CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Acupuncture Services

Rule Number(s):

New Rule 5160-8-51, Acupuncture services

Rule 5160-8-11, Spinal manipulation and related diagnostic imaging services

Date: June 12, 2017

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- ☐ Rescinded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.

   New rule 5160-8-51, "Acupuncture services," is proposed for adoption to describe Medicaid coverage of acupuncture services. It lists providers who will be eligible to receive Medicaid payment for rendering acupuncture services, and describes how payment will be made. It will allow acupuncturists practicing in non-institutional settings to submit claims to the Ohio Department of Medicaid independently and to allow other eligible non-institutional providers to submit claims to the Department. Payment may be made for covered acupuncture services rendered to treat either low back pain or migraine.

   In conjunction with this work, language for acupuncture services is being added to rule 5160-8-11 to allow chiropractors to receive payment for covered acupuncture services.

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

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

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

   No.

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

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

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

   Medicaid rules perform several core business functions. They establish and update coverage and payment policies for medical goods and services. They set limits on the types of entities that can receive Medicaid payment for these goods and services. They publish payment formulas or fee schedules for the use of providers and the general public.

   The rules for acupuncturists and spinal manipulation perform this function, and no alternative is readily apparent.

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

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

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

ODM sent draft rule 5160-8-51 by e-mail to the following stakeholders on February 9, 2017: State Medical Board of Ohio, Ohio State Chiropractic Board, Ohio Association of Acupuncture and Oriental Medicine, Ohio State Chiropractic Association, Ohio State Medical Association, American Acupuncture Council, National Certification Commission for Acupuncture and Oriental Medicine, National Institute of Health, National Center for Complementary and Integrative Health, American Academy of Medical Acupuncture, Ohio Association of Advanced Practice Nurses, Ohio Association of Physician Assistants, Ohio Association of Community Health Centers, Ohio Department of Health, State Office of Rural Health, Rural Health Centers, Ohio Board of Nursing, and Association of Ohio Health Commissioners. ODM sent draft rule 5160-8-51 by e-mail to the following stakeholders on May 16, 2017: Ohio Physical Therapy Association, Ohio Occupational Therapy Association, and the Ohio Dental Association. ODM also included its Medicaid managed care plans and the Ohio Department of Health in the review of the draft acupuncture regulation.

ODM sent draft rule 5160-8-11 by e-mail to the Ohio State Chiropractic Association and the Ohio State Chiropractic Board on May 16, 2017.

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

American Academy of Medical Acupuncture, Ohio Association of Advanced Practice Nurses, and Ohio State Chiropractic Association thanked ODM for including them in ODM's stakeholder outreach. They stated that they were appreciative of the proposed rule, which offers an alternative option for pain management.

An individual who received acupuncture for more than 30 years called to express his support for Medicaid covering and paying for acupuncture services. He shared his personal experience with acupuncture services and asked ODM to cover acupuncture for additional conditions such as "nerve regeneration." ODM clinical staff considered coverage of additional diagnoses, but the strongest available evidence for medically necessary acupuncture services in the United States is for low back pain and migraine. Therefore, ODM will continue to focus on the high yield diagnoses of low back pain and migraine.

Ohio State Chiropractic Board and Northeast Ohio Academy of Chiropractors asked that separate payment be made for evaluation and management services provided by chiropractors. No separate payment for evaluation and management services provided by chiropractors is planned at this time. ODM is not expanding fee-for-service payments at this time and are instead focusing on episode-based payments to create value for individuals covered by Medicaid. ODM responded that chiropractors will be able to share in value-based purchasing opportunities that are underway.

Ohio Association of Acupuncture and Oriental Medicine requested that ODM cover acupuncture services for diagnoses other than low back pain and migraine, include acupuncture services with electrical stimulation in the policy, and allow providers to render these services in a home setting. ODM clinical staff considered coverage of additional diagnoses, but made a decision to limit diagnoses to evidence-based coverage for low back pain and migraine for the reasons stated above. ODM added acupuncture services with

electrical stimulation to the policy. ODM will start with covering and paying for acupuncture services in healthcare settings where expertise is readily available and safety standards are easily met.

The Ohio State Chiropractic Association and the Ohio State Chiropractic Board were supportive of the addition of acupuncture services to rule 5160-8-11, and had no further input.

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?**

   ODM researched acupuncture coverage and adopted coverage policies that are consistent with evidence-based scientific studies that demonstrate acupuncture is an effective treatment for certain medical conditions.

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

    ODM considered not covering acupuncture services performed by acupuncturists. Other providers such as physicians and chiropractors are able to perform the service. It was determined, however, that this policy should be expanded because acupuncturists are licensed practitioners regulated by the Ohio State Medical Board.

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

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

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

    Rules involving Medicaid providers are housed exclusively within agency 5160 of the Ohio Administrative Code. Within this division, rules are generally separated out by topic. 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 policy changes are being incorporated into: (1) internal Medicaid processes, and (2) MITS, which is ODM's electronic claim-payment system. Incorporation into ODM processes and systems will ensure that the rules are applied consistently and predictably.

    ODM is also working with the Medicaid managed care plans to ensure acupuncture services are covered and their systems are ready to pay for these services starting 10/1/2017.

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;

Rule 5160-8-51 affects Medicaid providers of acupuncture services, which include acupuncturists as defined by the Ohio State Medical Board, individuals certified to practice oriental medicine, physicians, and chiropractors. Other providers such as advanced practice registered nurses and physician assistants can provide acupuncture services to Medicaid recipients by obtaining certification from the Ohio State Medical Board as an acupuncturist.

Rule 5160-8-11 affects chiropractors, mechanotherapists, and other providers who practice spinal manipulation and related diagnostic imaging services.

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

For rule 5160-8-51, to receive payment for acupuncture services, a provider must be enrolled with Medicaid and obtain a Medicaid acupuncture specialty in MITS by showing proof of acupuncture certification or licensure from the Ohio State Medical Board, or in the case of physicians, medical training in acupuncture.

For rule 5160-8-11, the rendering provider must be licensed as a chiropractor or mechanotherapist.

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.

The adverse impact of complying with the licensure and certification requirements of these regulations cannot be directly attributable to these rules. Any expenses for licensure and medical training would be required in order to meet existing professional standards; these costs would be incurred before providers enroll with Medicaid. Providers interested in submitting claims to Medicaid for acupuncture services are not expected to incur additional costs as a result of these rules.

Acupuncturists must hold a certificate issued under Chapter 4762. of the Revised Code. The certificate is obtained from the Ohio State Medical Board (OSMB). The application fee for initial acupuncture licensure is $100.00. All applicants for licensure are also required by the OSMB to complete an FBI and Ohio BCI criminal records check. Criminal Record Check fees are $24.00 (FBI) and $22.00 (Ohio BCI), plus vendor processing fees.

Providers such as advanced practice registered nurses and physician assistants must become acupuncturists through the OSMB in order to provide acupuncture services. The cost is the same as listed above for acupuncturists.

Other recognized acupuncture providers include physicians and chiropractors. To receive Medicaid payment, a physician must hold a current and active designation from the National Certification Commission for Acupuncture and Oriental Medicine as a diplomate in acupuncture. The cost to obtain this credential (application and examination fees) ranges from $775 to $895 plus preparation time. The cost of obtaining an acupuncture certificate through the Ohio State Chiropractic Board is $100.

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

Adverse impacts to providers of acupuncture services as a result of rule 5160-8-51 are minimal. While ODM must put in place standards for participating in the Medicaid program, ODM is using existing professional standards, which would apply to those providers even if they did not enroll with Medicaid.

Regulatory Flexibility

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

Medicaid regulations apply uniformly to all providers regardless of size.

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

There are no fines or penalties in these regulations.

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

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

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

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

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

5160-8-51 **Acupuncture services.**

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

(B) Definitions.

(1) "Acupuncture" has the same meaning as in Chapter 4762. of the Revised Code.

(2) "Acupuncturist" is an individual who holds at least one of the following certificates:

(a) A valid certificate to practice as an acupuncturist issued under Chapter 4762. of the Revised Code; or

(b) A valid certificate to practice as an oriental medicine practitioner issued under Chapter 4762. of the Revised Code.

(3) "Recognized acupuncture provider" is an individual medicaid provider who may receive payment for providing covered acupuncture services, without enrolling separately in medicaid as an acupuncturist, by virtue of holding the credential indicated in the following list:

(a) Chiropractor – a valid certificate to practice acupuncture issued under section 4734.283 of the Revised Code;

(b) Physician – completion of medical training in acupuncture with a current and active designation, or an equivalent designation, as a diplomate in acupuncture from the national certification commission for acupuncture and oriental medicine; or

(c) Other individual medicaid provider (e.g., advanced practice registered nurse, physician assistant) – a valid certificate as an acupuncturist.

(C) Providers. The following eligible providers may receive medicaid payment for submitting a claim for a covered acupuncture service:

(1) An acupuncturist;

(2) A recognized acupuncture provider;

(3) An ambulatory health care clinic as defined in Chapter 5160-13 of the Administrative Code;

(4) A federally qualified health center (FQHC);

(5) A rural health clinic (RHC); or

(6) A professional medical group.

(D) Coverage.

(1) Payment may be made only for an acupuncture service that meets the following criteria:

(a) It is medically necessary in accordance with rule 5160-1-01 of the Administrative Code;

(b) It is performed at the written order of a practitioner in accordance with section 4762.10 or 4762.11 of the Revised Code;

(c) It is rendered by a practitioner who is enrolled in the medicaid program;

(d) It is rendered for treatment only of the following conditions:

(i) Low back pain; or

(ii) Migraine; and

(e) The place of service is none of the following locations:

(i) A hospital (inpatient hospital, outpatient hospital, emergency department);

(ii) An ambulatory surgery center;

(iii) A long-term care facility; or

(iv) The individual's private residence.

(2) Payment for more than thirty acupuncture visits per benefit year requires prior authorization.

(3) No separate payment is made for both an evaluation and management service and an acupuncture service rendered by the same provider to the same individual on the same day.

(4) No separate payment is made for services that are an incidental part of a visit (e.g., providing instruction on breathing techniques, diet, or exercise).

(5) No payment will be made for additional treatment in either of the following

circumstances:

(a) Symptoms show no evidence of clinical improvement after an initial treatment period; or

(b) Symptoms worsen over a course of treatment.

(E) Claim payment.

(1) For a covered acupuncture service rendered at an FQHC or RHC, payment is made in accordance with Chapter 5160-28 of the Administrative Code.

(2) For a covered acupuncture service rendered at any other valid place of service, payment is the lesser of the provider's submitted charge or the maximum amount specified in appendix DD to rule 5160-1-60 of the Administrative 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:	5164.02

5160-8-11 **Spinal manipulation and related diagnostic imaging services.**

(A) Scope. This rule sets forth provisions governing payment for professional, non-institutional spinal manipulation and related diagnostic imaging services. Provisions governing payment for such services performed in a federally qualified health center are set forth in Chapter 5160-28 of the Administrative Code.

(B) Providers.

(1) Rendering providers. The following eligible providers may render a service described in this rule:

(a) A chiropractor (an individual who holds a valid license as a chiropractor under Chapter 4734. of the Revised Code and works within the scope of practice defined by state law); or

(b) A mechanotherapist (an individual who holds a valid license as a mechanotherapist under Chapter 4731. of the Revised Code and works within the scope of practice defined by state law).

(2) Billing ("pay-to") providers. The following eligible providers may receive medicaid payment for submitting a claim for a covered service on behalf of a rendering provider:

(a) A chiropractor;

(b) A mechanotherapist;

(c) A professional medical group, which is described in rule 5160-1-17 of the Administrative Code;

(d) A hospital, rules for which are set forth in Chapter 5160-2 of the Administrative Code; or

(e) A fee-for-service clinic, rules for which are set forth in Chapter 5160-13 of the Administrative Code.

(C) Coverage.

(1) Payment for manual manipulation of the spine may be made only for the correction of a subluxation, the existence of which must be determined either by physical examination or by diagnostic imaging. If the determination is made by physical examination, the following criteria must be met:

(a) At least one of the following two conditions exists:

(i) Asymmetry or misalignment on a sectional or segmental level; or

(ii) Abnormality in the range of motion; and

(b) At least one of the following two symptoms is present:

(i) Significant pain or tenderness in the affected area; or

(ii) Changes in the tone or characteristics of contiguous or associated soft tissues, including skin, fascia, muscle, and ligament.

(2) Payment may be made only for the following services:

(a) Spinal manipulation.

(i) Chiropractic manipulative treatment (CMT); spinal, one to two regions.

(ii) Chiropractic manipulative treatment (CMT); spinal, three to four regions.

(iii) Chiropractic manipulative treatment (CMT); spinal, five regions.

(b) Diagnostic imaging to determine the existence of a subluxation.

(i) Spine, entire; survey study, anteroposterior and lateral.

(ii) Spine, cervical; anteroposterior and lateral.

(iii) Spine, cervical; anteroposterior and lateral; minimum of four views.

(iv) Spine, cervical; anteroposterior and lateral; complete, including oblique and flexion and/or extension studies.

(v) Spine, thoracic; anteroposterior and lateral views.

(vi) Spine, thoracic; complete, with oblique views; minimum of four views.

(vii) Spine, thoracolumbar; anteroposterior and lateral views.

(viii) Spine, lumbosacral; anteroposterior and lateral views.

(ix) Spine, lumbosacral; complete, with oblique views.

(x) Spine, lumbosacral; complete, including bending views.

(c) Acupuncture services in accordance with rule 5160-8-51 of the Administrative Code.

(D) Requirements, constraints, and limitations.

(1) The following coverage limits, which may be exceeded with prior authorization, are established for the indicated services:

(a) Spinal manipulation, one treatment per date of service;

(b) Diagnostic imaging of the entire spine to determine the existence of a subluxation, two sessions per benefit year;

(c) All other imaging, two sessions per six-month period; and

(d) Visits in an outpatient setting, thirty dates of service per benefit year for an individual younger than twenty-one years of age, fifteen dates of service per benefit year for an individual twenty-one years of age or older.

(2) Payment will not be made under this rule for any of the following services:

(a) A service that is not medically necessary, examples of which are shown in

the following non-exhaustive list:

(i) A service unrelated to the treatment of a specific medical complaint;

(ii) Treatment of a disease, disorder, or condition that does not respond to spinal manipulation, such as multiple sclerosis, rheumatoid arthritis, muscular dystrophy, sinus problems, and pneumonia;

(iii) Preventive treatment;

(iv) Repeated treatment without an achievable and clearly defined goal;

(v) Repeated imaging or other diagnostic procedure for a chronic, permanent condition;

(vi) Treatment from which the maximum therapeutic benefit has already been achieved and the continuation of which cannot reasonably be expected to improve the condition or arrest deterioration within a reasonable and generally predictable period of time; and

(vii) A service performed more frequently than the standard generally accepted by peers;

(b) A service that is performed by someone other than a chiropractor or mechanotherapist who is an eligible provider; and

(c) A service that is performed by a chiropractor or mechanotherapist who is an eligible provider but that is neither chiropractic manipulation nor diagnostic imaging to determine the existence of a subluxation, illustrated by the following examples:

(i) Diagnostic studies;

(ii) Drugs;

(iii) Equipment used for manipulation;

(iv) Evaluation and management services;

(v) Injections;

(vi) Laboratory tests;

(vii) Maintenance therapy (therapy that is performed to treat a chronic, stable condition or to prevent deterioration);

(viii) Manual manipulation for purposes other than the treatment of subluxation;

(ix) Orthopedic devices;

(x) Physical therapy;

(xi) Supplies; and

(xii) Traction.

Effective:

Five Year Review (FYR) Dates: 05/08/2021

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02
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