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# Medicare

## Intermediary Manual

### Part 3 - Claims Process

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
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CHANGE REQUEST 1972

**HEADER SECTION NUMBERS**

3166.1 - 3166.2

**PAGES TO INSERT**

3-64.15b - 3-64.16 (2 pp.)

**PAGES TO DELETE**

3-64.15b - 3-64.16 (2 pp.)

**NEW/REVISED MATERIAL--*EFFECTIVE DATE: April 1, 2002***

***IMPLEMENTATION DATE: April 1, 2002***

Section 3166.2, is revised to remove Paragraph G, Therapeutic Pheresis (Apheresis). Removal of this language will provide consistency between the Medicare Intermediary Manual and §35-60 of the Coverage Issues Manual.

**These instructions should be implemented within your current operating budget.**

**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.

4. Supplies.--Supplies include all durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis. Supplies include (but are not limited to): dialyzers, forceps, sphygmomanometer with cuff and stethoscope, scales, scissors, syringes, alcohol wipes, sterile drapes, needles, topical anesthetics, and rubber gloves.

5. Support Services.--Support services include (but are not limited to): 1) periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis; 2) visits by trained technical personnel made in accordance with a plan prepared and periodically reviewed by a professional team which includes the physician; 3) individual's unscheduled visits made on an as-needed basis; e.g., assistance with difficult access situations; 4) ESRD related laboratory tests covered under the composite rate; and 5) providing, installing, repairing, testing, and maintaining home dialysis equipment, including appropriate water testing and treatment. (See §3171.3 for CAPD support services.)

6. Support Equipment.--Support equipment is equipment used in conjunction with the basic dialysate delivery system. Such equipment includes (but is not limited to) pumps, such as blood and heparin pumps, alarms, such as bubble detectors, water purification equipment used to improve the quality of the water used for dialysis, and adjustable dialysis chairs.

F. 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. Specifically, the facility would be hospital-based only if all the following conditions are met:

- o The facility and hospital are subject to the bylaws and operating decisions of a common governing board. All authority in management flows from this administrative body which approves all personnel actions, appoints medical staff and carries out similar management functions.

- o The ESRD facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him to the governing board.

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

- o The administrative functions of the facility (that is, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital.

- o The dialysis unit and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of hospital overhead to the facility through the required step-down methodology.

The existence of an agreement or an arrangement between a facility and a hospital with respect to the referral of patients, a shared service arrangement between a facility and a hospital (a common practice recognized by both Medicare and Medicaid), or the physical location of a dialysis unit on the premises of a hospital, does not mean that a facility is hospital-based. Any facility that does not meet all of the above criteria would be considered an independent facility.

**G. Ultrafiltration.**--A process of removing excess fluid from the blood through a dialysis membrane by exerting pressure. It is not a substitute for dialysis. Occasionally, medical complications may occur which require that ultrafiltration be performed separately from the dialysis treatment.

3166.2 Frequency of Dialysis Sessions.--Hemodialysis and peritoneal dialysis are covered under the composite rate:

A. Hemodialysis

The usual pattern of hemodialysis consists of three sessions weekly, and these may be covered routinely. If the ESRD facility bills for any sessions in excess of this frequency, the bills must be accompanied by medical justification acceptable to the intermediary.

B. Peritoneal Dialysis

Peritoneal dialysis sessions are covered routinely at the same frequency as hemodialysis described above. However, the pattern of peritoneal dialysis may vary, in which case an equivalence is established between peritoneal and hemodialysis as described in §3644. If the facility bills for any sessions in excess of this frequency, the bills must be accompanied by medical justification acceptable to the intermediary.

3167. OUTPATIENT MAINTENANCE DIALYSIS--COVERAGE

Maintenance dialysis treatments are covered by Medicare when they are provided to end-stage renal disease (ESRD) patients by an approved ESRD hospital-based renal dialysis facility, including a renal dialysis center, an independent renal dialysis facility, or a special purpose renal dialysis facility. Dialysis treatments are covered in various settings: hospital inpatient, hospital outpatient, independent renal dialysis facility, or the patient's home. Dialysis treatments at renal dialysis facilities differ according to the types of patients being treated, the types of equipment and supplies used, the preferences of the treating physician, and the capability and makeup of the support staff. Although all facilities do not provide an identical range of services, the most common elements of a dialysis treatment are overhead costs, personnel services, administrative services (registered nurse, licensed practical nurse, technician, social worker, dietitian), equipment and supplies--dialysis machine and its maintenance, ESRD related laboratory tests, certain injectable drugs (such as heparin and its antidote) and biologicals.