CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: **Ohio Bureau of Workers' Compensation**

Regulation/Package Title: **Ambulatory surgical center arthroplasty center**

Rule Number(s): **4123-6-02.22**

Date: **December 21, 2014**

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- ☐ **Rescinded**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.

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.

   This rule establishes the criteria for voluntary participation in BWC's ambulatory surgical center (ASC) arthroplasty program. Specifically the rule details:

- Criteria for an ASC to be able to perform specified arthroplasty procedures (i.e. joint replacements);
- BWC ability to credential and recredential a facility; and
- Criteria under which an ASC may be decertified, refused certification or recertification.

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

   ORC 4121.441(A)(1)(k) and (l)

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?**

   No.

   If yes, please briefly explain the source and substance of the federal requirement.

   N/A

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)?**

   Many joint replacement surgeries are currently covered only when they are performed in the hospital setting. This rule allows BWC to increase injured worker access to quality medical care in a lower cost quality service environment. The rule expands coverage of certain joint replacement procedures to ASCs, while also facilitating quality services by putting into place relevant criteria which ensures the procedures are performed in qualified ASC facilities.

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

   BWC will measure success by demonstrating Ohio's injured workers' increased access to quality medical care while assuring a competitive ambulatory surgical center fee schedule. The rule also has the potential for cost savings, reduced medical complications and a faster return to work.

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 proposed ambulatory surgical center services payment rule was posted on BWC's website for stakeholder feedback on November 9, 2015 with a two week open comment and a notice was e-mailed to the following lists of stakeholders:

   - BWC's Managed Care Organizations and the MCO League representative
   - 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.

8. **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 grid.

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?**

   BWC's ambulatory surgical center fee schedule, including the coverage of procedures, is based largely on Medicare's outpatient prospective payment system (OPPS) which includes ambulatory surgical center coverage and reimbursement rates. Medicare determines coverage status based on the safety and efficacy for typical Medicare patients who are older and have higher rates of co morbid medical conditions that may adversely affect surgical outcomes. Our injured worker population often includes younger, healthier patients who would more often pose lower surgical risks.

   The development of this program was recommended and approved by BWC's Health Care Quality Assurance Advisory Committee (HCQAAC) which is comprised of physicians and other health care clinicians. We also worked collaboratively with the Ohio Association of

Ambulatory Surgery Centers and their membership to obtain information on their current joint replacement programs and recommendations. In addition, BWC researched similar payers of these services and other states' workers' compensation programs. BWC also complied research regarding the safety and efficacy of performing certain joint arthroplasty procedures in ASC that have demonstrated the ability to deliver safe, high quality medical care.

The research and professional medical opinions support the implementation of this program which also includes safeguards for appropriate physician credentialing and patient selection.

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?**

    None. Pursuant to the recommendation s of the HCQAAC, the regulation was determined necessary to ensure the ASC facilities wanting to perform joint replacement services would present a quality and safe enviorment in which the services could be performed. As part of the BWC's fiduciary responsibility, the Agency must ensure that injured workers are not unnecessarily exposed to low quality care. Therefore, the criteria setforth in the rule were determined appropriate as an initial step to allow a facility to undertake the services.

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. Pursuant to BWC's statutory responsibilities and the direction of the HCQAAC, it was critical for BWC to establish the criteria which ensures the safety of injured workers receiving these services in a qualified ASC facility. Further, this rules clearly setforth the expectations which an ASC is able to make an informed decision as to whether the facility will provide the expanded services. The rule reflects minimum certification requirements and allows ASCs flexibility to achieve compliance.

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

    These rules are specific to BWC, and for coverage and reimbursement for ambulatory surgical center services in that program. Since BWC is the only state agency that administers workers' compensation in Ohio, there is no duplication between these rules and other rules in the Ohio Administrative Code.

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.**

BWC will ensure internal staff members are fully trained on the rule and related policies/procedures by the 5/1/16 implementation date. BWC will also educate physicians, ASCs and managed care organizations on the rule, policies and procedures through our established communication channels (e.g. Provider Billing and Reimbursement Manual, provider stakeholder meetings, provider associations, provider e-news, BWC-MCO billing and reimbursement workgroups, MCO quarterly training, etc.).

ASCs submitting applications to participate in the program will be reviewed consistently to ensure they meet the criteria set forth in the rule. If application deficiencies are suspected, BWC may utilize clinical resources such as our medical director and Health Care Quality Assurance Advisory Committee to opine whether or not the application meets the minimum requirements to ensure patient safety.

As noted in the rule, BWC will follow the existing recredentialing and decertification processes (4123-6-02 and 4123-6-17).

Finally, during the initial phases of the program, we will be collecting data to ensure injured workers continue to receive quality medical care and to assess program impacts. We will review the outcomes of each injured worker receiving these services against established quality measures. We will also track and monitor other program outcomes such as injured worker return to work rates; individual ASC performance; and estimated cost savings.

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 business community consists of the ambulatory surgical centers that provide services to injured workers and self insuring employers that also administer this rule.

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

Implementation of fee schedule changes is a necessary part of yearly methodology updates for both ambulatory surgical centers and self insuring employers. Because this rule is only a slight deviation from Medicare, both ambulatory surgical centers and self insuring employers will realize minimal adverse impacts. The adverse impact to the self insured employers will be employer time and/or reimbursement business expense for understanding the rule and related policies and procedures and

incorporating them into their existing workflows. The adverse impact to ambulatory surgical centers will be the cost of ambulatory surgical centers to complete the application to become an ASC arthroplasty center; however, ASC participation in this program is voluntary.

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 estimated that self insuring employers and ambulatory surgery centers would require less than 4 hours of time in order to comply with this rule.

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

The intent of this rule is to ensure access to quality health care for all Ohio employers' workers who experience a workplace injury. Increasing site of service options for injured workers may lead to faster return to work rates, reduced complication rates and lower medical costs which, in turn, also directly affect the business community.

Regulatory Flexibility

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

No. This rule is applied equitably across all ambulatory surgical centers which meet the patient safety criteria listed in the rule.

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 for paperwork violations under these rules.

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

BWC posts information related to provider rules on the BWC website at Ohiobwc.com. Also, providers that provide ambulatory surgical center care can contact BWC's Provider Relations Department or Medical Services Division for assistance with issues related to this rule.