CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: BHPP 'Unbundling' rules

Rule Number(s):

Rule 5101:3-10-03 (Rescinded/New), Appendix A (Rescinded/New), Appendix B (Rescinded);

Rule 5101:3-10-08 (Amended), Appendix A (Rescinded);

Rule 5101:3-10-13 (Rescinded/New), Appendix A (Rescinded/New);

Rule 5101:3-10-13.1 (Rescinded), Appendix A (Rescinded);

Rule 5101:3-10-16 (Amended);

Rule 5101:3-15-02.8 (Amended)

Date: September 19, 2013

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- ☑ Rescinded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.

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

CSIOhio@governor.ohio.gov

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.

A nursing facility (NF) that participates in Medicaid is paid a daily amount (a "per diem") for providing a defined package—or bundle—of goods and services to its Medicaid-eligible residents. Amended Substitute House Bill 59 (130th General Assembly) has removed three items from this bundle: (1) custom wheelchairs and major wheelchair repairs, (2) oxygen, and (3) transportation by ambulance or wheelchair van. Payment for these items and services is no longer included in the NF per diem. These services may now be furnished by eligible Medicaid providers on a fee-for-service basis.

The following rules are being amended accordingly.

Rule 5101:3-10-03, titled "Medicaid supply list," describes the coverage of medical/surgical supplies, durable medical equipment, and supplier services by the Ohio Medicaid program. The appendix to the rule indicates whether an item is covered for all places of service, is covered only when it is provided in someone's personal residence, or is not covered when it is provided in a NF. This rule is being rescinded and replaced by new rule 5101:3-10-03.

New rule 5101:3-10-03, titled "Medical supplies and the medicaid supply list," describes the coverage of medical/surgical supplies, durable medical equipment, and supplier services by the Ohio Medicaid program. The appendix to the rule indicates whether an item is covered for all places of service, is covered only when it is provided in someone's personal residence, or is not covered when it is provided in a NF. This rule replaces current rule 5101:3-10-03.

Changes: The body of the rule has been reorganized and streamlined and unnecessary references have been removed. The nursing facility (NF) limitation on the coverage of oxygen and custom wheelchairs has been removed from appendix A. Form JFS 01913 (a certificate of medical necessity) is still referenced in the body of the rule, but it is no longer incorporated into the rule as appendix B. These changes take effect on December 31, 2013.

Rule 5101:3-10-08, titled "Repair of medical equipment," sets forth coverage and payment provisions for the repair of medical equipment.

Changes: The exclusion of fee-for-service coverage of custom wheelchair repair for nursing facility (NF) residents has been removed. The required modifier for certain repairs has been changed from RP (replacement and repair) to RB (replacement of a part during a repair), and Healthcare Common Procedure Coding System (HCPCS) procedure code K0739 has been adopted to represent a labor component of durable medical equipment (DME) repairs for which no other specific procedure code exists. Form JFS 01904 (a certificate of medical necessity) is still referenced in the body of the rule, but it is no longer

incorporated into the rule as an appendix. These changes take effect on December 31, 2013.

Rule 5101:3-10-13, titled "Oxygen: covered services and limitations in a private residence," sets forth coverage and payment provisions for oxygen provided in a person's home. This rule is being rescinded and replaced by new rule 5101:3-10-13.

Rule 5101:3-10-13.1, titled "Oxygen: covered services and limitations in an intermediate care facility for the mentally retarded (ICF-MR)," sets forth coverage and payment provisions for oxygen provided to residents of long-term care facilities. This rule is being rescinded and replaced by new rule 5101:3-10-13.

New rule 5101:3-10-13, titled "Oxygen services," sets forth coverage and payment provisions for oxygen. This rule replaces current rules 5101:3-10-13 and 5101:3-10-13.1.

Changes: The exclusion of fee-for-service coverage of oxygen for NF residents has been removed. Maximum fee amounts for oxygen services have been revised and are now listed in a new appendix to the rule instead of Appendix DD to rule 5101:3-1-60 of the Ohio Administrative Code. Rental of oxygen-delivery systems is now limited (capped); no additional payment is made after the thirty-sixth month of the useful life of a system. These changes take effect on December 31, 2013.

Rule 5101:3-10-16, titled "Wheelchairs," sets forth coverage and payment provisions for wheelchairs.

Changes: The exclusion of fee-for-service coverage of custom wheelchairs for NF residents has been removed. The required modifier for certain repairs has been changed from RP to RB. References to ODJFS have been updated, and other minor corrections have been made to the text. These changes take effect on December 31, 2013.

Rule 5101:3-15-02.8, titled "Medical transportation services: eligible providers," sets forth the conditions under which businesses may be enrolled as providers of ambulance or wheelchair van (ambulette) services. It also specifies that for transportation services provided to residents of a NF, payment will no longer be made on a fee-for-service basis and that the provisions in Chapter 5101:3-15 of the Ohio Administrative Code (transportation rules governing ambulance and wheelchair van services) no longer apply.

Change: The exclusion of fee-for-service coverage of transportation services for NF residents has been removed. This change takes effect on January 1, 2014.

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.

Ohio Medicaid receives federal matching funds for coverage of medically necessary durable medical equipment and transportation. 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 methodologies or fee schedules for the use of providers and the general public.

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 according to three criteria:

a. The extent to which payment is made not through the per diem allocation but on a fee-for-service basis for the following items and services provided to Medicaid-eligible residents of nursing facilities (NFs):

   (1) Custom wheelchairs;

   (2) Major wheelchair repairs;

   (3) Oxygen; and

   (4) Medically-related transportation;

b. The extent to which a time limit (cap) is applied to the rental of oxygen-delivery systems; and

c. The extent to which DME suppliers and providers of medically-related transportation are able to submit claims that are correctly paid.

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 proposal to shift payment from the nursing facility (NF) per diem allocation to a fee-for-service basis for custom wheelchairs and major wheelchair repairs for NF residents originated with stakeholders who worked with their elected legislators to include this provision in Amended Substitute House Bill 59. This proposal was subject to the public process as the budget bill moved through House, Senate, and Conference Committees.

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

On September 5, 2013, representatives from the Medicaid Director's Office discussed with the Ohio Association of Medical Equipment Suppliers (OAMES) the proposed changes in the rules, particularly the changes affecting fees paid for oxygen services as well as requests from federal auditors to move Ohio's medical equipment pricing strategy to be more in line with Medicare selective contracting. OAMES members expressed concern about the changes to the fee schedule and acknowledged the difficulties faced by the department. Both OAMES and the department will continue to work on resolution of the fee schedule and it is anticipated that based upon continued negotiations, modifications may be made to the fee structure. Drafts of the rules will be submitted to Clearance shortly. All comments received will be carefully reviewed to determine whether modifications are necessary to the rules before they are formally filed with the Joint Committee on Agency Rule Review (JCARR). Any suggestions made by stakeholders will be sent to the CSI Ohio office, along with the responses given and a description of any changes made as a result of those suggestions.

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 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?

No alternatives were considered to shifting payment from the nursing facility (NF) per diem allocation to a fee-for-service basis for custom wheelchairs and major wheelchair repairs for NF residents, because this requirement was set forth in the biennial budget. No alternatives were considered to "capping" rental of oxygen-delivery systems, because this payment limitation is currently imposed by Medicare nationwide; aligning the coverage and payment policies of Ohio Medicaid and Medicare makes it easier for providers to do business with both payers.

Another impetus for reducing fees came in August 2013 in the form of a request made by the Columbus-based Medicaid Audit Coordinator for the Centers for Medicare & Medicaid Services (CMS). Citing an April 2013 report issued by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services, the Coordinator asked ODM about its plans to reduce its expenditures for DME items and to compare its projected savings with the 32% reduction identified by the OIG.

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.

A performance-based regulation is inappropriate in this instance because of the regulatory requirement that services paid for by Medicaid must be medically necessary as described in OAC rule 5101:3-1-01.

Medical necessity is a fundamental criterion not just for Medicaid and Medicare but for every commercial insurance company. The medical necessity of a product or service is documented on a form known as a certificate of medical necessity (CMN). Without documentation of medical necessity, Ohio Medicaid would be unable to qualify for matching federal funds.

Ohio Medicaid's CMN for oxygen is very similar to the form required by the Centers for Medicare & Medicaid Services (CMS) for oxygen services provided to Medicare beneficiaries. Because oxygen is considered a drug in Ohio, the Ohio State Board of Pharmacy requires sellers of oxygen services to obtain an order (a prescription) from an authorized prescriber. The Medicaid CMNs for oxygen, for wheelchairs, and for repair of DME serve essentially as prescription forms.

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 division 5101:3 of the Ohio Administrative Code. Medicaid staff ensured no duplication in the subsequent sections of OAC.

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 proposed changes to the payment for custom wheelchairs, major wheelchair repairs, oxygen, and medically-related transportation will be incorporated into the Medicaid Information Technology System (MITS) as of the effective date of the applicable rule. They will therefore be automatically and consistently applied by the department'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;

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

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.

a. The proposed changes to the payment for custom wheelchairs, major wheelchair repairs, oxygen, and medically-related transportation affect nursing facilities (NFs) and providers of DME and medically-related transportation.

b. These rules impose no license fees or fines. The reporting requirements laid out in these rules involve the documentation of medical necessity, to provide medically appropriate equipment to Medicaid consumers.

c. Any adverse operational impact, either on individual providers or in the aggregate, is attributable to securing and maintaining documentation of medical necessity.

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

Prior authorization processes are common in the healthcare industry and are effective tools to ensure quality and cost effectiveness and to avoid fraud, waste and abuse. In

the context of medical equipment, the tests or measurements required to be documented by these rules are consistent with those in the private health insurance industry and the federal Medicare program, and are necessary to ensure that the Ohio Medicaid program is not called upon to reimburse a provider for medical equipment that would be insufficient or in appropriate to meet the medical needs of the Medicaid beneficiary.

Regulatory Flexibility

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

These rules do not require any compliance action on the part of providers other than to submit claims when they want Medicaid payment.

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.

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