Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Bureau of Workers' Compensation

Rule Contact Name and Contact Information:

Aniko Nagy (614) 466-3293

Regulation/Package Title (a general description of the rules' substantive content):

Payment for spinal cord stimulator

Rule Number(s): 4123-6-35

Date of Submission for CSI Review: April 6, 2022

Public Comment Period End Date April 27, 2022:

Rule Type/Number of Rules:

New/ 1 rules

No Change/____ rules (FYR? ___)

Amended/____ rules (FYR? ___)

Rescinded/____ rules (FYR? ___)

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 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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

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. ☐ **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.

   This rule governs BWC's payment for a spinal cord stimulator implantation to treat a work related injury or occupational disease where one or more of the following conditions are allowed in the claim:

   - Failed thoracic or lumbar spinal surgery
   - Complex regional pain syndrome
   - Non-operable peripheral vascular disease/limb ischemia
   - Neuropathic pain post-thoracic or post-lumbar surgery
   - Chronic thoracic or lumbar radiculopathy.
   - Spinal cord injury dysesthesias

   The injured worker must undergo at least sixty-days of conservative care as described in the rule in addition to being personally evaluated by the operating surgeon through a comprehensive evaluation, requiring documentation of key elements as described in the rule.

Prior to approval and reimbursement of a permanent spinal cord stimulator implantation, the rule allows for reimbursement for a seven-day spinal cord stimulator trial when the injured worker and the physician of record, treating physician, or operating surgeon have reviewed and signed the educational document "What BWC Wants You to Know About Spinal Cord Stimulators" , with reimbursement for permanent implantation dependent upon the trial providing documentation demonstrating the injured worker's improvement in various areas as described in the rule.

The rule also outlines specific diagnoses and conditions where reimbursement for a spinal cord stimulator is prohibited.

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.**

   Authorize: 4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.66

   Amplify: 4121.12, 4121.121, 4121.44, 4121.441, 4123.66

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.

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

   Not applicable.

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)?**

   This rule supports the Agency's responsibility under R.C. 4123.66, which provides that the BWC Administrator "shall disburse and pay from the state insurance fund the amounts for medical, nurse, and hospital services and medicine as the administrator deems proper," and that the Administrator "may adopt rules, with the advice and consent of the BWC board of directors, with respect to furnishing medical, nurse, and hospital services and medicine to injured or disabled employees entitled thereto, and for the payment therefor."

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?** BWC will measure trends in requests and utilization of spinal cord stimulator implants, costs associated with the implants, as well as feedback from injured workers and stakeholders involved with services related to spinal cord stimulators.

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.

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.

BWC's proposed *Payment for Spinal Cord Stimulator* rule OAC 4123-6-35 was e-mailed to the following lists of stakeholders on December 16, 2021 with comments due back by December 31, 2021:

- 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)
    - 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

Stakeholder responses received by BWC are summarized on the Stakeholder Feedback Summary Spreadsheet.

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

Please see the Stakeholder Feedback Summary Spreadsheet attached to this BIA. This feedback was used to consider changes in the final draft of the rule.

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?**

BWC's Health Care Quality Assurance Advisory Committee (HCQAAC) was consulted in this matter, as well as several resources cited in the "What You Should Know About Spinal

Cord Stimulators" appendix to the rule, in addition to the references listed below citing studies on utilization, cost, and outcomes.

According to studies, spinal cord stimulator trials using CPT codes 63650 and 63655 respectively increased from 12,680 in 2009 to 36,280 in 2018 which demonstrates a 186% increase over the designated time period (Manchikanti et al., 2021).

Additional studies demonstrated health care expenditures associated with spinal cord stimulators increased a staggering 291% from 2009 to 2018, equating to a 16.4% increase year over year, resulting in $292,153,701 spent in 2009 and reaching $1,142,434,137 in 2018 (Manchikanti et al., 2021).

Placement of pulse generators from 2009 to 2018 grew over 200% where 7,640 spinal cord stimulators were implanted in 2009 and 22,960 were implanted in 2018 (Manchikanti et al., 2021).

According to research in 2017, a population was studied throughout 2007 to 2012 regarding removal of spinal cord stimulators, and roughly 9% of patients underwent removal of the device and noted a high correlation of higher baseline and total costs associated with care as well as a higher number of procedures to aid in pain management among these patients (Han et al., 2017)

This data supports the regulation being proposed because it demonstrates increased utilization trends associated with higher health care expenditures. Furthermore, injured workers may benefit from informed decision-making when electing to proceed with a spinal cord stimulator implant, which may lead to less devices being removed based upon our research across the health care industry.

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?**

    None. No regulatory alternatives which could be considered have been identified.

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.***

    No.

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

    This rule is specific to BWC and defines reimbursement for spinal cord stimulators in the Ohio workers' compensation system. Since BWC is the only state agency that administers workers'

compensation in Ohio, there is no duplication between this rule and other rules in the Ohio Administrative Code.

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 Bureau will provide notification to employers, injured worker representatives, providers, and MCOs via letters and other written materials, which will be supplied to impacted injured workers and employers.

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:** Employers, MCOs and medical providers participating in and managing workers' compensation claims.
    b. **Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,):** Initially, there will be some increase in resources devoted to communication, education, and claim review.
    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 data reviewed would suggest that clearer guidance on appropriate services for spinal cord stimulator implantation would be expected to decrease costs to the system over the long term.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?** The public purpose of the HPP is to effectively and efficiently address the needs of injured workers arising out of a workplace injury. The proposed new rule will facilitate BWC's effort to develop innovative practices which will create additional informed decision-making among injured workers and physicians while seeking to improve outcomes and minimize health care expenditures with the right care at the right time and setting.

Regulatory Flexibility

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

    No. The rule governs reimbursement for spinal cord stimulators performed by any service provider regardless of size.

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?**

    Not applicable.

20. **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 and Managed Care Organization staff are available to assist injured workers, providers, and employers in addressing relevant compliance issues.

Ohio | Bureau of Workers' Compensation
30 W. Spring St.
Columbus, OH 43215-2256

Governor **Mike DeWine**
Administrator/CEO **Stephanie McCloud**
www.bwc.ohio.gov
1-800-644-6292

Stakeholder Feedback Health Partnership Program
Ohio Administrative Code 4123-6-35
Payment for spinal cord stimulator

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
1	4123-6-35/Spinal Cord Stimulator	Paul Scheatzle, D.O.	"The indication and contraindication list looks good."	"A common theme I hear from MCOs is the extremely high cost of the stimulator."	N/A	No change
2	4123-6-35/Spinal Cord Stimulator	John Brannan, M.D.	"I think the "surgeons" in paragraph 2 should be changed to treating physicians."	This change should occur due to both surgeons and non-surgeons being involved with the care of injured workers utilizing this device.	After review of the suggestion, it is appropriate to change surgeons to treating physicians in paragraph 2 of the proposed rule.	Changed
3	4123-6-35/Spinal Cord Stimulator	Ron Hawes, M.D.	"I like it very much. It is fair and comprehensive and will help to reduce the unwarranted procedures currently being performed."	"This kind of guidance is what is needed from the BWC."	N/A	No change

Ohio | Bureau of Workers' Compensation
30 W. Spring St.
Columbus, OH 43215-2256

Governor **Mike DeWine**
Administrator/CEO **Stephanie McCloud**
www.bwc.ohio.gov
1-800-644-6292

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
4	4123-6-35/Spinal Cord Stimulator	Kalyan Lingham, M.D.	"Under Section B, when SCS will not be covered, point C (failed cervical spine surgery.....) might pose some problems."	"I believe the point trying to be made is that SCS will not be approved to TREAT these conditions. However, in the description for section B, it says "...when the following conditions or comorbidities are documented." This would imply that if I have a patient with CRPS of the lower extremity for which I request a lumbar SCS trial, if they had concurrent cervical radiculopathy, they would not be a candidate. However, this the SCS is being requested for a completely different, unrelated body part. Was this the intent of this criteria? The others listed are appropriate reasons for exclusion of the SCS as they are more systemic issues that would have an direct impact on the success of SCS. This cervical pathology criteria however is very specific to one body part, and would not have the same direct effect on SCS outcome."	BWC has recognize how this may create consternation among stakeholders and modified the language to provide more clarity.	Changed

Ohio | Bureau of Workers' Compensation
30 W. Spring St.
Columbus, OH 43215-2256

Governor **Mike DeWine**
Administrator/CEO **Stephanie McCloud**
www.bwc.ohio.gov
1-800-644-6292

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
5	4123-6-35/Spinal Cord Stimulator	Kalyan Lingham, M.D.	"The second document "What BWC wants you to know about Spinal Cord Stimulators" is pretty tilted."	"While patients should be educated about a treatment modality, this document is pretty much doom and gloom. There are a lot of variables at play with these studies, and studies which document poor long term outcomes can be found for any treatment modality (surgery, PT, chiropractic care, medication management, etc...). Do we have the actual study references for validation of the quality of the studies, was the sample size appropriate, was the power of the study strong, etc....Also, as with other highly reimbursable procedures, many patients had these done without proper indications, resulting in high failure rates. Perhaps this contributed to outcomes of certain studies. I am not disagreeing with some of the information, but it just seems the document provides very negatively	BWC feels the current references provide objectivity and does not warrant any changes.	No change

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
				skewed numbers. With technological improvements in programming capabilities (as I said in my email to Dave Kukielka at ODG), we are able to adapt to changing pain complaints over time, enabling maintenance of pain control over the long term, something that has not been able to be done as well in the past. Again, I think it's a very good idea to make the patient aware of outcomes of a treatment modality, but if I were a patient reading this document, I would never want one done. Also as a physician performing the SCS trial and subsequent implant, after the patient reads this document, I would likely have to really convince the patient to go through with the trial. But, also, if they happen to fail, there would be significant damage to the physician-patient relationship,		

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
				with feelings that the patient was forced into the procedure, knowing the outcome beforehand."		
6	4123-6-35/Spinal Cord Stimulator	Kalyan Lingham, M.D.	"One final thing to note about long term failures of SCS. Pain as you know is very subjective. If a patient has a pain level of 8/10, and they undergo a treatment which provides them relief, to say 4/10, they are happy at first. Over time, as with anything new, the "excitement" wears off. Eventually, a new baseline is established, where in this case, the 4/10 is now the new "8/10". Many patients are not aware of this. Some do, but many don't. I've heard this so many times, with stimulators. They say their stimulator doesn't help anymore, but I ask if they have ever turned it off to see if it is truly not helping, and they say "no." Once they do, they realize how much it is in fact helping them. Without digger deeper like this, the SCS is reported to be a "failure" long term."	N/A	BWC recognizes Dr. Lingham's comments regarding long term failures and pain, however, this does not cause BWC to make any additional changes to the proposed rule based upon the feedback.	No change