CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: Requirements for 340B Covered Entities

Rule Number(s): 5160-1-17.11

Date: 12/15/2016

Rule Type:

- X 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- ☐ Rescinded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.

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 5160-1-17.11, entitled "Requirements for 340B covered entities," is a new rule that is being proposed by the Ohio Department of Medicaid. This rule implements Medicaid policy related to the 340B drug pricing program enacted under the Veteran's Health Care Act of 1992 and

provides United States Code references where definitional information for the program is provided and entities eligible to participate are defined.

This rule sets forth ODM's status reporting requirements and process for Ohio Medicaid providers who participate in the 340B drug pricing program. This includes clearly identifying provider, sub-entity, and contract facility participation in the 340B drug pricing program. This rule requires participating providers to file claims in accordance with ODM's 340B instructions to clearly identify when drugs acquired through the 340B drug pricing program are provided to a Medicaid recipient. This rule requires participating providers to file claims in accordance with ODM's non-340B instructions when a provider uses a drug that is not acquired through the 340B drug pricing program for a Medicaid recipient. This rule requires 340B covered entities to exclude drugs purchased through the 340B drug pricing program from being billed by 340B contract pharmacies. Drugs purchased through the 340B drug pricing program can only be billed by 340B covered entities. A 340B covered entity is responsible for ensuring that the contract pharmacy does not bill for drugs purchased under the 340B drug pricing program. This rule implements a program integrity measure to ensure duplicate discounts are not provided under the 340B drug pricing program and the Medicaid Drug Rebate Program.

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

   Ohio Revised Code sections 5162.03 and 5164.02 authorize ODM to adopt this regulation.

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.

   Yes, this rule implements Medicaid policy related to program requirements under the Veteran's Health Care Act of 1992, Public Law 102-585, codified as Section 340B of the Public Health Services Act, 42 U.S.C. 256b (April 1, 2016). These federal requirements set forth 340B drug pricing program eligibility and registration, and limitations on prices of drugs purchased by 340B covered entities.

   The Centers for Medicare and Medicaid Services (CMS) regulations at 42 C.F.R. Part 447 require Medicaid programs to identify claims for drugs purchased through the 340B drug pricing program and remove them from drug rebate invoicing to avoid duplicate discounts.

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

   This rule implements Medicaid policy related to the 340B drug pricing program requirements and exceeds the federal requirements by excluding contract pharmacies from billing drugs purchased through the 340B drug pricing program to Medicaid. CMS recommends this exclusion

to ensure duplicate discounts are not provided under the 340B drug pricing program and the Medicaid Drug Rebate Program.

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 ensure duplicate discounts are not provided under the 340B drug pricing program and the Medicaid Drug Rebate Program. This regulation will clearly define the reporting requirements and responsibilities for Ohio Medicaid providers participating in the 340B drug pricing program to ensure ODM remains in compliance with 340B drug pricing program regulations and the Medicaid Drug Rebate Program.

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

   ODM will measure the success of this regulation and compliance with this rule by reviewing claims and enrollment data.

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 Ohio Department of Medicaid solicited feedback from several stakeholder groups representing hospitals, federally qualified health centers, rural health clinics, health departments, family planning clinics, and provider groups.

   On December 1, 2016, ODM distributed the draft rule via e-mail communication requesting written feedback. Stakeholders who provided input include the Ohio Hospital Association (OHA) and the Ohio Association of Community Health Centers (OACHC).

   On December 6, 2016, ODM policy and pharmacy staff also conducted a call with representatives from OHA.

   ODM will continue facilitating opportunities for discussion with stakeholders.

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

   OHA asked clarifying questions related to the initial draft of the rule and how it will be operationalized once in effect. ODM staff provided clarification where available and recorded questions to be answered once technical processes are further developed. OHA suggested ODM develop a simplified process for reporting to minimize the burden on hospital providers and to

use the same claim reporting requirements across professional and hospital claims. This is a stance ODM agrees with and intends to simplify reporting requirements as much as possible.

The Ohio Association of Community Health Centers (OACHC) provided written comments in response to the initial draft of the rule. OACHC requested the opportunity to review the prescribed process for reporting and claim submission so they could perform a full analysis of the implications for their stakeholders. Technical processes for reporting are under development and ODM has taken stakeholder feedback into consideration.

OACHC expressed concerns about the application of the CMS regulations to managed care plans and ODM's exclusion of contract pharmacies. The CMS regulations clearly apply to managed care plans and CMS encourages exclusion of contract pharmacies.

Input received from stakeholders was not centered on the rule language and was primarily centered on the technical processes involved to comply with this rule. ODM will continue working with stakeholders in the development and implementation of this regulation.

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?**

   In developing this rule, ODM identified and examined claims from 340B covered entities. Through the review of these claims, it was not clear which drugs were 340B versus non-340B, therefore accurate reporting was difficult. This proposed regulation will support more accurate reporting of 340B drugs in the future so ODM can remain in compliance with federal requirements to avoid duplicate discounts.

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 Ohio Department of Medicaid considered alternative regulations which would have excluded any drugs purchased through the 340B drug pricing program from being billed to Medicaid. ODM chose to implement this Medicaid policy requiring thorough reporting to meet federal program requirements and CMS recommendations.

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 Ohio Department of Medicaid did not consider a performance-based regulation because the process regulated stakeholders must use to comply with this rule is determined by ODM.

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

This proposed rule was thoroughly reviewed by ODM legal and legislative staff, and other policy areas to ensure it does not duplicate an existing Ohio regulation.

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.

ODM plans to implement this regulation with a standardized process for all providers participating in the 340B drug pricing program to comply with reporting and claim submission requirements. Under this regulation, 340B covered entities, their sub-entities, and contract facilities will be required to report to ODM their participation in the 340B drug pricing program. By reviewing Medicaid claims data for drugs purchased through the 340B drug pricing program, ODM can ensure the regulation is applied consistently and predictably for the regulated community.

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;

The impacted business community is limited to those entities which qualify under the 340B drug pricing program requirements and choose to participate.

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

This rule requires the reporting of 340B drug pricing program participation at least yearly and following any change to 340B drug pricing program participation or entity type. 340B covered entities are required to follow claim submission requirements for 340B and non-340B acquired drugs.

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.

The adverse impact from this rule, reporting 340B covered entity status and including additional modifiers on claims for drugs purchased through the 340B drug pricing program, is expected to be minimal and administrative in nature. Ohio Medicaid providers who participate in the 340B drug pricing program are accustomed to general Ohio Medicaid policies under the provider agreement and have existing infrastructure to bill for Medicaid services. The use of modifiers is standard practice in medical billing and additional claim instructions for reporting 340B drug pricing program drugs are not significantly different from claim submission for other services. The process of reporting 340B covered entity status on a yearly or situational basis does not require significant resources to complete and will be done electronically when possible, similar to the existing provider enrollment and revalidation process.

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

ODM determined that the regulatory intent justifies the adverse impact to the regulated business community because this rule ensures the integrity of Ohio Medicaid by ensuring all

providers participating in the 340B drug pricing program consistently meet all requirements and submit claims accurately. The implementation of this rule supports ODM's compliance with the 340B drug pricing program requirements and the Medicaid Drug Rebate Program, and ensures duplicate discounts will not be provided through these programs.

Regulatory Flexibility

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

This regulation does not provide any exemptions or alternative means of compliance for small businesses because it is a voluntary federal program. Due to the nature of the 340B drug pricing program, small businesses are highly unlikely to be included in this regulation.

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?

This does not apply as the rule does not impose any fine or penalty for a paperwork violation.

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

Due to the nature of the 340B drug pricing program, small businesses are highly unlikely to be included in this regulation. Providers who need assistance complying with this regulation may call the provider hotline at 1-800-686-1516 or access several resources on the Ohio Medicaid website, www.medicaid.ohio.gov.

DRAFT - NOT FOR FILING

5160-1-17.11 Requirements for 340B covered entities.

(A) Definitions

(1) "340B drug pricing program" means the program enacted under the Veteran's Health Care Act of 1992, Public Law 102 - 585, codified as Section 340B of the Public Health Services Act, 42 U.S.C. 256b (April 1, 2016).

(2) "340B covered entity" means an entity that is listed in 42 U.S.C. 256b(a)(4) that meets the requirements of 42 U.S.C. 256b(a)(5) (April 1, 2016) and is eligible to participate in the 340B drug pricing program.

(B) No later than thirty days following the effective date of this rule, Ohio medicaid providers participating in the 340B drug pricing program as of the effective date of this rule shall notify the Ohio department of medicaid (ODM) of their 340B covered entity status by following the process prescribed on the ODM website, www.medicaid.ohio.gov. Thereafter, the provider shall notify ODM every year when it recertifies its eligibility for the 340B drug pricing program.

(C) Applicants seeking a Medicaid provider agreement after the effective date of this rule shall follow the process prescribed on the ODM website, www.medicaid.ohio.gov, to notify ODM of their 340B covered entity status. Thereafter, if a provider agreement is entered into with ODM, the provider shall notify ODM every year when it recertifies its eligibility for the 340B drug pricing program.

(D) When a 340B covered entity with an Ohio medicaid provider agreement uses drugs acquired through the 340B drug pricing program for a medicaid recipient, the 340B covered entity shall file claims in accordance with ODM's 340B drug claims filing requirements.

(E) When a 340B covered entity with an Ohio medicaid provider agreement uses a drug that is not acquired through the 340B drug pricing program for a medicaid recipient, the 340B covered entity shall file claims in accordance with ODM's non-340B drug claims filing requirements.

(F) Drugs acquired through the 340B drug pricing program and dispensed by an entity under contract with the 340B covered entity are not covered by medicaid fee-for-service or managed care and no claim shall be submitted for medicaid reimbursement. It is the responsibility of the 340B covered entity to assure compliance by its contractors.