

Chapter 182-540 WAC

KIDNEY DISEASE PROGRAM AND KIDNEY CENTER SERVICES

WAC

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KIDNEY DISEASE PROGRAM (STATE FUNDED)

WAC 182-540-001 Purpose. This section (WAC 388-540-001 through 388-540-065) contains rules for the state-funded kidney disease program (KDP). The kidney disease program is designed to help clients who have end-stage renal disease, but who do not meet the eligibility standards for medicaid.

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WAC 182-540-005 Definitions. The following definitions and those found in WAC 388-500-0005, apply to this chapter for the purpose of administering the kidney disease program.

"Adequate consideration" means that the reasonable value of goods or services received in exchange for transferred property approximates the reasonable value of the property transferred;

"Affiliate" means a facility, hospital, unit, business, or person having an agreement with a **kidney center** to provide specified services to **ESRD** patients;

"Application for eligibility" means the form provided by MAA, which the client completes and submits to the contracted kidney center to determine KDP eligibility;

"Application documentation" means either a "medicaid medical determination" letter from the DSHS community services office, or a KDP "client recertification waiver" form.

"Assets" means income, resources, or any real or personal property that a person or the person's spouse owns and could convert to cash to be used for support or maintenance;

"Certification" means the **kidney center** has determined a client eligible for the KDP for a defined period of time;

"End-stage renal disease (ESRD)" means that stage of renal impairment which is irreversible and permanent, and requires dialysis or kidney transplant to ameliorate uremic symptoms and maintain life;

"KDP application period" means the time between the date the client signed the completed application for eligibility and the date the client is certified for participation in the program;

"KDP client" means a resident of the state who has a diagnosis of ESRD and meets the financial and medical eligibility criteria as determined by a KDP contractor;

"KDP client recertification waiver for medicaid review" means a KDP eligibility form that may in some circumstances be used in place of a "medicaid medical assistance determination letter."

"KDP contract manual" means a set of policies and procedures for contracted kidney centers;

"KDP contractor" means a kidney center or other ESRD facility that has contracted with the Washington state department of social and health services (DSHS), kidney disease program to provide ESRD-related services to KDP clients.

"Kidney center" means a facility as defined and certified by the federal government to:

(1) Provide **ESRD** services;

(2) Promote and encourage home dialysis for a client when medically indicated; and

(3) For the purposes of WAC 388-540-032 through 388-540-060, it is a facility that has entered into a contract with Washington state department of social and health services (DSHS), kidney disease program to provide ESRD-related services.

"Kidney disease program (KDP)" means a state-funded program that provides financial assistance to eligible clients with the costs of **ESRD**-related medical care;

"Medicaid medical assistance determination letter" means a medical assistance client eligibility letter from the DSHS community services office.

"Resident" means a person who lives in Washington state on more than a temporary basis.

"Substantial financial change" means the increase or decrease of income or assets that may affect eligibility.

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WAC 182-540-015 Client eligibility for kidney disease program (KDP). Clients must meet the following criteria to be considered KDP eligible:

- (1) Be a Washington state resident;
- (2) Be diagnosed with end-stage renal disease (ESRD);
- (3) Be determined ineligible for medicaid;
- (4) Exhaust or be ineligible for all other resources providing similar benefits;
- (5) Have countable income which is equal to or less than:
 - (a) Two hundred percent of the federal poverty level (FPL) or;
 - (b) Three hundred percent of the FPL with an annual deductible required equal to the income amount which is in excess of two hundred percent of the FPL.
- (6) Have countable resources that are either equal to or less than fifteen thousand dollars, or are exempt. Exempt resources are:
 - (a) A home, defined as real property owned by a client as principal place of residence together with surrounding and contiguous property, not to exceed five acres;
 - (b) Household furnishings; and
 - (c) An automobile.
- (7) The effective date of eligibility is the first day of the month the application for eligibility is signed by the client.

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WAC 182-540-025 Kidney disease program (KDP) eligibility determination. The kidney center and client must comply with the following rules to determine KDP eligibility:

- (1) The KDP contractor must:
 - (a) Inform the client of the requirements for KDP eligibility as defined in this chapter and provide the client with necessary department forms and instructions;
 - (b) Determine client eligibility using department policies, rules, and instructions; and
 - (c) Forward the completed application for eligibility, and the application documentation to the KDP program manager at the medical assistance administration (MAA). (The KDP program manager may amend or terminate a client's certification period within thirty days of receipt if the application is incomplete or inaccurate.)
- (2) A person applying for KDP must:
 - (a) Complete the application for eligibility and submit any necessary documentation to the kidney center;
 - (b) Apply for medicaid, obtain a written medicaid medical assistance determination letter, submit a copy to the kidney center; and
 - (c) Apply for medicare.
- (3) A client reapplying for continued eligibility must:

(a) Complete the KDP application for eligibility and submit any documentation necessary to determine eligibility to the kidney center;

(b) Apply for medicaid forty-five days before the end of the KDP certification period, obtain a written medicaid eligibility determination, and submit a copy to the kidney center; or

(c) Have applied for medicaid within the previous five years and continue to be ineligible.

(4) The KDP application period is:

- (a) One hundred and twenty days for a new client; and
- (b) Forty-five days prior to the end of a certification period for a client requesting recertification.

(5) The KDP contractor may request an extension of application time limits from MAA when extenuating circumstances prevent the client from completing the application or recertification process within the specified time limits.

(6) The KDP contractor certifies the client for no more than one year from the first day of the month of application, unless the client:

- (a) Needs medical coverage for less than one year; or
- (b) Has a substantial financial change, in which case the client must complete a new application for eligibility.

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WAC 182-540-035 Kidney disease program (KDP)—Transfer of resources without adequate consideration. A person may be ineligible for the KDP if the person knowingly and willfully assigns or transfers nonexempt resources at less than fair market value within two years preceding the date of application, for the purpose of qualifying or continuing to qualify for the program.

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WAC 182-540-045 Kidney disease program (KDP) provider requirements. (1) The KDP contractor must:

- (a) Be a medicare-certified end-stage renal disease (ESRD) facility; and
- (b) Have a valid KDP client services contract with the department.

(2) The KDP contractor must provide, directly or through an affiliate:

(a) Professional consultation, personal instructions, medical treatment and care, drug products and all supplies necessary for carrying out a medically-sound end-stage renal disease (ESRD) treatment program;

(b) Dialysis for clients with ESRD when medically indicated;

(c) Kidney transplant treatment, either directly or by referral, when medically indicated;

(d) Treatment for conditions directly related to ESRD such as anemia or venous access infections; and

(e) Supplies and equipment for home dialysis.

(3) The provider must maintain adequate records for audit and review purposes, including:

- (a) Medical charts and records that meet the requirements of WAC 388-502-0020; and
- (b) Eligibility determination records.
- (4) The contractor must meet other obligations as required by their contract with the KDP program.

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WAC 182-540-055 Kidney disease program (KDP) covered services. The KDP program covers the cost of health care services essential to the treatment of end stage renal disease (ESRD) and its complications. Covered services include:

- (1) Mandatory services that must be provided by the KDP contractor:
 - (a) Dialysis:
 - (i) Center dialysis—Covers the cost of dialysis and related services provided in a kidney center;
 - (ii) Home dialysis—Covers the cost of providing dialysis and related services in the home; and
 - (iii) Dialysis while hospitalized—Covers the cost of dialysis and related services while the client is confined to an acute care facility and is unable to dialyze at his/her regular site.
 - (b) Medication—As defined in the approved drug list in the KDP manual.
- (2) Optional services that may be provided by the KDP contractor:
 - (a) Venous access surgery—Covers costs associated with surgically preparing the client for dialysis and medical complications related to the venous access site;
 - (b) Laboratory tests and X rays considered to be part of the overall treatment plan for ESRD;
 - (c) Post-transplant visit to assess client's ESRD status; and
 - (d) Health insurance premiums including copays and deductibles, when found to be cost-effective.

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WAC 182-540-065 Kidney disease program (KDP)—Reimbursement. (1) The medical assistance administration (MAA) reimburses KDP contractors:

- (a) Within the limits of legislative funding for the program;
- (b) According to the terms of each kidney center's contract with the department; and
- (c) According to the provisions of the KDP contract manual.
- (2) The KDP contractor must submit the following documentation to MAA:
 - (a) A description of the services for which reimbursement is requested; and
 - (b) Statement of client's financial eligibility for the KDP.
 - (3) MAA limits KDP reimbursement for out-of-state services to fourteen days per calendar year. Reimbursement is paid only to KDP contractors. Out-of-state dialysis providers

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must operate under subcontract or agreement with an in-state KDP contractor in order to receive reimbursement under this program.

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KIDNEY CENTER SERVICES

WAC 182-540-101 Purpose and scope. This section describes the medical assistance administration (MAA) reimbursement rules for free-standing kidney centers providing dialysis and end-stage renal disease services to MAA clients.

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WAC 182-540-105 Definitions. The following definitions and those found in WAC 388-500-0005, apply to this chapter.

"Acute dialysis" means dialysis given to patients who are not ESRD patients, but who require dialysis of temporary kidney failure due to a sudden trauma (e.g., traffic accident or ingestion of certain drugs, etc.).

"Affiliate" means a facility, hospital, unit, business, or person having an agreement with a kidney center to provide specified services to ESRD patients.

"Agreement" means a written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

"Back-up dialysis" means dialysis given to a patient under special circumstances, in a situation other than the patient's usual dialysis environment. Examples are:

- (1) Dialysis of a home dialysis patient in a dialysis facility when patient's equipment fails;
- (2) Inhospital dialysis when the patient's illness requires more comprehensive care on an inpatient basis;
- (3) Pre- and post-operative dialysis provided to transplant patients.

"Composite rate" means a payment method in which all standard equipment, supplies, and services are calculated into a blended rate. All in-facility dialysis and all home dialysis treatments are billed under the composite rate system.

"Continuous ambulatory peritoneal dialysis (CAPD)" means a type of dialysis where the patient's peritoneal membrane is used as the dialyzer. The patient dialyzes at home, using special supplies, but without the need for a machine. (See "Peritoneal dialysis.")

"Continuous cycling peritoneal dialysis (CCPD)" means a type of peritoneal dialysis where the patient dialyzes at home and utilizes an automated peritoneal cyclor for delivering dialysis.

"Dialysate" means an electrolyte solution, containing elements such as potassium, sodium chloride, etc., surrounding the membrane or fibers and allowing exchange of substances with the patient's blood in the dialyzer.

"Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

"Dialysis session" means the period of time beginning when the patient arrives at the facility and ending when the patient departs from the facility. In the case of home dialysis, the time period beginning when the patient prepares for dialysis and ending when the patient is disconnected from the machine.

"Dialyzer" means the synthetic porous membrane or fibers, contained in a supporting structure, through which blood flows for the purpose of eliminating harmful substances, and replacing them with useful ones.

"Drug-related supplies" means nonpharmaceutical items necessary for administration or delivery of a drug.

"Durable medical equipment (DME)" means equipment that:

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to a person in the absence of illness or injury; and
- (4) Is appropriate for use in the client's place of residence.

"End-stage renal disease (ESRD)" means the stage of renal impairment that is irreversible and permanent, and requires dialysis or kidney transplant to ameliorate uremic symptoms and maintain life.

"Epoetin alpha (EPO)" means the biologically engineered protein that stimulates the bone marrow to make new red blood cells. It is used in the treatment of anemia.

"Free-standing kidney center" means a limited care facility, not operated by a hospital, certified by the federal government to provide ESRD services.

"Hemodialysis" means a method of dialysis in which blood from a patient's body is circulated through an external device or machine and then returned to the patient's bloodstream. Hemodialysis is usually done in a kidney center or facility. It can be done at home with a trained dialysis helper.

"Home dialysis" means any dialysis performed at home.

"Home dialysis helper" means a person trained to assist the client in home dialysis.

"In-facility dialysis," for the purpose of this chapter only, in-facility dialysis means dialysis of any type performed on the premises of a kidney center or other free-standing ESRD facility.

"Intermittent peritoneal dialysis (IPD)" means a type of peritoneal dialysis in which dialysis solution is infused into the peritoneal cavity, allowed to remain there for a period of time, and then drained out. IPD is usually done in a kidney center or facility. It can be done at home with a trained home dialysis helper.

"Kidney center" means a facility as defined and certified by the federal government to:

- (1) Provide ESRD services;
- (2) Provide the services specified in this chapter; and
- (3) Promote and encourage home dialysis for a client when medically indicated.

"Maintenance dialysis" means the usual periodic dialysis treatments given to a client who has ESRD.

"Peritoneal dialysis" means a procedure that introduces dialysate into the abdominal cavity to remove waste products through the peritoneum. Three forms of peritoneal dialysis are continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis, and intermittent peritoneal dialysis.

"Self-dialysis unit" means a unit in a free-standing kidney center where dialysis is performed by an ESRD client who has completed training in self-dialysis.

"Standard ESRD lab tests" means certain laboratory tests that the Centers for Medicare and Medicaid include in their composite rate calculations. These tests are identified in MAA's kidney center billing instructions.

"Take home drugs" means outpatient prescription drugs that are administered outside of a provider's office.

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WAC 182-540-110 Eligibility. (1) To be eligible for the kidney center services described in this section, a client must be diagnosed with end-stage renal disease (ESRD) or acute renal failure and be covered under one of the following programs:

- (a) Categorically needy program (CNP);
- (b) Children's health insurance program (CHIP);
- (c) General assistance-unemployable (GAU);
- (d) Limited casualty program—Medically needy program (MNP);
- (e) Alien emergency medical; or
- (f) Qualified Medicare beneficiary (QMB)—(MAA pays only for Medicare premium, coinsurance and deductible).

(2) Managed care enrollees must have dialysis services arranged directly through their designated plan.

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WAC 182-540-120 Provider requirements. To receive reimbursement from the medical assistance administration (MAA) for providing care to MAA clients, a kidney center must:

- (1) Be a Medicare-certified end-stage renal disease (ESRD) facility and have a signed core provider agreement with MAA (see chapter 388-502 WAC);
- (2) Meet requirements found in chapter 388-502 WAC;
- (3) Provide only those services within the scope of their provider's license; and
- (4) Provide, either directly or through an affiliate, all physical facilities, professional consultation, personal instructions, medical treatment, care, and all supplies necessary for carrying out an medically sound ESRD treatment program, including all of the following:
 - (a) Dialysis for ESRD clients;
 - (b) Kidney transplant treatment, either directly or by referral, for ESRD clients when medically indicated;
 - (c) Treatment for conditions directly related to ESRD;

- (d) Training and supervision of supporting personnel and clients for home dialysis, medical care, and treatment; and
- (e) Supplies and equipment for home dialysis.

[11-14-075, recodified as § 182-540-120, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-120, filed 10/8/03, effective 11/8/03.]

WAC 182-540-130 Covered services. (1) The department covers the following services and supplies subject to the restrictions and limitations in this section and other applicable published WAC:

- (a) In-facility dialysis;
- (b) Home dialysis;
- (c) Training for self-dialysis;
- (d) Home dialysis helpers;
- (e) Dialysis supplies;
- (f) Diagnostic lab work;
- (g) Treatment for anemia; and
- (h) Intravenous drugs.

(2) Covered services are subject to the limitations specified by the department. Providers must obtain prior authorization (PA) or expedited prior authorization (EPA) before providing services that exceed specified limits in quantity, frequency or duration (refer to WAC 388-501-0165 and 388-501-0169).

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WAC 182-540-140 Noncovered services. (1) The department does not reimburse kidney centers for the following:

- (a) Blood and blood products (refer to WAC 388-540-190);
- (b) Personal care items such as slippers, toothbrushes, etc.; or
- (c) Additional staff time or personnel costs. Staff time is paid through the composite rate. Home dialysis helpers are the only personnel cost paid outside the composite rate (refer to WAC 388-540-160).

(2) The department evaluates a request for any service listed as noncovered in this chapter under the provisions of WAC 388-501-0160.

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WAC 182-540-150 Reimbursement—General. (1) Kidney center services described in this section are paid by one of two methods:

(a) **Composite rate payments**—This is a payment method in which all standard equipment, supplies and services are calculated into a blended rate.

(i) A single dialysis session and related services are reimbursed through a single composite rate payment (refer to WAC 388-540-160).

(ii) Composite rate payments for continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD) are limited to thirty-one per month for an individual client.

(iii) Composite rate payments for all other types of dialysis sessions are limited to fourteen per month for an individual client.

(b) **Noncomposite rate payments**—End-stage renal disease (ESRD) services and items covered by the department but not included in the composite rate are billed and paid separately (refer to WAC 388-540-170).

(2) **Limitation extension request**—The department evaluates billings for covered services that are subject to limitations or other restrictions, and approves such services beyond those limitations or restrictions when medically necessary under the provisions of WAC 388-501-0165 and 388-501-0169.

(3) **Take-home drugs**—The department reimburses kidney centers for take-home drugs only when they meet the conditions described in WAC 388-540-170(1). Other drugs for at-home use must be billed by a pharmacy and be subject to the department's pharmacy rules.

(4) **Medical nutrition**—Medical nutrition products must be billed by a pharmacy or a durable medical equipment (DME) provider.

(5) **Medicare eligible clients**—The department does not reimburse kidney centers as a primary payer for medicare eligible clients.

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WAC 182-540-160 Items and services included in the composite rate. (1) The following equipment, supplies, and services for in-facility and home dialysis are included in the composite rate:

- (a) Medically necessary dialysis equipment;
- (b) All dialysis services furnished by the facility's staff;
- (c) Standard end-stage renal disease laboratory tests (refer to WAC 388-540-180);
- (d) Home dialysis support services including delivery, installation, and maintenance of equipment;
- (e) Purchase and delivery of all necessary dialysis supplies;
- (f) Dec clotting of shunts and any supplies used to declo t shunts;
- (g) Oxygen and the administration of oxygen;
- (h) Staff time used to administer blood and nonroutine parenteral items;
- (i) Noninvasive vascular studies; and
- (j) Training for self-dialysis and home dialysis helpers.

(2) The medical assistance administration (MAA) issues a composite rate payment only when all of the above items and services are furnished or available at each dialysis session.

(3) If the facility fails to furnish or have available any of the above items, MAA does not pay for any part of the items and services that were furnished.

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WAC 182-540-170 Items and services not included in the composite rate. The following items and services are not included in the composite rate and must be billed separately, subject to the restrictions or limitations in this section and other applicable published WAC:

- (1) Drugs related to treatment, including but not limited to epoetin alpha (EPO) and diazepam. The drug must:
 - (a) Be prescribed by a physician;
 - (b) Meet the rebate requirements described in WAC 388-530-1125; and
 - (c) Meet the requirements of WAC 246-905-020 when provided for home use.
- (2) Supplies used to administer drugs and blood;
- (3) Blood processing fees charged by the blood bank (refer to WAC 388-540-190); and
- (4) Home dialysis helpers.

[11-14-075, recodified as § 182-540-170, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-170, filed 10/8/03, effective 11/8/03.]

WAC 182-540-180 Laboratory services. (1) Laboratory services included in the composite rate, performed by either the facility or an independent laboratory, must not be billed separately except as provided for in (b) of this subsection:

(a) Standard end-stage renal disease (ESRD) lab tests are included in the composite rate when performed at recommended intervals (see billing instructions for current list).

(b) The standard ESRD lab tests referred to in (a) of this subsection can be reimbursed separately from the composite rate only when it is medically necessary to test more frequently:

- (i) Proof of medical necessity must be documented in the client's medical record when billing for more frequent testing. A diagnosis of end-stage renal disease is not sufficient;
- (ii) The claim must include information on the nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s); or
- (iii) An ICD-9CM diagnosis code may be shown in lieu of a narrative description.

(2) All separately billable, ESRD laboratory services must be billed by and reimbursed to the lab that performs the test.

[11-14-075, recodified as § 182-540-180, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-180, filed 10/8/03, effective 11/8/03.]

WAC 182-540-190 Blood products and services. (1) The medical assistance administration (MAA) reimburses free-standing kidney centers for:

- (a) Blood processing and other fees assessed by non-profit blood centers that do not charge for the blood or blood products themselves; and
- (b) Costs incurred by the center to administer its in-house blood procurement program.

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(2) MAA does not reimburse centers for blood or blood products (refer to WAC 388-550-6500).

(3) Staff time used to administer blood or blood products is reimbursed only through the composite rate (refer to WAC 388-540-150 and 388-540-160).

[11-14-075, recodified as § 182-540-190, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-190, filed 10/8/03, effective 11/8/03.]

WAC 182-540-200 Epoetin alpha (EPO) therapy. The medical assistance administration (MAA) reimburses the kidney center for EPO therapy when:

- (1) Administered in the kidney center to a client:
 - (a) With a hematocrit less than thirty-three percent or a hemoglobin less than eleven when therapy is initiated;
 - (b) Continuing EPO therapy with a hematocrit between thirty and thirty-six percent; or
 - (c) Medical justification documented in the client's record is required for hematocrits greater than thirty-six or hemoglobins greater than twelve. Medical justification includes:
 - (i) Documentation that dose is being titrated downward to bring a patient's hematocrit back within target range; or
 - (ii) Documentation that it is medically necessary for the client to have a target hematocrit greater than thirty-six percent.
- (2) Provided to a home dialysis client:
 - (a) Under the same hematocrit/hemoglobin guidelines as stated in (1)(a) and (b) of this section; and
 - (b) When permitted by Washington board of pharmacy rules. (Refer to WAC 246-905-020 Home dialysis program—Legend drugs.)

[11-14-075, recodified as § 182-540-200, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-200, filed 10/8/03, effective 11/8/03.]

WAC 182-540-210 Injectable drugs given in the kidney center. Injectable drugs administered in the kidney center are reimbursed up to the medical assistance administration's (MAA) published maximum fees.

[11-14-075, recodified as § 182-540-210, filed 6/30/11, effective 7/1/11. Statutory Authority: RCW 74.08.090, 74.09.510, 74.09.520, 74.09.522, and 42 C.F.R. 405.2101. 03-21-039, § 388-540-210, filed 10/8/03, effective 11/8/03.]