

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title: Enhanced provider expectations and lumbar fusion surgery rules.

Rule Number(s): 4123-6-32

Date: July 18, 2017

Rule Type:

New

5-Year Review

Amended

Rescinded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.

Rule 4123-6-32 is a new rule and is being proposed to ensure the incorporation of best current clinical practices, injured workers' awareness of treatment options, promote a two-month course of comprehensive conservative care, and to provide criteria for consideration of lumbar fusion surgery.

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This rule provides standards and criteria for governing the Bureau's reimbursement of lumbar fusion surgery. Specific sections of the proposed rule outlines and a summary of what is addressed are:

- Paragraph A set forth prerequisites which should be addressed prior to consideration of lumbar fusion surgery;
- Paragraph B set forth the authorization criteria for a lumbar fusion surgery where the injured worker has no prior history having any lumbar surgery;
- Paragraph C set forth the authorization criteria for a lumbar fusion surgery where the injured worker does have a history of prior lumbar surgery;
- Paragraph D set forth the specific expectations for Lumber fusion surgical after care.

Finally, the rule provides an acknowledgement form which the injured worker, physician of record, and the operating surgeon must sign which attest that the information contained as a part of the form was shared and discussed with the injured worker. The information is designed to fully inform the injured worker of potential outcomes of spine fusion surgery; thus, allowing the injured workers and their physician to make the best decision possible regarding surgery.

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

R.C. 4121.44, 4121.441, 4121.443, 4123.05

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.

n/a

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)?

The purpose of the regulations is BWC's responsibility for implementing rules to effectively execute the Agency's charge pursuant to the fiduciary responsibility embedded in the statutes governing The Health Partnership Program (HPP). Ohio Revised Code 4121.441(A)(1)(k) and (A)(1)(i) provide that the Administrator, with the advice and consent of the BWC Board of Directors, shall adopt rules for implementation of the HPP "to provide medical, surgical, nursing, drug, hospital, and rehabilitation services and supplies to an employee for an injury or occupational disease" which shall include, but are not limited to:

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- (k) Standards and criteria for the bureau to utilize in certifying or recertifying a health care provider . . . for participation in the health partnership program;
- (i) Standards for the bureau to utilize in penalizing or decertifying a health care provider from participation in the health partnership program.

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

BWC will evaluate providers involved in this service in terms of their effectiveness with:

- Ensuring the incorporation of best current clinical practices in the utilization of lumbar fusion surgery in the treatment of injured workers;
- Ensuring injured workers' awareness of treatment options for allowed lumbar conditions
- Utilization of a minimum two-month course of comprehensive conservative care for allowed lumbar conditions unless otherwise indicated, prior to consideration of lumbar fusion surgery; and
- Adherence to the rule's criteria for consideration of lumbar fusion surgery when the injured worker's condition has remained unchanged or worsened despite utilization of conservative care.

Additionally, BWC will evaluate the rule's overall impact on the reduction in the number of lumbar fusion surgeries, increase in positive outcomes of lumbar fusion surgeries performed, as well as reduction of overall medical and indemnity costs associated with claims with allowed lumbar injurers.

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.

The Bureau has distributed these rules for comments to:

- BWC's Managed Care Organizations
- BWC's internal medical provider stakeholder list - 68 persons representing 56 medical provider associations/groups
- BWC's Healthcare Quality Assurance Advisory Committee
- Ohio Association for Justice
- Employer Organizations
- Council of Smaller Enterprises (COSE)
- Ohio Manufacturer's Association (OMA)
- National Federation of Independent Business (NFIB)

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- Ohio Chamber of Commerce
- BWC's Self-Insured Division's employer distribution list
- BWC's Employer Services Division's Third Party Administrator (TPA) distribution list
- The Bureau's rules distribution list, and
- The general public via the E-Notification System

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

The Bureau received multiple comments from stakeholders which are provided below with BWC's response.

The Ohio Athletic Trainers' Association submitted a comment recommending changes to paragraph A(1)(b)(v). The Association expressed a perspective that physical therapy is a specific service provided by a licensed physical therapist or physical therapist assistant; and that occupational therapy is provided by licensed occupational therapists and occupational therapy assistants. Given those points, the Association felt that listing only physical and occupational therapy would eliminate athletic trainers from providing rehabilitation to the injured worker; and that the generic term that describes all these services would be "rehabilitation services." Thus, the Association recommended modifying the language to reflect: "Rehabilitation services as provided by licensed Athletic Trainers, Physical Therapists and Occupational Therapists." BWC, to address the concern presented by the Association, modified the original language to reflect physical medicine services as set forth in OAC 4123-6-30, which clearly indicates Athletic Trainers as providers who can be reimbursed for relevant rehabilitation services.

The Health Plan submitted 3 questions: 1. What provider types were involved in the development of the lumbar fusion surgery rule? 2. Were neurosurgeons included? 3. After the rule is finalized, can they be accessed through ODG by a link specifying Ohio BWC specific guideline or similar method? BWC indicated that there were two subject matter expert physicians involved in the development of the rule. Both providers are highly regarded Ohio physicians, one being a neurosurgeon, and the other an orthopedic spine surgeon, who is a member of Case Western Reserve and lectures on this procedure. Additionally, BWC collaborated with OSU on the continuum of spine care, with the Clinical Lumbar Motion Monitor Pilot being a direct part of that collaboration. Moreover, the involvement of BWC's Health Quality Assurance Advisory Committee in developing the protocols of this rule, reflected direct involvement of representatives from the various medical associations. The rule itself will not be accessible through ODG by a link, as the ODG guidelines are proprietary and separate from Ohio laws. However, the rule will be

included on BWC Website and links to the rule will be appropriately added to the provider reimbursement manual and other tools.

Plaintiff/injured worker counsel commented that Paragraph 4123-6-32(3) of the rule reflected issues which will prevent an injured worker from ever meeting the criteria established. It was pointed out that the paragraph requires the injured worker to undergo a comprehensive evaluation, including some evaluations such as a vocational assessment which will not be permitted. Given BWC's intent was not to require a formal vocational assessment, but rather to ensure that the provider at a minimum discussed vocational rehabilitation possibilities with the injured worker, relevant language was modified to read: Discussion and consideration of opportunities for vocational rehabilitation.

Plaintiff/injured worker counsel also asserted that health behavioral assessments will not be authorized without an allowed psychological condition, and that MCOs presently do not authorize these types of assessments. BWC emphasized that a psychological condition is not needed and would be inappropriate for an injured worker to receive a health behavioral assessment. Additionally, BWC will provide training to the MCOs that the expectation is that a health behavioral assessment will be approved in claims where a lumbar fusion is being contemplated.

Plaintiff/injured worker counsel further pointed out that presently, the BWC global surgical policy will cause confusion and difficulty in implementing the part of the rule which requires surgical after care from both the physician of record and surgeon. Understanding the concern, BWC will modify the current fee schedule language to allow both the physician of record and surgeon to be paid during the global surgical period to facilitate compliance with this rule's provision. Thus, no language modification to this rule was needed. In addition, to reduce the possible confusion of how long impacted surgeons and physicians were expected to follow the injured worker after a lumbar fusion, BWC added the phrase "the allowed lumbar conditions" to the end of the originally proposed paragraph to clarify that stated MMI or maximum medical improvement period was relative only to the lumbar conditions allowed in a claim, as there may be other allowed conditions in the claim which are causing the claim not to be MMI.

Plaintiff/ injured worker counsel also proposed adding the following additional language to the rule: Notwithstanding any procedure in the Billing and Reimbursement Manual, the MCO shall respond to a C9 for a lumbar fusion procedure within 21 days. During the 21 days, the MCO shall communicate and discuss with the provider the medical necessity and criteria treatment guidelines adopted by the BWC for a lumbar fusion. If the MCO and provider agree that a second opinion is necessary, the MCO may pend the C9 until the second opinion is received and discussed with the provider. If the MCO and provider agree

that other additional treatment procedures need to be implemented prior to considering the lumbar fusion, the MCO shall dismiss the C9 and authorize the agreed additional treatment. If the MCO authorizes the C9 for lumbar fusion, the following shall occur: The MCO shall forward a copy of the “Lumbar Fusion Fact Sheet” to the injured worker. The injured worker, physician of record, and surgeon shall sign the “Acknowledgement Understanding” form prior to scheduling the surgery.” The stated goal of this recommendation was an attempt to propose an approach which for this type of surgery would permit more time for communication between MCO and providers than is presently supported in the system. BWC’s position is that the recommended language change was unnecessary and would itself cause unneeded delays in MCOs’ responses to this type of treatment request. BWC claims data indicates that on average a lumbar fusion surgery occurs more than 2 years after the date of injury. Thus, the medical information that is needed to ensure compliance with the rule should and in a majority of cases will already appear in the claimant’s file. Additionally, prior to a fusion surgery, a treatment authorization request of a surgery consult is as a routine matter submitted to the MCOs. This action will itself provide the MCOs the opportunity to engage the physician of record and the now known surgeon on the expectations of the rule. Given the ample opportunity to engage the physician of record and the surgeon, modifying the timeframe of the MCOs to render a decision on the treatment request would drive unnecessary increased time into the claim process.

Plaintiff/injured worker counsel recommended that the “Fact Sheet” be placed on the BWC website (and of course constantly updated). BWC agreed with this recommendation and will take action accordingly.

Plaintiff/injured worker counsel recommended that BWC and the MCO should discuss how to proceed with communicating this new rule with the surgeon. BWC agreed with this recommendation and will execute MCO training to clarify the Agency’s expectations of the MCOs in how they handle providers seeking a lumbar fusion treatment for an injured worker.

Plaintiff/injured worker counsel recommended that BWC should begin communication with the different servicing providers, corresponding with them over the “lumbar fusion” authorization procedure. BWC agreed with this recommendation. BWC has moved the effective date of the rule to January 1, 2018, which will allow for execution of a robust communication plan with physician of records and surgeons on the rule’s requirements.

Based on comments from the BWC Chief Medical Officer the original rule’s language in Paragraph A(1)(b)(i) was modified from the initial language of (i) Rest / ice / compression / elevation (RICE) to the more appropriate language of Relative rest / ice / heat.

Finally, pursuant to comments initiated by a BWC Board Member, regarding a sentence contained within the Acknowledgement and Understanding document found in the Appendix

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of the rule, BWC modified the language by deleting the sentence, deeming it unnecessary and serving only to create unwarranted angst and confusion. Specifically, BWC deleted the sentence which originally read: “If you continue to have pain after your surgery and I cannot find a medical reason for it, the BWC/MCO may not continue to pay and/or authorize further medical care.”

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?

A number of national studies, as well a specific Ohio lumbar fusion outcomes study were relied on to establish the basis for and parameters of the rule. Some of the data relied on in supporting the regulation as proposed is set forth below:

- General Lumbar Fusion Outcomes
 - a) The chance of an injured worker no longer being disabled 2 years after lumbar fusion is 32%.
 - b) More than 50% of workers who received lumbar fusion through the Washington workers’ compensation program felt that both pain and functional recovery were no better or were worse after lumbar fusion.
 - c) Smoking at the time of fusion greatly increases the risk of failed fusion.
 - d) Pain relief, even when present, is NOT likely to be 100%.
 - e) The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.
 - f) Lumbar fusion for the diagnoses of disc degeneration, disc herniation, and/or radiculopathy in work comp setting is associated with significant increase in disability, opiate use, prolonged work loss, and poor return to work status.
- Ohio Specific Lumbar Fusion Outcomes Study: (2 year follow-up – 1450 total patients)
 - a) Back pain patients treated with fusion were able to return to work (activity) only 26% of the time, workers treated non-surgically were able to return to work (activity) 67% of the time.
 - b) Re-operation rate was 27% in fused patients.
 - c) Complications occurred in 36% of fused patients.
 - d) Narcotic use increased 41% in fused patients, and continued for over 2 years in 76% of fused patients.
 - e) 17 of the fused patients died during the course of the study and 11 non-surgical patients.
- National/International Lumbar Fusion Statistics.
 - a) Surgical fusion outcomes are NOT better than cognitive therapy and exercise.
 - b) Surgical fusion for previous herniated disk is NOT better than non-operative treatment.
 - c) Surgical satisfaction was reportedly high even in injured workers with ongoing pain and no improvement in function observed.

- d) Some patients described less pain, improvement of 1 or 2 points on a 10 point pain scale, but any functional benefit of having a fusion was not demonstrated.
- Opioid use has been associated with significant long term morbidity and mortality in both surgical and non-surgical patients. Back pain patients are at risk for long term opioid use. Fusion patients have greater narcotic/opioid usage than non-operative patients.

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?

There were no alternative regulations considered.

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.*

No other performance based regulations were identified as appropriate for the content of these rules. While there are some elements of dictating the process, such as the provider needing to show there was where appropriate at least 60 days of a conservative care approach taken, the rule is does not totally dictate how a provider's decision regarding the necessity of a lumbar fusion for their injured worker client. Language in the rule expressly state that the rule "*...is not meant to preclude, or substitute for, the surgeon's responsibility to exercise sound clinical judgment in light of current best medical practices when treating injured workers.*" Thus, current best medical practices standards are expected to be adhered to, which are memorialized within the language of the rule.

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

The Bureau is the only state agency regulating workers' compensation claims, and the certification and enrollment of providers in the Health Partnership Program, and thus there is not another agency promulgating rules on lumbar fusion surgery.

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 Bureau will post the rules on its website, www.ohio.bwc.gov, and will distribute the rules to affected parties. Internal training will occur with Medical and Health Services staff, including provider relations, regarding the administration of the modified rule language. The MCOs will receive explicit training on the rule and the expectation of the MCOs in administering those rules. Injured workers and/or providers will be able to receive personal

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assistance from the BWC Medical Policy staff and MCOs members in interpreting or addressing unintended impacts of the rules' modifications.

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;

The impacted community includes providers involved with managing an Ohio injury claim leading to a possible lumbar fusion surgery.

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

Providers' additional administrative actions and time to ensure compliance with the documentation requirement reflected in the rule.

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.

It is expected that providers will incur less than 10 annual hours to meet the additional documentation across all potential lumbar spine surgery claims handled by a practice. It should be noted that all additional hours will be compensation pursuant to the BWC fee schedule rates for the services rendered.

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

As reflected in the language of the above statutory citations, BWC's is responsible for ensuring injured workers receive quality services to facilitate a successful outcome to a workplace injury. Spine care is a high impact area for quality initiatives. High variability exists in its delivery and the outcomes are all too frequently poor. Inappropriate utilization of the lumbar fusion procedures drives iatrogenic disease – more opioid dependence, psychiatric conditions, and disability. The goal of the rule is not to prevent those who the surgery can benefit, from receiving this treatment. Rather this rule will ensure proper education and quality decision-making is undertaken as such treatment is contemplated.

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Regulatory Flexibility

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

No.

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?

Not applicable. This new rule does not expose employers to fines or penalties.

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

Bureau rules and policies are available on www.ohio.bwc.gov. Also, BWC personnel, specifically the Claims Customer Care Team, Provider Relations business area, and the Managed Care Organization staff are available to assist injured workers, providers, and employers in addressing relevant compliance issues.