CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Chapter 5160-13 - Ambulatory health care clinic services.

Rule Number(s):

New: (1) 5160-13-01 - Service-based ambulatory health care clinics: general provisions, and (2) 5160-13-02 - Service-based ambulatory health care clinics: end-stage renal disease (ESRD) dialysis clinics

To Be Rescinded: (1) 5160-13-01 - Fee-for-service ambulatory health care clinics (AHCCs): general provisions, (2) 5160-13-01.1 - Fee-for-service ambulatory health care clinics (AHCCs): primary care clinics, (3) 5160-13-01.3 - Fee-for-service ambulatory health care clinics (AHCCs): public health department clinics, (4) 5160-13-01.4 - Fee-for-service ambulatory health care clinics (AHCCs): outpatient rehabilitation clinics, (5) 5160-13-01.5 - Fee-for-service ambulatory health care clinics (AHCCs): family planning clinics, (6) 5160-13-01.6 - Fee-for-service ambulatory health care clinics (AHCCs): professional optometry school clinics, (7) 5160-13-01.7 - Fee-for-service ambulatory health care clinics (AHCCs): professional dental school clinics, (8) 5160-13-01.8 - Fee-for-service ambulatory health care clinics (AHCCs): speech-language/audiology clinics and diagnostic imaging clinics, and (9) 5160-13-01.9 – Fee-for-service ambulatory health care clinics (AHCCs): end-stage renal disease (ESRD) dialysis clinics.

Date: November 29, 2016

Rule Type:

- ☑ New
- ☐ Amended
- ☑ 5-Year Review
- ☑ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   As a result of five-year rule review, ODM is proposing to reorganize, streamline, and clarify the text of the existing rules in Chapter 5160-13. With the exception of the end-stage renal disease (ESRD) dialysis clinic rule (5160-13-01.9), ODM proposes to rescind and consolidate the rules in Chapter 5160-13 into one new rule (5160-13-01) that will address all ambulatory health care clinics. ODM proposes to address ESRD dialysis clinics separately in a new rule numbered 5160-13-02.

   Changes to the rules include the following:

   - An outdated and overarching Medicare enrollment requirement is removed for primary care clinics, public health department clinics, family planning clinics, professional optometry school clinics, professional dental school clinics, and speech-language-audiology clinics.
   - All references to diagnostic imaging clinics have been deleted because no diagnostic imaging clinic exists in Ohio, and the relevant services are addressed in the independent diagnostic testing facility (IDTF) section of Chapter 5160-11 of the Ohio Administrative Code.
   - In existing rule 5160-13-01.9, maximum payment amounts for ESRD dialysis clinic services are listed indirectly by reference to appendix DD to rule 5160-1-60. In new rule 5160-13-02, maximum payment amounts are expressed instead by formula, as a percentage of the corresponding 2016 Medicare allowed amounts for the services. The resulting slight increases in payment are negligible.
   - References to the Medicaid agency number (5160) and to OAC rules are updated.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   ODM is promulgating these rules under section 5164.02 of the Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   The proposed rules in Chapter 5160-13 do not implement a federal requirement, but the proposed regulations do align with federal regulations by only requiring Medicare enrollment for Medicare providers.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   The proposed regulations do not exceed any federal requirements. The rules set forth payment policies for ODM that are not found in federal law.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Medicaid rules perform several core business functions. They establish and update coverage and payment policies for medical goods and services. They set limits on the types of entities that can receive Medicaid payment for these goods and services. They publish payment formulas or fee schedules for the use of providers and the general public. The administrative rules for clinics perform these functions, and no alternative is readily apparent.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of these regulations can be measured by correct payment of claims by the Medicaid Information Technology System (MITS).

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   Provider associations representing each type of clinic were identified and then notified by e-mail on July 29, 2014, September 23, 2014, and August 25, 2015 that Chapter 5160-13 was up for "five year rule review" and comments were welcome. Provider associations and other stakeholders identified included: Association of Ohio Health Commissioners, Ohio Optometric Association, The Ohio State University College of Dentistry, Ohio Dental Association, Ohio Physical Therapy Association, Ohio Speech-Language-Hearing Association, Ohio State Speech and Hearing Clinic, Cleveland Hearing and Speech Center, Ohio Physical Therapy Association, Academy of Family Physicians, Ohio Chapter of American College of Physicians, Ohio Physical Therapy Network, Ohio State Radiological Society, International Association of Rehab Professionals, ESRD Association, Ohio Renal Association, Ohio State Medical Association, Ohio Association of County Behavioral Health Authorities, Ohio Council of Behavioral Health and Family Services Providers, Ohio Association of Community Health Centers, Ohio State Independent Living Centers, and Ohio Provider Resource Association. No concerns were expressed by the above listed stakeholders.

   On November 24, 2015, ODM reached out to the Ohio Association of Community Action Agencies (OACAA) on another matter and it became apparent that this association and its members may also be interested in providing comments. Two concerns were expressed.

   On January 27, 2016, ODM asked the Ohio Department of Health to reach out to Ohio's Public Health Departments on behalf of ODM; no concerns were expressed.

   On June 27, 2016, ODM reached out to the Medicaid managed care plans; no concerns were expressed.

   On June 28, 2016, ODM reached out all the associations listed above one last time; no concerns were expressed.

Finally, as part of the public participation process, ODM solicited and encouraged input from affected organizations and individuals by posting the draft regulation into Clearance for one week at: http://www.medicaid.ohio.gov/RESOURCES/LegalandContracts/Rules.aspx. One concern was expressed.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Two comments were received from Community Action Agencies (CAAs) concerning the Medicare enrollment requirement. In brief, they said it was difficult and sometimes impossible for their organizations to meet the Medicare enrollment requirement because their organization does not provide services to individuals covered by Medicare (e.g., some public health departments, family planning clinics, and pediatric primary care clinics). They also said it was costly to enroll in Medicare and that Medicare dis-enrolled them from the program when they did not submit a sufficient number of claims each year.

ODM removed the Medicare enrollment requirement for most clinics except ESRD dialysis clinics and outpatient rehabilitation clinics. ODM researched the necessity of the Medicare enrollment requirement and concluded that the other requirements listed in the rule (certifications, accreditations, etc.) would suffice for most clinics.

One question regarding coverage and payment was received. In brief, the reviewer asked if the same lab procedures would be covered under the new regulation. While the comment did not affect the draft regulation, a clarifying response was sent to the stakeholder stating the intent of the rules remain the same along with payment and coverage.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Not applicable.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

ODM considered keeping all existing requirements for Medicare enrollment, but decided to remove this requirement for some clinics to enhance access to services for some Medicaid-eligible individuals

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The concept of performance-based regulations does not apply to these services.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Rules involving Medicaid providers are housed exclusively within agency 5160 of the Ohio Administrative Code. Within this division, rules are generally separated out by topic.

Service-based ambulatory health care clinics are grouped in Chapter 5160-13. Duplicate language was found in the existing Chapter 5160-13 and has now been removed. The text of the chapter was reorganized, streamlined, and clarified; nine rules were combined into two.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The removal of the Medicare enrollment requirement for certain clinics will be implemented by working with MITS staff and ODM's provider enrollment section to update their processes for enrolling and revalidating clinics.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

Rules in Chapter 5160-13 apply to all service-based ambulatory health care clinics that are or want to be Medicaid providers.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Chapter 5160-13 rules do not impose any fees, fines, penalties, or reporting of information. The existing adverse impact of being a Medicare provider is being removed from the rule. This chapter does require certain accreditations, certifications, legal statuses, state or federal grants, licensures, and/or affiliations to be a Medicaid provider.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

A positive impact on providers is expected to result from the removal of the Medicare enrollment requirement for certain clinics that will no longer be required to enroll as Medicare providers.

The costs to participating providers are estimated in the following paragraphs.

- ***Primary care clinics*** are required to: (1) be either certified or accredited by the Joint Commission, Accreditation Association for Ambulatory Health Care (AAAHC), Healthcare Facilities Accreditation Program of the American Osteopathic Association, or the Community Health Accreditation Program (CHAP), or (2) receive state or federal grant funds for the provision of health services. Accreditation fees range from about $7,200 a year for small businesses to more than $40,000 a year for large organizations. The cost to apply for a grant is existing staff time. According to Labor Market Information (LMI) data published by the Ohio Department of Job and Family Services in 2016, the median salary statewide hourly wage for professionals performing

services related to accreditation is $24.76 (program director) and adding 30 per cent for fringe benefits brings the figure to $32.19. Therefore, the estimated cost associated with applying for a grant is about $1,300.

- Any organization applying to be a ***public health department clinic*** provider with Medicaid must have legal status as a county, city, or combined health district; and meet the standards for boards of health and local health departments in accordance with Chapter 3709 and Section 3701.342 of the Revised Code. ODM reached out to the Ohio Department of Health regarding the cost of their requirement, and they said the cost of this requirement has never been quantified. There is no expected adverse impact as a result of these rules on existing public health department clinics as they already meet this requirement prior to enrolling with Medicaid.

- ***Outpatient rehabilitation clinics*** are required by Medicare to be certified by Medicare as either an outpatient rehabilitation agency or a comprehensive outpatient rehabilitation facility (CORF). Outpatient rehabilitation agencies and CORFs are not licensed in Ohio. Federal standards for Medicare certification are found at 42 CFR Part 485, Subpart B, 42 CFR Part 485.703, and 42 CFR Part 485.51. As long as outpatient rehabilitation clinics follow federal standards for Medicare certification, which they must do regardless of whether they enroll in Medicaid, there is no additional adverse impact in order to become a Medicaid provider.

- ***Family planning clinics*** are required to comply with federal guidelines set forth in 42 U.S.C. 300 and receive funding for pregnancy prevention services through Title X of the Public Health Services Act. There is no additional adverse impact.

- ***Professional optometry school clinics*** are required to be associated with an accredited optometry school. Professional optometry schools are accredited by organizations such as the Accreditation Council on Optometry Education (ACOE) of the American Optometric Association (AOA). According to AOA's website, application and annual fees are: (1) Professional Optometric Degree Programs - $30,629, (2) Optometric Residency Programs - $2,226, and (3) Optometric Technician Programs - $2,226. This requirement is consistent with existing professional standards, not an additional Medicaid requirement or cost.

- ***Professional dental school clinics*** are required to be associated with a professional dental school. Professional dental schools are accredited by organization such as the commission on dental accreditation (CODA) of the American dental association (ADA). According to the ADA's website, application fees for new professional dental schools require a one-time payment of $4,000. Annual fees for existing professional dental schools are currently $6,740. This requirement is consistent with existing professional standards, not an additional Medicaid requirement or cost.

- Professionals working at ***speech-language/audiology clinics*** must hold a certificate from the American Speech-Language Hearing Association (ASHA). The cost of a certificate issued by ASHA ranges from $256-$511 (dues and

fees are paid annually). The costs, however, are normally assumed by the practitioner working at the clinic and not the clinic itself.

- ***ESRD dialysis clinics*** must: (1) be certified by Medicare as a dialysis facility; (2) be licensed by the Ohio Department of Health in accordance with Chapter 3701-83, and (3) if a non-Ohio provider, be licensed by their respective state's authority. All freestanding dialysis centers are required to be licensed by the Ohio Department of Health under section 3702.30 of the Ohio Revised Code. As long as dialysis clinics follow Ohio standards for licensure and federal standards for Medicare certification, which they must do regardless if they enroll in Medicaid, there is no additional adverse impact due to these rules.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Adverse impacts to clinics as a result of Chapter 5160-13 rules are minimal. While ODM must put in place standards for participating in the Medicaid program, ODM is using existing professional standards, which would apply to those providers even if they did not enroll with Medicaid.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Medicaid regulations apply uniformly to all providers regardless of size.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

There are no fines or penalties in these regulations.

18. What resources are available to assist small businesses with compliance of the regulation?

Providers submitting claims through an electronic clearinghouse (a “trading partner”) can generally rely on the clearinghouse to know current ODM claim-submission procedures.

Providers choosing to submit claims through ODM’s MITS web portal, can find instructions on ODM’s website. Providers may also call the Provider Call Center for assistance at: (800) 686-1516.

Information sheets and instruction manuals on various claim-related topics are readily available on ODM’s website.

Providers may also request group training or an individual consultation on ODM’s website or at 614-644-1399.

Policy questions may be directed via e-mail to the Non-Institutional Benefit Management section of ODM’s policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

5160-13-01 **Service-based ambulatory health care clinics: general provisions.**

(A) Unless otherwise noted, any limitations or requirements specified in the Revised Code or in agency 5160 of the Administrative Code apply to services addressed in this rule.

(B) Definitions.

(1) "Clinic" is an entity that meets all of the following criteria:

(a) It renders clinic services on an outpatient basis under the direction of a physician or dentist. Clinic services are defined in 42 CFR 440.90 (October 1, 2016).

(b) It operates from a fixed location, a specifically designed mobile unit, or both. It is not necessary that a fixed location be administered by a physician or dentist.

(c) It is freestanding—administratively, organizationally, and financially independent of an institution such as a hospital or long-term care facility. It may be physically located in a hospital or long-term care facility so long as it remains independent.

(d) It does not provide overnight accommodations.

(2) "Service-based ambulatory health care clinic" is a clinic to which medicaid makes separate payment for each service or item provided. Policies governing cost-based clinics (federally qualified health centers, rural health clinics, and outpatient health facilities—to which medicaid makes payment on the basis of a visit or encounter) are set forth in Chapter 5160-28 of the Administrative Code.

(C) The following entities may enroll in medicaid as a service-based ambulatory health care clinic:

(1) An end-stage renal disease (ESRD) dialysis clinic, defined in 42 C.F.R. 494.10 (October 1, 2016), that meets the following criteria:

(a) It is certified by medicare as a dialysis facility;

(b) It is licensed by the Ohio department of health in accordance with Chapter 3701-83 of the Administrative Code or, if it is located outside of Ohio, is licensed by its respective state's authority; and

(c) It provides services in accordance with rule 5160-13-02 of the Administrative Code;

(2) A family planning clinic that meets the following criteria:

(a) It is a public or nonprofit organization;

(b) It complies with federal guidelines set forth in 42 U.S.C. 300 (as in effect October 1, 2016);

(c) It receives funding for pregnancy prevention services through Title X of the Public Health Services Act; and

(d) It provides pregnancy prevention services in accordance with Chapter 5160-21 of the Administrative Code;

(3) An outpatient rehabilitation clinic that delivers rehabilitation services at a medicare-certified rehabilitation agency, defined in 42 C.F.R. 485.703 (October 1, 2016), or at a medicare certified comprehensive outpatient rehabilitation facility (CORF), defined in 42 C.F.R. 485.51 (October 1, 2016);

(4) A primary care clinic that meets either of the following criteria:

(a) It receives state or federal grant funds for the provision of health services; or

(b) It provides primary care services by virtue of certification or accreditation by one of the following entities:

(i) The joint commission;

(ii) The accreditation association for ambulatory health care (AAAHC);

(iii) The healthcare facilities accreditation program of the American osteopathic association (AOA); or

(iv) The community health accreditation program (CHAP);

(5) A professional dental school clinic associated with an accredited dental school;

(6) A professional optometry school clinic associated with an accredited optometry school;

(7) A public health department clinic that meets the following criteria:

(a) It has legal status as local health department created by a city health district, general health district, or combined health district in accordance with Chapter 3709. of the Revised Code; and

(b) It meets the standards set forth in section 3701.342 of the Revised Code; or

(8) A speech-language-audiology clinic that specializes in and provides speech, language, or audiology services delivered by professionals who have been certified by the American speech-language-hearing association (ASHA).

Replaces: 5160-13-01, 5160-13-01.1, 5160-13-01.3, 5160-13-01.4, 5160-13-01.5, 5160-13-01.6, 5160-13-01.7, 5160-13-01.8

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02
Prior Effective Dates:	04/07/1977, 12/21/1977, 12/30/1977, 01/08/1979, 01/14/1983, 04/02/1983, 06/03/1983, 10/01/1987, 04/01/1988, 09/01/1989, 07/01/1993, 07/12/1993 (Emer), 10/01/1993, 05/17/2001, 03/01/2005, 01/01/2008, 07/01/2009

5160-13-02 **Service-based ambulatory health care clinics: end-stage renal disease (ESRD) dialysis clinics.**

(A) Coverage and limitations.

(1) Medicaid coverage of dialysis services for eligible individuals with end-stage renal disease (ESRD) begins with the first dialysis treatment. If an individual is eligible for both medicare and medicaid, then coverage by medicaid as the primary payer continues only until medicare coverage begins.

(2) Payment may be made to an ESRD dialysis clinic for hemodialysis or for any of three types of peritoneal dialysis: intermittent peritoneal dialysis (IPD), continuous ambulatory peritoneal dialysis (CAPD), or continuous cycling peritoneal dialysis (CCPD). These four types of dialysis service may be delivered in any of three ways:

(a) Chronic maintenance dialysis is defined in rule 3701-83-23 of the Administrative Code. It is available to individuals in either an ESRD dialysis clinic or a home setting. In a home setting, it is often called "Method I home dialysis," a medicare term for a payment option under which a dialysis provider assumes responsibility for furnishing all equipment, supplies, and support services.

(b) Dialysis support services include but are not limited to periodic monitoring of an individual’s adaptation to home dialysis, visits by trained personnel, certain ESRD-related laboratory tests, maintenance of home dialysis equipment, ordering of supplies, and record-keeping. The individual receiving dialysis support services makes arrangements for securing necessary supplies and equipment, in either an ESRD dialysis clinic or a home setting. The delivery of dialysis support services in a home setting is often called "Method II home dialysis," a medicare term for a payment option under which a dialysis provider assumes responsibility for furnishing only treatment-related services and a separate provider (usually a supplier of durable medical equipment) furnishes the dialysis equipment and supplies.

(c) Dialysis with self-care training includes dialysis treatment along with instruction of the individual or a caregiver on how to perform self-dialysis with little or no professional assistance.

(3) The following frequency limits apply:

(a) Chronic maintenance dialysis performed in an ESRD dialysis clinic – one session per day, three sessions per week;

(b) Chronic maintenance dialysis performed in a home setting – one session per day;

(c) Dialysis support services – one session per month;

(d) Hemodialysis with self-care training – a total of fifteen sessions to be conducted within a period not to exceed ninety-one days;

(e) IPD with self-care training – a total of twelve sessions to be conducted within a period not to exceed twenty-eight days; and

(f) CAPD or CCPD with self-care training – a total of fifteen sessions.

(4) Frequency limits may be exceeded only if the medical necessity of the additional service is documented in the medical record by the practitioner who is primarily responsible for the dialysis services.

(B) Payment.

(1) Payment for covered dialysis services rendered by an ESRD dialysis clinic is made as an all-inclusive composite amount per visit. This composite amount includes all related services, tests, equipment, supplies, and training furnished on the same date.

(2) The medicaid maximum composite payment amount for a covered dialysis service is the product of two figures:

(a) The calendar year 2016 ESRD prospective payment system (PPS) base rate published by the centers for medicare and medicaid services (CMS), which can be found on the CMS website at http://www.cms.gov; and

(b) The applicable percentage from the following list:

(i) Chronic maintenance dialysis performed in an ESRD dialysis clinic – fifty-eight and three quarters per cent;

(ii) Chronic maintenance dialysis performed in a home setting – three sevenths of the percentage for chronic maintenance dialysis performed in an ESRD dialysis clinic;

(iii) Dialysis support services – thirty-three and three quarters per cent; or

(iv) Dialysis with self-care training – sixty-seven and three quarters per cent.

(3) Separate payment may be made to an ESRD dialysis clinic for covered professional services of a medical practitioner and for covered laboratory services and pharmaceuticals that are not directly related to dialysis treatment. Payment methods and amounts for such items and services are determined in accordance with the relevant portion of agency 5160 of the Administrative Code.

Replaces: 5160-13-01.9

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5162.03, 5164.02, 5164.70
Prior Effective Dates:	04/02/1983, 03/30/2001, 10/01/2003, 01/01/2008

TO BE RESCINDED

5160-13-01 Fee-for-service ambulatory health care clinics (AHCCs): general provisions.

Requirements outlined in this rule apply to all fee-for-service AHCCs identified in paragraph (B) of this rule.

(A) Definitions.

(1) "Ambulatory health care clinic (AHCC)" is a free-standing ambulatory healthcare facility that furnishes outpatient (non-institutional) health care by or under the direction of a physician or dentist, without regard to whether the clinic itself is administered by a physician or dentist.

(2) "Ambulatory health care facility" is a facility or distinct part of a facility that:

(a) Provides services on an outpatient basis in a fixed location or specifically designed mobile unit; and

(b) Does not provide overnight accommodations.

(3) "Cost-based ambulatory health care clinic" is an AHCC that is eligible for reimbursement on an encounter basis (in accordance with Chapter 5101:3-16, 5101:3-28, or 5101:3-29 of the Administrative Code) rather than on a service code basis.

(4) "Department," for the purposes of this chapter, is the Ohio department of job and family services (ODJFS).

(5) "Fee-for-service ambulatory health care clinic" is an AHCC that is eligible for reimbursement on a service code basis (in accordance with Chapter 5101:3-13 of the Administrative Code) rather than an encounter basis.

(6) "Free-standing" means having no administrative, organizational, financial or other connection with a hospital or long-term care facility. A free-standing clinic may be physically located in a hospital or long-term care facility as long as the clinic remains independent, as evidenced by cost reports and separate employer identification number (EIN).

(7) "Medical services" are, for the purposes of this chapter, defined in accordance with rule 5101:3-1-01 of the Administrative Code.

(8) "Non-specialty clinic" is an AHCC that provides a broad range of health care services.

(9) "Specialty clinic" is an AHCC that provides a limited or focused scope of healthcare services (e.g., dental, vision, dialysis).

(B) Medicaid providers eligible to be reimbursed by the department for AHCC services are either non-specialty or specialty clinics.

(1) Non-specialty clinics are:

(a) Primary care clinics, in accordance with rule 5101:3-13-01.1 of the Administrative Code; and

(b) Public health department clinics, in accordance with rule 5101:3-13-01.3 of the Administrative Code.

(2) Specialty clinics are:

(a) Community mental health services clinics, in accordance with rule 5101:3-13-01.2 of the Administrative Code;

(b) Outpatient rehabilitation clinics, in accordance with rule 5101:3-13-01.4 of the Administrative Code;

(c) Family planning clinics, in accordance with rule 5101:3-13-01.5 of the Administrative Code;

(d) Professional optometry school clinics, in accordance with rule 5101:3-13-01.6 of the Administrative Code;

(e) Professional dental school clinics, in accordance with rule 5101:3-13-01.7 of the Administrative Code;

(f) Speech-language/audiology clinics and diagnostic imaging clinics, in accordance with rule 5101:3-13-01.8 of the Administrative Code; and

(g) End-stage renal disease (ESRD) dialysis clinics, in accordance with rule 5101:3-13-01.9 of the Administrative Code.

(C) Any organization applying to be a fee-for-service AHCC medicaid provider on or after January 1, 2008 must:

(1) Meet the definition of an AHCC in accordance with paragraph (A)(1) of this rule;

(2) Not be eligible as a medicaid provider as a professional association of physicians, dentists, optometrists, opticians, podiatrists, or limited practitioners such as physical therapists, psychologists, or chiropractors in accordance with division (B)(5)(c)(i) of section 2317.02 of the Revised Code;

(3) Be enrolled as a medicare provider;

(4) Bill medicare as the primary insurer for services provided to patients eligible for both medicare and medicaid;

(5) Meet all specific requirements of at least one medicaid provider type listed under paragraph (B) of this rule;

(6) Submit to the department appropriate documentation of compliance with the requirements set forth in paragraphs (C)(1) to (C)(5) of this rule, in accordance with Chapter 5101:3-1 of the Administrative Code and the Ohio medicaid provider application/agreement for organizations, job and family services (JFS) 0651 (rev. 5/2006).

(D) Covered services include services identified per specific AHCC provider type set forth in rules 5101:3-13-01.1 to 5101:3-13-01.9 of the Administrative Code and the executed Ohio medicaid provider application/agreement for organizations, JFS 0651 (rev. 5/2006). AHCCs may be eligible providers of:

(1) Physician services in accordance with paragraph (D)(1) of rule 5101:3-4-01 of the Administrative Code;

(2) Dental services in accordance with rule 5101:3-5-01 of the Administrative Code;

(3) Vision services in accordance with paragraph (A)(5)(a) of rule 5101:3-6-01 of

the Administrative Code;

(4) Podiatry services in accordance with Chapter 5101:3-7 of the Administrative Code;

(5) Advance practice nurse services in accordance with rules 5101:3-8-20 to 5101:3-8-23 of the Administrative Code;

(6) Laboratory services in accordance with rule paragraph (A)(2) of rule 5101:3-11-02 of the Administrative Code, if certified to perform laboratory procedures under Clinical Laboratory Improvement Act (CLIA);

(7) Psychology services in accordance with paragraph (E)(1) of rule 5101:3-8-01 of the Administrative Code;

(8) EPSDT services in accordance with Chapter 5101:3-14 of the Administrative Code;

(9) Transportation services in accordance with Chapter 5101:3-15 of the Administrative Code;

(10) Disability medical assistance in accordance with Chapter 5101:3-23 of the Administrative Code; and

(11) Therapy services in accordance with Chapter 5101:3-34 of the Administrative Code.

(E) Limitations.

(1) AHCCs must follow all applicable general medicaid provisions of Chapter 5101:3-1 of the Administrative Code, including, but not limited to:

(a) The co-payment program set forth in rule 5101:3-1-09 of the Administrative Code; and

(b) Co-payments in managed care settings set forth in Chapter 5101:3-26 of the Administrative Code.

(2) AHCCs are limited to specific types of services and/or reimbursement codes as specified by provider type in rules 5101:3-13-01.1 to 5101:3-13-01.9 of the Administrative Code.

(3) Coverage limitations set forth in Chapter 5101:3-4 of the Administrative Code apply to AHCC services provided by physicians.

(4) Coverage limitations set forth in Chapter 5101:3-5 of the Administrative Code apply to AHCC services provided by dentists.

(5) Coverage limitations set forth in Chapter 5101:3-6 of the Administrative Code apply to AHCC services provided by opticians and optometrists.

(6) Coverage limitations set forth in Chapter 5101:3-7 of the Administrative Code apply to AHCC services provided by podiatrists.

(7) Coverage limitations set forth in rule 5101:3-8-23 of the Administrative Code also apply to advanced practice nurse services provided under the auspices of an AHCC.

(8) Take-home drugs must be billed through the pharmacy program as described in Chapter 5101:3-9 of the Administrative Code.

(9) Durable medical equipment (DME) for take-home use must be billed through the DME program as described in Chapter 5101:3-10 of the Administrative Code.

(10) Coverage limitations set forth in Chapter 5101:3-11 of the Administrative Code also apply to laboratory services provided by AHCCs.

(11) Coverage limitations set forth in rule 5101:3-8-05 of the Administrative Code apply to AHCCs providing psychology services.

(12) Coverage limitations set forth in Chapter 5101:3-14 of the Administrative Code apply to AHCCs providing services to individuals age birth to twenty-one years of age.

(13) Coverage limitations set forth in rules 5101:3-8-05 and 5101:3-4-29 of the Administrative Code also apply to mental health services provided under the auspices of an AHCC.

(14) Coverage limitations set forth in Chapters and 5101:3-15 of the Administrative Code apply to AHCCs providing transportation services.

(15) Coverage limitations set forth in Chapters 5101:3-17 and 5101:3-21 of the Administrative Code, regarding abortion and sterilization procedures, apply to AHCCs.

(16) Coverage limitations set forth in Chapter 5101:3-23 of the Administrative Code apply to AHCCs providing disability medical assistance medical program services.

(17) Coverage limitations set forth in Chapter 5101:3-26 of the Administrative Code apply to AHCCs with medicaid managed care program contracts. For consumers in the medicaid managed care program, claims submission requirements, including prior authorization requests for AHCC services, are specified in rules 5101:3-26-03.1 and 5101:3-26-05.1 of the Administrative Code.

(18) Coverage limitations set forth in Chapter 5101:3-34 of the Administrative Code also apply to therapy services provided under the auspices of an AHCC.

(F) The department reimburses fee-for-service AHCCs in accordance with rule 5101:3-1-60 of the Administrative Code.

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TO BE RESCINDED

5160-13-01.1 **Fee-for-service ambulatory health care clinics (AHCCs): primary care clinics.**

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

(A) Definitions.

(1) "Primary care clinic" is an AHCC that provides primary care services in one location. This type of clinic may be administered by a number of different types of agencies/organizations, including community action agencies, or independent and un-affiliated local agencies/foundations.

(2) "Primary care" is health care rendered by licensed health care providers delivering services within their scope of practice, who are specifically trained for and skilled in comprehensive first contact and continuing care for persons with any sign, symptom, or health concern not limited by problem origin, organ system, or diagnosis. Primary care includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses, appropriate medication management in a variety of health care settings and in coordination/collaboration with other health care professionals and systems (e.g., office, inpatient, critical care, long-term care, home care, day care, etc.).

(3) "Primary care physician" is a generalist physician who provides definitive care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient's care. Such a physician must be specifically trained to provide primary care services. Primary care physicians devote the majority of their practice to providing primary care services to a defined population of patients. The style of primary care practice is such that the personal primary care physician serves as the entry point for substantially all of the patient's medical and health care needs - not limited by problem origin, organ system, or diagnosis. Primary care physicians are advocates for the patient in coordinating the use of the entire health care system to benefit the patient.

(4) "Primary health care" is a method of health care delivery in which teams of providers are accountable for providing comprehensive services to their patients.

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care primary care 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;

(2) Meet the definition of a primary care clinic, in accordance with paragraph (A) of this rule; and

(3) Be certified or accredited by:

(a) The joint commission;

(b) The accreditation association for ambulatory health care (AAAHC);

(c) The healthcare facilities accreditation program of the American osteopathic association;

(d) The community health accreditation program (CHAP); or

(4) Receive state or federal grant funds for the provision of health services.

(C) A primary care clinic may provide all or some of the covered services identified in and provided in accordance with paragraph (D) of rule 5101:3-13-01 of the Administrative Code.

(1) If a primary care clinic does not provide a service, it must have a formal working arrangement with other medical providers for the services needed by the individual beyond the capability of the clinic.

(2) Primary care clinic services must be provided in accordance with the limitations identified in paragraph (E) of rule 5101:3-13-01 of the Administrative Code.

(D) Federally qualified health centers (FQHCs), rural health clinics (RHCs), and outpatient health facilities (OHFs) may submit claims as a primary care clinic only when billing for services that are not covered under the prospective payment system (PPS) base rate, in accordance with Chapters 5101:3-28, 5101:3-16, and 5101:3-29 of the Administrative Code. These services include:

(1) Inpatient hospital surgery;

(2) Inpatient hospital visits or consultations;

(3) Services provided to dual-eligibles when medicare cross-over claims for services are not paid through the automatic medicare crossover process in accordance with rule 5101:3-1-05 of the Administrative Code; and

(4) Services submitted as disability medical assistance claims.

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TO BE RESCINDED

5160-13-01.3 Fee-for-service ambulatory health care clinics (AHCCs): public health department clinics.

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

(A) Definitions.

(1) "Local health department" means a health department operated by the board of health of a city or general health district or the authority having the duties of a board of health under Chapter 3709. of the Revised Code.

(2) "Public health department," for the purposes of this chapter, has the same meaning as "local health department."

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care public health department 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;

(2) Have legal status as a county, city, or combined health district; and

(3) Meet the standards for boards of health and local health departments in accordance with Chapter 3709. and section 3701.342 of the Revised Code.

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TO BE RESCINDED

5160-13-01.4 **Fee-for-service ambulatory health care clinics (AHCCs): outpatient rehabilitation clinics.**

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

(A) Definitions.

(1) "Outpatient rehabilitation clinic" is defined in accordance with 42 C.F.R. 485.703 (10/01/2006). An outpatient rehabilitation clinic provides "basic rehabilitation services," including any or all of the following services: physical therapy, occupational therapy, speech-language pathology services, audiology services.

(2) "Comprehensive outpatient rehabilitation facility (CORF)" is defined in accordance with 42 C.F.R. 485.51 (10/01/2006). A CORF provides more rehabilitation services than physical therapy, occupational therapy, speech-language pathology (SLP) services, audiology services. A CORF might also provide services such as cardio/pulmonary rehab

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care outpatient rehabilitation 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:

(a) As either an outpatient rehabilitation clinic; or

(b) A CORF.

(3) Provide services in accordance with division level 5101:3 of the Administrative Code, including, but not limited to physical therapy, occupational therapy, and speech language pathology (SLP)/audiology services in accordance with Chapter 5101:3-34 of the Administrative Code.

(C) Coverage limitations set forth in Chapter 5101:3-33 of the Administrative Code also

apply to therapy services provided under the auspices of an AHCC.

Effective:

Five Year Review (FYR) Dates:

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Date

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TO BE RESCINDED

5160-13-01.5 **Fee-for-service ambulatory health care clinics (AHCCs): family planning clinics.**

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

(A) Definitions.

(1) "Family planning," in accordance with rule 5101:3-4-07 of the Administrative Code, is the means of enabling individuals of childbearing age, including minors who can be considered to be sexually active, to determine freely the number and spacing of their children.

(2) "Family planning clinics" are ambulatory health care clinics (AHCCs) whose primary function is to provide family planning services.

(3) "Family planning services" are defined in accordance with rule 5101:3-4-07 of the Administrative Code.

(4) "Qualified family planning provider (QFPP)" means any public or nonprofit health care provider that complies with federal guidelines/standards and receives funding for family planning services either under Title X of the Public Health Services Act or from the Ohio department of health.

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care family planning 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) Meet one or more of the following qualifications:

(a) Affiliation with the planned parenthood federation of America (PPFA);

(b) Receive a grant award for the provision of family planning services under Title X of the Public Health Services Act; or

(c) Receive a grant award through the Ohio department of health for family

planning services under the child and family health services program; and/or

(d) Receive a grant award through the Ohio department of health's women's health services, in accordance with rule 3701-68-01 of the Administrative Code.

(C) Covered services are family planning services, including medical, consultative, and educational services as specified in accordance with rule 5101:3-4-07 of the Administrative Code.

(D) Coverage limitations set forth in Chapter 5101:3-26 of the Administrative Code apply to AHCCs. Medicaid managed care plan members are permitted to self-refer to any qualified family planning provider (QFPP). In accordance with Chapter 5101:3-26 of the Administrative Code, medicaid managed care plans are responsible for payment of claims for family planning services delivered by non-contracting QFPPs at the lesser of one hundred per cent of the Ohio medicaid program fee-for-service reimbursement rate or billed charges in effect for the date of service.

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TO BE RESCINDED

5160-13-01.6 **Fee-for-service ambulatory health care clinics (AHCCs): professional optometry school clinics.**

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

(A) Any organization applying to be a medicaid fee-for-service ambulatory health care professional optometry school 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 a professional optometry school clinic accredited by the accreditation council on optometry education (ACOE) of the American optometric association.

(B) Covered services are optometry services specified in accordance with Chapter 5101:3-6 of the Administrative Code.

(C) In accordance with paragraph (A)(5)(a) of rule 5101:3-6-01 of the Administrative Code, AHCCs are eligible providers of vision services. Coverage limitations set forth in Chapter 5101:3-6 of the Administrative Code apply to AHCC services provided by opticians and optometrists.

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TO BE RESCINDED

5160-13-01.7 **Fee-for-service ambulatory health care clinics (AHCCs): professional dental school clinics.**

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

(A) Any organization applying to be a medicaid fee-for-service ambulatory health care professional dental school 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) Function as a training facility for a professional dental school clinic accredited by the commission on dental accreditation (CODA) of the American dental association (ADA).

(B) Covered services are covered dental services in accordance with Chapter 5101:3-5 of the Administrative Code.

(C) Limits.

(1) In accordance with rule 5101:3-5-01 of the Administrative Code, AHCCs are eligible providers of dental services. Coverage limitations set forth in Chapter 5101:3-5 of the Administrative Code apply to AHCC services provided by dentists.

(2) Individual dentists working within an ambulatory health care professional dental school clinic are not required to have provider numbers. The clinic must retain proof of legal authorization for each dentist without medicaid provider number to provide services.

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TO BE RESCINDED

5160-13-01.8 Fee-for-service ambulatory health care clinics (AHCCs): speech-language/audiology clinics and diagnostic imaging clinics.

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

(A) Definitions.

(1) "Diagnostic imaging," in accordance with rule 3701-83-51 of the Administrative Code, means the production of images used for medical diagnosis using magnetic resonance imaging (MRI), positron emission tomography (PET), computed tomography (CT), nuclear medicine. Diagnostic imaging does not mean the production of images used for medical diagnosis using diagnostic x-ray, mammography, or ultrasound.

(2) "Freestanding diagnostic imaging center," in accordance with rule 3701-83-51 of the Administrative Code, means a facility, or part of a facility, at which diagnostic imaging services are provided. A freestanding diagnostic imaging center does not include hospitals registered under section 3701.07 of the Revised Code

(3) "Mobile diagnostic imaging center," in accordance with paragraph (J) of rule 3701-83-51 of the Administrative Code, means any arrangement in which diagnostic imaging services are transported to various sites. A mobile diagnostic imaging center does not include movement within a hospital or movement to a site where the equipment will be located permanently and does not include the provision of diagnostic imaging by an entity that is reviewed as part of a hospital accreditation program.

(4) "Speech and hearing clinic" is an AHCC that provides speech, language, and audiology services designed to improve and restore the functioning of an individual.

(B) Any organization applying to be a medicaid fee-for-service ambulatory health care speech-language/audiology clinic or diagnostic imaging clinic 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;

(2) Specialize in either speech-language/audiology services or diagnostic imaging services;

(3) Not meet the requirements of any other AHCC type identified in Chapter 5101:3-13 of the Administrative Code;

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

(5) If providing diagnostic imaging services, be:

(a) A freestanding diagnostic imaging center; or

(b) A mobile diagnostic imaging center; and

(c) Licensed, registered, and credentialed in accordance with applicable, federal, state, and local laws.

(6) If providing speech and hearing services, deliver such services:

(a) In accordance with rule 5101:3-4-17 of the Administrative Code; and

(b) By professionals holding a certificate of clinical competence in speech-language pathology (CCC-SLP) and/or a certificate of clinical competence in audiology (CCC-A), issued by the American speech-language hearing association (ASHA).

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TO BE RESCINDED

5160-13-01.9 **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.

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
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5101:3-13-01.9

APPENDIX A

Revenue Center Codes (RCCs) for Composite Rates (CRs) must be used by Dialysis Facilities for Payment of ESRD Treatment Services (must use 837I or UB-92 with bill type 721)-

CRs for Dialysis Facility Payments:	RCCs for Hemodialysis:	RCCs for Intermittent Peritoneal Dialysis (IPD):	RCCs for Continuous Ambulatory Peritoneal Dialysis (CAPD):	RCCs for Continuous Cycling Peritoneal Dialysis (CCPD):
Maintenance Dialysis Treatment CR	0821; Limited to one per day and three per week	0831; Limited to one per day and three per week	0841; Limited to one per day and three per week	0851; Limited to one per day
Dialysis Support Services ("Method II") CR	0825; Limited to one per 30 days Does not include services, equipment, or supplies	0835; Limited to one per 30 days Does not include services, equipment, or supplies	0845; Limited to one per 30 days Does not include services, equipment, or supplies	0855; Limited to one per 30 days Does not include services, equipment, or supplies
Dialysis Treatment with Self-care Training CR	0829; Limited to 15 per 91 days	0839; Limited to 12 per 28 days	0849; Limited to 15	0859; Limited to 15
Services Not Included In Composite Rates for Dialysis Facilty Payments:	RCCs below require use of procedure codes:	RCCs below require use of procedure codes:	RCCs below require use of procedure codes:	RCCs below require use of procedure codes:
Specific Drug: Epoetin	0634	0634	0634	0634
Specific Drug: Epoetin	0635	0635	0635	0635
Specific Drug: Other	0636	0636	0636	0636
Specific Laboratory Services	0304, 0310	0304, 0310	0304, 0310	0304, 0310
Diagnostic Services	0730	0730	0730	0730

Equipment included in composite rates for Maintenance Dialysis Treatment and Dialysis Treatment with Self-care Training (Dialysis Support Services ("Method II") does not include equipment)-

artificial kidney
automated peritoneal dialysis machines
support equipment
installation, which includes: identification, ordering, performing of any minor plumbing and electrical changes required to accommodate the equipment (no rewiring or new plumbing installed); delivery and installation (hookup) and necessary testing for proper installation and function
Maintenance, which includes: travel to patients home to repair or transport of equipment to repair site; actual repair; parts;water purification equipment maintenance includes; replacing a filter on a reverse osmosis device; regenerating the resin tanks on deionizing device; chemicals in water softener; periodic water testing; (patient performed maintenance is not covered)

All durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis are included in composite rates for Maintenance Dialysis Treatment and Dialysis Treatment with Self-care Training (Dialysis Support Services ("Method II") does not include supplies)-

dializers
forcepts
sphygmanometer with cuff and stethoscope
scales
scissors
syringes
alcohol wipes
sterile drapes
needles
topical anesthetics
rubber gloves

Laboratory tests included in composite rates for Maintenance Dialysis Treatment, Dialysis Support Services ("Method II"), and Dialysis Treatment with Self-care Training-

Tests:	Hemodialysis	IPD	CAPD	CCPD
hematocrit (HCT)	once per date of service	once per date of service	no	once per date of service
hemoglobin (HGB)	once per date of service	once per date of service	no	once per date of service
clotting time	once per date of service	once per date of service	no	once per date of service
prothrombin time	once per 7 days/only if on anticoagulants	once per 7 days/only if on anticoagulants	no	once per 7 days/only if on anticoagulants
serum creatinine	once per 7 days	once per 7 days	once per 30 days	once per 7 days
blood urea nitrogen (BUN)	once per 7 days	once per 7 days	once per 30 days	once per 7 days
serum calcium	once per 30 days	once per 30 days	once per 30 days	once per 30 days
serum potassium	once per 30 days	once per 30 days	once per 30 days	once per 30 days
serum chloride	once per 30 days	once per 30 days	no	once per 30 days
serum albumin	once per 30 days	once per 30 days	once per 30 days	once per 30 days
serum bicarbonate	once per 30 days	once per 30 days	once per 30 days	once per 30 days
serum phosphorus	once per 30 days	once per 30 days	once per 30 days	once per 30 days
lactic acid dehydrogenase (LDH)	once per 30 days	once per 30 days	once per 30 days	once per 30 days
total protein	once per 30 days	once per 30 days	once per 30 days	once per 30 days
alkaline phosphatase	once per 30 days	once per 30 days	once per 30 days	once per 30 days
complete blood count (CBC)	once per 30 days	once per 30 days	no	once per 30 days
serum aspartate amino transferase/glutamic oxaloacetic transminase (AST/SGOT)	once per 30 days	once per 30 days	once per 30 days	once per 30 days

OR automated batery of tests (SMA 12)	once per 30 days	once per 30 days	once per 30 days	once per 30 days
dialysate protein	no	no	once per 30 days	no
sodium	no	no	once per 30 days	no
magnesium	no	no	once per 30 days	no
carbon dioxide	no	no	once per 30 days	no
WBC	no	no	once per 91 days	no
RBC	no	no	once per 91 days	no
platelet count	no	no	once per 91 days	no
24 hour uvrrf	no	no	once per 183 days	no

Pharmaceuticals (drugs) included in composite rates for Maintenance Dialysis Treatment, Dialysis Support Services ("Method II"), and Dialysis Treatment with Self-care Training-

heparin
glucose
saline
heparin antagonists antidotes
local anesthetics
mannitol
antiarrythmics
antihypertensives
pressor drugs
antihistimines
dextrose
protamine
hydralazine
benedryl
Inderal
Dopamine
leviphed
Insulin
Lanoxin
Verapamil
Lidocaine
Sou-cortef
Antibiotics