: In the preamble of the proposed rule, we stated that we had opened the exceptions process in situations where there had not been a rate change, permitting facilities that had received partial approvals, new facilities, or facilities that had been previously denied exceptions the chance to file for an exception. We did not mean to imply that the exceptions process is only open to these facilities. Whenever we have opened the exceptions window, all facilities have been permitted to apply for an exception, regardless of previous circumstances. However, it is only when the exception window is open that a facility may seek an exception. Likewise, a facility wishing to retain its previously approved exception rate may only do so during the 30-day period prior to the opening of an exception cycle. We have added a sentence to § 413.180(b) to clarify this requirement.

Comment: One commenter pointed out that § 413.180(f)(5), which requires the facility to provide a comparative analysis of its costs in the most recent cost reporting period and prior years, does not specify the number of prior years' data required. The commenter believed that in order to avoid arbitrarily denying an exception request that did not contain enough comparative years, we should specify the number of years required.

Response: We agree with the commenter and have included language in § 413.180(f)(5) to state that the materials submitted to us must include a comparative analysis of the facility's costs in its most recently completed cost report with reported costs from (at least 2) prior years.

Comment: One commenter recommended that the regulation should specify the intermediary's review responsibilities during the 15 working days it has to make a recommendation to HCFA. Another commenter stated that the

intermediary's determinations regarding ''completeness'' invite subjective interpretations. Both commenters suggested the intermediary's 15 working day timeframe should be extended.

Response: The specific review responsibilities for intermediaries are detailed in Chapter 27 of the PRM. These responsibilities include: (a) Reviewing for completeness and accuracy the exception request, the cost report, the facility's projected costs, and any other documentation submitted by the facility to support its exception; (b) maintaining a composite rate exception log; (c) developing the content of the letter used to return an exception request to the facility; and (d) determining whether the facility's costs are reasonable and allowable. The intermediary makes the determination with respect to ''completeness,'' and, if the renal facility fails to submit the documentation required by Chapter 27 of the PRM, the exception request is returned to the facility. Rather than specify the intermediary's responsibilities in the regulation, we believe the PRM is the appropriate place to do so. Because of the statutory deadline (section 1881(b)(7) of the Act) that an exception request is deemed approved unless we disapprove it within 60 working days, and the volume of exceptions received during an exceptions window, we believe the present timeframes (15 working days for the intermediary and 45 working days for HCFA) for processing exceptions should be maintained in order to ensure that all exceptions are processed timely.

Comment: One commenter was concerned about the implications of proposed § 413.180(l). The commenter stated that this section implies that the facility must submit an entirely new exception request if the first request (or any subsequent request) is denied. Furthermore, the commenter believed that facilities should be able to send all additional data or clarifications directly to HCFA. The commenter asserted that filing an entirely new request was unnecessary.

Response: As explained above, the intermediary has 15 working days to review the exception request for completeness and accuracy, and, if the exception request is denied because the ESRD facility did not submit the required documentation, the intermediary returns the exception request with a letter. Presently, the instructions in the PRM require that the entire exception request be returned when an exception is denied, and a new request must be submitted with the missing documentation.

We agree with the commenter that, in this situation, the submission of an entirely new exception request is not necessary. We have revised the instructions in the PRM to indicate that the denial letter from the intermediary to the ESRD facility will include a list of missing or inadequate documentation and the intermediary will request only the submission of the missing or corrected information. However, we do not agree with the suggestion that the ESRD facility should provide the additional information directly to HCFA. Because of the volume of exceptions received during an exception window, administratively it will be more efficient to have each servicing intermediary track the exceptions processed through its office and review the new information submitted by the ESRD facility. The intermediary will then forward the exceptions to us in accordance with Chapter 27 of the PRM.

Comment: One commenter suggested that because of the significant data gathering and analysis required for an exception, it should be understandable that some data elements are missed or that additional support or clarification may be required by the intermediary. The commenter suggested that providers should be permitted to submit this additional documentation after the 180-day period without an immediate exception denial. Furthermore, rate increases should be approved retroactively to the date that all detailed information is received.

Response: We disagree with the commenter. An ESRD facility that files its exception request promptly at the opening of a 180-day exception period and has its exception denied would have an additional opportunity to submit a new request before the exception period closes. If a facility chooses instead to file an exception request at or near the end of the 180-day exception period and it is not filed with all required documentation, we do not believe that it is unfair to deny the exception request. Facilities must accept the risk associated with filing their exception requests at the last minute. Since the composite rate system is a prospective payment system, we believe that it would be inconsistent to grant exceptions retroactively based on the subsequent receipt of information.

C. Criteria for Approval of Exception Requests (§ 413.182)

We proposed to redesignate the contents of § 413.170(g), Criteria for approval of exception requests, as § 413.182. In this section, we listed the criteria that may be the basis of a rate exception. These criteria are: atypical service intensity (patient mix) (new § 413.184); isolated essential facility (new § 413.186); extraordinary circumstances (new § 413.188); self-dialysis training costs (new § 413.190); and frequency of dialysis (new § 413.192).

We received no comments on this listing. Comments on the criteria themselves are discussed in the appropriate sections below.

D. Payment Exception: Atypical Service Intensity (Patient Mix) (§ 413.184)

In the proposed rule, we specified the documentation required of a facility requesting a rate exception based on patient mix.

In § 413.184(b)(1), we proposed to require that a facility submit a list of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing:

- Patients who received transplants, including the date of the transplant;
- Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, as well as projected transplants;
- Home patients;
- In-facility patients, staff-assisted or self-dialysis;
- Individual patient diagnoses;
- Diabetic patients;
- Patients isolated because of a contagious disease;
- Age of patients;
- Mortality rate, by age and diagnosis;
- Number of patient transfers, reasons for transfers, and any related information; and
- Total number of hospital admissions for the facility's ESRD patients, including reason and length of stay for each admission.

When adjudicating exception requests to determine if a substantial proportion of the facility's outpatient maintenance dialysis treatments involves more intense dialysis services and special dialysis procedures, we will compare the above data submitted by providers to data contained in our Patient Profile Tables. The information in the Tables is developed annually and represents information on persons with ESRD covered by Medicare.

In § 413.184(b)(2)(i), we proposed to require that a facility submit the following documentation on costs of nursing personnel (registered nurses (RNs), licensed practical nurses (LPNs), technicians and aides) incurred during the most recently completed fiscal or calendar year cost report showing:

- Amount of remuneration of each employee;
- Number of personnel;

• Amount of time spent in the dialysis unit; and

• Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

The facility must demonstrate that its nursing personnel costs have been allocated properly between each mode of care, and that the additional nursing hours per treatment are not the result of an excess number of employees in the outpatient maintenance renal dialysis department. Normally, we use staff-to-patient ratios to determine whether there is an excess number of employees assigned to a facility's dialysis department; however, we also may consider staffing schedules. Thus, an example of the type of records that a provider should submit to document its higher nursing costs could consist of staffing schedules, indicating staff and patients per shift. The facility could indicate on the schedules the patients with other medical conditions that were treated and the more experienced or additional staff needed to treat them.

When adjudicating exception requests, we will utilize the above data to determine if the facility's patients received significantly more nursing hours per treatment than patients would receive in other facilities and whether the facility's higher per treatment costs were necessitated by the special needs of the patients.

Proposed § 413.184(b)(2)(ii) included the requirement that a facility submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

• By modality, a complete list of supplies used routinely in a dialysis treatment;

• The make and model number and component cost of each dialyzer; and

• That the supplies are prudently purchased (for example, the facility uses bulk purchase discounts when available).

The facility must demonstrate that excess supply cost per treatment is caused by the special needs of the patients and is not the result of inefficiency.

When adjudicating exception requests, we will utilize the above data to determine if the facility's patients received supplies that are medically necessary to meet their special medical needs.

Comment: One commenter believed it is an unreasonable burden to require facilities to submit 12 months of staffing schedules, since these schedules are not normally kept as permanent files and a facility might not be able to anticipate the opening of an exception window. The commenter suggested that 3 to 6 months of staffing schedules would be more than reasonable to sufficiently document a facility's normal staffing ratios.

Response: Staffing schedules were only mentioned in the proposed rule as an example of the type of records a provider could submit to document its higher nursing costs and/or to demonstrate that there is not an excessive number of employees assigned to a facility's dialysis department. These schedules are basic source documents representing services rendered, and we believe that renal dialysis facilities maintain these schedules. We continue to believe that it is not unreasonable for a facility to submit 12 months of staffing schedules in support of its higher nursing costs. Regardless of the nature of the supporting documentation submitted, the facility must ensure that the data adequately substantiate its higher labor costs for the entire cost reporting year.

Comment: One commenter wanted the meaning of ''productive and nonproductive hours'' clarified. The commenter was confused as to where activities such as educational meetings, lunch breaks, paperwork, and charting fit into the documentation of staff costs.

Response: The term ''productive hours'' means the amount of paid nursing staff time spent on direct (hands-on) patient care and any hours explicitly connected to patient care, such as charting. All other paid nursing staff time, such as training, education, management, holidays, vacations, sick time, and lunch breaks, is considered ''nonproductive hours''.

Comment: One commenter believed that serving an atypical patient population could result in cost increases in areas beyond staff and supplies. Specifically, patients with severe cardiac complications might require additional monitoring equipment, and patients with communicable respiratory diseases (such as tuberculosis) might require special ventilation systems. The commenter recommended that documented overhead costs should be included in the calculation of a higher exception rate.

Response: We agree with the commenter and have in the past approved exception amounts for overhead costs related to (a) special equipment necessary for the care of patients with other medical conditions, and (b) isolation areas required for the care of hepatitis or other patients where the facility can show that isolation is necessary. For these costs to be considered under this set of exception criteria, documentation must be submitted demonstrating the basis of the higher costs and the incremental impact on per treatment costs. The documentation must also explain how these costs relate to the atypical patient mix exception criteria. We have added § 413.184(b)(2)(iii) to state that the facility must submit documentation on overhead costs incurred during the most recently completed cost reporting year showing—

• The basis of the higher overhead costs;

• The impact on the specific cost components; and

• The effect on per treatment costs.

Comment: One commenter suggested that we should publish a complete, detailed list of supplies used in the typical dialysis treatment, including the cost of those supplies and the volume of each that is used per treatment. The commenter recommended that the listing should be in the same format as we require the facilities to use. The commenter also stated that we must publish the components of the composite rate in order to allow appropriate comparisons, including the costs, staffing ratios, and employee mix (that is, anything that we deem to be essential in order to make the comparison).

Response: When evaluating the reasonableness of a facility's component costs shown in its exception request, we use national data and general program statistics. Chapter 27 of the PRM includes our median cost per treatment data as follows:

Cost component	Amount
Salaries	$40.00
Supplies	33.00
Overhead, excluding employee benefits	47.00
Overhead, including employee benefits	54.00
Employee benefits	7.00
Laboratory	3.00

We do not maintain detailed breakdowns of the above cost components. The cost components were derived from audited cost reports of hospital-based and independent renal dialysis facilities. Therefore, it would be difficult for us to publish an accurate list of these components to use as comparisons.

Comment: One commenter stated that where a provider had demonstrated that higher nursing staff costs are necessary to care for the sicker patients being treated, we should also recognize the higher amount of administrative and general (A & G) costs that will be allocated through the step-down process on the hospital's cost report. The

commenter also stated that since Medicare cost reporting policy recognizes ''accumulated cost'' as a fair and accurate basis for allocating A & G costs for cost reporting purposes, we must consider these allocated A & G costs when adjudicating ESRD exception requests.

Response: As stated in the proposed rule, the accounting protocol used for cost reporting is separate and distinct from identifying the actual A & G costs that are directly attributable to higher nursing staff costs. For a hospital-based facility, if the direct cost of nursing staff salaries in the dialysis department increased, the A & G allocated to that department would automatically increase. This is the result of the hospital cost reporting accounting protocol, which requires A & G costs to be allocated on the basis of the accumulated costs of the other departments. Since the total A & G costs represent costs allocated to the dialysis department, they do not accurately reflect the actual A & G costs incurred as a result of the additional nursing staff salary costs.

In accordance with § 413.180(f)(3), a facility must submit materials that show that the elements of excessive costs are specifically attributable to one or more of the conditions specified by the exception criteria set forth in § 413.182. According to § 413.182, HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates with convincing objective evidence that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of Part 413 and its per treatment costs, in excess of its payment rate, are directly attributable to any of the exception criteria.

Our regulations do not require that the same principles of cost allocations and cost apportionment be used to determine which costs, in excess of the payment rate, are directly attributable to the exception criteria. Moreover, a provider that is granted an exception is not automatically entitled to the same payment it would have received under cost reimbursement. The excess costs must be directly attributable to the exception criteria.

E. Payment Exception: Isolated Essential Facility (§ 413.186)

We proposed to include the requirements of existing § 413.170(g)(2) as new § 413.186, and add documentation requirements for facilities that apply for a payment rate exception based on being an isolated essential facility.

1. Isolated Facility

To be considered isolated, a facility must document that it is located outside an established Metropolitan Statistical Area (MSA) and provides dialysis to a permanent patient population as opposed to a transient patient population.

2. Essential Facility

To be considered essential, the facility must document that a substantial number of its patients cannot obtain dialysis services elsewhere without substantial additional hardship and the additional hardship the patients will incur, generally, will be in travel time and cost.

3. Cost Per Treatment

The facility must document that its cost per treatment is reasonable and explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria. For example, if a facility incurs higher supply costs, it must identify the additional costs incurred on a per treatment basis and then relate that additional cost per treatment to the exception criteria.

4. Additional Information

The facility must also furnish, in a format that concisely explains the facility's cost and patient data to support its request, the following information:

- A list of current and requested payment rates for each modality.
- An explanation of how the facility's costs in excess of its composite rate payment are attributable to the isolated essential facility criteria.
- An explanation of any unusual geographic conditions in the area surrounding the facility.
- A copy of the latest filed cost report and a budget estimate for the next 12 months on cost report forms.
- An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.
- The name, location of, and distance to the nearest ESRD facility.
- A list of patients, treatment modality, commuting distance, and commuting time to the current and next to nearest ESRD facility.
- The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.
- A computation of the facility's treatment capacity, computed by dividing the maintenance treatments actually furnished by the total maintenance treatments that could have been furnished (in other words, total stations multiplied by the number of hours of operation divided by the average length of dialysis) for the year.
- The geographic boundaries and population size of the facility's service area.

Comment: One commenter sought an explanation of the basis for the existing volume of treatment criterion (redesignated § 413.186(b)(3)). The commenter also recommended the establishment of a guideline for the necessary size of a facility's permanent patient population and a guideline related to a facility's minimum utilization rate.

Response: Facilities applying for an isolated essential facility exception are required to submit information with respect to the volume of treatments in order to permit comparisons with similar facilities and to determine a facility's treatment capacity. We will review the issue of developing guidelines for permanent patient population size and minimum utilization rates to determine whether it is appropriate to establish national guidelines.

Comment: One commenter requested that we clarify the language in § 413.186(b)(4) pertaining to usage of the facility ''by area residents other than the applying facility's patients.''

Response: We have revised § 413.186(b)(4) to specify that in determining whether a facility qualifies for an exception based on its being an isolated essential facility, we will consider the extent to which dialysis facilities (other than the applying facility's patients) are used by area residents.

Comment: One commenter suggested that a facility could be located in an MSA but still be the only supplier of dialysis in its geographical area. The commenter recommended that § 413.186(c)(1) be revised to prevent an otherwise ''isolated'' and ''essential'' facility from being automatically denied because it is located in an MSA.

Response: We agree with the commenter that it is possible that an ''isolated'' facility might be located in an MSA but still qualify for an exception based on all other criteria specified in this section. We are aware of several unique situations in this country where only one dialysis facility is located in a particular area that is considered an MSA. In these situations, given the characteristics associated with most MSAs, we look more closely at whether these facilities are truly

isolated (for example, increased availability of mass transportation, better road conditions, and stronger commuting patterns).

Further, we are aware that sole community hospitals (SCHs) and isolated essential facilities are defined utilizing different criteria. SCHs and isolated essential facilities render distinct care, with SCHs responsible for normal inpatient hospital stays, and isolated essential facilities responsible for routine outpatient maintenance dialysis that can be provided by a hospital-based or independent dialysis facility. Also, SCHs are defined under 42 CFR Part 412—Prospective Payment Systems for Inpatient Hospital Services, and isolated essential facilities are defined under 42 CFR Part 413, subpart H—Payment for End-Stage Renal Disease Services. However, in one criterion, location in an MSA, the definitions are similar. Within this definition, an SCH located in an MSA is automatically disqualified from being designated as an SCH. Because of the differences between isolated essential facilities and SCHs and the fact that several isolated essential facilities are unique (as explained above) we are changing the definition for isolated essential facilities located in an MSA.

Therefore, we are revising § 413.186(c)(1) to state that to be considered isolated, we would generally require the facility to document that it is located outside an established MSA.

F. Payment Exception: Extraordinary Circumstances (§ 413.188)

We proposed to redesignate existing § 413.170(g)(4) as § 413.188.

We received no comments on this proposed change.

G. Payment Exception: Self-Dialysis Training Costs (§ 413.190)

We proposed to repeat the content of existing § 413.170(g)(5) in new § 413.190(a) and to specify the documentation that we would require of a facility requesting a rate exception under this provision. We proposed to require that a facility justify its exception request by separately identifying those elements contributing to its costs in excess of the composite training rate. In adjudicating these exception requests, we would consider the facility's total costs, cost finding, and apportionment, including its allocation methodology, to determine if costs are properly reported by treatment modality. Exception requests for a higher training rate will be granted only with respect to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). Overhead and other indirect costs do not generally form a basis for granting an exception for purposes of self-dialysis training costs.

Under § 413.190(e), we proposed that the facility must provide the following information to support its exception request:

- A copy of the facility's training program.
- Computation of the facility's cost per treatment for maintenance and training sessions, including an explanation of the cost difference between the two modalities.
- Class size and patients' training schedules.
- Number of training sessions required, by treatment modality, to train patients.
- Number of patients trained for the current year and the prior 2 years on a monthly basis.
- Projection for the next 12 months of future training candidates.
- Number and qualifications of staff at training sessions.

Proposed § 413.190(f) provided that an ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (which normally is three times a week). If an ESRD facility elects to train all its patients using a particular modality more often than during each dialysis treatment and, as a result, the number of actual training sessions exceeds the billable limit, the facility may request a composite rate adjustment limited to the lesser of the facility's projected training cost per treatment or calculate the cost per treatment using the minimum and maximum training sessions discussed below.

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 training sessions for continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) training. To ensure adequate patient training, we presume a minimum number of training sessions per patient in calculating exception rates, 15 for hemodialysis and 5 for CAPD and CCPD, where the renal facility's actual experience is less than the minimum number of training sessions.

To justify an accelerated training exception request, the proposed rule required that an ESRD facility document that all training sessions provided under a particular modality are to be provided during the shorter but more condensed period. The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's name, age, and training status (completed, not completed, being retrained, or in the process of being trained). The total treatments from the patient list must agree with the total treatments reported on the cost report filed with the request. We proposed to deny any exception request that a facility submits without the above documentation.

For purposes of clarification, we have revised § 413.190(f)(2) to state that a facility may request an exception if the facility elects to train its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of its billable training dialysis sessions is less than its actual training sessions.

Comment: One commenter objected to the current criterion under which a facility must train at least five patients per year in order to qualify for a self-dialysis training exception. The commenter believed that establishing a minimum number of patients trained may serve as a disincentive for facilities to start a new home training program and may conflict with the requirement of section 1881(b)(7) of the Act and proposed § 413.174(a)(3) states that our payment policies provide incentives for increasing the use of home dialysis.

Response: This criterion was not addressed in the proposed rule. However, we do use a minimum number of three patients per modality as a qualifying criterion for a self-dialysis training exception. To determine if a facility qualifies, we use each facility's average number of patients trained for the 2 previous years (if 2 years are available). We believe each facility must have a minimum number of patients to ensure that it is operating an ongoing cost-effective training program. Based on our experience and review of this subject we determined the number to be three.

Comment: One commenter suggested that the overhead and physical plant cost components represent real, necessary, and unavoidable facility costs and should be included in the calculation of training exception rates.

Response: In the proposed rule at § 413.190(d), we stated that the higher training costs do not generally include overhead and other indirect costs. However, we agree with the commenter that it is appropriate to include overhead and physical plant costs for exception request purposes. Therefore, we have revised this section to state that ''the exception requests for higher training rates are limited to those cost components relating to training such as

technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.''

Comment: One commenter stated that under proposed § 413.190(f)(1), accelerated training exceptions evidently are based on training sessions for hemodialysis training, since hemodialysis is normally furnished three times a week. The commenter believed the regulations should also provide for exceptions for accelerated training associated with CAPD or CCPD, which are typically daily treatment modalities.

Response: The proposed rule may not have been clear with respect to exceptions related to CAPD and CCPD training. Although CAPD and CCPD are daily treatment modalities, ESRD facilities are paid for training sessions based on the equivalent of three hemodialysis treatments a week for each week that CAPD and CCPD treatments are provided. Accordingly, we are revising § 413.190(f)(1) to specify the basis for payment of training sessions for CAPD and CCPD patients. Thus, exceptions for accelerated training are considered for each modality (including CAPD and CCPD) based on the number of actual training sessions in excess of billable training sessions (three per week).

Comment: One commenter objected to our proposed requirement that every training session for a particular modality be provided during the shorter, but more condensed, training period.

Response: We have revised proposed § 413.190(f)(5) to change the requirement that ''all'' training sessions be provided on an accelerated basis and are instead requiring that an ESRD facility must show that ''a significant number of training sessions for a particular modality are provided during a shorter, but more condensed, period.'' Based on our experience and review of this subject we determined that 80 percent represents a significant number of training sessions.

H. Payment Exception: Frequency of Dialysis (§ 413.192)

We proposed to redesignate § 413.170(g)(6) as § 413.192 and add several new requirements as discussed below.

Existing § 412.170(g)(6) specifies that, to qualify for an exception to the prospective payment rate based on frequency of dialysis, the facility must have a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week. A facility that furnishes a substantial portion of outpatient maintenance dialysis services to patients who dialyze less frequently than three times per week typically has higher costs per treatment because the treatments that are furnished to these patients last longer and involve higher labor and supply costs. For a facility to qualify as having a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week, a facility must be able to document that it has a decrease in treatments in excess of 15 percent and cost increases due to frequency.

To document that it furnishes a substantial number of dialysis treatments at a frequency of less than three times per week, we proposed that a facility must submit a list of patients who received outpatient dialysis treatments for the latest historical cost report that is being filed with the request. The list must indicate—

- Whether the patients are permanent, transient (vacationing patients or frequently relocating patients), or temporary;
- The medically prescribed frequency of dialysis; and
- The number of dialysis treatments that each patient received on a weekly and yearly basis and an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's cost report.

We also proposed that the facility must submit a list of patients used to project treatments. The list must indicate—

- Whether the patients are permanent, transient, or temporary;
- The medically prescribed frequency of dialysis; and
- The number of dialysis treatments that each patient is projected to receive on a weekly and yearly basis, an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's projected cost report, and an explanation for any change between prior, actual, and projected data.

In order for us to determine if the facility meets the 15 percent requirement discussed above, the following information must be submitted:

- A schedule showing the number of treatments to be furnished twice a week and the number of treatments that would have been furnished if each beneficiary were dialyzed three times a week, including a computation of the facility's projected cost per treatment using projected treatments based on the twice a week calculation and the three times a week calculation.
- A schedule showing the computation of the percentage decrease in the number of treatments, which must be at least 15 percent to be deemed substantial for approval of an exception.

We received no comments on these proposed provision.

I. Appeals (§ 413.194)

We proposed to redesignate existing § 413.170(h) as § 413.194. In addition, we proposed to specify that exhaustion of administrative remedies is a prerequisite for judicial review.

We did not receive any comments on these proposed changes.

J. Notification of Changes in Rate-Setting Methodologies and Payment Rates (§ 413.196)

We proposed to redesignate existing § 413.170(i) as § 413.196 with only coding and editorial changes.

We did not receive any comments on these proposed changes.

K. Recordkeeping and Cost Reporting Requirements for Outpatient Maintenance Dialysis (§ 413.198)

We proposed to redesignate existing § 413.174 as § 413.198.

We did not receive any comments on this proposed change.

L. Organ Acquisition Costs (§ 412.113)

Under § 412.113, Medicare pays for kidney, heart, liver, and lung acquisition costs incurred by transplant centers on a reasonable cost basis. Currently, Medicare-certified transplant centers compute Medicare acquisition costs for these organs on Supplemental Worksheet D–6 of the Hospital Cost Report (Form HCFA–2552). The average acquisition costs of hearts, livers, and lungs transplanted in patients other than Medicare beneficiaries are deducted from the total acquisition costs for all hearts, livers, and lungs. Medicare reimburses the remaining balance as program costs for these organs. Based on recent cost analyses, we are concerned about the high Medicare costs associated with acquiring a small number of hearts, livers, and lungs. As a result, we proposed to change the method of computing heart, liver, and lung acquisition costs to determine more accurately the costs of acquiring organs transplanted in Medicare recipients. The method we proposed for computing acquisition costs for hearts, livers, and lungs conforms to the method used for

kidney acquisition costs, which more accurately accounts for Medicare's portion of such costs, including organ wastage. The formula for payment for kidney acquisition is specified in existing § 413.179. We also proposed to revise the heading in paragraph (d) of this section by replacing the terms ''heart, kidney, liver, and lung'' with ''organ'' and revising the cross-reference to indicate that ''organs are defined in § 486.302.''

In the August 26, 1994 proposed rule, we made the following specific proposals:

1. Payment to Independent Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories

We proposed to redesignate existing § 413.178 as § 413.200. In proposed § 413.200(b), we revised the definition of ''freestanding'' to provide that an OPO or a histocompatibility laboratory is freestanding unless it—

- Is subject to the control of the hospital with regard to the hiring, firing, training, and paying of employees; and
- Is considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

We also proposed to remove from the definition of ''freestanding'' the requirement that hospital-based OPOs service a single transplant center. Section 4009(g) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203) required that OPOs be designated by Medicare to include no more than one OPO per service area. As the certification process limited only one OPO to an area and some of the OPOs were hospital-based, limiting the OPO's responsibility to a single transplant center became impractical. An OPO (whether independent or hospital-based) is required to service all transplant centers in its area. Accordingly, a hospital-based OPO may not necessarily service a single transplant center.

We received no comments on this proposed revision.

2. OPO or Transplant Center Costs for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries

We proposed to redesignate existing § 413.179 as § 413.202 with the changes discussed below.

We proposed to expand the applicability of redesignated § 413.202 to include hearts, livers, and lungs by making it apply to ''organs'' instead of ''kidneys.'' We believed that this revision would result in a more reasonable determination of Medicare heart, liver, and lung acquisition costs because the formula for determining kidney acquisition costs more fairly accounts for Medicare's portion of such costs, including organ wastage. We cross referred § 412.113 to § 413.202 to ensure proper cost determination.

Comment: Several commenters asserted that substituting the term ''organs'' for ''kidneys'' in redesignated § 413.202 inappropriately imposed the revised methodology for determining Medicare's share of heart, liver, and lung acquisition costs on OPOs. They argued that OPOs do not have the data necessary to allocate organs between Medicare and non-Medicare patients.

Response: We agree with the commenters that substituting the term ''organs'' for ''kidneys'' would impose the revised methodology for determining Medicare's share of heart, liver, and lung acquisition costs on OPOs. Our intention in the proposed notice was to revise the methodology for Medicare transplant centers, but the proposed revision of redesignated § 413.202 inadvertently applied to OPOs as well. Therefore, we have returned to the original language in redesignated § 413.202 by resubstituting ''kidneys'' for ''organs'' and removing any reference to transplant centers; however, this section is now only applicable to OPOs. To account for all organs acquired by all transplant centers, we have added § 413.203. In addition, we have specified that the term ''organs'' is defined in § 486.302.

Comment: Several commenters suggested that the payment method that we proposed to apply to heart, liver, and lung acquisition costs is not always accurate. The number of Medicare beneficiaries awaiting kidneys and receiving ancillary pretransplant services could be greater or less than the percentage of Medicare beneficiaries ultimately receiving transplants. The commenters suggested revising Supplemental Worksheet D–6 (HCFA Form 2552), so that the kidney acquisition ancillary charges can be segregated into two columns, one for Medicare beneficiary services and another for the non-Medicare patients, thereby assuring that the appropriate ancillary service costs for each payer group could be accurately identified. The other direct kidney acquisition costs such as the kidney itself, transportation costs, etc., flowing through the step-down process could be determined based on the ratio of usable kidneys transplanted into Medicare and non-Medicare patients. The commenters believed that this approach would ensure that we would not be in violation of the requirement under section 1861(v)(1)(A) of the Act that the costs of services be borne by the appropriate payer.

Response: We will consider the suggested ancillary cost report revisions during our next review of Supplemental Worksheet D–6.

M. Payment for Erythropoietin/Epoietin (EPO) (§ 413.174(f))

Erythropoietin (EPO) is an anti-anemia drug given to dialysis patients with a specified level of anemia. Payments to ESRD facilities for EPO are based on increments of 1,000 unit doses, rounded to the nearest 100 units. Section 13566 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66) amended section 1881(b)(11)(B)(ii) of the Act to reduce the maximum payment for EPO from $11 to $10 per 1,000 units. HCFA may adjust this amount, as appropriate, within stated limits. Existing § 413.170(c)(6)(iii)(B) provides for annual publication of a **Federal Register** notice indicating whether an update in the EPO payment amount is appropriate and requesting public comment. We proposed to revise § 413.174(f) to add the statutory reference and to state that we would only publish a **Federal Register** notice proposing a revision to the EPO payment amount when we determine that an adjustment to the payment amount is necessary. We would no longer publish an annual notice.

Comment: One commenter supported our proposal to eliminate the requirement to publish an annual notice regarding EPO payment when there is no payment change. However, the commenter objected to the provision under proposed § 413.174(f)(3)(iii) that limited any EPO payment increases to the percentage increase in the implicit price deflator for the gross national product. The commenter believed that this provision is unfair to ESRD providers because the providers cannot control the cost of EPO. The commenter noted that other drugs given to dialysis patients are reimbursed based on acquisition costs or wholesale prices, or both.

Response: Proposed § 413.174(f)(3)(iii) is merely a redesignation of existing § 413.170(c)(6)(iii)(c). This provision is mandated by section 1881(b)(11)(B)(ii)(II) of the Act, which gives the Secretary authority to adjust the EPO payment rate (beginning in 1995), but limits the amount of any payment increase. Since this requirement is statutorily mandated, we do not have the authority to eliminate

this provision. However, in assessing the need for an adjustment to the EPO payment rate, we would consider the actual costs incurred by ESRD facilities for EPO. If we determined that the payment limit set by statute is inadequate to ensure access to EPO by Medicare beneficiaries, we would seek a legislative change.

N. Bad Debts (§ 413.178)

In the proposed rule, we proposed to redesignate existing § 413.178 as § 413.200 and move the requirements of existing § 413.170(e) to new § 413.178. New § 413.178 will cover the proceedings for payment and reimbursement of bad debts.

Comment: One commenter suggested that the language in proposed § 413.178, implies that ESRD facilities can be reimbursed for all Medicare bad debts incurred for all covered services provided. The commenter contended that past policy had allowed reimbursement for Medicare bad debts incurred in the provision of ''composite rate'' dialysis services only. Therefore, the commenter recommended that the wording be modified to clarify that only bad debts related to composite rate services are subject to reimbursement.

Response: We have not made any changes to our existing bad debt policy. Medicare bad debts for ESRD services (that is, services covered under the composite rate) will continue to be determined by calculating a facility's unrecovered reasonable costs, which represent the difference between a facility's total Medicare revenues (including beneficiaries' payments) and Medicare total reasonable costs. Payment for allowable bad debts is limited to the lesser of the unrecovered reasonable costs or the total of Medicare uncollectible deductibles and coinsurance. An example can be found in chapter 27 of the PRM. We reimburse each facility its allowable Medicare bad debts in a single lump sum payment after the facility's cost reporting period ends. As the commenter suggested, we have revised § 413.178(c) to clarify, consistent with our longstanding policy, that reimbursement for bad debts is available only for covered services under the composite rate.

IV. Provisions of Final Regulations

As discussed above, we have considered the public comments received on the August 26, 1994 proposed rule and we are adopting that rule as final with the following modifications:

- In § 413.178(c), we state that a facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list of all specific uncollectable amounts related to covered services under the composite rate.
- We have added a sentence to § 413.180(b) to clarify the requirement that a facility wishing to retain its previously approved exception rate may only do so during the 30-day period prior to the opening of an exception cycle.
- We have added § 413.180(e) to state that a facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

(1) The conditions under which the exception was granted have not changed;

(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

- We specify in § 413.180(f)(5) that the facility must compare its most recently completed cost report with cost reports from ''(at least 2)'' prior years.
- We have added new § 413.184(b)(2)(iii), stating that the facility must submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost report showing the basis of the higher overhead costs, the impact on the specific cost components, and the effect on per treatment costs.
- We have revised § 413.186(b)(4) to clarify that in determining whether a facility qualifies for an exception based on its being an isolated essential facility, we consider other dialysis facility usage by area residents (other than the applying facility's patients).
- We have revised § 413.186(c)(1) to state that to be considered isolated, ''generally'' a facility is located outside an established MSA and provides dialysis to a permanent patient population.
- In § 413.190(d), we have specified that an exception request for a higher training rate may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.
- In § 413.190(f)(1), we have added language to state that although CCPD and CAPD are daily treatment modalities, ESRD facilities are paid the equivalent of three hemodialysis training treatments for each week that CAPD and CCPD training treatments are provided.
- We have revised § 413.190(f)(2) to state that a facility may request an exception if the facility elects to train its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of its billable training dialysis sessions is less than its actual training sessions.
- We have revised § 413.190(f)(5) to state that, to justify an accelerated training exception request, an ESRD facility must document that a ''significant number of'' training sessions, rather than ''all'' sessions for a particular modality are provided during a shorter but more condensed period.
- In redesignated § 413.198, we have revised the cross-references.
- We have made several changes related to organ acquisition costs.

+ In § 412.113(d), we revised the paragraph heading, and replaced the terms ''heart, kidney, liver, and lung'' with ''organ''. We also revised the cross-reference to indicate that ''organs are defined in § 485.12''.

+ In § 413.202, we revised the section title and made other technical changes.

+ We added a new § 413.203 that specifies the transplant centers' costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

- We also have made minor technical changes to the regulation text for readability and ease of use.

V. Impact Statement

HCFA has examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity. The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities. We do consider all hospitals and ESRD facilities as small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

A. Payment Exception Requests

The purpose of this portion of this final rule is generally to codify in regulations existing policy concerning an ESRD facility's request for an exception to its prospectively determined payment rate. This policy is contained in chapter 27 of the PRM. This final rule affects all ESRD facilities, including hospital-based and freestanding, that file a request for an ESRD exception.

Our records indicate that as of December 31, 1994, there were 2,526 renal dialysis facilities, all of which were eligible to file exception requests. Of these, 377 or 15 percent of the facilities filed exception requests during our most recent exception cycle, November 1, 1993 to April 29, 1994. Of these requests, 293 facilities were granted exceptions (mostly partially granted), and 84 were denied.

Currently, a facility whose request is granted only partially or is denied an exception may appeal this determination to the PRRB. The PRRB is bound by the statute and regulations but not by program instructions; thus, it may come to a different conclusion than if it followed program instructions. Codifying in regulations details now found in the PRM instructions will bind the PRRB to more specific bases for adjudicating an appeal of a partially denied or denied exception request.

B. Organ Acquisition Costs

In 1994, there were 72 hospitals certified to perform heart transplants, and 40 hospitals certified to perform liver transplants. These hospitals constitute less than 2 percent of all Medicare-participating hospitals. In 1994, there were 381 heart transplants and 283 liver transplants performed on Medicare beneficiaries. Although the number of Medicare transplants represents 10 percent of the total number of heart and liver transplants, a preliminary review of cost report data indicates the average Medicare acquisition cost per heart and liver is higher than the average non-Medicare acquisition cost. We believe that the current method of cost reimbursement contains the potential for transplant centers to include some non-Medicare costs in the Medicare costs.

This final rule extends the formula used to compute kidney acquisition costs to other organs, including hearts, livers, and lungs. Acquisition costs will be based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total overall number of usable organs. This ratio will not affect our obligation to pay allowable organ acquisition costs, but will prevent Medicare from bearing costs associated with non-Medicare procedures. Based on the number of Medicare organ transplants, we anticipate annual Medicare program savings associated with this provision of less than $5 million. Facilities that have been correctly reporting non-Medicare acquisition costs will not be affected by this rule. Facilities that have not will find their Medicare payments reduced to better reflect Medicare's share of allowable acquisition costs.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined and certify that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the **Federal Register** and solicit public comments before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The information collection requirements (42 CFR 413.178, 413.180, 413.182, 413.184, 413.186, 413.188, 413.190, 413.192, and 413.194) associated with requiring ESRD facilities to provide documentation for payment exception requests are currently approved by OMB under 0938–0296, HCFA–9044, that expires on May 31, 1998.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Chapter IV is amended as set forth below:

A. Part 412 is amended as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

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

Subpart H—Payments to Hospitals Under the Prospective Payment Systems

2. Section 412.113 is amended by revising paragraph (d) to read as follows:

§ 412.113 Other payments.

* * * * *

(d) *Organ acquisition*. Payment for organ acquisition costs incurred by hospitals with approved transplantation centers is made on a reasonable cost basis. The term ''Organs'' is defined in § 486.302 of this chapter.

B. Part 413 is amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(a), and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

2. Subpart H is revised to read as follows:

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services and Organ Procurement Costs

Sec.
413.170 Scope.
413.172 Principles of prospective payment.
413.174 Prospective rates for hospital-based and independent ESRD facilities.
413.176 Amount of payments.
413.178 Bad debts.
413.180 Procedures for requesting exceptions to payment rates.
413.182 Criteria for approval of exception requests.
413.184 Payment exception: Atypical service intensity (patient mix).
413.186 Payment exception: Isolated essential facility.
413.188 Payment exception: Extraordinary circumstances.
413.190 Payment exception: Self-dialysis training costs.
413.192 Payment exception: Frequency of dialysis.
413.194 Appeals.
413.196 Notification of changes in rate-setting methodologies and payment rates.
413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.
413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.
413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.
413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

§ 413.170 Scope.

This subpart implements sections 1881 (b)(2) and (b)(7) of the Act by—

(a) Setting forth the principles and authorities under which HCFA is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of an ESRD facility approved under subpart U of part 405 of this chapter (referred to as ''facility'' in this section). For purposes of this section and § 413.172 through § 413.198, ''outpatient maintenance dialysis'' means outpatient dialysis, home dialysis, self-dialysis, and home dialysis training, as defined in § 405.2102 (f)(2)(ii), (f)(2)(iii), and (f)(3) of this chapter, and includes all items and services specified in §§ 410.50 and 410.52 of this chapter.

(b) Providing procedures and criteria under which a facility may receive an exception to the prospective payment rates; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

§ 413.172 Principles of prospective payment.

(a) Payments for outpatient maintenance dialysis are based on rates set prospectively by HCFA.

(b) All approved ESRD facilities must accept the prospective payment rates established by HCFA as payment in full for covered outpatient maintenance dialysis.

(c) HCFA publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the **Federal Register**.

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* HCFA establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based facilities and independent ESRD facilities;

(2) Effectively encourages efficient delivery of dialysis services; and

(3) Provides incentives for increasing the use of home dialysis.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, HCFA considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. For purposes of rate-setting and payment under this section, HCFA determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, HCFA does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in § 414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in § 414.313.

(f) *Erythropoietin/Epoietin (EPO).* (1) When EPO is furnished to an ESRD patient by a Medicare-approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in paragraph (f)(3) of this section.

(2) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that HCFA determines.

(3) HCFA determines the payment amount in accordance with the following rules:

(i) The amount is prospectively determined, as specified in section 1881(b)(11)(B)(ii) of the Act, reviewed and adjusted by HCFA, as necessary, and paid to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(ii) If HCFA determines that an adjustment to the payment amount is necessary, HCFA publishes a **Federal Register** notice proposing a revision to the EPO payment amount and requesting public comment.

(iii) Any increase in this amount for a year does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(iv) The Medicare payment amount is subject to the Part B deductible and coinsurance.

(g) *Additional payment for certain drugs.* In addition to the prospective payment described in this section, HCFA makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. HCFA makes this payment

directly to the ESRD facility. The facility must accept the allowance determined by HCFA as payment in full. Payment for these drugs is made as follows:

(1) *Hospital-based facilities.* HCFA makes payments in accordance with the cost reimbursement rules set forth in this part.

(2) *Independent facilities.* HCFA makes payment in accordance with the methodology set forth in § 405.517 of this chapter for paying for drugs that are not paid on a cost or prospective payment basis.

§ 413.176 Amount of payments.

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary pays the facility 80 percent of its prospective payment rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary subtracts the amount applicable to the deductible from the facility's prospective rate and pays the facility 80 percent of the remainder, if any.

§ 413.178 Bad debts.

(a) HCFA will reimburse each facility its allowable Medicare bad debts, as defined in § 413.80(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period.

(b) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from HCFA for uncollectible amounts. Section 413.80 specifies the collection efforts facilities must make.

(c) A facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectable amounts related to covered services under the composite rate.

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a facility projects on the basis of prior year costs and utilization trends that it will have an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable to one or more of the factors in § 413.182, the facility may request, in accordance with paragraph (d) of this section, that HCFA approve an exception to that rate and set a higher prospective payment rate. However, a facility may only request an exception or seek to retain its previously approved exception rate when authorized under the conditions specified in paragraphs (d) and (e) of this section.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.

(d) *Payment rate exception request.* A facility must request an exception to its payment rate within 180 days of—

(1) The effective date of its new composite payment rate(s);

(2) The effective date that HCFA opens the exceptions process; or

(3) The date on which an extraordinary cost-increasing event occurs, as specified (or provided for) in §§ 413.182(c) and 413.188.

(e) *Criteria for retaining a previously approved exception rate.* A facility may elect to retain its previously approved exception rate in lieu of any composite rate increase or any other exception amount if—

(1) The conditions under which the exception was granted have not changed;

(2) The facility files a request to retain the rate with its fiscal intermediary during the 30-day period before the opening of an exception cycle; and

(3) The request is approved by the fiscal intermediary.

(f) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to HCFA its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by HCFA to be needed to adjudicate each type of exception. HCFA may audit any cost report or other information submitted. The materials submitted to HCFA must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(g) *Completion of requirements and criteria.* The facility must demonstrate to HCFA's satisfaction that the requirements of this section and the criteria in § 413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(h) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its intermediary.

(i) *Determination of an exception request.* In determining the facility's payment rate under the exception process, HCFA excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(j) *Period of approval: Payment exception request.* Except for exceptions approved under §§ 413.180(e), 413.180(k), 413.182(c), and 413.188, a prospective exception payment rate approved by HCFA applies for the period from the date the complete exception request was filed with its intermediary until the earlier of the—

(1) Date the circumstances justifying the exception rate no longer exist; or

(2) End of the period during which the announced rate was to apply.

(k) *Period of approval: Payment exception request under §§ 413.182(c) and 413.188.* A prospective exception payment rate approved by HCFA under §§ 413.182(c) and 413.188 applies from the date of the extraordinary event until the end of the period during which the prospective announced rate was to apply, unless HCFA determines that another date is more appropriate. If HCFA does not extend the exception period and the facility believes that it continues to require an exception to its rate, the facility must reapply in accordance with the procedures in this section.

(l) *Denial of an exception request.* HCFA denies exception requests submitted without the documentation specified in § 413.182 and the applicable regulations cited there.

(m) *Criteria for refiling a denied exception request.* A facility that has been denied an exception request during the 180 days may file another exception request if all required documentation is filed with the intermediary by the 180th day.

§ 413.182 Criteria for approval of exception requests.

HCFA may approve exceptions to an ESRD facility's prospective payment rate if the facility demonstrates, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(a) Atypical service intensity (patient mix), as specified in § 413.184.

(b) Isolated essential facility, as specified in § 413.186.

(c) Extraordinary circumstances, as specified in § 413.188.

(d) Self-dialysis training costs, as specified in § 413.190.

(e) Frequency of dialysis, as specified in § 413.192.

§ 413.184 Payment exception: Atypical service intensity (patient mix).

(a) To qualify for an exception to the prospective payment rate based on atypical service intensity (patient mix)—

(1) A facility must demonstrate that a substantial proportion of the facility's outpatient maintenance dialysis treatments involve atypically intense dialysis services, special dialysis procedures, or supplies that are medically necessary to meet special medical needs of the facility's patients. Examples that may qualify under this criterion are more intense dialysis services that are medically necessary for patients such as—

(i) Patients who have been referred from other facilities on a temporary basis for more intense care during a period of medical instability and who return to the original facility after stabilization;

(ii) Pediatric patients who require a significantly higher staff-to-patient ratio than typical adult patients; or

(iii) Patients with medical conditions that are not commonly treated by ESRD facilities and that complicate the dialysis procedure.

(2) The facility must demonstrate clearly that these services, procedures, or supplies and its per treatment costs are prudent and reasonable when compared to those of facilities with a similar patient mix.

(3) A facility must demonstrate that—

(i) Its nursing personnel costs have been allocated properly between each mode of care; and

(ii) The additional nursing hours per treatment are not the result of an excess number of employees.

(b) *Documentation.* (1) A facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed fiscal or calendar year showing—

(i) Patients who received transplants, including the date of transplant;

(ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;

(iii) Home patients;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Individual patient diagnosis;

(vi) Diabetic patients;

(vii) Patients isolated because of contagious disease;

(viii) Age of patients;

(ix) Mortality rate, by age and diagnosis;

(x) Number of patient transfers, reasons for transfers, and any related information; and

(xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

§ 413.186 Payment exception: Isolated essential facility.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on being an isolated essential facility—

(1) The facility must be the only supplier of dialysis in its geographical area;

(2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

(b) *Criteria for determining qualifications.* In determining whether a facility qualifies for an exception based on its being an isolated essential facility, HCFA considers—

(1) Local, permanent residential population density;

(2) Typical local commuting distances from medical services;

(3) Volume of treatments; and

(4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation.* (1) *Isolated.* Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential.* To be considered essential, the facility must document—

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

(3) *Cost per treatment.* The facility must—

(i) Document that its cost per treatment is reasonable; and

(ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

(4) *Additional information.* The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

(i) A list of current and requested payment rates for each modality.

(ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.

(iii) An explanation of any unusual geographic conditions in the area surrounding the facility.

(iv) A copy of the latest filed cost report and a budget estimate for the next 12 months prepared on cost report forms.

(v) An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.

(vi) The name, location of, and distance to the nearest renal dialysis facility.

(vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.

(viii) The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.

(ix) A computation showing the facility's treatment capacity, arrived at by taking the total stations multiplied by the number of hours of operation for the year divided by the average length of a dialysis treatment.

(x) The geographic boundaries and population size of the facility's service area.

§ 413.188 Payment exception: Extraordinary circumstances.

(a) To qualify for an exception to the prospective payment rate based on extraordinary circumstances, the facility must substantiate that it incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster.

(b) HCFA will not grant an exception based on increased costs if a facility has chosen not to—

(1) Maintain adequate insurance protection against such losses (through the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative); or

(2) File a claim for losses covered by insurance or utilize its self-insurance program.

§ 413.190 Payment exception: Self-dialysis training costs.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* HCFA considers the facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) An ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally three times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If an ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility would have received in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, HCFA uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

§ 413.192 Payment exception: Frequency of dialysis.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on frequency of dialysis, the facility must establish that it has a substantial portion of outpatient maintenance dialysis treatments furnished to patients who dialyze less frequently than three times per week.

(b) *Definition.* For purposes of this section, ''substantial'' means the number of treatments furnished by the facility is at least 15 percent lower than the number would be if all patients dialyzed three times a week.

(c) *Limitation for per treatment payment rates.* Per treatment payment rates granted under this exception may not exceed the amount that produces weekly payments per patient equal to three times the facility's prospective composite rate, exclusive of any exception amounts.

(d) *Documentation.* To document that an ESRD facility furnishes a substantial number of dialysis treatments at a frequency less than three times per week per patient, the facility must submit the following information:

(1) A list of patients receiving outpatient dialysis treatments for the

cost report that is filed with the request. The list must indicate—

(i) Whether the patients are permanent, transient, or temporary;

(ii) The medically prescribed frequency of dialysis; and

(iii) The number of dialysis treatments that each patient received on a weekly and yearly basis and an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's cost report.

(2) A list of patients used to project treatments. The list must indicate—

(i) Whether the patients are permanent, transient, or temporary;

(ii) The medically prescribed frequency of dialysis;

(iii) The number of dialysis treatments that each patient is projected to receive on a weekly and yearly basis, an explanation of any discrepancy between that calculation and the number of treatments reported on the facility's projected cost report, and an explanation for any change among prior, actual, and projected data.

(3) A schedule showing the number of treatments to be furnished twice a week and the number of treatments that would have been furnished if each patient were dialyzed three times a week.

(4) A computation of the facility's projected costs per treatment using the—

(i) Projected number of treatments furnished twice a week; and

(ii) Number of treatments if patients dialyze three times a week.

(5) A schedule showing the computation of the percentage decrease in the number of treatments.

§ 413.194 Appeals.

(a) *Appeals under section 1878 of the Act.* (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by HCFA under § 413.178 may request review by the intermediary or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R of part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with § 413.180 may request review from the intermediary or the PRRB if HCFA has denied the request in whole or in part. In such a case, the procedure in subpart R of part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by HCFA on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under § 405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the intermediary or the PRRB, any additional information or cost data that had not been submitted to HCFA at the time HCFA evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) HCFA or the facility's intermediary notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the **Federal Register** without opportunity for prior comment. Revisions of the rate-setting methodology are published in the **Federal Register** in accordance with the Department's established rulemaking procedures.

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and Scope.* This section implements section 1881(b)(2)(B)(i) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities approved under subpart U of part 405 of this chapter. The records and reports will enable HCFA to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate HCFA-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or servicess (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.200, Reimbursement of OPAs and histocompatibility laboratories;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, and §§ 415.55

through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

§ 413.200 Payment of independent organ procurement organizations and histocompatibility laboratories.

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement organizations (OPOs) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this part. Services furnished by freestanding OPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive adjustment, directly with the OPO or laboratory, based upon a cost report filed by the OPO or laboratory. (The reasonable costs of services furnished by hospital based OPOs or laboratories will be reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* For purposes of this section:

Freestanding refers to an OPO or a histocompatibility laboratory that is not—

(1) Subject to the control of the hospital with respect to the hiring, firing, training, and paying of employees; and

(2) Considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

Histocompatibility laboratory means a laboratory meeting the standards and providing the services for kidneys or other organs set forth in § 413.2171(d) of this chapter.

OPO means an organization defined in § 486.302 of this chapter.

(c) *Agreements with independent OPOs and laboratories.* (1) Any freestanding OPO or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with HCFA under which the OPO or laboratory agrees—

(i) To file a cost report in accordance with § 413.24(f) within three months after the end of each fiscal year;

(ii) To permit HCFA to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPO or laboratory;

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) To pay to HCFA amounts that have been paid by HCFA to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO or laboratory; and

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an OPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c) (1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of a freestanding OPO or histocompatibility laboratory that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPO or laboratory.

(2) The interim rate will be based on the average cost per service incurred by an OPO or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to the OPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all freestanding OPOs and histocompatibility laboratories shall be disseminated to all transplant hospitals and intermediaries.

(e) *Retroactive adjustment.* (1) *Cost reports.* Information provided in cost reports by freestanding OPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in paragraphs (a) through (e) of § 413.24. These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the intermediary to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by a freestanding OPO or histocompatibility laboratory will be reviewed by the intermediary and a new interim reimbursement rate for the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between that intermediary and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of part 485, subpart D of this chapter.

(g) *Appeals.* Any OPO or histocompatibility laboratory that disagrees with an intermediary's cost determination under this section is entitled to an intermediary hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is $1,000 or more.

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 435.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediaries. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the

fiscal intermediary for review and approval of these arrangements.

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal intermediaries.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

C. Part 414 is amended as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

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

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

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.313 [Amended]

2. In § 414.313(a), the reference ''in § 413.170 of this chapter'' is revised to read ''in part 413, subpart H of this subchapter''.

§ 414.314 [Amended]

3. In § 414.314(a)(5), the reference ''(§ 413.170)'' is revised to read ''(part 413, subpart H of this subchapter)''.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 7, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 97–21444 Filed 8–14–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 961210346–7035–02; I.D. 081197A]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for Massachusetts

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

ACTION: Commercial quota harvest.

SUMMARY: NMFS announces that the summer flounder commercial quota available to the Commonwealth of Massachusetts has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Massachusetts for the remainder of calendar year 1997, unless additional quota becomes available through a transfer. Regulations governing the summer flounder fishery require publication of this notice to advise the Commonwealth of Massachusetts that the quota has been harvested and to advise vessel and dealer permit holders that no commercial quota is available for landing summer flounder in Massachusetts.

DATES: Effective August 13, 1997, through December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Dana Hartley, Fishery Management Specialist, 508–281–9226.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The initial total commercial quota for summer flounder for the 1997 calendar year was set equal to 11,111,298 lb (5,040,000 kg) (March 7, 1997, 62 FR 10473). The percent allocated to vessels landing summer flounder in Massachusetts is 6.82046 percent, or 757,841 lb (343,751 kg).

Section 648.100(d)(2) stipulates that any overages of commercial quota landed in any state be deducted from that state's annual quota for the following year. In the calendar year 1996, a total of 800,704 lb (363,193 kg) were landed in Massachusetts. The amount allocated for Massachusetts landings in 1996 was 752,092 lb (328,350 kg), creating a 48,612 lb (22,050 kg) overage that was deducted from the amount allocated for landings in the Commonwealth of Massachusetts during 1997 (July 15, 1997, 62 FR 37741). The resulting 1997 quota for Massachusetts is 709,229 lb (321,701 kg).

Section 648.101(b) requires the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor state commercial quotas and to determine when a state's commercial quota is harvested. The Regional Administrator is further required to publish a notice in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. Because the available information indicates that the Commonwealth of Massachusetts has attained its quota for 1997, the Regional Administrator has determined based on dealer reports and other available information, that the Commonwealth's commercial quota has been harvested.

The regulations at § 648.4(b) provide that Federal permit holders agree as a condition of the permit not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective August 13, 1997, further landings of summer flounder in Massachusetts by vessels holding commercial Federal fisheries permits are prohibited for the remainder of the 1997 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective the date above, federally permitted dealers are also advised that they may not purchase summer flounder from federally permitted vessels that land in Massachusetts for the remainder of the calendar year, or until additional quota becomes available through a transfer.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12286.

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

Dated: August 11, 1997.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97–21669 Filed 8–12–97; 2:16 pm]

BILLING CODE 3510–22–F