Medicare
State Operations Manual
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Chapter 2		
2184 – 2195 (Cont.)	2-53 – 2-56 (4 pp.)	2-53 – 2-56 (4 pp.)
2286 – 2290	2-93 – 2-96 (4 pp.)	2-93 – 2-96 (4 pp.)
2779 –2779 (Cont.)	2-163 – 2-164 (2 pp.)	2-163 – 2-164 (2 pp.)
	2-168.1 – 2-168.2 (2 pp.)	------

NEW/REVISED MATERIAL--*EFFECTIVE DATE: August 31, 2001*

Section 2194, Surveying Health Maintenance Organization (HMO)-Operated Home Health Agencies (HHAs) Providing Home Health Services Through Medicare Survey and Certification Process, is revised to clarify that HMO-operated HHAs must meet the same requirements as other HHAs. Additionally, that HMOs providing HHA services under an arrangement must use Medicare-approved HHAs.

Section 2287, Classification of Maintenance Dialysis Facilities as Hospital-Based or Independent: Prospective Pay, is modified to correct the references to the sections in the Provider Reimbursement Manual.

Section 2779, RO Assessment of Provider and Supplier Identification Numbers, is supplemented to add an explanation of when to assign a potential ESRD identification number to an ESRD facility, and revised to identify correcting the name and types of ESRD facilities that are approved under Medicare.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

The SA should report these separate entity situations to the CMS RO, along with any recommendations the State has concerning the operation of two distinct entities. The State should also indicate whether the HHA refused access to records or information that make it impossible for the surveyor to make a determination concerning whether the applicant or approved HHA complies with the HHA CoPs.

The surveyor should inform the approved HHA that the SA must report the alleged separate entity to the CMS RO that in turn must report this information to the intermediary and, if necessary, to the State Medicaid Director.

2184. OPERATION OF HHAs ACROSS STATE LINES

When an HHA provides services across State lines, whether through its own personnel, or a branch, or subunit, each respective SA must be aware of and approve the action. Each SA must verify that applicable State licensure, personnel licensure, and other State requirements are met in its respective State. Any branch or subunit of the HHA must meet applicable State and local laws in the State that it is serving.

In most circumstances, the provision of services across State lines is appropriate. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of HHA services.

When an HHA provides services across State lines, it must be certified in all States in which it provides services and its personnel must be qualified in all States in which they provide services. Certification activities within a particular State are done by the appropriate SA for that State. The involved States must have a written reciprocal agreement permitting the HHA to provide services in this manner. The reciprocal agreement must indicate that both States are aware of their respective responsibilities for assessing the HHA's compliance with the CoPs within their State. The agreement should assure that home visits are conducted to a sample of all patients served by the HHA in all States served by the HHA.

The CMS RO will review the required reciprocal agreement between the States to assure that the SA in which the branch resides is assuming responsibility for any necessary surveys of the branch. If the SAs involved are unable to come to a reciprocal agreement on assuring the necessary surveys of the branch, the branch should not be approved.

In the event that an HHA operates in two CMS ROs, the CMS RO responsible for the State in which the parent resides should take the lead in assuring that the required survey and certification activities are met.

A branch office may also be physically located in a neighboring State if it is near enough to the parent agency to share administration, supervision, and services on a daily basis, and if the SAs responsible for certification in each State approve the operation.

Subunits of an HHA may be physically located in more than one State. A separate certification is made by the SA where each subunit is located.

While the HHA may notify the SA of its proposal to provide services on an interstate basis, and the SA may make a recommendation to the CMS RO in a particular case, it is the CMS RO which has the Medicare approval authority of the parent HHA and assumes final responsibility for approval of the operation across State lines.

2186. HEALTH FACILITY-BASED HHAs

An HHA based to a hospital, SNF, hospice, or rehabilitation facility is expected to be an integral but subordinate part of the institution. Administrative and fiscal controls may be exercised over the HHA. However, the HHA's policies, personnel files, and clinical records must be separate and identifiable. Time records must be maintained for all personnel who provide home health services and must be identifiable as home health regardless of whether they are part-time or full-time. The HHA's concurrent use of personnel employed by a hospital, SNF, hospice, or rehabilitation facility is acceptable provided the HHA's operating hours are definite and not arbitrarily subject to the operation of the other institution, and provided the other institution's operation does not interfere with the HHA's maintaining compliance with the CoPs.

An HHA's services must be supervised by an employee of the HHA. If members of the institution's governing body serve the HHA as the group of professional personnel, minutes must reflect meetings of this group. Clinical records may be maintained in the record room or department. However, the clinical records must contain information pertinent only to the delivery of home health services, and should be readily available for either claims review or review by the SA.

In surveying the health facility-based HHA, the SA considers the institution's ability to share its administrative structure and personnel in fulfilling the needs and requirements of the HHA on a continuing basis. The CoPs for HHAs must be applied and met independently.

2188. SURVEY OF STATE-OPERATED HHAs

The same general procedures applicable to surveying other types of HHAs apply to HHAs operated by a State. However, individuals associated with the HHA in an administrative, supervisory, or service capacity must not be involved in the certification and consultation functions of the SA.

2194. SURVEYING HEALTH MAINTENANCE ORGANIZATION (HMO)-OPERATED HOME HEALTH AGENCIES (HHAs) PROVIDING HOME HEALTH SERVICES THROUGH MEDICARE SURVEY AND CERTIFICATION PROCESS

HMOs (Medicare+Choice) which contract with Medicare to furnish HHA services may provide such services either directly by the HMO or through Medicare-approved HHAs that have a provider agreement/number with Medicare. (See 42 CFR Part 417.416(a) and 42 CFR Part 422.20(b)(3).) If an HMO provides home health services directly as an integral part of the HMO, the HHA is still required to meet the HHA CoPs, including the OASIS requirements, have a Medicare provider number, enter into a provider agreement with the Secretary, and meet other survey and certification requirements, including Office of Civil Rights and enrollment requirements, that an HHA approved under 42 CFR Part 484.1 would have to comply with.

When the SA receives a request to survey an HMO-operated HHA for compliance with the HHA CoPs, it schedules an unannounced standard survey. The SA conducts the survey, and documents its findings on Form HCFA-1572. The SA completes Form HCFA-2567, obtains a PoC when necessary, and sends this information along with a completed Form HCFA-1539 to the CMS RO.

The SA resurveys approved HMO-operated HHAs according to the survey frequency allowed by the Secretary and determined by the SA to assure quality care and to ascertain whether they continue to meet the HHA CoPs. In essence, these HHAs are surveyed and certified the same as any other Medicare-approved HHAs.

2195. GUIDELINES FOR DETERMINING SURVEY FREQUENCY

Section 1891(c)(2)(A) of the Act states that standard surveys will occur not later than 36 months after the previous standard survey, and that the Secretary shall establish a frequency for surveys within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

A. An HHA may be placed on a 36-month survey cycle if it meets the following criteria:

- o No condition-level deficiencies in the last three recertification surveys;
- o No deficiencies at 42 CFR Part 484.18 or 42 CFR Part 484.55 in the previous standard survey; and
- o No complaints resulting in deficiency citations since the previous survey.

In order to avoid giving notice of the survey, conduct the standard survey during a range of 30 - 36 months.

B. An HHA may be placed on a 12 - 36-month survey cycle if the following criteria are met:

- o No condition-level deficiencies within 24 months of the most recent survey;
- o No complaints resulting in deficiency citations since the previous survey; and
- o Deficiencies at 42 CFR Part 484.18 and/or 42 CFR Part 484.55 in the previous standard survey, and the plan of correction was acceptable. In these situations, consider the following criteria in determining survey frequency:
  - Number of standard-level deficiencies cited;
  - Deficiencies cited under 42 CFR Parts 484.10 and/or 484.14(g); 484.18, and/or 484.55;
  - Number and resolution of complaints received concerning the HHA;
  - Changes in HHA management; and
  - Licensure information.

We expect that the majority of these HHAs will be surveyed at least every 24 months; however, SAs may use their discretion in surveying more or less often.

C. An HHA must be placed on a 12-month survey cycle if the following criteria are met:

- o An HHA has been Medicare-approved for less than 3 years at its most recent survey;
- o An HHA has had a change of ownership since the previous standard survey;

- An HHA had a condition-level deficiency cited within 24 months;
- An HHA had a complaint survey resulting in deficiency citations since the last standard survey; or
- An HHA has been reviewed by a State, regional, or national fraud and abuse initiative.

In order to avoid giving notice of the survey, you should conduct the standard survey during a range of 9 - 15 months.

D. More Frequent Surveys.--An HHA that fails to meet one or all of the Medicare CoPs will be considered to be providing substandard care and will require closer scrutiny. Such an HHA will be placed under the appropriate termination procedures until the HHA comes into compliance with the CoPs or is terminated. If the HHA comes back into compliance with the CoPs, the HHA will receive a standard survey within 4 - 6 months from the date that compliance was established. If the HHA continues to comply with the CoPs, then the HHA will be placed on the 12-month survey cycle until the HHA is free of condition-level deficiencies for no less than 2 consecutive years.

E. Random Surveys.--Each SA will randomly select, on an annual basis, a 5 percent sample of HHAs on the 36-month survey cycle. Surveyors will conduct a standard survey on this sample of HHAs within 16 - 20 months following the recertification survey. Appropriate survey frequency decisions may be made based on the results of the random survey.

The form and substance of the documentation required to remove the sanction depends upon the reasons for applying a sanction. For example, if a facility is sanctioned for failing to submit data forms, the RO removes the sanction when the facility submits the delinquent forms. A site visit to verify compliance is not necessary. On the other hand, if the RO sanctions a facility for failure to comply with established criteria and standards relating to quality and appropriateness of care, then a plan of correction in conjunction with a site visit might be necessary to document when the reason for the sanction has been eliminated.

Each sanction notice must explain what is required for correction of the particular problem or problems. Once the facility informs the RO of its corrective actions, the RO verifies its compliance with the requirements and informs the intermediary that the sanction is to be removed with the Provider Tie-In Notice, HCFA-2007. Also, the RO informs the network organization and CMS.

2285.4. NOTICE AND APPEAL RIGHTS

If the RO proposes to apply an alternative sanction, it gives the facility notice of the proposed sanction and 15 days in which to request a hearing. The effective date of the sanction should be 45 days from the date of the notice, which allows the RO to implement the sanction immediately if the facility does not request a hearing. After 15 days, the RO notifies the public about the reasons for the sanction and when it will take effect unless the facility requests a hearing. If it requests a hearing, the RO provides an informal hearing by an official who was not involved in making the appealed decision. During the informal hearing, the facility:

- o May be represented by counsel;
- o Has access to the information on which the allegation was based; and
- o May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

If the written decision of the informal hearing supports application of the alternative sanction, the RO provides the facility and the public at least 30 days notice before the effective date of the sanction that specifies the effective date and the reasons for the sanction.

2286. CONTINUOUS AMBULATORY PERITONEAL DIALYSIS COVERAGE (CAPD)

The Medicare program has approved coverage for CAPD. Since the CAPD procedure is one which the patient can carry out in any location, training and support services are the only facility services involved.

A. How CAPD is Performed.--CAPD does not require machinery or water supplies since the dialysate comes prepackaged in plastic bags ready for use. CAPD requires implantation of an indwelling catheter to provide access to the peritoneum. The patient connects the 2-liter plastic bag of the dialysate to the catheter, and the fluid pours into the peritoneal cavity. Four to six hours later, the patient drains the fluid into the same plastic bag, detaches it, attaches a new bag and refills the cavity with fresh dialysate. The procedure is accomplished three to five times daily, with the first exchange made upon arising and the last at bedtime. The procedure not only frees the patient from a machine but allows him a diet without many of the restrictions associated with other types of dialysis.

B. Application and Determination Procedure.--Facilities must file Form HCFA-3427, Part I, plus a detailed statement explaining how they expect to meet the criteria for delivering CAPD. Unless CON approval specifically for the CAPD services is required by State law, a CAPD facility is not required to document "need."

Approval is based on the following:

o The facility must furnish CAPD training directly, but may provide the required support services via an arrangement or an agreement with another ESRD-approved facility.

o The director of the renal dialysis center or renal dialysis facility must agree to furnish a certificate of completion, including any pertinent limitations, whenever a patient has successfully completed a course of training. He/she must also assure that instructional materials are available for use of all trainees during training and at times other than during the dialysis procedure. The director must also assure that personnel involved in training have adequate knowledge of the CAPD process.

o The nurse responsible for CAPD training must meet the standards in 42 CFR Part 405.2102(d) and have documented experience in peritoneal dialysis and in the care and maintenance of peritoneal access devices.

o Upon completion of the patient's CAPD training, the facility must furnish the following support services either directly or under arrangement with another ESRD facility approved to furnish staff-assisted peritoneal dialysis or peritoneal self-dialysis training:

- Surveillance of the CAPD patient's home adaption, including provisions for visits to the home or patient visits to the facility;

- Consultation for the CAPD patient with a qualified social worker and a qualified dietitian;

- A recordkeeping system which assures continuity of care for the CAPD patient;

- CAPD supplies ordered on an ongoing basis;

- Periodic visits, at least once every 90 days, to monitor the CAPD patient's medical condition, review his continuing capability to perform CAPD, and record whether the patient has, or has had, peritonitis requiring physician or hospital care; and

- Hemodialysis or intermittent peritoneal dialysis as required.

The RO notifies the facility of its determination and forwards a copy of all such letters to the SA. (See Exhibit 161.)

The RO prepares a HCFA-1539 indicating denial or approval. In addition, the RO completes the Provider Tie-In Notice, HCFA-2007, and under item V, Remarks, enters: "Approval of training and support services in CAPD."

2287. CLASSIFICATION OF MAINTENANCE DIALYSIS FACILITIES AS HOSPITAL-BASED OR INDEPENDENT: PROSPECTIVE PAYMENT

Based on the regularly scheduled ESRD survey results and any additional information forwarded by the facility's intermediary, the RO prepares a classification determination as to whether an ESRD facility is hospital-based or an independent entity. The RO determines classification in the course of the regular scheduled ESRD survey cycle.

If inconsistencies are noted between the SA survey and the intermediary's findings regarding a facility's classification, the RO recontacts the SA and intermediary as necessary to resolve any differences or discrepancies.

The RO determines the classification using the following criteria:

A. Hospital-Based ESRD Facility.--An ESRD facility is hospital-based if it is an integral and subordinate part of a hospital and is operated with other departments of the hospital under common licensure, governance, and professional supervision, with all services of the hospital and facility fully integrated. A renal dialysis unit is considered hospital-based only if all of the following criteria are met. These criteria are based upon regulations at 42 CFR Part 413.174(c).

o The facility and hospital have a common governing body and are subject to the bylaws and operating policies of this body. All management authority flows from this board which has final administrative responsibility over both entities. The common governing body approves all personnel actions and appoints medical staff in addition to other management functions.

o There is a clearly established line of authority between the facility's director or administrator and the hospital's chief executive officer. The director or administrator of the dialysis facility reports to the common governing body through the chief executive officer of the hospital.

o The facility has personnel policies and practices that conform to those of the hospital.

o There is a merging of administrative functions between the facility and the hospital. For example, there is an integration of records, housekeeping and laundry services, and common purchasing and billing practices.

o The dialysis facility and hospital are financially integrated and the hospital is required to allocate hospital overhead costs to the facility through the required step-down methodology. For example, where a single dialysis department in a hospital is responsible for inpatient and outpatient dialysis and the costs are subsequently split between inpatient and outpatient, the RO classifies the department as hospital-based. In determining compliance with this criterion, the key issue is whether §2306 of the Provider Reimbursement Manual would require the hospital to make this cost allocation, rather than whether the hospital has actually made the allocation. If no allocation is made because the hospital failed to follow §2306 of the Provider Reimbursement Manual, the hospital must resubmit a corrected cost report, and the facility will normally be classified as hospital-based.

The RO should not give any weight to the existence of an agreement between the facility and hospital for referral of patients, a shared service arrangement, or the physical location of the dialysis unit on the premises of the hospital, in determining whether a facility is hospital-based.

B. Independent ESRD Facility.--Any ESRD facility that does not qualify as a hospital-based facility is an independent renal dialysis facility.

Providers of Outpatient Physical Therapy or Outpatient Speech Pathology (OPT/OSP) Services

2290. OPT/OSP - CITATIONS

The statutory basis for providers of OPT/OSP services is found in §1861(p) of the Act. The CoPs are found in 42 CFR 485, Subpart H. Appendix E contains surveyor and interpretive guidelines.

2292. TYPES OF OPT/OSP PROVIDERS

There are three types of organizations which may qualify as OPT/OSP providers:

A. Rehabilitation Agency.--An agency which provides an integrated, multidisciplinary program designed to upgrade the physical functions of handicapped, disabled individuals by bringing together, as a team, specialized rehabilitation personnel. At a minimum, a rehabilitation agency must provide physical therapy or speech language pathology services and a rehabilitation program which, in addition to physician therapy or speech language pathology services, includes social or vocational adjustment services.

B. Clinic.--A facility established primarily for the provision of outpatient physicians' services. To meet the definition of a clinic, the facility must meet the following test of physician participation:

- The medical services of the clinic are provided by a group of 3 or more physicians practicing medicine together; and

- A physician is present in the clinic at all times during hours of operation to perform medical services (rather than only administrative services).

C. Public Health Agency.--An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by providing environmental health services, preventive medical services, and in certain instances, therapeutic services.

2294. EXCEPTIONS TO CoPs

In order for clinics, rehabilitation agencies, and public health agencies to be eligible to participate as providers of OPT/OSP services, they must be in compliance with all applicable CoPs, except the following: 42 CFR Part 485.709, Administrative Management, is not applicable to public health agencies, and 42 CFR Part 485.717, Rehabilitation Program, is not applicable to clinics or public health agencies.

2296. SA VERIFICATION OF SERVICES PROVIDED

During the course of the SA survey, it verifies that the services that the provider proposes to offer are actually being provided. The SA evaluates the cumulative records of services actually provided. Work schedules of personnel providing services will show utilization data for various services.

2298. SITE OF SERVICE PROVISION

A. Limitations.--An OPT/OSP provider may provide services on its own premises, on the premises of another provider of services, e.g., hospital or SNF, or in the individual's place of residence. The services may not be furnished on the premises of a supplier of services, unless they are provided under arrangements with the supplier by public health agencies.

Deficiencies and Plan of Correction, Form HCFA-2567, to ensure that the SA's documentation supports the SA certification recommendation, acceptable plan of correction (PoC), or waiver request. The RO notes the timeliness and quality of SA processing, and extract information relating to administrative or program problems that the case reveals so that identified program problems can be corrected on the regional or national level.

In Medicaid-only cases, the SA certifies its determination as to the provider's compliance with the participation requirements. The SMA must accept certification determinations as final and may not enter into a provider agreement with a NF or ICF/MR unless the SA has certified the provider as in compliance with applicable requirements for program participation. It may, however, for good cause, refuse to execute an agreement with a NF or ICF/MR certified by the SA. (See 42 CFR Part 442.12(d).)

Certification documents are official statements of the SA which may not to be altered. The RO uses the Request for Additional Information, Form HCFA-1666 (Exhibit 15), to request additional information or documentation. (See §2776.)

If a deficiency is subsequently corrected, the corrective action will be shown on Form HCFA-2567 or the Post-Certification Revisit Report, Form HCFA-2567B, as appropriate. If the deficiencies have not been corrected at the time of the revisit, they are shown on a new Form HCFA-2567. The OSCAR system accumulates data on the ability of providers and suppliers to meet program participation requirements at the time of the survey. OSCAR data from Form HCFA-2567 and Form HCFA-2567B are used to measure the extent of progress providers and suppliers make in complying with program requirements.

In case of an unreconciled interpretive disagreement with the SA, the RO can arrive at a determination disagreeing with the SA, provided there is evidence to support a contrary decision. If the RO disagrees with the SA certification, it justifies its rejection in writing and attempts to resolve the disagreement. If necessary, a disagreement over interpretive policy can be referred to HCFA CO for resolution.

2779. RO ASSIGNMENT OF PROVIDER AND SUPPLIER IDENTIFICATION NUMBERS

A. Numbering System For Medicare Providers and Suppliers of Service.--Processing of requests for payment is keyed to the identification number. The RO enters provider and supplier identification numbers on all forms and communications and maintains adequate controls.

1. Provider Identification Numbers.--The identification numbers for providers and suppliers paid under Part A have six digits. The first two digits identify the State in which the provider is located. The last four digits identify the type of facility.

Following is a list of all State Codes:

Alabama	01	New Hampshire	30
Alaska	02	New Jersey	31
Arizona	03	New Mexico	32
Arkansas	04	New York	33
California	05, 55	North Carolina	34
Colorado	06	North Dakota	35
Connecticut	07	Ohio	36
Delaware	08	Oklahoma	37
District of Columbia	09	Oregon	38
Florida	10, 68	Pennsylvania	39
Georgia	11	Puerto Rico	40
Hawaii	12	Rhode Island	41

Idaho	13	South Carolina	42
Illinois	14	South Dakota	43
Indiana	15	Tennessee	44
Iowa	16	Texas	45, 67
Kansas	17	Utah	46
Kentucky	18	Vermont	47
Louisiana	19	Virgin Islands	48
Maine	20	Virginia	49
Maryland	21, 80	Washington	50
Massachusetts	22	West Virginia	51
Michigan	23	Wisconsin	52
Minnesota	24	Wyoming	53
Mississippi	25	Canada	56
Missouri	26	Mexico	59
Montana	27	American Samoa	64
Nebraska	28	Guam	65
Nevada	29	Commonwealth of the Northern Marianas Islands	66

Assign the last four digits sequentially from within the appropriate block of numbers.

Use the following blocks of numbers for the types of facilities indicated:

0001-0879	Short-term (General and Specialty) Hospitals
0880-0899	Reserved for hospitals participating in ORD demonstration project
0900-0999	Multiple Hospital Component in a Medical Complex (Numbers Retired)
1000-1199	Reserved for future use
1200-1224	Alcohol/Drug Hospitals (Numbers Retired)
1225-1299	Medical Assistance Facilities
1300-1399	Critical Access Hospitals
1400-1499	Continuation of Community Mental Health Centers (4900-4999 series)
1500-1799	Hospices
1800-1989	Federally Qualified Health Centers
1990-1999	Religious Nonmedical Health Care Institutions (formerly Christian Science Sanatoria (Hospital Services)
2000-2299	Long-Term Hospitals (Excluded from PPS)
2300-2499	Hospital Based Renal Dialysis Facilities
2500-2899	Independent Renal Dialysis Facilities
2900-2999	Independent Special Purpose Renal Dialysis Facility 1/
3000-3024	Formerly Tuberculosis Hospitals (Numbers Retired)
3025-3099	Rehabilitation Hospitals (Excluded from PPS)
3100-3199	Continuation of Subunits of Nonprofit and Proprietary Home Health Agencies (7300-7399) Series 3/
3200-3299	Continuation of Comprehensive Outpatient Rehabilitation Facilities (4800-4899) Series
3300-3399	Children's Hospitals (Excluded from PPS)
3400-3499	Continuation of Rural Health Clinics (Provider-based) (3975-3999) Series
3500-3699	Hospital Based Satellite Renal Dialysis Facilities
3700-3799	Hospital Based Special Purpose Renal Dialysis Facility 1/
3800-3974	Rural Health Clinics (Free-Standing)
3975-3999	Rural Health Clinics (Provider-Based)
4000-4499	Psychiatric Hospitals (Excluded from PPS)

1/ These facilities (SPRDFs) will be assigned the same provider number whenever they are recertified.

J. ESRD Identification Numbers.--It is important for both reimbursement and survey purposes to assign the ESRD facility the correct identification number in accordance with the guidelines contained in SOM §2779 A.1.

ESRD facilities and their identification numbers are as follows:

Hospital-Based Renal Dialysis Facilities	2300-2499
Hospital-Based Renal Dialysis Satellite Facilities	3500-3699
Hospital-Based Special Purpose Renal Dialysis Facilities	3700-3799
Independent Renal Dialysis Facilities	2500-2899
Independent Special Purpose Renal Dialysis Facilities	2900-2999

1. Hospital-Based Renal Dialysis Facilities, 2300-2499.--CMS is required to make determinations concerning hospital-based and independent ESRD facilities to determine their proper reimbursement in accordance with §1881(b)(7), 42 CFR Part 413.174, and SOM §2287. Please note that in accordance with 42 CFR Part 413.174(d)(3), "In determining whether a facility is hospital-based, CMS will not consider . . . the physical location of a facility on the premises of a hospital." The reason for this is because some ESRD facilities on the hospital's premises merely lease space from the hospital and would not meet the regulatory criteria to be hospital-based.

ESRD supplier numbers 2300-2499, for Hospital-Based Renal Dialysis Facilities are used for ESRD facilities that have been determined by the CMS to be hospital-owned, hospital-administered ESRD facilities physically located on the hospital's premises as opposed to independent ESRD facilities and Hospital-Based Renal Disease Satellite Facilities. The satellites are hospital-based, but are physically located off the hospital's premises.

2. Hospital-Based Renal Dialysis Satellite Facilities, 3500-3699.--ESRD supplier numbers 3500-3699 for Hospital-Based Renal Dialysis Satellite Facilities are used for those ESRD facilities that are hospital-owned and hospital administered, but that are not located on the hospital's premises. This is why they are referred to as hospital-based satellites. In determining whether such a satellite facility is hospital-based, use the same criteria as you would in making a hospital-based determination under the 2300-2499 series, except that you would assign a 3500-3699 number to such a facility because it is off the premises of the hospital to which it is based. The word premises per se is not defined in the statute, regulations, or in the SOM, but there is a definition of "furnishes on the premises" at 42 CFR Part 405.2102 that states "the ESRD facility furnishes services on its main premises; or its other premises that are: (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility." Thus, in addition to the regulations, which should assist you in determining whether the facility is an integral part of the hospital, you may use the "furnishes on the premises" definition to distinguish between a hospital-based entity under the 2300-2499 series as opposed to an entity under the 3500-3699 number series. Also, we do not believe that these satellites will be furnishing inpatient dialysis services. CMS will make or approve the determination that a particular ESRD facility meets the requirements to be hospital-based, and if it is off the hospital's premises, a hospital-based satellite.

It is conceivable that a hospital-based ESRD facility could have a 2300-2499 number assigned to the location on the hospital's premises, and one or more 3500-3699 numbers for those locations (satellites) off the premises (each satellite is given a separate 3500-3699 number). If an ESRD facility that is assigned a 2300-2499 number moves off the hospital's premises and is determined to be a satellite, it should receive a number in the 3500-3699 series. However, if a satellite changes its address but is still considered off the hospital's premises, it should retain the 3500-3699 number

it was originally issued rather than being issued a new 3500-3699 number. Any questions concerning billing should be referred to the RO financial component or the fiscal intermediary as you determine appropriate.

NOTE: In determining whether an entity is hospital-based for reimbursement purposes, the requirements at SOM §2287 must be met.

3. Hospital-Based Special Purpose Renal Dialysis Facilities, 3700-3799.--In order to be classified as a Hospital-Based Special Purpose Renal Dialysis Facility and issued a number under the 3700-3799 series, an ESRD facility must be determined to be hospital-based, and meet the definition at 42 Part CFR 405.2102, and the requirements at 42 Part CFR 405.2164 for such a facility. A facility under this category should bill Medicare under the provider number of the hospital to which it is based. There should be very few of these facilities.

4. Independent Renal Dialysis Facilities, 2500-2899.--Independent Renal Dialysis Facilities, issued a number under the 2500-2899 series, are independent ESRD facilities. These facilities do not meet the definition of hospital-based irrespective of whether they are located on or off the hospital's premises. A determination of independent, as opposed to hospital-based, will be based on the statutory and regulatory provisions and manual instructions. Independent facilities bill under their own numbers. ESRD facilities located at skilled nursing facilities will be determined to be independent.

5. Independent Special Purpose Renal Dialysis Facilities, 2900-2999.--The same requirements that apply to a Hospital-Based Special Purpose Renal Dialysis Facility apply to a facility of the same type which is independent except that the independent facility by virtue of its independent status, bills under its own number which is in the 2900-2999 series.

Other

When an ESRD facility proposes to change from hospital-based to independent or vice-versa, an onsite survey is not necessary unless there is a physical relocation of the facility. However, a determination as to the proper facility definition and if necessary, the changing of the number designation, must be made in accordance with the guidance described here and in SOM §2287. If an ESRD facility proposes to add a location that has not been previously surveyed, an onsite inspection would be required. In the absence of an onsite survey and certification, the proposed facility has no authority to bill Medicare for ESRD services provided at the proposed site. (See SOM §3222.)

Information contained in Medicare approval letters of ESRD facilities that are issued numbers under the above categories is essential in central office for data collection and program information purposes. Therefore, please send a copy of all Medicare approval letters issued in your region to the Office of Clinical Standards and Quality, Information Systems Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, Maryland 21244-1850. You should also send to the Office of Clinical Standards and Quality (OCSQ)notices of any numbers that are terminated or changed (e.g., hospital-based to independent or vice-versa) for whatever reasons. In addition, it would be helpful if all ESRD facility notices, including those sent to the fiscal intermediary, contain the identification number of the ESRD facility to which the notice applies (numbers of both the ESRD facility and the hospital to which it is based, when applicable). You should apprise the appropriate ESRD network of the information mentioned above at the same time that you notify OCSQ. A Form HCFA-855 must be completed by the ESRD facility when there is a change, addition, or deletion affecting an ESRD facility. You should follow the instructions for issuing a Provider Tie-In Notice, HCFA-2000, when an ESRD facility is being added, deleted, or changed. This is particularly important because fiscal intermediaries often cross regional boundaries.