CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: ERF 184699

Rule Number(s): 5160-4-06, "Specific provisions for evaluation and management (E&M) service."

Date: 02/27/2019

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Rescinded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.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Rule 5160-4-06, "Specific provisions for evaluation and management (E&M) Service," sets forth Medicaid coverage and payment policies for specific types of evaluation and management services (office visits). The amendment to this rule will allow separate payment for medication-assisted treatment for the treatment of substance abuse disorder, in addition to payment for an E&M service for eligible providers in office-based settings.

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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

Section 5164.02 of the 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.

   Physician services are a mandatory Medicaid benefit.

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

   Federal law does not require coverage of medication-assisted treatment in office settings for the treatment of substance abuse disorder. ODM has determined it to be cost effective and beneficial to cover this service.

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 regulation is to provide medication-assisted treatment for substance abuse in the office setting.

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

   The success of this rule will be measured by the extent to which claims for E&M services and medication-assisted treatment submitted by a physician, physician assistant (PA) or advanced practice registered nurse (APRN) are correctly processed in the Medicaid Information Technology System (MITS).

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 agency contacted the Ohio State Medical Association (OSMA), Ohio Association of Physician Assistants (OAPA), and Ohio Association of Advanced Practice Nurses (OAAPN) through e-mail for initial review of the draft regulation.

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

   The Ohio Association of Physician Assistants (OAPA) provided input that physician assistants (PAs) are included in the definition of "qualified providers" in both the

Comprehensive Addiction and Recovery Act (Public Law 114-198) enacted in 2016 and the U.S. Department of Health and Human Services rule 42 CFR Part 8: Medication Assisted Treatment for Opioid Use Disorders. The OAPA also explained that PAs are authorized to prescribe drugs used in medication assisted treatment listed in the PA formulary in accordance with R.C. 4730.40 and rules adopted in accordance with R.C. 4730.55. In response to this input, the proposed rule was changed to allow payment for any provider that has obtained a waiver issued under Section 303(g)(2) of the Drug Addiction Treatment Act of 2000, and a license from the Ohio Board of Pharmacy, if necessary.

Additional comments were provided by the Ohio State Medical Association (OSMA), the Ohio Society of Addiction Medicine (OSAM), and the Ohio State Board of Pharmacy.

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 relevant**.**

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 considers Administrative Code rules the most appropriate type of regulation for the provisions contained in the physician services program as the considered alternatives added a level of superfluous complexity when compared to these proposed OAC changes. Under R.C. 5164.02, ODM is required to adopt rules to establish coverage of Medicaid services and payment for those services.

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 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 within agency 5160 of the Ohio Administrative Code. Within this division, rules are generally separated out by topic. ODM checked to make sure this rule was not duplicative.

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 policy changes will be incorporated into (1) internal Medicaid processes and (2) the Medicaid Information Technology System (MITS), which is the department's electronic claim-payment system. Incorporation into ODM processes and systems will ensure that the rules are applied consistently and predictably.

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. This rule affects physicians, physician assistants, advanced practice registered nurses (APRNs) who are current and future ODM providers.

b. This rule requires additional certification for Medicaid payment for an E&M service and medication assisted treatment.

c. Under this rule, physicians, physician assistants, and advanced practice registered nurses must receive a waiver under Section 303(g)(2) of the Drug Addiction Treatment Act of 2000 (DATA 2000). This permits the rendering provider to treat narcotic dependence without registering separately with the United States drug enforcement administration as an opioid program. For physicians, this requires 8-hours of training through either classroom situations, seminars at professional society meetings, electronic communications, or training otherwise provided by the Substance Abuse and Mental Health Services Administration (SAMHSA) and other organizations. The estimated fiscal impact for physicians for an 8-hour day to attend training is $734.00. This figure takes the average salary of a physician in Ohio and converted into an hourly wage divided by 8 hours.

For physician assistants and eligible APRNs, this requires 24 hours of training to be eligible for a prescribing waiver. The estimated fiscal impact for physician assistants for 24 hours to attend training is $1,207 and for eligible APRNs is $1,017. These figures also take the average salary of a physician assistant and APRN in Ohio converted into an hourly wage divided by 24 hours. These estimates were obtained from the U.S News and Rankings. Specialists in

psychiatry may have already obtained their board certification in addiction psychiatry from the American Board of Medical Specialties.

Even in the absence of the training described above, SAMHSA will consider other criteria in determining whether to grant a DATA 2000 waiver. SAMHSA will consider training or experience that the state's medical licensing board considers a demonstration of the physician's ability to treat and manage patients with an opioid dependency. The applicable laws of Ohio's State Medical Board for medication-assisted treatment are set forth in R.C. 4731.83, 4731.056 (requirements for physicians), 4730.55, and 4730.56 (requirements for physician assistants). Currently, State Medical Board rule 4731-11-12 contains requirements for office-based opioid treatment; however, it is ODM's understanding that this rule will soon be rescinded and replaced by new State Medical Board rules in O.A.C. Chapters 4730-4 and 4731-33.

SAMHSA will also consider whether a licensed physician has completed other training or experience that that HHS considers a demonstration of the physician's ability to treat and manage patients with an opioid dependency. The applicable federal rules and federal guidance do not indicate how SAMHSA will apply this criterion. Accordingly, we cannot provide any additional detail regarding the training and experience that HHS might find to be a demonstration of the physician's ability in this area.

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

ODM is following federal requirements that in order for these practitioners to provide medication-assisted treatment, the practitioner must hold a DATA 2000 waiver.

By issuing a rule, the agency will clearly communicate the policy with providers, ensure consistent delivery of services, and expand access to medication-assisted treatment services to address the opioid crisis.

Regulatory Flexibility

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

Medicaid payment policies are not predicated on the size of an entity and cannot be waived on that basis.

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?**

    The rule imposes no fines or penalties.

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

    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.

    ODM staff members are available to provide policy interpretation through email at, non_institutionalpolicy@medicaid.ohio.gov.