CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)

Regulation/Package Title: Spinal manipulation and related diagnostic imaging services

Rule Number(s):

SUBJECT TO BUSINESS IMPACT ANALYSIS:

5160-8-11 (To be rescinded), 5160-8-11 (New)

Date: November 30, 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- ☑ Rescinded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.

   Existing rule 5160-8-11, "Covered chiropractic physician services and limitations," sets forth provisions for coverage of chiropractic services rendered in non-institutional settings. This rule is being rescinded and replaced with a new rule of the same number.

   New rule 5160-8-11, "Spinal manipulation and related diagnostic imaging services," sets forth provisions for coverage of spinal manipulation and related diagnostic imaging services rendered in non-institutional settings. This rule replaces a rescinded rule of the same number. The text of the rule is reorganized and streamlined, and a clarification is added that mechanotherapists are eligible providers of services. The new rule title specifies services by type rather than by provider.

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.

   Chiropractic treatment is an optional Medicaid service. These rules comport with but do not implement federal requirements.

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 this rule will be measured by the extent to which providers can continue to receive payment for rendering covered services.

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 staff members meet with representatives of the Ohio State Chiropractic Association (OSCA) approximately every 18 to 24 months and sometimes annually. These meetings cover a variety of topics of interest to chiropractors, either related directly to the Medicaid program or of broader impact such as Ohio licensure. Communication is also maintained with the OSCA and individual chiropractors through ODM news releases and through e-mail and telephone conversations regarding program coverage, prior authorization, and claim payment.

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

   Few if any suggestions concerning spinal manipulation services are received from stakeholders. Since Medicaid coverage of chiropractic services for adults was reinstated in January 2008 (after having been eliminated in January 2004 as a result of state budget cuts), there have been no requests for change in coverage. Providers are generally appreciative that ODM has maintained coverage of services for adults.

   On 03/23/2015, ODM sent a draft of the rule packet to the Ohio State Chiropractic Association and the Ohio State Chiropractic Board for review. To date, no response has been received from these organizations.

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?**

   The updating of this rule involves no substantive change in policy.

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?

Specific documentation requirements in the existing rule duplicate provisions set forth in Chapter 5160-1 of the Ohio Administrative Code. Removing the requirements was determined to be preferable to leaving them intact.

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 updating of this rule involves no substantive change in policy. Notification of the update will be published and made available to all affected providers.

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 in this policy affect providers of spinal manipulation and related diagnostic imaging services.

b. New rule 5160-8-11 specifically identifies a rendering provider as either a chiropractor licensed under Chapter 4734. of the Ohio Revised Code or a mechanotherapist licensed under Chapter 4731. of the Ohio Revised Code.

   Existing rule 5160-8-11 requires providers to document the medical necessity of services rendered; it sets forth a specific checklist of information to be included in an individual's medical file:

   At the initial visit for a new condition:
   - ✓ Medical history
   - ✓ Chief complaint
   - ✓ Subjective findings from physical examination
   - ✓ Objective findings including any X-ray results
   - ✓ Diagnosis
   - ✓ Treatment plan including goals, schedule, and metrics
   - ✓ Treatment given and specific regions manipulated
   - ✓ Treatment date

   At periodic reassessments:
   - ✓ Current status and change since last treatment
   - ✓ Change in chief complaint since last visit
   - ✓ Results of physical examination
   - ✓ Treatment given and specific regions manipulated
   - ✓ Treatment date

   These documentation requirements, which duplicate provisions set forth in Chapter 5160-1 of the Ohio Administrative Code, are eliminated in the new rule.

c. The specification of licensure is a means of identifying providers by credentials they already possess; these provisions impose no additional requirements.

   Documentation of medical necessity consists of spending a few minutes making or transferring notations in a medical file. The time involved in documentation is less than 15 minutes, an estimate based on ODM's knowledge of the type and quantity of information needed and an understanding of provider office operations and staffing. The median statewide hourly wage for a chiropractor, according to Labor Market Information (LMI) data published by the Ohio Department of Job and Family Services, is $42.17; adding 30% for fringe benefits brings this figure to $54.82. So the cost associated with documenting medical necessity can be up to $13.71.

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

The statement of the documentation requirements in the existing rule serves as a reminder to providers and a tool for auditors to maintain program integrity. It is eliminated in the new rule.

Regulatory Flexibility

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

The documentation requirements in the existing rule are not predicated on the size of the provider, and no alternate means of compliance is available.

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?

This rule imposes 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.

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

5160-8-11 **Covered chiropractic physician services and limitations.**

For dates of service from January 1, 2004 through December 31, 2007, chiropractic services provided by chiropractic physicians were not covered medicaid services for adults twenty-one years of age and older.

(A) Definitions:

(1) "Subluxation" means an incomplete dislocation, off centering, misalignment, fixation, or abnormal spacing of the vertebrae anatomically, and must be demonstrated by x-ray film or other diagnostic test; and

(2) "Maintenance therapy" means therapy that is performed to treat a chronic, stable condition or to prevent deterioration.

(B) Treatment by means of manual manipulation of the spine to correct a subluxation which exceeds normalcy is a covered service. The existence of the subluxation must be demonstrated either by a diagnostic x-ray or by physical examination, as described in paragraph (C) of this rule. Evidence must be retained as a part of the consumer's medical record that a subluxation exists. The manual manipulation must have a direct therapeutic relationship to the consumer's condition as documented in the medical record. The lack of documentation specifying the relationship between the consumer's condition and treatment shall result in the service being nonreimburseable.

(C) At least two of the following criteria must exist and be documented to demonstrate a subluxation by physical examination. One of the two criteria must be asymmetry/misalignment or range of motion abnormality.

(1) Pain/tenderness evaluated in terms of location, quality and intensity;

(2) Asymmetry/misalignment identified on a sectional or segmental level;

(3) Range of motion abnormality; or

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

(D) Covered chiropractic services shall be limited to the chiropractic procedures listed in paragraph (D)(1) of this rule and diagnostic x-rays meeting the provisions described in paragraph (D)(2) of this rule. The service must relate to the diagnosis and treatment of a significant health problem in the form of a neuromusculoskeletal condition necessitating manipulative treatment.

(1) The chiropractic procedures listed below are covered under the medicaid program if the service is deemed medically necessary. The limit is one unit of service for each consumer for each date of service.

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

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

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

(2) Diagnostic x-rays to determine the existence of a subluxation are covered with certain limitations. Two units of service, as defined below, will be covered during any six-month period unless otherwise stated. For purposes of this rule, the six-month period begins on the date the diagnostic x-ray is taken and ends one hundred eighty days from the date. The covered units of service are as follows:

(a) Spine, entire; survey study, anterior-posterior, and lateral. Only two units per one year (three hundred and sixty five days) period are covered.

(b) Spine, cervical; antero-posterior, and lateral.

(c) Spine, cervical; antero-posterior, and lateral; minimum of four views.

(d) Spine, cervical; antero-posterior, and lateral; complete, including oblique and flexion and/or extension studies.

(e) Spine, thoracic; anterior-posterior, and lateral views.

(f) Spine, thoracic; complete, including obliques; minimum of four views.

(g) Spine, thoracolumbar; antero-posterior lateral views.

(h) Spine, lumbosacral; antero-posterior, and lateral views.

(i) Spine, lumbosacral; complete, with oblique views; and

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

(E) Limitations of coverage:

(1) Spinal axis aches, strains, sprains, nerve pains, and functional mechanical disabilities of the spine are considered to provide therapeutic grounds for chiropractic manipulative treatment. Most other diseases and disorders do not provide therapeutic grounds for chiropractic manipulative treatment. Examples of non-covered diagnoses are multiple sclerosis, rheumatoid arthritis, muscular dystrophy, sinus problems and pneumonia.

(2) Repeat x-rays or other diagnostic tests in consumers with chronic, permanent conditions will not be considered medically necessary and are not a covered service.

(3) If there is no reasonable expectation that the continuation of treatment would improve or arrest deterioration of the condition within a reasonable and generally predictable period of time, coverage will be denied.

(4) Continued repetitive treatments without an achievable and clearly defined goal will be considered maintenance therapy and will not be considered covered services.

(5) Once the maximum therapeutic benefit has been achieved for any given condition, ongoing therapy is considered maintenance therapy which is not considered medically necessary.

(6) When services are performed more frequently than generally accepted by peers, chiropractic manipulation will be considered excessive and will be denied as not medically necessary.

(F) There must be documentation to support each service billed. Documentation should exist in the consumer's medical record and must verify that the services billed were rendered and that the services were medically necessary.

(1) The following information should be documented in the consumer's medical record on the initial visit for a new condition:

(a) Consumer's history;

(b) Consumer's chief complaint;

(c) Subjective findings from physical examination including evaluations of the musculoskeletal and nervous systems;

(d) Objective findings including x-ray results, if given;

(e) Diagnosis;

(f) Treatment plan which includes the following:

(i) Goals;

(ii) Plans for continued treatment including duration and frequency of visits; and

(iii) Objective measures that will be used to evaluate the effectiveness of treatment.

(2) The following information should be documented on periodic reassessments:

(a) Consumer's status on each visit date including how the consumer's condition has changed since the last treatment;

(b) Review of how the chief complaint has changed since the last visit; and

(c) Results of physical exam.

(3) On each visit, the treatment given on each visit date must be documented including the specific region(s) manipulated.

(G) The following services are not covered:

(1) Visits in excess of thirty dates of service per consumer per twelve-month period in an outpatient setting if the consumer is under the age of twenty-one;

(2) Effective for dates of service on or after January 1, 2008, visits in excess of

fifteen dates of service per consumer per twelve-month period in an outpatient setting if the consumer is twenty-one years of age or older.

(3) Services rendered to consumers in an inpatient or outpatient hospital setting are not covered in this rule but are covered in Chapter 5101:3-2 of the Administrative Code;

(4) Services unrelated to the treatment of the specific medical complaint, services unnecessary for the treatment of an ailment, and treatment of a preventative medicine nature;

(5) Services determined by another third-party payer (especially medicare Title XVIII) as not medically necessary. Services denied by medicare will be considered medically unnecessary by the department and will not be considered covered services by medicaid;

(6) X-rays, except for those delineated in paragraph (B)(2) of this rule;

(7) Services which are not personally performed by the chiropractic physician with whom the department has a provider agreement:

(a) Services provided by licensed individuals with whom the department does not have an individual provider agreement are not reimbursable even though the covered services are provided under the personal supervision of a licensed chiropractic physician with whom the department does have a provider agreement.

(b) Services provided by unlicensed individuals under the personal supervision of a licensed chiropractic physician are not reimbursable.

(c) Services provided by students during an internship are not covered services.

(8) Any service other than manual manipulation for treatment of subluxation of the spine and x-rays as described in paragraph (D) of this rule are not covered services. The following are examples of services (not an all-inclusive list) that, when performed or ordered by the chiropractor, are excluded from coverage:

(a) Maintenance therapy;

(b) Laboratory test;

(c) Evaluation and management services;

(d) Physical therapy;

(e) Traction;

(f) Supplies;

(g) Injections;

(h) Drugs;

(i) Diagnostic studies;

(j) Orthopedic devices;

(k) Equipment used for manipulation; and

(l) Any manipulation which the x-ray or other tests does not support the primary diagnosis.

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, 5162.20, 5164.02, 5164.70, Section 309.30.60 of Am. Sub. H.B. 119 (127th G.A.)
Prior Effective Dates:	02/10/1986, 12/31/1996 (Emer), 03/22/1997, 07/01/2002, 01/01/2004, 01/01/2008

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.

(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.

Replaces: 5160-8-11

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5164.02
Prior Effective Dates:	02/10/1986, 12/31/1996 (Emer), 03/22/1997, 07/01/2002, 01/01/2004, 01/01/2008