CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department Of Medicaid

Regulation/Package Title: Podiatric Services

Rule Number(s): To be amended: Rules 5160-7-01, 5160-7-02 and 5160-7-04.

Included for information only: 5160-7-03.

Date: June 24, 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- ☐ Rescinded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.

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.

   Medicaid rules 5160-7-01, 5160-7-02, 5160-7-03 and 5160-7-04 are being filed in accordance with mandatory five year rule review.

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Rule 5160-7-01, "Eligible providers of podiatric services," provides guidance in regards to provider types authorized to bill for podiatric services reimbursed by the Ohio Medicaid program. This rule is amended to comply with mandatory five year rule review. A change was made to update the department's name.

Rule 5160-7-02, "Podiatric medicine: scope of coverage," details acceptable podiatry procedures that are authorized to be performed and billed to the Ohio Medicaid program by podiatry physicians. This rule is amended to comply with mandatory five-year rule review. Changes include updating rule language and OAC references.

Rule 5160- 7-03, "Covered podiatric services and associated limitations," defines specific podiatry codes and examinations which are eligible for reimbursement by the Ohio Medicaid program. This rule is amended to comply with mandatory five-year rule review. Changes include payment for additional evaluation and management services when provided by a podiatrist and updating rule language and OAC references.

The additional evaluation and management services payable when provided by a podiatrist are for services which require medical decision making of moderate complexity: 99204, 99214, 99343, 99344 and 99349.

Rule 5160-7-04, "Podiatric Medicine: non-covered services," details examinations and procedures that are not covered by the Ohio Medicaid program. This rule is amended to comply with mandatory five-year rule review. Changes include updating rule language and OAC references.

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.

   No.

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 formulas or fee schedules for the use of providers and the general public.

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

   The success of these rules will be measured by the extent to which operational updates to the Medicaid Information Technology System (MITS) result in the correct payment of claims.

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.

   ODM and Ohio Foot and Ankle Medical Association (OFAMA) began discussion of Medicaid rules and coverage in February 2014. Between April and September 2014, ODM and an OFAMA workgroup met in person and by telephone several times to review current Medicaid rules and to discuss possible changes to podiatric covered services. The State Medical Board of Ohio, which licenses podiatrists also provided input on the proposed rules.

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

   As a result of its meetings with ODM, OFAMA recommended that ODM add a number of medical procedures and evaluation and management services to those covered when provided by a podiatrist including those covered services being added through this rule amendment. ODM agreed to add these additional covered services. The recommendations that did not require a rule change were implemented by ODM in late 2014. The recommendations that require OAC rule changes are being implemented through these proposed rules.

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?**

    These rules involve the coverage of and payment for podiatric procedures. Whatever the policy may be, the form of the rule is the same; no alternative is readily apparent.

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 rule-making does not apply to these items and 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 ODM'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;**
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
    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. Changes to these rules affect podiatrists and other eligible Medicaid providers of podiatric services, such as fee-for-service and cost based clinics.

b. These rules impose no license fees or fines. The existing rules and new rules indicate that no eligible provider may receive payment without a valid Medicaid provider agreement. Both the existing rules and new rules specify that participating practitioners must hold a current license and, as appropriate, maintain documentation that the services were provided and the medical necessity of the services.

c. The adverse impact lies in the time needed to complete documentation of medical necessity and the services provided. Completing documentation of medical necessity and the services provided whether or not a prior authorization request is required takes between five and thirty minutes of provider staff time. This estimate is based on the personal experience of practicing podiatrists, including the ODM medical technical advisor (MTA). The wage cost depends on who performs the task. The median statewide hourly wage for a billing clerk, according to Labor Market Information (LMI) data published by the Ohio Department of Job and Family Services, is $16.10; for a podiatrist, it is $58.03. Adding 30% for fringe benefits brings these figures to $20.96 and $75.43. So generating a necessary document costs between $1.76 (five minutes at $20.96 per hour) and $37.71 (thirty minutes at $75.43 per hour).

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

The documentation requirements spelled out in these rules are an effective tool for preventing fraud, waste, and abuse and for promoting quality and cost-effectiveness; they help to ensure that the Ohio Medicaid program pays for podiatry services that are most appropriate to the needs of the person who will receive them. Furthermore, the documentation of medical necessity and the services provided helps to substantiate the appropriateness of the services rendered to Medicaid-eligible individuals. These requirements are consistent with professional standards, and are imposed for program integrity purposes.

Regulatory Flexibility

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

These rules outline actions all providers must take in order to receive Medicaid payment. They do not set forth requirements for engaging in business, and no exception is 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?

Providers that submit claims through an electronic clearinghouse (a "trading partner") can generally rely on the clearinghouse to know current Medicaid claim-submission procedures.

Information sheets and instruction manuals on various claim-related topics are readily available on the Medicaid website.

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.

5160-7-01 **Eligible providers of podiatric services.**

(A) Definitions.

(1) A doctor of podiatric medicine is included within the definition of "physician" but only in respect to functions he or she is legally authorized to perform as defined in section 4731.51 of the Revised Code.

(2) "Podiatric physician" means an individual currently licensed under state of Ohio law or another state's law to practice podiatry.

(3) Interns and residents of podiatric medicine are explicitly excluded from the definition of "podiatric physician" and are covered as part of hospital services. This exclusion applies whether or not the intern or resident may be authorized to practice as a podiatric physician under the laws of the state in which services are performed. Residents having a staff or faculty appointment or designated as a fellow are also excluded from the definition of podiatric physician.

(4) "Podiatric group practice" means a professional association organized under Chapter 1785. of the Revised Code for the purpose of providing podiatric services.

(B) All podiatric physicians currently licensed to practice podiatry under sections 4731.51 to 4731.61 of the Revised Code are eligible to participate in Ohio's medicaid program and provide podiatric medicine services upon execution of an Ohio medicaid provider agreement.

(C) A professional association (podiatric medicine group practice) is considered eligible to participate in Ohio's medicaid program if it is an association organized under Chapter 1785. of the Revised Code for the purpose of providing podiatric medicine services.

(D) Podiatric physicians licensed under another state law to practice medicine and surgery are eligible to participate in Ohio's medicaid program and provide covered podiatric medicine services as long as:

(1) The services are rendered to eligible Ohio consumers in the state in which the provider is licensed to practice; and

(2) The provider of podiatric medicine services has a current valid provider agreement with the Ohio department of ~~job and family services (ODJFS)~~ medicaid (ODM).

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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Prior Effective Dates:	4/7/77, 12/30/77, 5/9/86, 2/1/90, 8/15/05, 11/4/10

5160-7-02 **Podiatric medicine: scope of coverage.**

(A) Podiatric physicians may ~~perform~~ receive medicaid payment for covered services (as defined in Chapter ~~5101:3-7~~ 5160-7 of the Administrative Code) which consist of the medical, mechanical and surgical treatment of ailments of the foot, the muscles and tendons of the leg governing the foot, and superficial lesions of the hand other than those associated with trauma. The podiatric physician may also ~~treat~~ receive medicaid payment for treatment of the local manifestation of systemic disease as they appear in the hand and foot, but the ~~consumer~~ individual must be concurrently referred to an eligible prescriber for treatment of the systemic disease itself.

(B) Podiatric medicine services provided by non-physicians under the direct and general supervision of a podiatric physician are covered in accordance with rule ~~5101:3-4-02~~ 5160-4-02 of the Administrative Code.

(C) Hospital-based podiatric physicians and surgeons are covered in accordance with rule ~~5101:3-4-01~~ 5160-4-01 of the Administrative Code.

(D) Podiatric medicine services provided in a teaching setting are covered as set forth in ~~paragraphs (A) to (D)(2), (E)(1) and (F) of rule 5101:3-4-05~~ rule 5160-4-05 of the Administrative Code.

(E) Podiatric medicine services provided in a long-term care setting are covered as detailed in ~~rule~~ rules ~~5101:3-3-19~~ 5160-3-19 and 5123:2-7-11 of the Administrative Code.

(F) Podiatric medicine services provided by a physician assistant are covered in accordance with rule ~~5101:3-4-03~~ 5160-4-03 of the Administrative Code.

(G) By report services are covered in accordance with rule ~~5101:3-4-02.1~~ 5160-4-02.1 of the Administrative Code. For these services, a provider must submit ~~In addition,~~ a report ~~must be provided~~ documenting the following:

(1) Complete description of the services or procedures;

(2) Diagnosis, both preoperative and postoperative;

(3) Size, location, and number of lesions;

(4) Indication of primary, secondary, or tertiary procedure;

(5) The nearest similar current procedural terminology (CPT) code whenever possible;

(6) Estimated number of visits for follow-up; and

(7) Operative time.

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5160-7-03 **Covered podiatric services and associated limitations.**

(A) Visit limitations.

(1) Visits are covered in accordance with rules ~~5101:3-3-19~~ 5160-3-19, 5123:2-7-11 and ~~rule 5101:3-4-06~~ 5160-4-06 of the Administrative Code.

(2) In addition, the following limitations apply:

(a) ~~Reimbursable~~ Payment for evaluation and management services shall be limited to the following ~~CPT codes~~ services:

(i) Office or other outpatient visit, requiring medical decision making of straightforward, low or moderate complexity;

(ii) Hospital inpatient services, requiring medical decision making of straightforward, low or moderate complexity;

(iii) Hospital discharge services, 30 minutes or less;

(iv) Office or outpatient consultations, requiring medical decision making of straightforward or low complexity;

(v) Inpatient consultations, requiring medical decision making of straightforward or low complexity;

(vi) Nursing facility services, initial or subsequent care, requiring medical decision making of straightforward, low, moderate or high complexity;

(vii) Domiciliary, rest home (eg. boarding home) or custodial care services, requiring medical decision making of straightforward, low, moderate or high complexity; and

(viii) Home services, requiring medical decision making of straightforward, low or moderate complexity; and

~~99201 to 99203~~

~~99211 to 99213~~

~~99221 to 99222~~

~~99231 to 99232~~

~~99238~~

~~99241 to 99243~~

~~99251 to 99253~~

~~99304 to 99328~~

~~99341 to 99342~~

~~99347 to 99348~~

(b) ~~Reimbursement~~ Payment by the department is limited to one long term care facility (LTCF) visit per month.

(B) Therapeutic injections and prescribed drugs are covered in accordance with rule ~~5101:3-4-13~~ 5160-4-12 of the Administrative Code. In addition, vitamin B-12 injections for strengthening tendons, ligaments, or other components of the foot are not covered.

(C) Surgeries.

(1) Surgeries are covered in accordance with rules ~~5101:3-4-09, 5101:3-4-22~~ 5160-4-22 and ~~5101:3-4-23~~ 5160-4-23 of the Administrative Code.

(2) In addition, the following limitation applies: reimbursement for debridement of nails is limited to a maximum of one treatment within a sixty-day period.

(D) Laboratory services are covered in accordance with Chapters ~~5101:3-4~~ 5160-4 , 5160-3 , 5160-11 and ~~5101:3-11~~ 5123:2-7 of the Administrative Code.

(E) Radiology services.

(1) Radiology services are covered in accordance with Chapters ~~5101:3-4~~ 5160-4 and ~~5101:3-11~~ 5160-11 of the Administrative Code.

(2) In addition, the following radiology services are not covered as podiatric medicine services:

(a) Bilateral x-rays when only a unilateral condition or surgery is reported, unless documented as medically indicated;

(b) X-rays in excess of three views unless the necessity due to trauma or infection is fully documented;

(c) X-rays for soft tissues unless for reasons of infections which is fully documented;

(d) Postoperative x-rays unless there is bone involvement necessitating the surgical procedure or cases of suspected postoperative infections; and

(e) The use of x-rays or radium for therapeutic purposes.

(F) Physical medicine services.

(1) Physical medicine services are covered in accordance with Chapter ~~5101:3-8~~ 5160-8 of the Administrative Code.

(2) In addition, the following limitations apply:

(a) Reimbursement for physical medicine services provided within the scope of practice of podiatric medicine and surgery as specified in the Revised Code is limited to acute conditions only. For those recipients in which the disease has reached a chronic stage, reimbursement will be made only for the periods of acute exacerbation of the disease.

(b) Range of motion studies may not be billed separately from an examination of the foot, unless substantiated by a complete report.

(G) Medical supplies and durable medical equipment (DME).

(1) A podiatric physician may not be separately reimbursed for medical supplies and equipment (e.g., tape, dressing, or surgical trays) utilized in podiatrist's office, clinic, or patient's home during a podiatric visit.

(2) A podiatric physician may be reimbursed for medical supplies and medical equipment dispensed in the podiatric physician's office, clinic or patient's home for use in the patient's home, if the podiatric physician has a "supplies and medical equipment" category of service.

(3) The scope and extent of coverage for medical supplies and durable medical equipment, including orthopedic shoes and foot orthoses, are covered in

Chapters ~~5101:3-4~~ 5160-4 and ~~5101:3-10~~ 5160-10 of the Administrative Code.

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5160-7-04 **Podiatric medicine: noncovered services.**

(A) The following services are noncovered:

(1) All services exceeding the policies and limitations defined in Chapters ~~5101:3-4~~ 5160-4 and ~~5101:3-7~~ 5160-7 of the Administrative Code.

(2) Services determined by the department as not medically necessary as defined in Chapter ~~5101:3-1~~ 5160-1 of the Administrative Code.

~~(3) Services of a preventive nature.~~

(B) In addition, the following services are noncovered, unless ~~a consumer~~ an individual has a localized infection or is under the care of an eligible prescriber for a metabolic disease such as diabetes mellitus, or another condition that may result in a circulatory impairment or desensitization in the legs or feet:

(1) Examinations and diagnostic services associated with routine foot care performed in the absence of a localized illness, symptoms or injury;

(2) Cutting or removal of corns and calluses;

(3) Nail trimming, cutting or clipping of nails not associated with nail surgery, unless a systemic condition is present such as metabolic, neurologic, or peripheral vascular disease that may require scrupulous foot care by ~~a professional~~ an eligible prescriber;

(4) Foot care provided for hygienic services;

(5) The treatment of uncomplicated, chronic foot conditions such as flat feet or a sublaxated structure in the foot; and

(6) Treatment of mycotic nails for an ambulatory and nonambulatory ~~consumer~~ individual unless the eligible prescriber attending the patient's mycotic condition documents that:

(a) There is clinical evidence of onychomycosis of the toenail; and

(b) The ~~consumer~~ individual has mycosis/dystrophy of the toenail causing secondary infection and/or pain that results or would result in marked

limitation of ambulation and require the professional skills of a podiatrist podiatric physician.

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