

Common Sense Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Carrie Kuruc, Director

Business Impact Analysis

Agency, Board, or Commission Name: <u>Ohio Department of Medicaid (ODM)</u>
Rule Contact Name and Contact Information:
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Regulation/Package Title (a general description of the rules' substantive content):
Podiatry services
Rule Number(s):
SUBJECT TO BUSINESS IMPACT ANALYSIS:
<u>5160-7-01 (To be rescinded). 5160-7-02 (To be rescinded).</u>
NOT SUBJECT TO BUSINESS IMPACT ANALYSIS, INCLUDED FOR INFORMATION ONLY:
<u>5160-7-01 (New). 5160-7-03 (To be rescinded). 5160-7-04 (To be rescinded).</u>
Date of Submission for CSI Review: <u>08/21/2020</u>
Public Comment Period End Date: <u>08/28/2020</u>
Rule Type/Number of Rules:
New/_1_rules No Change/rules (FYR?)
Amended/rules (FYR?) Rescinded/rules (FYR?Y)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing

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regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. 🛛 Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- **b.** \Box Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. 🛛 Requires specific expenditures or the report of information as a condition of compliance.
- d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

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

The following rules in Chapter 5160-7 of the Ohio Administrative Code set forth Medicaid coverage and payment policies for podiatry services:

Rule 5160-7-01, "Eligible providers of podiatric services"

Rule 5160-7-02, "Podiatric medicine: scope of coverage"

Rule 5160-7-03, "Covered podiatric services and associated limitations"

Rule 5160-7-04, "Podiatric Medicine: non-covered services"

These existing rules are being proposed for rescission, and their provisions are being consolidated into a single new rule.

New rule 5160-7-01 "Podiatry Services" details eligible providers, coverage and payment in the Ohio Medicaid podiatry services program. There are no changes to coverage or policy, however, ODM is clarifying that podiatrists may be paid to

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administer vaccinations within a podiatrist's normal scope of practice in accordance with state law and rule 5160-4-12 of the Administrative Code.

The purpose of these changes is to comply with five-year rule review, streamline, remove or update rule language and rule references, as well as, remove regulatory restrictive words in accordance with section 121.95 of the Ohio Revised Code as enacted under House bill 166.

The effective date of this rule change is December 1, 2020.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Section 5164.02 of the Ohio Revised Code.

4. 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. These rules do not implement a federal requirement.

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

This regulation does not include provisions specifically required by the federal government. However, it is consistent with federal expectations for this type of service and is in accordance with ODM's federally-approved state plan.

6. 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.

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

The success of this rule will be measured by the extent to which Medicaid-eligible individuals are able to receive covered podiatry services from Medicaid-eligible podiatry providers and operational updates to the Medicaid Information Technology System (MITS) result in the correct payment of claims for these services.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931? *If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No. These rules are not being submitted pursuant to these revised codes.

Development of the Regulation

9. 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.

Over a period of at least a year, the following stakeholders have had the opportunity to review and shape the policies expressed in the podiatry services rule:

- Ohio Foot and Ankle Medical Association
- Ohio State Medical Board
- Ohio Department of Medicaid's Medical Director
- Medicaid managed care plans
- Practicing Medicaid podiatrists.

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

ODM has been in contact with of the Ohio Foot and Ankle Medical Association on a regular basis since the last podiatry rule change effective November 11, 2017. ODM met to discuss this rule filing and review the initial consolidated rule draft on January 30, 2020 with follow-up communication the weeks of February 3rd and 24th, 2020. ODM shared podiatry program information and discussed the rule filing with the new Executive Director of the Ohio Foot and Ankle Medical Association during the weeks of July 6th and July 13th, 2020.

During the review stage of these rules, Senate Bill 178 of the 133rd General Assembly which would authorize podiatrists to administer flu vaccinations to individuals who are seven years of age or older passed in the Senate. Senate Bill 178 or similar legislation is expected to become law and expand the scope of practice of podiatrists to administer vaccinations.

Requests for input regarding the podiatry program and rules were communicated to Ohio Medicaid managed care plans through ODM's managed care plan contract administrators and plan representatives.

ODM and the Ohio Foot and Ankle Medical Association have remained in contact regarding the rule filing and S.B. 178 which would authorize podiatrists to administer flu vaccinations as specified in section 4731.512 of the Revised Code.

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Because of this input, the podiatry services rules are being consolidated into one rule and reference to OAC rule 4731-20-02 which authorizes podiatrists to perform ankle joint surgery has been added. Language clarifying that podiatrists may be paid to administer vaccinations within a podiatrist's normal scope of practice in accordance with state law and rule 5160-4-12 of the Administrative Code state law, whether or not ORC section 4731.512 becomes law, has been added. Additionally, rule language and rule references have been updated and regulatory restrictive words have been removed.

The aim of the podiatry services rule is to detail eligible podiatric providers, coverage and payment in the Ohio Medicaid program of services provided by podiatrists and to recognize changes in the practice of podiatry.

11. 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.

12. 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?

Policy governing the Medicaid program can be explained, clarified, and emphasized through means such as advisory letters and training sessions, but it is established in administrative rule. ODM is statutorily required to adopt rules to establish coverage of Medicaid services and payment for those services. The rules serves as 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.

13. 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 was determined to be beyond the scope of these program rules.

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

In the process of incorporating existing rule text into the new rules, ODM staff members took great care not to duplicate provisions. Any provision of another rule that applies specifically to these services is incorporated by reference. (Provisions in other rules that apply to the entire Medicaid program are not noted.) 15. 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 this rule will be incorporated into the Medicaid Information Technology System (MITS) claims payment system 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.

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

Adverse Impact to Business

- 16. 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; and
 - b. Identify the nature of all adverse impact (e.g., 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. These rules affect podiatrists and other eligible Medicaid providers of podiatry services, such as fee-for-service clinics.
 - b. These rules imposes no license fees or fines. Rule 5160-7-02 (To be rescinded) specifies that participating practitioners must maintain and, as appropriate, submit documentation that the services were provided and the medical necessity of the services. 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.
 - 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 takes between five and thirty minutes of provider staff time. This estimate is based on the personal experience of practicing podiatrists, including an ODM medical technical advisor (MTA). The wage costs depend on who performs the task. The median statewide hourly wage for a billing clerk is \$16.10, for a podiatrist, it is \$58.03. Adding 30% for fringe benefits brings these figures to \$20.93 and \$75.43. Generating the necessary documentation would therefore cost between \$1.75 (five minutes at \$20.93 per hour) and \$37.71 (thirty minutes at \$75.43 per hour).

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17. 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 serves as 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.

Regulatory Flexibility

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

These rules outlines actions all providers must take to receive Medicaid payment. They do not set forth requirements for engaging in business, and no exception is made based on the size of an entity.

19. 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.

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

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 Policy section of ODM's policy bureau, at noninstitutional_policy@medicaid.ohio.gov.

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5160-7-01 **Podiatry services.**

(A) For the purpose of this rule the following definitions apply.

- (1) "Doctor of podiatric medicine" (or "podiatric physician" or "podiatrist") is as described in section 4731.51 of the Revised Code.
 - (a) Doctors of podiatric medicine are deemed to be physicians only in respect to functions they are legally authorized to perform in accordance with section 4731.51 of the Revised Code and rule 4731-20-02 of the Administrative Code.
 - (b) For purposes of medicaid coverage and payment, an intern or resident of podiatric medicine is not a podiatric physician. This exclusion applies even if an intern or resident is authorized to practice as a podiatric physician under the laws of the state in which services are performed or a resident holds a staff or faculty appointment or is designated as a fellow. For purposes of medicaid coverage and payment, an intern or resident of podiatric medicine is not a podiatric physician.
- (2) "Podiatric group practice" is a professional association organized under Chapter 1785. of the Revised Code for the purpose of providing podiatric medicine services.

(B) Coverage.

- (1) Services and procedures performed by a doctor of podiatric medicine that are within the scope of practice of a podiatric physician are considered to be physician services. They are subject to and are covered in accordance with applicable medicaid rules in the Administrative Code concerning physician services.
- (2) The services of interns and residents of podiatric medicine rendered in a hospital setting are covered as hospital services in accordance with Chapter 5160-2 of the Administrative Code.
- (3) Podiatric medicine services provided by a physician assistant are covered in accordance with rule 5160-4-03 of the Administrative Code.
- (4) Podiatric medicine services provided by an advanced practice registered nurse are covered in accordance with rule 5160-4-04 of the Administrative Code.

(C) Constraints and limitations.

- (1) A "by report" podiatric medicine service or procedure is covered in accordance with rule 5160-1-60.4 of the Administrative Code.
- (2) Payment for evaluation and management (E&M) services is limited to the

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following services:

(a) Professional services of the following types necessitating straightforward medical decision-making or medical decision-making of low, moderate, or high complexity:

(i) Office or other outpatient visit;

(ii) Hospital inpatient services;

(iii) Office or outpatient consultations;

(iv) Inpatient consultations;

(v) Nursing facility services;

(vi) Domiciliary, rest home (e.g., boarding home), or custodial care services;

(vii) Home services; and

(b) Hospital discharge services, thirty minutes or less.

- (3) Payment for the debridement of nails is limited to one treatment per sixty-day period.
- (4) Payment may be made for the following services only if an individual has a localized infection; is under the care of another healthcare practitioner for a metabolic disease such as diabetes mellitus or another condition that may result in circulatory impairment or desensitization in the legs or feet; or has a systemic metabolic, neurologic, or peripheral vascular disease or condition that may require scrupulous foot care by another healthcare practitioner:
 - (a) Examinations and diagnostic services associated with routine foot care performed in the absence of a localized illness, symptoms, or injury;
 - (b) Cutting or removal of corns and calluses:
 - (c) Trimming, cutting, or clipping of nails not associated with nail surgery;
 - (d) Foot care provided for hygienic purposes; and
 - (e) Treatment of uncomplicated, chronic foot conditions such as flat feet or a subluxated structure in the foot.
- (5) Payment may be made for the treatment of mycotic toenails only if the healthcare practitioner attending the mycotic condition furnishes the podiatric

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physician with clinical evidence of at least one of the following conditions:

(a) Onychomycosis of the toenail; and

- (b) Mycosis or dystrophy of the toenail causing secondary infection or pain that has resulted or could result in marked limitation of ambulation.
- (6) Payment may be made for the following radiology services as podiatric medicine services only if the indicated criterion is fully documented:
 - (a) A bilateral radiograph for a unilateral condition or surgical procedure when it is medically indicated;
 - (b) Radiographs in excess of three views when trauma or infection is present;
 - (c) A radiograph of soft tissue when infection is present; and
 - (d) A postoperative radiograph when bone involvement necessitated the surgical procedure or postoperative infection is suspected.
- (7) Payment for physical medicine services is limited to acute conditions. When a disease or condition has reached a chronic stage, payment may be made only for services or procedures performed during periods of acute exacerbation.
- (8) Payment may be made for a range-of-motion study separately from an examination of the foot only if the need is substantiated by a complete report.
- (9) Payment may be made for vaccinations administered within a podiatrist's normal scope of practice in accordance with state law and rule 5160-4-12 of the Administrative Code.
- (10) The following services are not covered as podiatric medicine services:
 - (a) Vitamin B-12 injection for strengthening tendons, ligaments, or other components of the foot;
 - (b) Medical supplies and equipment (e.g., tape, dressing, surgical trays) that are provided during a podiatric medicine visit and are not intended for take-home use; and
 - (c) The use of radiography or radioactive material for therapeutic purposes.

TO BE RESCINDED

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 medicaid (ODM).

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Certification

Date

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TO BE RESCINDED

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

- (A) Podiatric physicians may receive medicaid payment for covered services (as defined in Chapter 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 receive medicaid payment for treatment of the local manifestation of systemic disease as they appear in the hand and foot, but the 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 5160-4-02 of the Administrative Code.
- (C) Hospital-based podiatric physicians and surgeons are covered in accordance with rule 5160-4-01 of the Administrative Code.
- (D) Podiatric medicine services provided in a teaching setting are covered as set forth in rule 5160-4-05 of the Administrative Code.
- (E) Podiatric medicine services provided in a long-term care setting are covered as detailed in rules 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 5160-4-03 of the Administrative Code.
- (G) By report services are covered in accordance with rule 5160-4-02.1 of the Administrative Code. For these services, a provider must submit a report 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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TO BE RESCINDED

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

(A) Visit limitations.

- (1) Visits are covered in accordance with rules 5160-3-19, 5123:2-7-11 and 5160-4-06 of the Administrative Code.
- (2) Payment for evaluation and management services shall be limited to the following services:
 - (a) Office or other outpatient visit, requiring medical decision making of straightforward, low, moderate or high complexity;
 - (b) Hospital inpatient services, requiring medical decision making of straightforward, low, moderate or high complexity;
 - (c) Hospital discharge services, thirty minutes or less;
 - (d) Office or outpatient consultations, requiring medical decision making of straightforward, low, moderate or high complexity;
 - (e) Inpatient consultations, requiring medical decision making of straightforward, low, moderate or high complexity;
 - (f) Nursing facility services, initial or subsequent care, requiring medical decision making of straightforward, low, moderate or high complexity;
 - (g) Domiciliary, rest home (eg. boarding home) or custodial care services, requiring medical decision making of straightforward, low, moderate or high complexity; and
 - (h) Home services, requiring medical decision making of straightforward, low, moderate or high complexity.
- (B) Therapeutic injections and prescribed drugs are covered in accordance with rule 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.

TO BE RESCINDED

- (1) Surgeries are covered in accordance with rules 5160-4-22 and 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 5160-4, 5160-3, 5160-11 and 5123:2-7 of the Administrative Code.
- (E) Radiology services.
 - (1) Radiology services are covered in accordance with Chapters 5160-4 and 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 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 5160-4 and 5160-10 of the Administrative Code.

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TO BE RESCINDED

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

- (A) The following services are noncovered:
 - (1) All services exceeding the policies and limitations defined in Chapters 5160-4 and 5160-7 of the Administrative Code.
 - (2) Services determined by the department as not medically necessary as defined in Chapter 5160-1 of the Administrative Code.
- (B) In addition, the following services are noncovered, unless 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 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 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 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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