CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Office of Medical Assistance

Regulation/Package Title: Hearing Aids

Rule Number(s): 5101:3-10-11

Date: 5/22/13

Rule Type:

- ☐ New
- X 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- ☐ Rescinded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.**

Rule 5101:3-10-11, titled "Hearing aids," sets forth the coverage and reimbursement provisions for hearing aids for Medicaid consumers.

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

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Ohio Revised Code Sections 5111.01 and 5111.02.

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?**

Yes. Under federal law (including sections 1901 and 1905 of the Social Security Act), federal funding is provided to States for providing Medicaid services when those services are medically necessary. (This requirement is replicated in State law at Ohio Administrative Code Rule 5101:3-1-01.) In addition, 42 CFR 440.70(b)(3)(i) states that "a recipient's need for medical supplies, equipment, and appliances must be reviewed by a physician annually."

A certificate of medical necessity (CMN) is the mechanism by which OMA assures a recipient's need for the service provided, in this case a hearing aid. The documentation required in this rule is the background information necessary to determine medical necessity.

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

The federal language broadly states that a recipient's need must be established by a physician. The CMN is a succinct, standardized form that documents the physician's annual review while also outlining the clinical criteria required to demonstrate the need for the device(s). The standardization of the form allows for ease in process on both the side of the providers as well as for the agency in reviewing the CMN.

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 public purpose of this regulation is to provide hearing aid suppliers, who are subject to regulation under Ohio Revised Code Chapters 4747 and 4753 (by the Hearing Aid Dealers and Fitters Licensing Board and the Board of Speech-Language Pathology and Audiology, respectively) the authority to seek reimbursement for fitting and dispensing hearing aids to Medicaid consumers. The regulation defines medical criteria that must be met before the Ohio Medicaid program will make reimbursement, thus ensuring that the services being reimbursed are sufficient, yet not excessive, to meet the medical need of the consumer.

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

The success of the Medicaid hearing aid program will be measured by validating that Medicaid consumers can continue to access hearing aids via their preferred provider, and by monitoring the dispensing of hearing aids to assure that consumers are receiving the appropriate hearing aids required to meet their clinical needs as affirmed by a licensed prescriber.

Development of the Regulation

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

OMA consulted and collaborated with the Ohio Speech & Hearing Governmental Affairs Coalition, a group of 4000 licensed speech-language pathologists and audiologists in Ohio that provide hearing aid services to Ohio Medicaid consumers. This collaboration has been ongoing in order to address the hearing aid needs of Ohio Medicaid consumers since 2005, and this rule language has the broad backing of the Coalition.

Please reference the attached letters from various stakeholders regarding the fiscal impact of this proposed rule.

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

Stakeholders provided direct input into the development of the proposed rule from the outset of this project. They agree that the proposed rule is reflective of the current state of the hearing aid industry and that regulations reflected in the rule are appropriate for maintaining a quality hearing aid program for both adults and children.

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 medical necessity criteria contained in this proposed rule was developed in collaboration with clinicians who are part of the Ohio Speech & Hearing Governmental Affairs Coalition, a group of 4000 licensed speech-language pathologists and audiologists in Ohio which provide hearing aid services to Ohio Medicaid consumers.

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?**

OMA did not consider an alternative regulation because internal consensus and agreement with the stakeholders was reached early in the rule-making process.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.**

Performance-based regulations would not be appropriate for this service as this service is based on medical necessity (as established by a licensed prescriber), and the criteria are uniquely met by each affected consumer who requires a hearing aid or aids.

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

This is the only Ohio Administrative Code rule that addresses reimbursement for hearing aid providers by Ohio Medicaid. Under Ohio Revised Code Section 5101.01(B), OMA is the single state agency to supervise the administration of the Medicaid program, and it rules governing Medicaid are binding on other agencies that administer components of the Medicaid program. No agency may establish, by rule or otherwise, a policy governing Medicaid that is inconsistent with a Medicaid policy established, in rule or otherwise, by the medical assistance director.

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.**

Once the rule is final filed, OMA will issue a Medical Handbook Transmittal Letter explaining the program and will maintain a prior authorization requirement for prescriptions as mandated by administrative code. OMA maintains a strong working relationship with the Ohio Speech & Hearing Governmental Affairs Coalition and will readily respond to any concerns or suggestions for improvement as experience under the rule may dictate.

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;**
    Ohio Medicaid hearing aid providers and prescribing providers (physicians, nurse practitioners).
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
    Ohio Medicaid hearing providers must bill for medical equipment using the appropriate, HIPAA-compliant claim, prior authorization and provide medical necessity justification. This could result in added time for compliance.
    c. **Quantify the expected adverse impact from the regulation.**
    The aggregate estimate of the impact for a representative provider is $4.75 per prior authorization requested.

    This estimate was acquired from the Ohio Speech & Hearing Governmental Affairs Coalition, a group of 4000 licensed speech-language pathologists and audiologists in Ohio which provide hearing aid services to Ohio Medicaid consumers.

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 hearing aid context, the tests and measurements required to be documented by this rule 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 a hearing aid or aids that are insufficient or inappropriate to meet the medical needs of the Medicaid recipient.

Regulatory Flexibility

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

No, small businesses are subject to the same regulations as large businesses. There is no valid justification for treating these two groups differently, and we anticipate compliance costs to be low, as demonstrated by the estimate provided by the Ohio Speech & Hearing Governmental Affairs Coalition.

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?**

No penalties are included in the proposed rule. While reimbursement for a hearing aid or hearing aids may be denied if a provider fails to meet the conditions of this rule, the Ohio Medicaid program allows providers to resubmit claims for reimbursement to give them the opportunity to correct any deficiencies in their original claim. See Ohio Administrative Code rule 5101:3-1-19.

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

The Office has established a dedicated Durable Medical Equipment (DME) Question Line and Voice Mailbox to improve response time to provider questions regarding program coverage and limitations. The number for this service is 614-466-1503.

The main ODJFS web page includes links to valuable information about its services and programs; the address is http://www.jfs.ohio.gov. The web page of the Office of Medical Assistance (Medicaid) may be accessed through the ODJFS main page or directly at http://www.jfs.ohio.gov/ohp/. ODJFS maintains an "electronic manuals" web page of the department's rules, manuals, transmittal letters, forms, and handbooks. The web address for this "eManuals" web page is http://emanuals.odjfs.state.oh.us/emanuals/.

After July 1, 2013, we anticipate that this same information will be available via the new Ohio Department of Medicaid website. That website is currently under development.