CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Services Rendered Under the Supervision of a Teaching Practitioner; Allergy Services

Rule Number(s):

SUBJECT TO BUSINESS IMPACT ANALYSIS:

5160-4-05 (To be rescinded), 5160-4-05 (New),

5160-4-19 (To be rescinded), 5160-4-19 (New)

Date: June 3, 2015

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- ☑ Rescinded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.

   Rule 5160-4-05, "Teaching physician services," sets forth provisions for coverage of and payment for services performed by residents and teaching physicians. This rule is being rescinded and replaced with a new rule of the same number titled "Services rendered under the supervision of a teaching practitioner." The new rule is streamlined, clarified, and updated, and unnecessary provisions are removed. In particular, detailed requirements concerning the supervision of certain services are omitted; instead, in recognition of the fact that supervision is determined by practice standards, a statement is added that teaching practitioner must provide the level of supervision appropriate to a procedure or service.

   Rule 5160-4-19, "Allergy services," sets forth coverage and payment provisions for allergy services. This rule is being rescinded and replaced with a new rule of the same number. The new rule is extensively streamlined; policy provisions address groups of service by type rather than individual procedures by code, and claim-submission instructions are removed. In particular, a provision is removed that disallowed payment for both a professional allergy testing service and an evaluation and management service (i.e., an office visit).

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

   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 existing teaching physician services rule (5160-4-05) reflects the documentation requirements articulated by the Centers for Medicaid and Medicare Services (CMS) in Section 15016 of the Medicare Carriers Manual (November 2002).

   The allergy services rule (5160-4-19) does not implement a federal requirement.

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

   These rules do not exceed federal requirements.

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 schedules or formulas for use by providers and the general public.

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

   Medicaid is updating these rules to comply with the five-year review requirement. An additional objective in revising rule 5160-4-19 was to allow separate payment for a nitric oxide allergy test performed on the same date as an evaluation and management service (i.e., an office visit).

   The success of rule 5160-4-19 will be measured by the extent to which eligible providers of allergy services can submit claims and receive payment for a nitric oxide allergy test performed on the same date as an office visit.

   The success of rule 5160-4-05 will be measured by the extent to which eligible teaching physicians can continue to submit claims and receive payment for services provided to Medicaid recipients.

Development of the Regulation

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.

   Drafts of these rules were shared with the Ohio State Medical Association (OSMA) via e-mail on November 25, 2014.

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

   ODM has not received any input from OSMA on the proposed rules. One provider has contacted ODM by phone to express support for the removal of the provision that disallowed payment for both a professional allergy testing service and an evaluation and management service (i.e., an office visit).

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?**

   Utilization and expenditure data drawn from ODM's Quality Decision Support System were used in projecting the fiscal impact of the proposed changes.

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?**

    Each Medicaid rule in the Ohio Administrative Code is specific to a particular subject or aspect of a subject. No other rules specifically address either services supervised by teaching practitioners or allergy services provided in non-institutional settings.

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 regulation 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. It is clear which rules apply to which type of provider and item or service; in this instance, there was no duplication.

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 policies set forth in these rules will be incorporated into the Medicaid Information Technology System (MITS) as of the effective date of the applicable rule. They will therefore be automatically and consistently applied by the department's electronic claim-payment system whenever an appropriate provider submits a claim for an applicable service.

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:

These rules affect physicians and other practitioners qualified to provide the relevant services.

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

Existing rule 5160-4-05 and existing rule 5160-4-19 require providers to maintain certain documentation in a patient's medical file. Existing rule 5160-4-19 also specifies that payment for certain laboratory tests can be made only to providers certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); CLIA certification is a federal requirement and amounts to a definition of what constitutes a clinical diagnostic laboratory. Both of these rules are being rescinded.

In new rule 5160-4-05, most documentation requirements are replaced by a general statement that responsibility for the accuracy of a patient's file falls to the teaching practitioner (rather than the resident). New rule 5160-4-05 does continue a documentation requirement that applies to a primary care center at which services are performed by a resident without the presence of a supervising practitioner-provider; an authorized administrator of the primary care center must confirm in writing and maintain documentation that the primary care center administers a residency program conforming to federal policy. Any primary care center that complies with federal standards will maintain supporting documentation as a matter of course; in this respect, no adverse impact can be attributed to the rule. On the other hand, supplying written confirmation of compliance is a Medicaid-specific requirement; the impact is limited, however, in that the rule does not indicate a need for confirmation more than once.

The only surviving documentation requirement in new rule 5160-4-19 specifies that there must be evidence of reasonable probability that the individual was exposed to the antigen being used for a particular allergy test. This requirement is consistent with professional standards. The provision requiring notation in the person's file is imposed for program integrity purposes.

c. Quantify the expected adverse impact from the regulation.

Supplying written confirmation that a primary care center complies with federal standards can be accomplished in four steps:

1. Printing on letterhead "This primary care center administers a residency program conforming to the Medicare teaching practitioner policy set forth in 42 C.F.R. 415.174 (October 1, 2014) in [applicable specialties: family practice, general internal medicine, pediatrics, obstetrics and gynecology, geriatric medicine]" or a similar statement
2. Affixing the director's signature
3. Scanning the signed copy
4. Uploading the scanned document

This process takes between ten and fifteen minutes to complete, an estimate based on the experience of ODM staff members who have drafted and sent many items of correspondence over the years. The wage cost depends on who performs the task. The median statewide hourly wage for an administrative assistant, according to Labor Market Information (LMI) data published by the Ohio Department of Job and Family Services, is $15.50; for an executive assistant, it is $21.95. Adding 30% for fringe benefits brings these figures to $20.15 and $28.54. So generating and sending a confirmation letter entails a one-time cost of between $3.36 (ten minutes at $20.15 per hour) and $7.14 (fifteen minutes at $28.54 per hour).

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

Documentation of services in a patient's file is standard medical practice. The cost of each instance of documentation is minimal.

The requirement stated in rule 5160-4-05 that a primary care center must attest to compliance with provisions in the Code of Federal Regulations enables ODM to identify an eligible service site without imposing unnecessary paperwork on either the site or the provider.

Regulatory Flexibility

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

No alternate means of compliance is available, and no exception can be made on the basis of an entity's 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?

These rules impose no sanctions on providers.

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

Information on the documentation requirements for medical records is readily available on the Centers for Medicare and Medicaid Services (CMS) website.

The Bureau of Provider Services renders technical assistance to providers through its hotline, (800) 686-1516.

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.

TO BE RESCINDED

5160-4-05 **Teaching physician services.**

(A) Definitions

(1) "Teaching physician" means a physician (other than a resident) who involves residents in the care of his/her patients.

(2) "Resident" means an individual who participates in an approved graduate medical education (GME) program. The term includes interns and fellows in approved GME programs. A medical student is never considered a resident.

(3) "Teaching setting" means any hospital-based provider setting that receives medicare or medicaid payment for the services of residents under the direct GME payment methodology.

(4) "Student" means an individual who is enrolled in an accredited medical school. A student is never considered to be an intern or a resident.

(5) "Documentation" means notes recorded in the patient's medical records by a resident or teaching physician.

(6) "Physically present" means that the teaching physician is in the same room (or partitioned or curtained area, if the room is subdivided to accommodate multiple patients) as the patient and/or performs a face-to-face service.

(7) "Critical or key portions" means that part(s) of a service that is/are a critical or key part of the service. For the purpose of this rule, the these terms are used interchangeably. Critical or key portions means the following:

(a) For anesthesia services, it is the part of the service described in paragraph (C)(2) of rule 5101:3-4-21 of the Administrative Code;

(b) For procedures, it means the parts of the service described in paragraphs (E)(1)(a) to (E)(1)(h) of this rule;

(c) For evaluation and management services, it means the key portion of the service as defined in paragraph (E)(2)(b) of this rule. This definition does not apply to the evaluation and management codes listed in

paragraph (E)(3)(b) of this rule; and

(d) If none of the guidelines in this paragraph apply, the teaching physician determines the critical or key portions of the service.

(8) "CPT or codes" as used in this rule is defined in rule 5101:3-1-19.3 of the Administrative Code.

(B) General reimbursement requirements

Payment may be made directly to the teaching physician for services performed in teaching settings only under the following circumstances:

(1) The covered services are personally performed by a physician who is not a resident in a teaching setting; or

(2) The covered services are provided in a teaching setting jointly by a teaching physician and resident or by a resident in the presence of a teaching physician with certain exceptions listed in paragraph (E)(3) of this rule.

(C) A teaching physician may not be directly reimbursed for direct medical and surgical services if the teaching hospital elects to receive payment for direct medical and surgical services on a reasonable cost basis (expensed on the hospital's cost report).

(D) Documentation

(1) For a teaching physician to be eligible for reimbursement for services, the patient's medical record must document that the requirements for reimbursement as detailed in this rule were met. Documentation may be dictated and typed, hand written, or computer-generated.

(2) The teaching physician must meet the documentation instructions for evaluation and management (E/M) services stated in section 15016 of the medicare carrier's manual (11/2002) including, but not limited to the following requirements:

(a) To be eligible for reimbursement for evaluation and management services, the teaching physician must personally document the following, at a minimum:

(i) A teaching physician performed the service or was physically

present during the key or critical portion of the service when performed by the resident;

(ii) Documentation by the resident of the participation and presence of the teaching physician is not sufficient to establish the presence and participation of the teaching physician in the service;

(iii) The participation of the teaching physician in the management of the patient; and

(iv) The combined entries in the medical record by the teaching physician and resident together must document the medical necessity of the service.

(b) Documentation must identify:

(i) The service(s) provided;

(ii) Whether the teaching physician was present during the critical or key portions of the service provided by a resident;

(iii) The participation of the teaching physician in providing the service;

(iv) The combined entries in the medical record by the teaching physician and resident together must document the medical necessity of the service.

(v) The date; and

(vi) A legible signature or identity alone.

(c) Any contribution and participation of a student to the performance of a billable service (other than review of systems and/or past family/social history that are not separately billable, but are taken as part of an E/M service) must be performed in the physical presence of a teaching physician or physical presence of a resident in a service meeting the requirement set forth in paragraph (B) of this rule.

Students may document services in the medical record. However, the documentation of an E/M service by a student that may be referred to by the teaching physician is limited to documentation related to the

review of systems and/or past family/social history. The teaching physician may not refer to a student's documentation of physical exam findings or medical decision making in his or her personal note. If the medical students documents E/M services, the teaching physician must verify and redocument the history of present illness and peform and redocument the physical exam and medical decision-making activities of the service.

(d) The following are examples of unacceptable documentation because the documentation does not make it possible to determine whether the teaching physician was present, evaluated the patient, and/or had any involvement with the plan of care:

(i) "Agree with above," followed by legible countersignature or identity;

(ii) "Rounded, Reviewed, Agree," followed by legible countersignature or identity;

(iii) "Discussed with resident. Agree," followed by legible countersignature or identity;

(iv) "Seen and agree," followed by legible countersignature or identity;

(v) "Patient seen and evaluated," followed by legible countersignature or identity; and

(vi) A legible countersignature or identity alone.

(E) Special situations

Payment will be made for the services of a teaching physician only if the teaching physician is personally present during all critical or key portion(s) of the service.

(1) Procedures

(a) Surgery

The teaching physician must be present during all critical or key portions of the procedure and must be immediately available to provide services during the entire procedure. The teaching physician is not

required to be present during the opening and closing of the surgical area. During the periods of the surgery that are not key portions, the teaching physician must be immediately available to return to the procedure. He/she must not be involved in another procedure from which he/she cannot return.

Documentation of the teaching physician's presence during a surgery must be documented in the medical record by the physician, resident, or operating room nurse.

In order to bill for two overlapping surgeries, the teaching physician must be present during all critical and key portions of both operations. Therefore, the critical or key portions may not take place at the same time. When all of the critical or key portions of the initial procedure have been completed, the teaching physician may begin to become involved in a second procedure. The teaching physician must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures. The teaching physician may not bill for three or more concurrent surgical procedures. These are classified as a supervisory service to an individual patient and are not payable under the physician fee schedule.

(b) Minor procedures

For procedures that take five minutes or less, the teaching physician must be present for the entire procedure to be considered reimbursable procedures by the department.

(c) Endoscopy procedures

To be considered a reimbursable endoscopy procedure, the teaching physician must be present during the entire viewing including the insertion and removal of the device.

(d) Complex or high-risk procedures

For complex or high-risk procedures such as cardiac catheterization, cardiovascular stress tests, radiologic and cardiologic supervision, and interpretation codes, the teaching physician must be physically present with the resident and must supervise the performance of the procedure or he/she must personally perform the procedure.

(e) Maternity services

In order to be considered a reimbursable service the teaching physician must be present for the delivery. The teaching physician must be physically present for the initial prenatal visit. The teaching physician must also be present during any and all prenatal visits during which there are patient complaints requiring more detailed evaluation, abnormal findings, the need for non-routine testing (e.g. non-routine ultrasonography, fetal monitoring, non stress testing, etc.), or for post date equal to or greater than forty-two week gestation.

(f) Time-based codes

For procedure codes determined on the basis of time, the teaching physician must be present for the period of time for which the claim is made. For example, a code that specifically describes a service from twenty to thirty minutes should only be billed if the teaching physician is present for twenty to thirty minutes. Time spent by the resident in the absence of the teaching physician should not be added to time spent by the resident and teaching physician with the patient or time spent by the teaching physician alone with the patient.

(g) Interpretation of diagnostic radiology and other diagnostic tests

The department will reimburse for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by or reviewed by a teaching physician.

(h) Psychiatry

Time-based psychiatry codes must meet the requirements in paragraph (E)(1)(f) of this rule. A teaching physician may not add time spent by a resident in the absence of the teaching physician to the total amount of time billed for the service.

For certain psychiatric services, the presence of the teaching physician may be met by concurrent observation of the service through the use of a one-way mirror or video equipment. Audio-only equipment does not satisfy the physical presences of the teaching physician.

(i) Anesthesia

The department will reimburse for anesthesia services as outlined in rule 5101:3-4-21 of the Administrative Code for a teaching anesthesiologist involved in an anesthesia procedure with a resident. The teaching physician must document in the medical records that

he/she was present during all critical or key portions of the procedure. The teaching physician's physical presence during only the preoperative or post-operative visits with the patient is not sufficient to receive reimbursement.

(j) Assistants at surgery furnished at teaching hospitals

The department will not reimburse for an assistant at surgery in a teaching hospital when a resident qualified to perform the service is available to assist at surgery.

(2) Evaluation and management services

(a) The "documentation guidelines for evaluation and management services" published by the American medical association in the CPT book must be the basis for the selection of the most appropriate level of evaluation and management service.

(b) The teaching physician must be physically present during the medical decision making process.

(c) The teaching physician must personally document his/her presence and participation in the service in the medical records as described in paragraph (D) of this rule.

(d) For evaluation and management services and other services based on time, the teaching physician must be physically present for the entire period of time billed. Time spent by the resident in the absence of the teaching physician is not billable. Examples of codes falling in this category include, but are not limited to, individual psychotherapy codes, critical care services, inpatient neonatal and pediatric critical care services, and evaluation and management codes in which counseling and/or coordination of care is more than fifty per cent of the encounter and time is considered the controlling factor to qualify for that specific code.

(3) Evaluation and management services furnished at primary care centers

(a) The following primary care residency programs qualify for an exception to the teaching physician policies described in paragraph (E)(2) of this rule if the programs attest in writing that they meet all of the conditions in medicare's teaching physician policy as described in 42 C.F.R.

415.174 (10/1/2005). The primary care centers exercising the primary care exception must maintain records demonstrating that they qualify for the exception. Prior approval by the department is not required. The provider must make available a copy of this attestation to the department upon request.

(i) Family practice;

(ii) General internal medicine;

(iii) Pediatrics;

(iv) Obstetrics/gynecology; and

(v) Geriatric medicine.

(b) Payment may be made for the services of teaching physicians provided by residents without the presence of a teaching physician provided that all of the requirements listed in 42 C.F.R. 415.174 10/1/05 are met. The following lower and mid-level evaluation and management codes may be billed under this exception when provided at a primary care center:

(i) New patient office or other outpatient codes including 99201 to 99203;

(ii) Established office or other outpatient visit codes including 99211 to 99213;

(iii) New patient preventive medicine visits codes including 99381 to 99384;

(iv) Established patient preventive medicine visits including 99391 to 99394; and

(v) Prenatal services billed with the TH modifier and codes 99201 to 99203 or 99211 to 99213 except for those listed in paragraph (E)(1)(e) of this rule.

(c) The services must be furnished in a primary care center located in a hospital outpatient department or another ambulatory care entity in which the time spent by residents in patient care duties is included in

the GME payment made to a teaching hospital or hospital's fiscal agent.

(d) When a resident is assigned to a physician's office away from the hospital or primary care center where he/she is assigned or is making home visits, the primary care center exception does not apply and teaching physician services are not billable. In this situation, the physician's office where the resident is assigned should bill for services provided.

(F) Modifiers

To bill for services provided by a teaching physician that meet all the provisions of this rule, the following modifiers must be used to bill for services:

(1) To bill for services performed in part by a resident under the direction of a teaching physician, use modifier "GC."

(2) To bill for services performed by a resident without the presence of a teaching physician under the primary care exception rule described in paragraph (E)(3) of this rule, use modifier "GE."

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:	04/07/1977, 12/21/1977, 12/30/1977, 07/01/1980, 10/01/1987, 09/01/1989, 01/01/2001, 09/01/2005, 02/12/2006

5160-4-05 **Services rendered under the supervision of a teaching practitioner.**

(A) Definitions.

(1) "Resident" is an individual who participates in an approved graduate medical education (GME) program. The term includes both interns and fellows, but it excludes medical students enrolled at the undergraduate level.

(2) "Teaching practitioner" is a practitioner, other than a resident, who involves residents for pedagogical reasons in the care of the practitioner's patients.

(B) Coverage. Payment may be made to a teaching practitioner for services performed individually by a resident under supervision or jointly by the teaching practitioner and a resident. The following provisions apply:

(1) The teaching practitioner must provide the level of supervision appropriate to the procedure or service.

(2) The teaching practitioner need not be physically present when a resident performs a service if both of the following conditions are met:

(a) The resident provides one of the following low- or mid-level evaluation and management (E&M) services:

(i) Office or other outpatient visit, new patient;

(ii) Office or other outpatient visit, established patient;

(iii) Preventive medicine visit, new patient;

(iv) Preventive medicine visit, established patient; or

(v) E&M service reported as a prenatal visit; and

(b) The service is provided in a primary care center for which the following criteria are satisfied:

(i) The primary care center is located in a hospital outpatient department or other ambulatory care entity that receives GME payment for the time spent by residents in patient care duties; and

(ii) An authorized administrator attests in writing and maintains supporting documentation that the primary care center administers a residency program conforming to the medicare

teaching practitioner policy set forth in 42 C.F.R. 415.174 (October 1, 2014) in at least one of the following specialties:

(a) Family practice;

(b) General internal medicine;

(c) Pediatrics;

(d) Obstetrics and gynecology; or

(e) Geriatric medicine.

(C) Limitation. No payment is made to a teaching practitioner for services rendered by a resident practicing outside a primary care center without the presence of the teaching practitioner.

(D) Accountability. The teaching practitioner assumes responsibility for the accuracy of the patient's medical file.

Replaces: 5160-4-05

Effective:

Five Year Review (FYR) Dates:

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Certification

_____

Date

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TO BE RESCINDED

5160-4-19 **Allergy services.**

(A) Allergy testing.

(1) Providers of physician services may be reimbursed for the performance and evaluation of allergy sensitivity tests as set forth in appendix DD to rule 5101:3-1-60 of the Administrative Code.

(a) A complete medical and immunologic history and physical examination must be done prior to performing diagnostic testing and be made available to the department upon request; and

(b) The testing must be performed based on the medical and immunologic history and physical examination that documents that the antigen being used for the testing exists within a reasonable probability of exposure in the patient's environment and be documented in the patient's medical record; and

(c) Based on the information in the medical record, the testing must be limited to the minimal number of necessary tests to reach a diagnosis.

(2) The appropriate use of professional and technical modifiers and relevant place of service restrictions are set forth in rule 5101:3-4-11 of Administrative Code.

(3) Physician professional services associated with allergy testing are bundled into the code for evaluation and management services (visit).

(4) Percutaneous tests, intracutaneous/intradermal tests, photo patch tests, and patch tests, photo tests, or application tests are reimbursed on a per test basis. When billing, the provider must specify the number of tests performed.

(5) Quantitative or semi-quantitative in vitro allergen specific IgE tests (formerly referred to a RAST tests) are covered if skin testing is not possible or not reliable and they are performed by providers certified under the "Clinical Laboratory Improvement Amendment of 1988" (CLIA '88) to perform the tests and billed in accordance with Chapter 5101:3-11 of the Administrative Code.

(6) The qualitative multiallergen screen for allergen specific IgE, CPT code 86005, is not covered since it is not considered medically necessary.

(7) Ophthalmic mucous membrane tests and direct nasal mucous membrane tests are allowed only when skin testing cannot test allergens.

(8) Ingestion challenge tests are allowed once per patient encounter regardless of the number of items tested. Ingestion challenge tests include the evaluation of the patient's response to the test items.

(B) Allergen immunotherapy.

(1) "Allergen immunotherapy" is the provision of and parenteral administration of allergenic extracts as antigens at periodic intervals, usually on an increasing dosage scale to a dosage that is maintained as maintenance therapy.

(2) Providers may be reimbursed for the professional services necessary for allergen immunotherapy. Coverage and reimbursement of allergen immunotherapy is set forth in rule 5101:3-4-11 of the Administrative Code.

(3) The patient's medical record must document that allergen immunotherapy was determined by appropriate diagnostic procedures coordinated with clinical judgment and knowledge of the natural history of allergic diseases. Documentation must be made available to the department upon request.

(4) An office visit may be billed in addition to the allergen immunotherapy codes (95115, 95117, 95144-95180) only if other identifiable services are provided at that time. If an office visit code is billed with an allergen immunotherapy service, the modifier 25 must be used.

(5) Allergen immunotherapy will not be covered for the following antigens: newsprint, tobacco smoke, dandelion, orris root, phenol, formalin, alcohol, sugar, yeast, grain mill dust, goldenrod, pyrethrum, marigold, soybean dust, honeysuckle, wool, fiberglass, green tea, or chalk since they are not considered medically necessary.

(6) The department recognizes two components of allergen immunotherapy, one being the administration (injection) of the antigen, which includes all professional services associated with the administration of the antigen, and the other being the antigen itself. These two components must be billed separately, regardless of whether or not the provider who prescribes and

provides the antigen is the same as the provider who administers the antigen.

(a) Injections.

For reimbursement for the administration (injection) of allergenic extract or stinging insect venom, the provider must bill CPT code 95115 or 95117. The allergenic extract may be administered by the physician or by a properly instructed employee under the general supervision of the physician in an office setting. These codes may not be billed with CPT code 95144.

(b) Antigens (excluding stinging insect venoms).

(i) When the provider prescribes and provides single or multiple antigens for allergen immunotherapy in multiple-dose vials (i.e., vials containing two or more doses of antigens), the provider must bill CPT code 95165 in the procedure/service code block and the number of doses contained in the vial in the unit(s) block on the invoice. If the provider dispenses two or more multiple-dose vials of antigen, for each vial dispensed CPT code 95165 must be billed on a separate line along with the corresponding number of doses.

For example, if a patient cannot be treated with immunotherapy by placing all antigens in one vial and two multidose vials containing ten doses each must be dispensed, the CPT code 95165 must be billed on two separate lines and a "10" (for ten doses) must be entered for the corresponding units.

(ii) CPT code 95144, the single dose vial antigen preparation code, must not be billed as one of the components of a complete service performed by a provider. The code must be billed only if the provider providing the antigen is providing it to be injected by some other entity. The number of vials prepared must be indicated.

(iii) The department does not recognize CPT codes 95120 through 95134 because they represent complete services, i.e., services that include both the injection service as well as the antigen and its preparation. Only component billing will be allowed. Providers providing both components of the service must do component billing. The provider must, as appropriate, bill one of the injection CPT codes (95115 or 95117) and one of the antigen/antigen preparation CPT codes (95145 through 95149, 95165, or 95170).

The number of doses must be specified.

(c) Insect venoms in single dose vials or preparations.

(i) If the provider administers the venom(s), CPT code 95115 or 95117 must be billed for the injection(s) of the antigen(s).

(ii) When a provider prescribes and/or provides stinging insect venom antigens in single dose vials or preparations, CPT codes 95145 to 95149 must be billed.

(a) For each single dose vial or preparation provided, a unit of service of "1" must be reported.

(b) If the provider also administers the venom, CPT code 95115 or 95117 must be billed for the injection(s).

(iii) For any single dose vial or preparation of stinging insect venoms, the provider must use CPT codes 95145 to 95149 with a unit of service of "1" for each single dose vial/preparation provided.

(d) Insect venoms in multiple dose vials or preparations.

(i) When a provider prescribes and provides single or multiple stinging insect venom(s) in multiple dose vials, CPT codes 95145 to 95149 must be billed. The number reported as the unit of service must represent the total number of doses contained in the vial.

(ii) Regardless of the number of doses, the date of service reported should be:

(a) The date the vial is dispensed to the patient, if the patient takes the vial home to be administered elsewhere or at another time; or

(b) The date that the first dose is administered to the patient, if the vial is kept in the physician's office.

(iii) If the provider also administers the venom, CPT code 95115 or 95117 must be billed for the single or multiple injection(s). The correct quantity billed is one for either code.

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
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5160-4-19 **Allergy services.**

(A) Purpose. This rule addresses payment for the professional administration and evaluation of allergy sensitivity test procedures, which can be divided into three categories: allergy testing, ingestion challenge testing, and allergen immunotherapy. Payment for related laboratory tests is addressed in Chapter 5160-11 of the Administrative Code.

(B) Coverage.

(1) Allergy testing.

(a) There must be a reasonable probability, documented in the individual's medical file, that the individual was exposed to the antigen being used for the test.

(b) The unit of service is the test. Payment may be made only for the fewest number of tests necessary to reach a diagnosis.

(c) Payment includes all associated professional services. No payment is made for evaluation and management unless a separately identifiable service is performed.

(d) Payment may be made for a quantitative or semi-quantitative in vitro allergen-specific immunoglobulin E (IgE) blood test, an ophthalmic mucous membrane test, or a direct nasal mucous membrane test only when skin testing is not possible or not reliable. A qualitative multiallergen screen for allergen-specific IgE, however, is not considered to be medically necessary.

(2) Ingestion challenge testing.

(a) The unit of service is the encounter. Payment may be made only once per visit regardless of the number of items tested.

(b) Payment includes the evaluation of the individual's response to the test items.

(3) Allergen immunotherapy.

(a) Payment includes all associated professional services. No payment is made for evaluation and management unless a separately identifiable service is performed.

(b) Payment for the antigen is made separately. No payment will be made for

a service that includes administration (injection) as well as the antigen and its preparation.

(c) The unit of service is the dose-per-vial.

(d) Payment may be made for antigen preparation only if the provider prepares antigen for injection by another entity.

(e) The date of service is the date on which the first dose is administered or the date on which the vial is dispensed for future use.

(f) Immunotherapy is not considered to be medically necessary for the following antigens: newsprint, tobacco smoke, orris root, phenol, formalin, alcohol, sugar, yeast, grain mill dust, goldenrod, pyrethrum, marigold, soybean dust, honeysuckle, wool, fiberglass, green tea, and chalk.

Replaces: 5160-4-19

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