CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: Provider-Administered Pharmaceuticals

Rule Number(s):

To Be Rescinded: 5160-4-12

New: 5160-4-12

Date: March 10, 2015

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- ☑ Rescinded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 5160-4-12, "Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals," sets forth general provisions for coverage of and payment for injections and pharmaceuticals administered as physician services. This rule is being proposed for rescission.

   Rule 5160-4-12, "Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals," sets forth general provisions for coverage of and payment for injections and pharmaceuticals administered as physician services. This rule is being proposed for adoption to replace current rule 5160-4-12.

   Changes: Words based on reimburse (such as reimbursement) are replaced by forms of pay and payment; other unsatisfactory phrases, incorrect or missing references, and unnecessary statements are also cleaned up. Medicaid rule numbers are modified to comport with the new agency designation in the Ohio Administrative Code. For administration, payment may now be made either for the most appropriate administration procedure or for the least complex evaluation and management service rendered to an established patient. A provision concerning the coverage of immune globulin is condensed and streamlined. The current static maximum payment amount for medroxyprogesterone acetate (MPA) is removed. Payment for MPA will instead be determined by the method set forth in paragraph (E) of the rule, to which maximum allowable cost (MAC) is added as a reference source.

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.

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 schedules or methods (formulas) for use by providers and the general public.

   Changes to this rule are being proposed for three main reasons: (1) to update the provision concerning the coverage of immune globulin, (2) to bring the maximum payment amount for medroxyprogesterone acetate (MPA) into line with its current cost, and (3) to remove a restriction from payment for vaccine administration.

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

   These rules essentially involve internal operating procedures and place no requirements on providers. Their success, therefore, will be measured 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.

   These rules went through the Department's public review process (known as Clearance) from 10/15/2014 to 10/29/2014; no comments were submitted. The Department was contacted outside the formal Clearance process by a clinic provider of family-planning services and by the director of the Personal Health Division of the Delaware General Health District.

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

   The clinic provider of family-planning services has notified the Department that it no longer supplies MPA injections to Medicaid recipients because of the excessively low payment amount.

   The director of the Personal Health Division of the Delaware General Health District has pointed out deficiencies in the existing coverage criteria for immune globulin.

   As a result, the payment structure has been revised, and the coverage criteria have been revamped.

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 alternative was considered, because none was readily 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?**

    Rules involving Medicaid providers are housed exclusively within agency 5160 of the Ohio Administrative Code. 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 changes 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 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 changes affect providers, mainly physicians, that administer vaccines, toxoids, and other therapeutic injections.

b. This rule imposes no license fees or fines. It does direct providers to report on a claim the fewest number of procedure codes that together represent the administered dosage. And it requires providers of trigger-point injections to document the following information in the individual's medical record: (1) a proper evaluation including a patient history and physical examination leading to diagnosis of the trigger point, (2) the reason or reasons for selecting this therapeutic option, (3) the affected muscle or muscles, (4) the muscle or muscles injected and the number of injections, (5) the frequency of injections required, (6) the name of the medication used in the injection, (7) the results of any prior treatment, and (8) corroborating evidence that the injection is medically necessary.

c. No actual adverse impact is expected. It takes no more time and effort (in fact, it takes less) to report fewer codes on a claim. And the documentation requirement is really just an articulation of what should already be present in a medical record; such provisions are generally included in rule to assist auditors in their program integrity efforts.

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

The procedure code reporting requirement amounts to a claim-submission instruction; it is couched as a requirement in the rule mainly for the sake of emphasis. And the Department's interest in maintaining program integrity outweighs any benefit a provider might gain from not having to obtain the indicated documentation.

Regulatory Flexibility

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

Claim formats and submission requirements 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?

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.