# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

**Agency Name:** Ohio Department of Medicaid

**Regulation/Package Title:** Coverage of extra -corporeal -membrane -oxygenator (ECMO) services.

**Rule Number(s):**

**To be rescinded:** 5160-4-31

**Date:** March 19, 2017

**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- ☑ Rescinded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.***

   Rule 5160-4-31, "Coverage of extra -corporeal -membrane -oxygenator (ECMO) services," sets forth Medicaid coverage of and payment for professional services associated with ECMO procedures and treatments. This rule is proposed for rescission upon five-year rule review since ECMO covered services are set forth in Appendix DD to OAC rule 5160-1-60 and the most current guidelines for reporting professional ECMO procedures and treatments are included in the Current Procedure Terminology (CPT) codebook that is updated annually. Rule 5160-1-19, titled "Claim submission," states that medical claims must be submitted pursuant to the National Correct Coding Initiative (NCCI) and coding guidelines set forth in the Current Procedure Terminology (CPT) codebook. Therefore, rule 5160-4-31 is no longer necessary since ODM does not have additional ECMO treatment policies other than the requirement to report services in accordance with CPT guidelines.

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

   The Ohio Department of Medicaid (ODM) has promulgated this rule under 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.***

   No.

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

   These payment policies are not required by federal law, but they do fall within the federal authority granted to states in administering the Medicaid program.

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)?**

   This rule establishes coverage and payment policies for the professional services associated with ECMO procedures and treatments.

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

The success of the rescission of this rule will be measured by the extent to which the Medicaid Information Technology System (MITS) results in correct payment of claims for services and supplies rendered.

## 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 following associations were contacted by email prior to the public clearance process: the Ohio State Medical Association (OSMA), the Ohio Association of Advanced Practice Nurses (OAAPN), and the Ohio Association of Physician Assistants (OAPA). The associations were informed of the proposed rule rescission and the rationale for the proposed rescission. Each association was asked to respond with questions, comments, and/or recommendations regarding this proposed rule rescission.

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

   OAAPN and OAPA replied to thank the department for the chance to review the proposed rule rescission and neither association had questions, comments, concerns, or opposition.

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 use of scientific data does not apply to the development of this rule.

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?**

    No alternative was apparent.

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?**

Upon five year review, ODM determined that the professional guidelines from the CPT specifically direct how ECMO services should be reported when rendered by physician and non-physician practitioners. OAC rule 5160-1-19, titled "Claim submission," states that medical claims must be submitted pursuant to the National Correct Coding Initiative (NCCI) as well as the CPT reporting guidelines. The CPT and NCCI guidelines are updated annually at a minimum. Accordingly, ODM determined that 5160-4-31 is no longer necessary.

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 policies set forth in this rule are already incorporated into the Medicaid Information Technology System (MITS) through the application of the National Correct Coding Initiative editing. Therefore, the regulation is applied to the Department's electronic claim-payment system automatically and consistently whenever an appropriate provider submits a claim for an applicable service.

## 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 scope of the impacted business community consists of providers of professional services, including physicians and non-physician practitioners of ECMO treatments.

    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
       This rule imposes no license fees or fines. The adverse impact in this rule is the dictation and maintenance of required documentation in the individual's medical record.

    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.***

       This rule is being proposed for rescission; therefore, there will no longer be a departmental regulation requiring documentation in the medical records. Documentation of medical records is a national standard required by all practitioners for ECMO medical treatments based on the National Correct Coding Initiative and the CPT reporting guidelines. The cost of maintaining and updating an individual's medical record varies from practitioner to practitioner depending on a variety of

factors. For example, the technology used by a practitioner for documentation in electronic medical records could significantly differ from the cost of documenting services in hard copy medical records. This cost also depends on who performs the task. The median statewide hourly wage for a billing clerk, according to Labor Market information (LMI) data published by the Ohio Department of Job and Family Services, is $16.10; for a physician, it is $58.03. Adding 30% for fringe benefits brings these figures to $20.96 and $75.43, generating a documentation cost between $1.76 (five minutes at $20.96 per hour) and $37.71 (thirty minutes at $75.43 per hour). These documentation requirements are expected throughout the industry; therefore there is no actual adverse impact beyond what is standard and routine medical record documentation within the industry.

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

    The procedure code reporting requirements and national documentation requirements amount to claim-submission instructions based on the National Correct Coding Initiative and the CPT reporting guidelines. Documentation requirements are standard and routine within the industry. They help to ensure that the professional standards are consistent and appropriate to the needs of the persons receiving the treatments. Since this rule is to be proposed for rescission, there will no longer be a specific regulation requiring documentation for ECMO services.

## Regulatory Flexibility

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

    These requirements proposed for rescission are applied uniformly and no exception is made based on an entity's size.

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?**

    These rules impose 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 submission procedures. Providers and clearinghouses have public access to information sheets and instruction manuals on the Ohio Department of Medicaid's 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

5160-4-31 **Coverage of extra-corporeal-membrane-oxygenator (ECMO) services.**

(A) A physician may be reimbursed for the professional services associated with ECMO treatments for patients that meet the criteria for ECMO as set forth by the hospital where the service is performed. The hospital's criteria for ECMO must be consistent with acceptable medical practices.

(B) The department will not cover ECMO treatments performed for conditions for which the efficacy has not been established and the treatments have not been accepted as standard medical practice for the patient's condition. ECMO under these circumstances will be considered an experimental procedure. In general, ECMO is indicated for any cardiac and/or pulmonary condition (whether congenital or acquired) that is unresponsive to conventional therapy with a high likelihood of morbidity and/or mortality without ECMO.

(C) The physician who inserts the cannula for the ECMO procedure and initiates the ECMO treatment may be reimbursed for these services by billing current procedural terminology (CPT) code 36822. This procedure will be paid in addition to CPT code 33960 as noted in paragraph (I) of this rule.

(D) Reimbursement is available for professional services associated with the maintenance and management of ECMO treatments provided over a twenty-four-hour period.

(E) Except as provided for in paragraph (F) of this rule, reimbursement for evaluation and management services, including newborn critical care services, are bundled into the reimbursement for ECMO.

(F) Reimbursement is available for evaluation and management services, including newborn critical care services, provided prior to the initiation of ECMO treatments.

(G) Reimbursement is available for diagnostic, therapeutic, and surgical services that are not integral to ECMO treatment but are personally provided by the physician during the treatment.

(H) For the supervising physician to be entitled to reimbursement when residents, interns, or fellows are involved in the management of a patient during an ECMO treatment, the medical records must demonstrate that the supervising physician was personally present in the unit with sufficient regularity during the twenty-four hour period that

it could be concluded that the supervising physician was personally responsible for the patient's care during the ECMO treatment.

(I) Providers should bill CPT code 33960 for the first twenty-four hours and 33961 for each additional twenty-four hours.

Regardless of the number of providers, no more than twenty-four hours of ECMO services shall be reimbursed during a twenty-four hour period.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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|---|---|
| Promulgated Under: | 119.03 |
| Statutory Authority: | 5164.02 |
| Rule Amplifies: | 5162.03, 5164.02, 5164.70 |
| Prior Effective Dates: | 5/25/91, 4/1/92 (Emer), 7/1/92, 3/31/94, 1/1/01 |