ACTION: Final

The Common Sense Initiative

CSI - Ohio

Business Impact Analysis

Agency Name: Ohio Department of Medicaid (ODM)	
Regulation/Package Title: <u>DMEPOS: Wheelchairs</u>	
Rule Number(s):	
SUBJECT TO BUSINESS IMPACT ANALYSIS:	
To Be Rescinded: 5160-10-16	
New: 5160-10-16	
NOT SUBJECT TO BUSINESS IMPACT ANALYSIS, INCLUDED FOR INFORMATION ONLY:	
To Be Rescinded: 5160-10-16.1	
Date: September 23, 2015	
Rule Type:	
☑ New □ Amended	☑ 5-Year Review ☑ Rescinded
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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.

Existing rule 5160-10-16, "Wheelchairs," sets forth coverage and payment policies for wheelchairs, related accessories, and seating options. This rule is being proposed for rescission. Coverage and payment policies for wheelchairs and related items are incorporated into new rule 5160-10-16.

Existing rule 5160-10-16.1, "Wheelchair rentals," sets forth coverage and payment policies for the rental of wheelchairs. This rule is being proposed for rescission. Coverage and payment policies for wheelchair rental are incorporated into new rule 5160-10-16.

New rule 5160-10-16, "DMEPOS: wheelchairs," sets forth coverage and payment policies for wheelchairs, related accessories, seating options, and wheelchair rental. This rule replaces rescinded rules 5160-10-16 and 5160-10-16.1.

The new rule comprises many substantive changes:

- The Medicare wheelchair groupings for power mobility devices are adopted. As a result, the current handful of procedure codes in the claim-payment system that represent power wheelchairs are replaced by dozens of additional, item-specific codes, each with its own maximum payment amount (which is often less than the amount currently paid).
- The concept of a basic equipment package is adopted. When a wheelchair is purchased, no separate payment is made for items in the basic equipment package.
- Definitions are clarified or created for key terms: basic equipment package, complex rehabilitation technology (CRT), custom wheelchair, customized seating system, individualized seating system, and need verification.
- Payment is allowed for a manual wheelchair in addition to a power mobility device if having that backup wheelchair significantly improves an individual's mobility and is cost-effective.
- Payment is allowed for the professional evaluation of an individual's needs for a wheelchair.
- A replacement schedule for equipment, parts, and accessories is established.
 The distinction between major and minor repairs is eliminated. Need
 verification rather than prior authorization is applied to most repair requests
 and to replacement requests that do not exceed the established frequency
 guidelines. Replacement requests for wear items (e.g., caster bearings, tires,
 arm pads) are exempted from need verification.

- Maximum payment amounts for equipment, parts, and accessories are specified by formula (a percentage of Medicare fee-for-service allowed amounts).
- A maximum payment amount for labor is established and specified by formula (based in part on a U.S. Bureau of Labor Statistics hourly wage for medical equipment repair technicians and on certain mileage assumptions).
- Three existing wheelchair-related certificates of medical necessity (CMNs) are merged into a single new form.
- 2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The Ohio Department of Medicaid (ODM) is promulgating these rules 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.

Provisions in 42 C.F.R. Part 447 Subpart B require each state Medicaid program to maintain documentation of the amounts it pays for supplies and services and to provide public notice of any significant proposed change in its methods and standards for establishing payment amounts. Changes involving the addition, revision, or discontinuation of Healthcare Common Procedure Coding System (HCPCS) codes are required to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA).

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

These rules do not exceed federal requirements.

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)?

Medicaid rules perform several core business functions: They establish and update coverage and payment policies for medical goods and services. They set limits on the types of entities that can receive Medicaid payment for these goods and services. They publish payment formulas or fee schedules for the use of providers and the general public.

ODM has four aims in proposing these changes to the wheelchair rules:

- To increase or enhance access to wheelchair-related services for Medicaid recipients
- To reduce the administrative burden on suppliers of wheelchairs and related equipment
- To increase administrative efficiency within ODM
- To strengthen program integrity
- 6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of these rules will be measured by the extent to which suppliers report the newly adopted procedure codes on the claims they submit and by the extent to which operational updates to the Medicaid Information Technology System (MITS) result in the correct payment of claims.

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.

01/21/2014: On-site educational visit with Ohio Association of Medical Equipment Services (OAMES) suppliers

02/14/2014: On-site educational visit with Sonshine Medical representatives (Canton)

02/20/2014: On-site educational visit with ABC Pediatric Therapy representatives (Cincinnati)

03/20/2014: On-site educational visit with OSU Seating Clinic representatives

03/21/2014: In-person meeting with OAMES representatives

03/26/2014 – 04/30/2014: Conference phone calls with Georgia, Michigan, and Washington Medicaid staff members

04/07/2014 - 04/22/2014: In-person meetings and conference phone calls with representatives of the Medicaid managed care plans

04/17/2014: In-person meeting with Ohio Department of Developmental Disabilities representatives

04/23/2014: In-person meeting with Ohio Department of Education representatives

04/29/2014: In-person meeting with an Ohio Respiratory Care Board representative

05/01/2014: In-person meeting with ARC of Ohio representatives

05/01/2014: In-person meeting with internal MyCare Ohio staff members

05/04/2014: In-person meeting with Dr. Rosalind Batley, clinical pediatrics specialist at Nationwide Children's Hospital

05/07/2014: In-person meeting with Ohio Department of Aging representatives

05/19/2014: In-person meeting with Ohio Developmental Disabilities Council representatives

06/24/2014: In-person meeting with representatives of BCMH (a program in the Ohio Department of Health)

07/15/2014: In-person meeting with CSIO representatives

01/28/2015 – 02/25/2015: Review of the draft rule by the Health Care Fraud Section of the Office of the Ohio Attorney General

02/03/2015 – 04/27/2015: Review of the draft rule by OAMES

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

01/21/2014, OAMES

Input: Information about the wheelchair process, especially the seating and fitting evaluation

Effect: Expansion of the focus of the rule, discussions, and inclusion of stakeholders

02/14/2014, Sonshine Medical

Input: Discussion about how current wheelchair policy affects suppliers of wheelchairs to nursing facility (NF) residents

Effect: Additional information

02/20/2014, ABC Pediatric Therapy

Input: Discussion of the supplier's therapy and wheelchair fitting services and the impact of wheelchair policy changes on its business; comment that the supplier is not currently paid for wheelchair fittings

Effect: Provision in the revised rule allowing payment for an assessment/evaluation

03/20/2014, OSU Seating Clinic

Input: Demonstration of operations

Effect: Use of the OSU Seating Clinic as a reference model; expansion of the focus of the rule, discussions, and inclusion of stakeholders

03/21/2014. OAMES

Input: Discussion of concerns with current wheelchair policy

Effect: Clarification of wording in the revised rule

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03/26/2014 - 04/30/2014, Washington, Georgia, and Michigan Medicaid

Input: Policy discussion

Effect: Development of the new payment methodology and the provision allowing payment for backup equipment

04/07/2014 – 04/22/2014, Medicaid managed care plans (MCPs)

Input: Information about MCP policies and procedures, in particular how each plan performs prior authorization review for wheelchairs, accessories, related equipment, and repairs

Effect: Clarification of wording in the revised rule

04/17/2014, Ohio Department of Developmental Disabilities

Input: Discussion of problems encountered in getting access to wheelchair evaluations

Effect: Further development of the provision allowing payment for an assessment/evaluation

04/23/2014, Ohio Department of Education

Input: Statements that there are many different points of entry for wheelchair-referral and that a prescribing physician, although necessary, is not always the starting point when an individual begins the process of obtaining a wheelchair Effect: Expansion of the focus of the rule, discussions, and inclusion of stakeholders

04/29/2014, Ohio Respiratory Care Board

Input: Board requirements for wheelchair providers

Effect: A better understanding of how to describe rendering and billing providers

05/01/2014, The ARC of Ohio

Input: Discussion of bottlenecks in the current overall wheelchair delivery system Effect: Other policy discussions and meetings with additional stakeholders

05/01/2014, MyCare staff

Informational meeting about upcoming wheelchair policy changes and discussion of potential impact on MyCare providers and recipients

05/04/2014, Dr. Rosalind Batley, Nationwide Children's Hospital

Input: Discussion of how the wheelchair-fitting process is conducted at Nationwide Children's Hospital

Effect: Further development of the provision allowing payment for backup equipment

05/07/2014, Ohio Department of Aging

Input: Information about how the waiver process works for wheelchairs, what types of wheelchair requests the waiver unit is receiving, and how the waiver unit approves those requests

Effect: Further development of the provision allowing payment for backup equipment

05/13/2014, Ohio Physical Therapy Association

Input: Statement that Ohio Medicaid recipients have to wait months for wheelchair evaluations/assessments because there are not enough physical therapists to perform them

Effect: Further development of the provision allowing payment for an assessment/evaluation.

05/19/2014, Ohio Developmental Disabilities Council

Input: Concerns about current prior authorizations and about obtaining backup wheelchairs (two topics that happen to be addressed in the proposed policy changes)

Effect: Further development of the provision allowing payment for backup equipment

06/24/2014, BCMH (a program in the Ohio Department of Health)

Input: Concerns about backup wheelchairs and the possibility of conducting a reevaluation for a new wheelchair before five years have passed

Effect: Further development of the provision allowing payment for backup

Effect: Further development of the provision allowing payment for backup equipment and removal of language implying a five-year waiting period for a new wheelchair

07/15/2014, CSIO

Informal presentation of the revised wheelchair rule and the results of the many months of meeting with external stakeholders, planning with internal stakeholders, and discussion with ODM managers

02/25/2015, Health Care Fraud Section of the Office of the Ohio Attorney General Input: Suggestion that the word *evidence* be added to the requirements for post-delivery record-keeping

Effect: Addition of the word *evidence* within a sentence structure somewhat different from the example offered

04/27/2015, OAMES

Input: Five suggestions for correction, removal, or clarification of wording; one suggestion for a modification to policy involving prior authorization of payment; and two objections to establishing Medicaid payment as a percentage of the corresponding Medicare allowed amount

Effect: Incorporation, with some modification, of the wording changes; rejection of the suggested change in payment policy (on the ground that authorization based on a determination of medical necessity does not in and of itself guarantee that payment will be made); and reaffirmation of the payment structure under development

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?

Utilization and expenditure data drawn from ODM's Quality Decision Support System were used in projecting the fiscal impact of the proposed changes.

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?

ODM developed this rule in collaboration with numerous stakeholders. The policy goals of improving access, reducing administrative burden on providers, and increasing efficiencies have been well received by all stakeholders.

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 rule-making does not apply to these items and services.

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

Rules involving Medicaid providers are housed exclusively within agency 5160 of the Ohio Administrative Code. Within this division, rules are generally separated out by topic. It is clear which rules apply to which type of provider and item or service; in this instance, there was no duplication.

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 the new rule will be incorporated into the Medicaid Information Technology System (MITS) as of the effective date of the rule. They will therefore be automatically and consistently applied by ODM's electronic claim-payment system 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;

Changes to policies, payment formulas, or payment amounts affect suppliers of durable medical equipment (DME).

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

The reporting requirements laid out in these rules involve the documentation of medical necessity, which helps to substantiate the appropriateness of the equipment dispensed to Medicaid-eligible individuals.

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 adverse impact lies in the time needed by a supplier to fill out paperwork (or the electronic equivalent). Completing a prior authorization request, which must be accompanied by a completed certificate of medical necessity and involves the entry of certain information (e.g., customer identification, HCPCS codes, part numbers, descriptions of repairs), takes between five and thirty minutes of supplier staff time. This estimate is based on the professional experience of ODM staff members and on figures reported by Medicaid providers. The wage cost 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 medical equipment repairer, it is \$24.23; for a higher-level manager, it is \$36.32. With an additional 30% for fringe benefits, submitting a prior authorization request costs between \$1.75 (five minutes at \$20.93 per hour) and \$23.61 (thirty minutes at \$47.22 per hour).

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

The paperwork requirements spelled out in these rules for testing, measurement, and documentation are consistent with requirements in the commercial health insurance industry and the federal Medicare program. They are effective tools for preventing fraud, waste, and abuse and for promoting quality and cost-effectiveness; they help to ensure that the Ohio Medicaid program pays for medical equipment that is most appropriate to the needs of the person who will use it.

Regulatory Flexibility

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

These rules outline actions all providers must take in order to receive Medicaid payment. They do not set forth requirements for engaging in business, and no exception is made on the basis of an entity's size.

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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 claim-submission procedures.

Information sheets and instruction manuals on various claim-related topics are readily available on the Medicaid 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*.

For questions about program coverage of and limitations on DME, ODM maintains the DME Question Line and Voice Mailbox, (614) 466-1503.