

### **Business Impact Analysis**

Agency Name: Ohio Department of Medicaid	<del>-</del>
Regulation/Package Title: Ambulatory surgery cen	ter (ASC) services: provider eligibility,
coverage and reimbursement	
Rule Number(s): Subject to Business Impact Analysis: 5160-22-01 (R Not Subject to Business Impact Analysis, For Inform 5160-22-03 (Rescinded)	
Date:2/5/16	_
Rule Type:	
X New	X 5-Year Review
☐ Amended	X Rescinded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.

Rule 5160-22-01 (Rescinded) defines what an ambulatory surgery center (ASC) is, sets forth the standards for determining if an ASC can enroll in the Ohio Medicaid program, and how reimbursement for covered ASC services will be paid. This rule is being rescinded.

Rule 5160-22-01 (NEW) defines what an ambulatory surgery center (ASC) is, sets forth the standards for determining if an ASC can enroll in the Ohio Medicaid program, outlines covered and non-covered ASC surgical procedures, outlines covered facility services, and outlines the method of reimbursement. This is a new rule that will incorporate the covered

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and non-covered ASC services as outlined in Ohio Administrative Code (OAC) 5160-22-02 and the payment policies for facility services, laboratory services, radiological services and diagnostic and therapeutic procedures as outlined in OAC 5160-22-03.

Both OAC 5160-22-02 and 5160-22-03 are being rescinded as part of the 5 year review requirement and are included for informational purposes only.

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

Section 5164.02 of the Revised Code authorizes the Agency to adopt these rules.

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, the regulation does not implement a federal requirement.* 

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

Although ASCs are a mandatory service under the Medicaid program, neither federal law nor federal regulation dictates the eligibility requirements or manner of reimbursement. ODM has chosen, in this rule, to adopt the Medicare requirements for ASCs to prevent double licensure and certification costs on ASCs that would result if Medicaid adopted its own separate standards.

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 this rule is to set forth the requirements for an ambulatory surgery center (ASC) to become a Medicaid provider and be reimbursed for covered services.

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

The measurable outcomes of this regulation are the non-imposition of double licensure and certification costs on ASCs as well as the execution of provider agreements with ASCs and reimbursement for their services.

#### **Development of the Regulation**

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

The draft regulation was provided to the Ohio Association of Ambulatory Surgery Centers (OAASC) for review.

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

No comments were received from the Ohio Association of Ambulatory Surgery Centers (OAASC).

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?

Not applicable.

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. It would be time consuming and costly to both the Department and ambulatory surgery centers to set up and enforce an additional set of eligibility requirements for participation in Medicaid on top of those requirements already set forth by Medicare in 42 C.F.R. 416 subparts A to C.

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. Medicare's regulations set forth in 42 C.F.R. 416 already require quality assessment and performance improvement standards for ASCs to be accredited.

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

Medicaid rules were reviewed by Ohio Department of Medicaid staff, including legal and legislative staff. Ohio Administrative Code rule 5160-22-01 is the only regulation that defines how Ambulatory surgery centers can participate in the Medicaid program and how they are reimbursed.

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.

Rule 5160-22-01 sets forth the policies to determine which ambulatory surgery centers (ASCs) may be enrolled in the Medicaid program. To be eligible to participate in the Ohio Medicaid program, ASCs must have a valid agreement with CMS to provide ASC services in the Medicare program, thus ensuring predictability and consistency. ODM plans to release a public notice informing both the public and stakeholders of the updates.

#### **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;

This rule impacts all Ambulatory surgery centers who are or want to be an Ohio Medicaid provider.

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

This rule does not impose any license fees or fines. It does require ambulatory surgery centers to have a valid agreement with CMS to provide ASC services in the Medicare program.

c. Quantify the expected adverse impact from the regulation.

In order to obtain a valid agreement with CMS to provide ASC services in the Medicare program there is an estimated \$3000-\$5000 fee for accreditation (Source: The American Association for Accreditation of Ambulatory Surgery Facilities). However, as long as a valid agreement with CMS is maintained, there is no additional adverse impact in order to become a Medicaid provider. There is no expected adverse impact on existing ASC providers as they already meet the requirements.

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

There must be some standards for participation in the Medicaid program. Using the same standards as Medicare causes the least impact to providers and eliminates multiple certification processes and fees.

#### **Regulatory Flexibility**

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

No. Requiring ambulatory surgery centers (ASCs) have a valid agreement with CMS to provide ASC services in the Medicare program ensures that ASCs are providing safe and quality care to Medicaid consumers.

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 penalties or fines associated with this rule.

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

Providers needing enrollment assistance may contact ODM provider services at <a href="http://medicaid.ohio.gov/PROVIDERS/EnrollmentandSupport/ProviderEnrollment.aspx">http://medicaid.ohio.gov/PROVIDERS/EnrollmentandSupport/ProviderEnrollment.aspx</a> or hospital services at Hospital\_policy@medicaid.ohio.gov.

ASCs may email questions regarding rule 5160-22-01 to Hospital\_policy@medicaid.ohio.gov