5101:3-13-01.9 **Fee-for-service ambulatory health care clinics (AHCCs): end-stage renal disease (ESRD) dialysis clinics.**

Requirements outlined in rule 5101:3-13-01 of the Administrative Code apply to all fee-for-service AHCCs.

(A) Definitions.

(1) "Ambulatory health care ESRF dialysis clinic" is a renal dialysis facility that meets the requirements outlined in paragraph (C) of this rule and provides chronic maintenance dialysis for end-stage renal disease (ESRD).

(2) "Chronic maintenance dialysis," in accordance with rule 3701-83-23 of the Administrative Code, means the regular provision of dialysis for an end stage renal disease patient with any level of patient involvement.

(3) "Composite payment rate" is a prospective system for the comprehensive payment of all modes of outpatient (in-facility and method I home) maintenance dialysis services. The composite payment rate covers most items and services related to the treatment of a patient's ESRD. The composite rate covers the complete dialysis treatment, specific laboratory tests, diagnostic services, laboratory services, and drugs (including injections and immunizations) in specific quantities and frequencies, as described in appendix A to this rule. The composite rate does not cover physician professional services, separately billable laboratory services, or separately billable drugs. Dialysis composite rates are listed in rule 5101:3-1-60 of the Administrative Code.

(4) "Continuous ambulatory peritoneal dialysis" (CAPD) is a type of peritoneal dialysis in which the patient's peritoneal membrane is used as a dializer. CAPD is usually performed three to five times a day in four to six hour cycles.

(5) "Continuous cycling peritoneal dialysis" (CCPD) is a type of peritoneal dialysis in which the patient's peritoneal membrane is used as a dializer. CAPD is usually accomplished three times a night in approximately three hours cycles, using an automatic peritoneal dialysis cycler.

(6) "Dialysis" is a process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. The two types of dialysis procedures currently in common use are hemodialysis and peritoneal dialysis.

(7) "Dual-eligible," for the purposes of this rule, means a patient who is eligible for both medicare and medicaid coverage of ESRD services.

(8) "End-stage renal disease" (ESRD) occurs from the destruction of normal kidney tissues over a long period of time. The loss of kidney function in ESRD is

usually irreversible and permanent.

(9) "End-stage renal disease patient," in accordance with rule 3701-83-23 of the Administrative Code, means an individual who is at a stage of renal impairment that appears irreversible and permanent and who requires a regular course of dialysis or renal transplantation to ameliorate uremic symptoms and maintain life.

(10) "ESRD services" are diagnostic, therapeutic, rehabilitative, or palliative services, including:

(a) Services furnished at an ambulatory health care ESRD dialysis clinic by or under the general or direct supervision of a physician.

(b) Services furnished outside an ambulatory health care ESRD dialysis clinic by clinic personnel under the general or direct supervision of a physician to a patient who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(c) Services specified by revenue center codes delineated in appendix A to this rule.

(11) "Free-standing" is defined in accordance with rule 5101:3-13-01 of the Administrative Code.

(12) "Freestanding dialysis center" or "dialysis center," in accordance with rule 3701-83-23 of the Administrative Code, means a facility that provides chronic maintenance dialysis to ESRD patients on an outpatient basis, including the provision of dialysis services in the patient's place of residence. A freestanding dialysis center does not include a hospital or other entity that performs dialysis services that are reviewed and accredited or certified as part of the hospital's accreditation or certification as required by section 3727.02 of the Revised Code.

(13) "Home dialysis" is dialysis performed by an appropriately trained patient and patient caregiver at home. Home dialysis, in accordance with rule 3701-83-23 of the Administrative Code, means dialysis performed by an appropriately trained patient, with or without minimal assistance, at the patient's place of residence.

(14) "Home dialysis training" is a program that trains ESRD patients to perform home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing home dialysis.

(15) "Hospital-based ESRD facilities" are an integral and subordinate part of a hospital, as evidenced by the cost report, in accordance with Chapter 5101:3-2 of the Administrative Code.

(16) "Hemodialysis" is a renal dialysis procedure in which blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. Hemodialysis is usually accomplished in three to four hours sessions, three times a week.

(17) "In-facility dialysis" is dialysis furnished on an outpatient basis at an approved renal dialysis facility.

(18) "Intermittent peritoneal dialysis" (IPD) is a type of peritoneal dialysis in which waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. IPD is usually conducted for approximately thirty hours per week in three or fewer sessions of ten or more hours.

(19) "Method I" is medicare terminology used to describe the provision of home dialysis services whereby a renal dialysis facility assumes responsibility for providing all home dialysis equipment, supplies and support services.

(20) "Peritoneal dialysis" is a renal dialysis procedure in which waste products pass from a patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the dialysate is introduced and removed periodically. The three types of peritoneal dialysis are continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), and intermittent peritoneal dialysis (IPD).

(21) "Physician professional services," in accordance with rule 5101:3-4-14 of the Administrative Code, are age-specific services performed in an outpatient setting that are related to a patient's ESRD.

(22) "Renal dialysis center" is a hospital unit approved by medicare to furnish the full spectrum of services required for the care of ESRD dialysis patients.

(23) "Renal dialysis facility" is a unit approved by medicare to furnish dialysis services directly to ESRD patients.

(24) "Self-dialysis" is dialysis performed by an appropriately trained ESRD patient with little or no professional assistance.

(25) "Self-dialysis training" is a program that trains ESRD patients to perform self-dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis.

(26) "Staff-assisted dialysis" is dialysis performed by the staff of a renal dialysis center or facility.

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care dialysis clinic provider on and after January 1, 2008 must:

(1) Meet the criteria for fee-for-service AHCC providers in accordance with paragraph (C) of rule 5101:3-13-01 of the Administrative Code; and

(2) Be certified by medicare as a dialysis facility;

(3) Be licensed by the director of the Ohio department of health in accordance with Chapter 3701-83 of the Administrative Code and demonstrate to the director of health that it meets the requirements of section 3702.30 of the Revised Code and either meets the requirements of Chapter 3701-83 of the Administrative Code or has submitted an acceptable accreditation inspection report, in accordance with rule 3701-83-05 of the Administrative Code; and in accordance with rule 3701-83-02 of the Administrative Code, complies with rules 3701-83-23 to 3701-83-24 of the Administrative Code. Non-Ohio providers must be licensed by their respective state's authority if applicable.

(4) Provide services in accordance with division level 5101:3 of the Administrative Code.

(C) Dialysis clinic claims, billing, payment/reimbursement.

(1) Fee-for-service ambulatory health care dialysis clinic providers that have executed the standard medicaid provider agreement and meet all eligibility requirements specified in paragraph (C) of this rule may bill the department for ESRD dialysis services.

(2) All medicaid providers, including fee-for-service ambulatory health care dialysis clinics, must determine whether medicare or other third party insurers are responsible for the coverage of a medicaid patient's dialysis treatment for the date of treatment. Medicaid is the payer of last resort for ESRD services.

(a) Medicaid coverage of ESRD services for patients, including dual-eligibles, begins with the initial onset of dialysis treatment.

(i) If CMS determines that the patient is medicare eligible at the onset of the disease, medicaid coverage as the primary payer begins with the initial onset of dialysis and continues until medicare coverage begins (usually three months).

(ii) If CMS determines that the patient is not medicare eligible at the onset of the disease, medicaid coverage continues as long as the dialysis treatments are medically necessary and the patient is eligible for medicaid.

(b) The medicaid provider must pursue medicare eligibility for the patient through CMS within the first three months of a medicaid eligible patient's initial dialysis treatment.

(i) The provider must retain proof in the medical record that the patient has applied for medicare coverage and is ineligible.

(ii) The department may conduct a retrospective review to verify that the provider assisted the patient to apply for medicare coverage.

(iii) Fee-for-service ambulatory health care dialysis clinic providers shall bill medicare cross-over claims in accordance with rule 5101:3-1-05 of the Administrative Code.

(3) Dialysis clinic claims for "clinic facility dialysis services" are payable only if submitted in accordance with national uniform billing committee (NUBC) requirements, using revenue center code(s) and appropriate procedure code(s) as described in appendix A to this rule.

(4) Dialysis clinics must document in the patient's medical record the medical necessity, defined in accordance with rule 5101:3-1-01 of the Administrative Code, of each service provided and billed to the department. to verify that the services were rendered as billed on the claim.

(5) The department reimburses ambulatory health care dialysis clinics for dialysis treatment, dialysis support, and dialysis treatment with self-care training using composite rates, as described in appendix A to this rule. The composite rates include specific laboratory tests, diagnostic services, and drugs (including injections and immunizations) in specific quantities and frequencies, as described in appendix A to this rule. Items included in the composite rates may not be billed separately by the dialysis clinic or by any laboratory for the same date of dialysis treatment. Laboratory services may be performed in the clinic or by an outside laboratory if the clinic or laboratory is clinical laboratory improvement act (CLIA) certified. Laboratory tests are included in the composite rate regardless of where the tests are performed. Composite rates do not include a physician's professional supervision. Physician professional supervision may only be billed by physicians, in accordance with rule 5101:3-4-14 of the Administrative Code. Dialysis clinic composite rates are listed in rule 5101:3-1-60 of the Administrative Code.

(a) Composite rates for medicaid coverage of dialysis treatment.

(i) Dialysis treatment is available to patients in both clinic and home settings.

(ii) Limits.

(a) The department will reimburse dialysis clinics for in-facility and method I home dialysis at a maximum frequency of one treatment per recipient per day. These rates are to be used only by clinics providing care to patients who have elected medicare's method I payment system.

(b) Treatment sessions for hemodialysis and IPD are limited to three treatments per week. This limitation may be exceeded only if additional treatments are determined to be medically necessary, defined in accordance with rule 5101:3-1-01 of the Administrative Code, by the physician who is primarily responsible for dialysis services and the medical necessity for the services is documented in the medical record.

(c) Treatment sessions for CCPD and CAPD are limited to a daily composite rate. Treatments for CCPD and CAPD must be determined to be medically necessary by the physician who is primarily responsible for the dialysis services. The medical necessity for the services must be documented in the patient's medical record.

(b) Composite rates for medicaid coverage of dialysis support services.

(i) The patient may elect to make his/her own arrangements for securing necessary supplies and equipment in either the home or the clinic setting.

(ii) Only dialysis clinics using medicare's method II payment system may bill the department using the composite rate for support services.

(iii) The composite rate for support services does not include durable medical equipment (DME) or laboratory services. Payment for supplies will be made to the DME supplier at rates listed under rule 5101:3-10-03 of the Administrative Code entitled "medicaid supply list."

(iv) The department will reimburse a dialysis clinic for support services composite rates at a maximum frequency of once per month.

(c) Composite rates for medicaid coverage of dialysis treatment with self-care training.

(i) The composite rate for dialysis treatment with self-care training reflects training costs per session.

(ii) Limits.

(a) Hemodialysis treatment services with self-care training is limited to fifteen sessions or three months of training, whichever comes first.

(b) IPD treatment services with self-care training is performed in ten to twelve hour sessions and is limited to four weeks of training.

(c) CAPD treatment services with self-care training is performed five days a week and is limited to a maximum of fifteen training sessions.

(d) CCPD treatment services with self-care training is performed five to six days a week and is limited to a maximum of fifteen training sessions.

(6) The department reimburses dialysis clinics for medically necessary laboratory tests (as described in Chapter 5101:3-11 of the Administrative Code), diagnostic services, and prescribed drugs (including therapeutic injections as described in rule 5101:3-4-13 of the Administrative Code) and immunizations (as described in rule 5101:3-4-12 of the Administrative Code) not included in the composite rates or that exceed the frequency described in the composite rates as described in appendix A to this rule, if:

(a) The medical record documents the medical necessity for the laboratory test, diagnostic service, and/or drug; and

(b) The laboratory test, diagnostic service, and/or drug is a covered medicaid service.

(7) Laboratory tests, diagnostic services, and drugs provided in excess of the frequency described in the composite rates are subject to review and potential recovery.

(8) The department reimburses physician professional services associated with the medical management of ESRD patients in accordance with rule 5101:3-4-14 of the Administrative Code.

(9) The department reimburses durable medical equipment providers for supplies associated equipment and all related medical supplies necessary for the home dialysis patient who elects to receive such services under Method II, in accordance with rule 5101:3-10-10 of the Administrative Code.

(10) The department reimburses for medical transportation to and/or from dialysis

treatment in accordance with Chapter 5101:15 of the Administrative Code.

(11) The following services are non-covered:

(a) All blood products;

(b) All services exceeding the limitations defined in Chapters 5101:3-1, 5101:3-4, 5101:3-05, 5101:3-06, 5101:3-8, 5101:3-9, 5101:3-13, 5101:3-14, 5101:3-15, and 5101:3-24 of the Administrative Code;

(c) Services determined by the department as not medically necessary or that are duplicative of a service provided concurrently by another medicaid provider;

(d) Any service not provided in accordance with the criteria and protocols set forth by the Ohio law for advanced practice nurses, registered nurses, and physician assistants;

(e) All services itemized as non-covered in rule 5101:3-4-28 of the Administrative Code.

Replaces: Part of 5101:3-13-01, Part of 5101:3-13-07

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