CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Office of Medical Assistance

Regulation/Package Title: BHPP Schedule and fee updates, Summer 2013 (DGF)

Rule Number(s):

5101:3-1-60 (Rescinded/New), Appendix DD (Rescinded/New);

5101:3-4-06 (Amended);

5101:3-4-12 (Rescinded/New), Appendix A (Rescinded), Appendix B (Rescinded);

5101:3-4-13 (Rescinded/New)

Date: 22 May 2013, rev. 13 June 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- ☑ Rescinded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.

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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 5101:3-1-60, titled "Medicaid reimbursement," sets forth reimbursement policies for services furnished by professional providers. This rule is being proposed for rescission and replacement by a new rule of the same number and title.

Changes: The text of the rule is being reorganized, streamlined, and clarified; a new provision states explicitly that reimbursement limits may be set on the basis of the characteristics of an individual procedure, service, or supply or the relationships between procedures, services, or supplies.

The appendix to the rule is being amended in several ways:

- Typographical errors are corrected, new Healthcare Common Procedure Coding System (HCPCS) codes are added, obsolete HCPCS codes are discontinued, coverage is initiated for some previously noncovered HCPCS codes, adjustments are made to the professional/technical split of certain current HCPCS codes, and code descriptions are revised.
- The 'Visit' column, whose sole function has been to display an indicator for 12 blood-related procedures that may be separately reimbursable on the day of surgery, is being discontinued; this provision will now be addressed in the body of rule 5101:3-4-06.
- Pursuant to section 5111.021 of the Ohio Revised Code and paragraph (D) of this rule, the maximum fees for certain procedures, services, or supplies are reduced so that they do not exceed the corresponding maximum Medicare allowed amounts.
- Long sections of outdated items (such as old models of spectacle frames and lenses) are collapsed into single entries.
- Perhaps most significant, entries for vaccines and other provider-administered pharmaceuticals—represented, for example, by Current Procedural Terminology (CPT) codes in the range from 90476 to 90749, CPT codes in the range from 90281 to 90399, or HCPCS codes beginning with the letter J—are removed from this appendix and replaced with a reference to new rule 5101:3-4-12.

Rule 5101:3-4-06, titled "Physician visits," sets forth coverage and reimbursement policies for physician visits conducted in a variety of settings. This rule is being proposed for amendment.

Changes: In the section dealing with visits related to surgical procedures, references to the visit indicator in rule 5101:3-1-60 are being removed. Other corrections are being made to improve clarity and to update a reference to the Coordinated Services Program.

Rule 5101:3-4-12, titled “Immunizations,” sets forth general provisions for coverage and reimbursement of immunizations and vaccines. This rule is being proposed for rescission and replacement by a new rule of the same number, titled “Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals.”

Changes: The rule is being reorganized, streamlined, and clarified, and the content of existing rule 5101:3-4-13 is being incorporated. The two existing appendices to the rule are being discontinued; the new rule instead prescribes a methodology for establishing a maximum allowable fee for a covered provider-administered pharmaceutical, and it specifies a web location where a list of covered provider-administered pharmaceuticals will be found. A superfluous reference to national organizations and an unnecessary provision concerning the determination of medical necessity are being removed. A new provision will allow reimbursement for vaccine administration rather than an evaluation and management service (i.e., an office visit) when an immunization procedure is performed by a provider who is eligible for increased reimbursement in accordance with rule 5101:3-1-60.3.

Note: Practitioners furnishing provider-administered pharmaceuticals (e.g., vaccines and injectable drugs) routinely buy these materials and then submit claims for payment when the materials are administered. Our intent has always been to reimburse practitioners the amount of their actual cost, which can change quarterly. So long as the maximum fees for these materials are listed in a schedule (Appendix DD to rule 5101:3-1-60), any updates must be accomplished through the rule-filing process. By removing these items from rule 5101:3-1-60 and publishing their maximum fees in the form of a process description (methodology) rather than a static schedule, we will make it possible to update the fees each quarter and to ensure that providers are reimbursed in a more appropriate and timely manner.

Rule 5101:3-4-13, titled "Therapeutic injections (including trigger point injections) and prescribed drugs," sets forth general provisions for coverage and reimbursement of injections and pharmaceuticals administered as physician services. This rule is being proposed for rescission.

Changes: The content of the rule is being incorporated into new rule 5101:3-4-12, titled "Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals." A new rule 5101:3-4-13, titled "Relocated provisions concerning injections and provider-administered pharmaceuticals," is being proposed for adoption. This placeholder rule simply cites new rule 5101:3-4-12; it serves to ensure that existing references to rule 5101:3-4-13 remain functional until they can be updated.

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

RC 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?**
   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 of new Healthcare Common Procedure Coding System (HCPCS) codes and the discontinuation of obsolete 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.**

The only provision that goes beyond federal requirements is the restriction that Medicaid reimbursement may not exceed the maximum Medicare allowed amount for the same service under Medicare, which is spelled out in R.C. 5111.021 and in paragraph (D) of rule 5101:3-1-60.

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)?**

These 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?**

These rules essentially involve internal operating procedures. They place no requirements on providers (other than an expectation that providers will conduct their business in accordance with standard practices). Their success therefore will be measured by how well two systems-related criteria are met:

1. Changes in maximum fee amounts necessitated by these rules will be correctly entered into the Medicaid Information Technology System (MITS), and claims will be paid accordingly.
2. Updates to maximum fee amounts for provider-administered pharmaceuticals will be made in MITS on a regular quarterly basis, and claims will be paid accordingly.

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.

Over the past few years, we have been making preparations to remove fee amounts from the administrative code and to replace them with statements of payment methodology (supplemented, as necessary, by reference lists posted on the OMA website). Staff members have discussed this concept—and the progress we have made—with many different stakeholders: numerous individual physicians and group practices, the Ohio branch of the American Academy of Pediatrics, the Ohio Academy of Family Physicians, several drug companies and lobbying firms, the Family Planning Advisory Council, OMA's small-provider group, the Ohio Department of Health, a primary care provider coalition, and more than 50 local health departments and ambulatory care clinics.

Affected providers have uniformly expressed their support for changing the way in which maximum fees for provider-administered pharmaceuticals are published.

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

To solicit public input on its administrative rules, the Office of Medical Assistance (OMA) currently uses the Clearance process established by the Ohio Department of Job and Family Services (ODJFS). ODJFS Internal Policy/Procedure (IPP) 8901. describes the role of stakeholders in the process: "Any person with access to the ODJFS InnerWeb or the Internet may view the Clearance documents and submit comments.... The Originator [of the rule or rules] must review all Clearance comments and make appropriate changes to the draft documents. The Originator must respond to all people who submit comments advising them that their comments either resulted in a change or did not result in a change and why not."

The draft rules are currently in Clearance. All comments received will be carefully reviewed to determine whether modifications are necessary to the rules before they are formally proposed.

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 data drawn from OMA's Decision Support System were used in projecting the fiscal impact of the changes to be made in the rules. Future claim-payment data will show whether implementation of the rule changes has been successful (i.e., whether providers are paid appropriately in accordance with established policy).

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?**

The Centers for Medicare and Medicaid Services (CMS) actually prefers that states publish fees by methodology rather than in a fixed schedule format. For codes representing provider-administered pharmaceuticals, the obvious approach was to remove them from Appendix DD and to articulate the fee methodology in the relevant rule, 5101:3-4-12; no real alternative presented itself. Removing additional active codes from Appendix DD is beyond the scope of this current rule package. It is hoped that in the near future, however, fees for other groups of codes can be similarly published by methodology.

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.***

These rules place no requirements on providers (other than an expectation that providers will conduct their business in accordance with standard practices). The concept of performance-based regulation therefore does not apply.

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. 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.**

There is already a process in place for incorporating Appendix DD changes into the Medicaid Information Technology System (MITS). A process will be developed for making automatic quarterly updates to the fees for provider-administered

pharmaceuticals; it will be similar to the current process for updating the fees for drugs provided through the Medicaid pharmacy benefit.

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. Changes to fees listed in Appendix DD to rule 5101:3-1-60 affect professional, non-institutional providers: advanced practice nurses, ambulance providers, ambulatory health care clinics, ambulatory surgery centers, chiropractors, dentists, home health agencies, independent diagnostic testing facilities, independent laboratories, mammography suppliers, medical suppliers, occupational therapists, optometrists, physical therapists, physicians, physician assistants, podiatrists, portable X-ray suppliers, private duty nurses, psychologists, wheelchair van or ambulette providers, and other providers of limited practitioner services.

Changes to rule 5101:3-4-06 are administrative in nature and do not affect any provider in particular.

Changes to rules 5101:3-4-12 and 5101:3-4-13 affect providers, mainly physicians, that administer vaccines, toxoids, and other therapeutic injections.

b. These rules impose no license fees or fines. The activation, deactivation, or modification of particular procedure codes by the American Medical Association (AMA) or the Centers for Medicare and Medicaid Services (CMS) may require providers to update their billing systems in order to maintain compliance with industry standards, but any associated cost cannot be attributed to these rules or to changes in them. (Administrative costs associated with system updates could conceivably be attributed to Medicaid only if a provider chooses to maintain a discrete system solely for Medicaid claims; even in such a case, the amount of programming and data entry would be negligible.)

Most of the reporting requirements laid out in these rules are essentially billing instructions that enable providers to submit claims successfully. For example, the requirement that the "billed amount" reported on a Medicaid claim must be a provider's usual and customary charge is not a directive to submit a claim but rather a description

of the information to be included if a provider should submit a claim. Similarly, specifications concerning procedure code, dosage unit, or hospital admission provide guidance rather than impose obligation.

The requirement that providers must submit a claim to other payers before submitting it to Medicaid is an operational statement of the principle established in state law that Medicaid must be the "payer of last resort."

New rule 5101:3-4-12 does require that for trigger-point injections, certain information must be included in the patient's file to establish what service was provided and why it was medically necessary. We would expect that physicians already record such information as a matter of course and, therefore, this rule would not create any administrative burden. The requirement is spelled out in the rule more as a reminder than as an additional obligation.

c. Any adverse operational impact, either on individual providers or in the aggregate, is attributable to the activation, deactivation, or modification of particular procedure codes by the American Medical Association (AMA) or the Centers for Medicare and Medicaid Services (CMS), which may require some effort by providers to update their billing systems in order to maintain compliance with industry standards.

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

Even if no changes were being made in the Medicaid administrative rules, providers would need to maintain compliance with industry standards by updating their billing systems to accommodate the activation, deactivation, or modification of particular procedure codes by the American Medical Association (AMA) or the Centers for Medicare and Medicaid Services (CMS).

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 for 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 fines on providers for failing to submit claims in the proper format. Providers are subject to claims review and audit in accordance with state and federal law.

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.

Ohio | Office of Medical Assistance

John R. Kasich, Governor
John B. McCarthy, Director

TRANSMITTED VIA ELECTRONIC MAIL

June 7, 2013

Paula Steele
Common Sense Initiative – Ohio
Office of the Lieutenant Governor
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Columbus, OH 43215-6117

Dear Ms. Steele:

On May 22, 2013, the Office of Medical Assistance (OMA) in the Ohio Department of Job and Family Services (ODJFS) posted a Business Impact Analysis (BIA) with a package of four rules. In order to achieve the desired effective date of September 1, 2013, we must propose ("original-file") these rules **on Monday, June 17, 2013**. One of these rules, 5101:3-1-60, sets forth reimbursement policy for services furnished by professional, noninstitutional Medicaid providers; the appendix to this rule is a schedule of maximum fees the Medicaid program pays for a wide variety of services and items. We are writing to inform you that before the package is proposed, certain changes will be made to this appendix.

After the BIA was posted on May 22, we discovered and corrected typographical errors in the dates shown in the ambulatory surgery center (ASC) spans for four procedures, represented by Current Procedural Terminology (CPT) codes 50559, 65855, 66761, and 67109. These dates have been changed to reflect the rule's effective date of 09/01/2013.

When the draft rules were disseminated through the agency's Clearance process, OMA received a single question from a person seeking clarification of a provision in rule 5101:3-4-12. That question, concerning the reimbursement amount for medroxyprogesterone acetate reported with HCPCS procedure code J1050, and our response to it have been forwarded to the CSIO office. No change to the appendix was necessary.

The appendix lists 115 new CPT codes in the range from 81200 to 81479, which represent molecular pathology procedures. We have assigned most of these procedures to one of nine levels on the basis of complexity or effort involved, and we have established a maximum fee accordingly. Two laboratory providers have been encouraging us to adopt these procedure codes since their inception in 2012. During Clearance, we sent each provider a courtesy copy of the portion of the appendix listing these procedure codes and the associated maximum fees. Both providers expressed some dissatisfaction with the fees established for a few of these procedures.

The first provider owns proprietary rights to tests represented by CPT codes in the range from 81211 to 81217. After an initial conversation with company representatives, we decided to establish fees for two procedures, represented by CPT codes 81211 and 81214, that had previously been listed as noncovered. Another conference call was held to discuss the fee amounts, which are significantly below the company's asking prices. A review of the steps involved in one of the tests indicates to us that the gene-analysis process used by this provider consists of a highly automated combination of standard laboratory procedures. We have decided to leave the maximum fees unchanged for now; they can be raised later if additional information indicates that an increase is warranted.

Representatives from the second provider met with us to discuss our fee structure. They believed that six of the procedures (represented by CPT codes 81220, 81229, 81235, 81243, 81275, and 81383) had been either assigned to the wrong level or inappropriately listed as noncovered. We have considered their recommendations for fee changes. We agree that the fees associated with CPT codes 81220, 81229, and 81235 should be increased (although not to the level suggested by the provider). We will make the necessary changes to the appendix before the rules are proposed.

Corrections of dates and changes to fee amounts will all be completed in the appendix to rule 5101:3-1-60. No change has been or will be made to any of the other rules that were posted with the BIA. Neither the changes to the appendix nor the stakeholder comments that prompted them pertain to the reporting requirements or other potential adverse impacts on businesses that were addressed in the BIA, so we hope that they will not hinder our ability to propose these rules on June 17.

Thank you for your consideration of this matter.

Sincerely,

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