MEMORANDUM

TO: Bryan Stout, Ohio Department of Medicaid

FROM: Tess Eckstein, Regulatory Policy Advocate

DATE: January 13, 2017

RE: **CSI Review – Requirements for 340B Covered Entities (OAC 5160-1-17.11)**

On behalf of Lt. Governor Mary Taylor, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

Analysis

This rule package consists of one new rule being proposed by the Ohio Department of Medicaid (ODM). The rule package was submitted to the CSI Office on December 16, 2016, and the comment period remained open until December 23, 2016.

Rule 5160-1-17.11 is a new rule that implements Medicaid policy related to the 340B drug pricing program enacted under the federal 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. The rule is being proposed at this time due to a federal requirement issued in April 2016. The rule also sets forth reporting requirements and process for Ohio Medicaid providers who participate in the 340B drug pricing program; requires particular claims filing procedures for drugs acquired through the 340B program that are provided to a Medicaid recipient, and separate procedures for drugs not acquired through the 340B program; and requires 340B covered entities to exclude drugs purchased through the 340B drug pricing program from being billed by 340B contract pharmacies. This type of regulation of 340B drug pricing is federally mandated and is intended to ensure duplicate discounts are not provided under the 340B drug pricing program and the Medicaid Drug Rebate Program.

The rule impacts entities that qualify under the 340B drug pricing program requirements and that choose to participate. Potential adverse impacts of the rule include reporting participation at least

yearly and following claim submissions requirements for 340B and non-340B acquired drugs. These claim submission requirements require Ohio Medicaid providers who participate in the 340B drug pricing program to include additional modifiers on claims for drugs purchased through the program. The BIA prepared by ODM states that the rule is justified because it ensures compliance with federally-mandated requirements, safeguards the integrity of Ohio Medicaid by ensuring that all providers who participate in the 340B drug pricing program submit claims appropriately, and ensures that duplicate discounts are not provided through the 340B drug pricing program and the Medicaid Drug Rebate Program.

In December 2016, ODM engaged stakeholder groups representing hospitals, federally qualified health centers, rural health clinics, health departments, family planning clinics, and provider groups about the proposed draft for the new rule. Two stakeholders, the Ohio Hospital Association (OHA) and the Ohio Association of Community Health Centers (OACHC), provided feedback. As a result of this feedback, ODM provided clarification as requested and gathered information to influence the process of developing reporting and drug claims filing requirements, which have yet to be released. As input received was not directly related to the rule language but was instead focused on the technical processes involved to comply with the rule, ODM stated that it would continue to work with stakeholders in developing and implementing the referenced requirements.

During the CSI public comment period, eight stakeholders, including OHA and OACHC, again expressed concern about the yet-undeveloped drug claims filing requirements. In addition, stakeholders expressed concern about providers being required to bill for 340B drugs on outpatient hospital claims differently than this service is billed to other payers, since Medicare cost reporting guidance requires hospitals to maintain uniform charges for all patients, and because hospital providers work from consolidated charge masters (pricing files) and do not have the ability to carve out charges and replace them with the actual acquisition cost of a drug plus Medicaid's dispensing fee; a contradiction between a frequently asked questions **(**FAQ**)** document related to this program and rule 5160-2-21; pharmacies being required to bill at the 340B ceiling price, since the ceiling price is not publicly available nor can covered entities access the price for billing requirements; providers needing to identify 340B drug purchases at the claim level, since this adds an increased administrative and financial burden; a potential decrease in payments for 340B drugs from Medicaid fee-for-service (FFS) and managed care organization (MCO) plans; whether Ohio Medicaid agencies are even allowed to apply a prohibition on 340B contract pharmacies to Medicaid managed care plans; and different billing requirements for drugs purchased through the 340B drug pricing program, resulting in lower payments for drugs.

In response to the submitted comments, ODM released a document on January 9 providing useful clarification and explaining its rationale for deciding not to revise the proposed rule. In addition, the CSI Office engaged ODM in follow-up conversations to discuss outstanding concerns it had with the rule after this document was submitted to CSI. Between the document and subsequent conversations, ODM explained that, while drug claims filing requirements have not yet been released, ODM will continue to engage stakeholders in the development process and intends to replace the FAQ document with a policy summary citing rule 5160-1-17.11. In addition, the claim filing requirements

will not require covered entities to maintain separate pricing files. All claims for 340B drugs will simply need to include a standard modifier, in an attempt to make this process as minimally burdensome as possible. In addition, ODM agrees that hospital providers are required to bill the same rate to all payers, per Medicare cost reporting guidelines. As such, hospitals will not be required to replace charges for 340B drugs on claims for services provided in the outpatient hospital department with acquisition cost plus a dispensing fee, as is indicated in the FAQ.

Regarding the need to identify 340B drug purchases at the claim level, when complete, the drug claims filing guidance will require a standard modifier to be added to any medical claim, or a submission clarification code and basis of cost code to be added to any pharmacy claim, submitted for 340B drugs. Since similar modifiers are standard for medical claims billing for all services and payers, existing billing software should have the ability to add modifiers to these claims. Despite this clarification, two stakeholders were still concerned about needing to add a modifier to a claim at the time of submission, as doing this would require that eligibility be determined prior to a claim being submitted, rather than on the back end after a claim has been processed. In response to this concern, ODM stated that whether a particular claim is eligible for the 340B program is not a requirement that ODM is putting on covered entities, since that requirement comes from federal rules and guidance from the Health Resources and Services Administration (HRSA). Therefore, program participation costs are already incurred in order to comply with HRSA's regulations. ODM is only requiring 340B covered entities to identify claims that are, or are not, 340B-eligible so it can meet obligations under the Medicaid Drug Rebate Program and can assist 340B covered entities in preventing duplicate discounts. Any duplicate discount that does occur is the responsibility of the covered entity to fix, so it is to their benefit to file claims correctly. Lastly, providers have the option to not use their 340B-purchased drugs for Medicaid patients.

As for concern related to billing at an established ceiling price, facilities will not be required to bill at 340B ceiling prices. The ceiling price is simply the maximum that Medicaid can pay, as required by the Centers for Medicare and Medicaid Services (CMS). Instead, pharmacies will be required to bill at the 340B actual acquisition cost. As for a decrease in reimbursement for 340B drugs, the proposed rule does not address payment of claims. It only addresses identification of providers and billing instructions. Regarding concerns about treating MCO claims the same as fee-for-service claims, ODM agrees that the payment provisions of the CMS rule, Covered Outpatient Drug Final Rule (CMS-2345-FC), do not apply to MCO plan payments. That being said, claims submitted through MCOs are still subject to requirements under the Medicaid Drug Rebate Program, meaning that 340B claims must be identified and excluded from rebates to prevent duplicate discounts.

Finally, both HRSA and CMS highly recommend that all contract pharmacies use non-340B drugs for Medicaid in order to ensure that there is no diversion of 340B drugs. At contract pharmacies, it is extremely difficult to determine whether prescriptions were written at eligible sites, and the HRSA 340B audit program has even consistently found 340B drugs dispensed at contract pharmacies for prescriptions written at ineligible sites. Despite all this, ODM continues to be committed to working with stakeholders to find a way around this exclusion of contract pharmacies from billing for 340B drugs, as long as an adequate process is established that makes it feasible to

identify 340B drugs at point of sale at contract pharmacies. If an agreed upon process is not established before the rule becomes effective, contract pharmacies may bill Medicaid and Medicaid managed care plans for drugs purchased outside the 340B program using the non-340B billing instructions.

After reviewing ODM's responses to comments, engaging ODM in subsequent conversations, and following up with the stakeholders who had submitted comments, the CSI Office has determined the purpose of the rule to be justified.

Recommendations

For the reasons discussed above, the CSI Office does not have any recommendations for this rule package.

Conclusion

Based on the above comments, the CSI Office concludes that the Ohio Department of Medicaid should proceed with the formal filing of this rule package with the Joint Committee on Agency Rule Review.

cc: Mark Hamlin, Lt. Governor's Office