THE OHIO COUNCIL OF
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TESTIMONY BEFORE THE
JOINT COMMITTEE ON AGENCY RULE REVIEW
IN OPPOSITION TO CHANGES TO
OAC 5160-9-05, PHARMACY SERVICES: PAYMENT FOR PRESCRIBED DRUGS

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Good afternoon Chairman Duffey, Vice Chairman Uecker and members of the Joint Committee on Agency Rule Review. On behalf of the members of the Chain Drug Committee of the Ohio Council of Retail Merchants, I am here to offer testimony in opposition to proposed changes to OAC 5160-9-05, Pharmacy Services: Payment for Prescribed Drugs. Thank you for this opportunity.

Pharmacy reimbursements have two components—the drug cost payment and the professional dispensing fee payment for services provided in the pharmacy. Ohio Medicaid has historically grossly underpaid pharmacies for the cost of dispensing a prescription. As required by law, every two years they conduct a pharmacy cost of dispensing survey of licensed Ohio pharmacies and come up with an average cost to dispense a Medicaid prescription. Despite the survey findings, there was never a resulting increase in the dispensing fee. Until 2009, the professional dispensing fee was $3.70 per prescription, even though Medicaid's 2008 cost of dispensing survey indicated the average cost to dispense was $7.77. Late in the 2009 budget process, Governor Strickland proposed reducing the fee to $1.80 and the legislature approved it. That fee is still in place today--second lowest in the country--even though subsequent biennial surveys showed the average cost to dispense continually increasing.

The Affordable Care Act included language requiring that pharmacies participating in state Medicaid programs be reimbursed for prescription drugs based on actual acquisition costs plus an adequate professional dispensing fee. The deadline for implementation of the new reimbursement model is April 1, 2017, although states have until June 30 to submit a State Plan Amendment to CMS and begin making payments at the new rates, retroactive back to April 1. CMS has been approving State Plan Amendments proposing dispensing fees in the $10-13 range. This is intended to offset the drastic cuts in product cost reimbursement.

Late in November 2016, Ohio Medicaid released their 2016 cost of dispensing fee conducted by Mercer. Mercer's findings indicated the average cost to dispense a Medicaid prescription in Ohio was $10.49, which we applaud. What is very troubling is that they did not recommend paying this rate across the board to all pharmacies participating in Medicaid.

Based on the Mercer recommendations, Medicaid is proposing the following fee structure:

1. for pharmacies reporting fewer than fifty thousand prescriptions, the dispensing fee is $13.64;
2. for pharmacies reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, the dispensing fee is $10.80;
3. for pharmacies reporting between seventy-five thousand prescriptions and ninety-nine thousand nine hundred ninety-nine prescriptions, the dispensing fee is $9.51; or
4. for pharmacies reporting one hundred thousand or more prescriptions, the dispensing fee is $8.30. The $8.30 fee would be the lowest in the country and would likely apply to all of our members.

This faulty tiered model is troubling for a variety of reasons, one of them being that the results of the Mercer study are skewed due to poor participation by independent pharmacies. Usable responses from chain pharmacies totaled 1,281 while usable responses from independents totaled 189. According to the calculations of the National Association of Chain Drug Stores (NACDS), more than half of Ohio pharmacies would fall under the lowest two tiers—1,187 out of a universe of 2,033. While the proposed rule would increase the professional dispensing fees paid to pharmacy providers by approximately $44 million per year, it also includes a reduction in ingredient cost reimbursement of approximately $56.7 million per year, resulting in a reduction in payments to pharmacies of approximately $12.7 million per year.

There's another problem with the plan—current statute only authorizes a single dispensing fee. There is, however, language in the budget bill changing "fee" to "fees" and specifically authorizing tiered dispensing. The problem with that is while Medicaid's rule must be effective April 1, 2017, the budget language will not be effective until July 1, 2017. We are promoting an alternative proposal that is more fair to our members and provides us with more influence when setting dispensing fee rates, something we have never had through the administrative rule review process.

We are proposing that the dispensing fee be set in statute at $10.49, the average cost to dispense as determined by Mercer, to be reviewed biennially during the budget process. We fully support this proposal as administration after administration have whittled away at the pharmacy dispensing fee to the point that it is almost non-existent at $1.80 for fee-for-service patients. Despite the findings of their own biennial cost of dispensing surveys required by statute, Ohio Medicaid has always ignored the results of those surveys and set arbitrary dispensing fees based on budgetary concerns as opposed to an adequate payment. According to calculations by NACDS, reimbursing all pharmacies at $10.49 per prescription would be less than $1.5 million in additional costs to the Medicaid program over what they have proposed. They would still be saving more than $11 million per year over current pharmacy expenditures.

You should also have a document from NACDS opposing the tiered dispensing proposal. In addition, it speaks to the constitutionality of treating out-of-state providers differently than in-state providers for purposes of the professional dispensing fee. They also question whether CMS will view a $8.30 dispensing fee as "adequate."

Chairman Duffey, Vice Chairman Uecker and members of the Committee, thank you again for allowing me to share with you the reasoning behind the Council's strong opposition to the proposed changes to OAC 5160-9-05. At this time, I would be happy to answer any questions you may have.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 6, 2017

Joint Committee on Agency Rule Review

RE: Ohio Department of Medicaid Proposed Rule 5160-9-05, Pharmacy Services: Payment for Prescribed Drugs

Dear Chairman Duffey and Committee Members:

On behalf of the 1,635 chain pharmacies operating in the state of Ohio, the National Association of Chain Drug Stores (NACDS) is writing to express our concerns with the Ohio Department of Medicaid (ODM) proposed changes to the Administrative Rules of Ohio regarding Medicaid pharmacy reimbursement, and recommend changes.

Under the Proposed Rule, ODM is proposing to reimburse participating pharmacies based on the lower of the National Average Drug Acquisition Cost (NADAC) or wholesale acquisition costs (WAC) and the State Maximum Allowable Cost (SMAC) plus a tiered professional dispensing fee. NACDS and our members have concerns that the proposed changes are not fully consistent with the requirements established by the Centers for Medicare and Medicaid (CMS) Covered Outpatient Drugs Final Rule (Final Rule) for reimbursement of prescription drugs dispensed to Medicaid beneficiaries and may result in inadequate reimbursement for pharmacies.

Medicaid Drug Reimbursement and Tiered Dispensing Fees

In 5160-9-05(C) and (E), the ODM proposes to implement a new pharmacy reimbursement methodology using one of several average acquisition cost benchmarks, plus tiered dispensing fees ranging from $8.30 to $13.64 based on the total number of prescriptions filled by the pharmacy during the fiscal year preceding the most recent Ohio cost of dispensing survey. We believe that paying a lower reimbursement to certain providers based on certain characteristics is anti-competitive and creates an unfriendly and unfair business environment. To maintain equitability among pharmacy providers within the Ohio Medicaid program, we urge ODM to consider one flat dispensing fee to ensure that dispensing fees cover the cost of dispensing for all pharmacies.

As previously stated, ODM has outlined plans to implement a tiered dispensing fee based on total pharmacy volume.

1. for pharmacies reporting fewer than fifty thousand prescriptions, the dispensing fee is $13.64;

2. for pharmacies reporting between fifty thousand and seventy-four thousand nine hundred ninety-nine prescriptions, the dispensing fee is $10.80;
3. for pharmacies reporting between seventy-five thousand prescriptions and ninety-nine thousand nine hundred ninety-nine prescriptions, the dispensing fee is $9.51; or
4. for pharmacies reporting one hundred thousand or more prescriptions, the dispensing fee is $8.30.

NACDS and our members strongly oppose any proposal for tiered dispensing fees. Rather, we urge ODM to implement the flat dispensing fee of $10.49, the mean cost of dispensing result from ODM's cost of dispensing study. This would adequately cover the cost of dispensing for all pharmacies, as opposed to a tiered dispensing fee based on volume (or any other characteristics such as ownership or location).

To date, only 5 of 15 states that have adopted cost-based reimbursement have used tiered dispensing fees by volume. Moreover, the two lower proposed tiers ($9.51 and $8.30) are well below the mean dispensing fee from Ohio's own cost of dispensing study, resulting in pharmacies being reimbursed below the actual cost of dispensing drugs in the state. Equally important and of note, the bottom tier of $8.30 is the lowest dispensing fee of any state that has implemented volume-based tiers under cost-based reimbursement methodology. Since $10.49 plus the ingredient cost represents actual pharmacy costs, any dispensing fee below that combined amount would inadequately reimburse some pharmacies, in clear violation of the Final Rule, which requires that pharmacies be reimbursed at cost.

Despite our concerns, should ODM proceed with its initial proposal of a tiered system, at a minimum, we ask ODM to adopt their study's mean cost to dispense, $10.49, as the lowest tier, with $13.64 and $10.80 being the top two tiers. Since $10.49 plus the ingredient cost represents actual pharmacy costs, any dispensing fee below that combined amount would inadequately reimburse pharmacies, in clear violation of the Final Rule, which requires that pharmacies be reimbursed at cost. Based on NACDS' market analysis, any tiered dispensing fee system that reimburses pharmacies below $10.49 will result in over half of all Ohio pharmacies being reimbursed below costs. Our analysis shows that 1,187 pharmacies out of 2,033 in the state of Ohio would fall into ODM's bottom two dispensing fee tiers.

Moreover, should ODM adopt a tiered system, despite our concerns, we would ask ODM for clarification in the rule that the prescription volume determination used for setting the tier of dispensing for a given provider is made at the store level and not statewide for a chain of pharmacies.

Pharmacies in Ohio have long been paid Medicaid dispensing fees that are far below the true costs of dispensing prescriptions. The current Ohio Medicaid dispensing fee of $1.80 is only 17 percent of what the 2016 Ohio Cost of Dispensing Study found

to be the average cost of dispensing a medication ($10.49) to Medicaid beneficiaries in Ohio. Because of the constantly escalating pharmacy costs driven by pharmacist labor shortages and manufacturer drug price increases, the proposed tiers could potentially leave a large portion of the cost of dispensing a Medicaid prescription un-reimbursed to pharmacies.

Ensuring that dispensing fees are fair and adequate is of paramount importance as Ohio moves to product reimbursement based on acquisition cost. This is even more important given the recently implemented average manufacturer price (AMP) based federal upper limits (FUL) for multiple source drugs, which has had a significant impact on pharmacy reimbursement. The implementation of AMP-based FULs was officially the first step of moving pharmacy reimbursement to a cost-based reimbursement methodology for prescription drugs dispensed to Medicaid beneficiaries as required by the Final Rule. Although the Final Rule requires states to review reimbursement comprehensively with adequate adjustments to professional dispensing fees when moving to cost-based reimbursement methodologies, states are not required to adjust their professional dispensing fees with the adoption of the new AMP-based FULs. As a result, participating pharmacies have suffered recent cuts in generic product reimbursement with no increase in professional dispensing fees to offset the shift in payment methodologies. Therefore, it is critically important that pharmacy dispensing fees be adjusted to cover the cost of dispensing for all pharmacies as soon as possible.

We believe that setting a differential reimbursement rate for one type of Medicaid provider based on size or type of business within an industry like pharmacy sets a very negative precedent in the state. Recent government studies have failed to find a consistent differential in the product acquisition costs of chain and independent pharmacies, as independent pharmacies are achieving increased discounts through purchasing groups. In addition, federal courts have raised doubts about the legality and constitutionality of tiered reimbursement schemes, and Congress has expressed its displeasure within funding legislation around the tiered reimbursement.

Moreover, as a matter of public health policy, a tiered system that pays lower dispensing fees to higher volume pharmacy locations creates harmful disincentives against pharmacies from pursuing growth in their Medicaid business and against pursuing opportunities to provide better and more efficient service to Medicaid patients. Under ODM's proposed tiered system, the greater the Medicaid business for a pharmacy and the more efficient a pharmacy becomes at dispensing Medicaid drugs, the lower their dispensing fee. This imposes perverse economic incentives on Ohio pharmacies that could result in access problems for Medicaid patients to their prescription medications.

Overall, Medicaid reimbursement for prescription drug product and dispensing costs should be based on the cost of the product delivered and the costs incurred in

dispensing that product, not on the size or nature of the pharmacy. We support fair and adequate reimbursement under Medicaid and other public programs for all pharmacies throughout the state to help protect access to the highest quality pharmacy services for all Ohio residents.

Dispensing Fees for New Providers

We are also concerned with ODM's proposed dispensing fees for new out-of-state providers in Section 5160-9-05(E)(1)(b)(vi)(b). The proposal anticipates assigning different dispensing fees for new in-state providers versus new out-of-state providers, as well as providing seemingly arbitrary dispensing fees for all new out-of-state providers. This disparity in treatment and arbitrariness is an unconstitutional violation of the Commerce Clause, contrary to the federal Medicaid Covered Outpatients Drugs Final Rule, and likely arbitrary and capricious under the Administrative Procedures Act (APA).

Starting with the Commerce Clause, we believe that ODM's new provider dispensing fee proposal would be subject to a Dormant Commerce Clause challenge. We believe that regulation on its face discriminates against interstate commerce by treating new in-state providers differently than new out-of-state providers for purposes of dispensing fees. Specifically, new in-state providers' dispensing fees are set $13.64, while new out-of-state providers' dispensing fees are set at $8.30. This is direct discrimination and if a court finds that a statute directly discriminates, it is generally struck down without further inquiry. This portion of the regulation would appear to be motivated by "simple economic protectionism," rendering the regulation per se invalid.

Beyond the constitutional issue, there are two regulatory issues. First, in Section 42 CFR 447.502, the Final Rule defines the professional dispensing fee for Medicaid drugs to be based upon a provider's costs. Yet, ODM's proposal as to new out-of-state pharmacies provides no connection between the proposed dispensing fee and grounding that fee in a pharmacy's cost to dispense. In contrast, the other ODM proposed dispensing fee tiers are founded upon the ODM's cost of dispensing survey. Without a cost-based foundation for the new out-of-state provider dispensing fees, we do not believe CMS will approve such a SPA.

Along the same lines, it seems likely that the new out-of-state provider dispensing fees would be arbitrary and capricious under the APA. The new out-of-state provider dispensing fees appear to be arbitrary numbers without any source data. Under 5 USC Section 706(2)(A), the APA prohibits arbitrary and capricious agency rulemaking. Accordingly, either CMS would disapprove of the SPA because of the likelihood of arbitrary and capricious rulemaking, or a federal court would make such a finding in the future.

Regardless of whether ODM's new provider dispensing fee scheme survives constitutional and regulatory challenges, we are also asking ODM to clarify how a "new provider" is defined and/or criteria for determining whether a given provider should be considered a "new provider." Additionally, (assuming ODM adopts a tiered dispensing fee structure and the new provider provisions survive constitutional and regulatory challenges) we ask ODM to confirm that once a "new provider" is no longer considered a "new provider," regardless of whether that provider is in-state or out-of-state, that provider's dispensing fee transitions to the tiered dispensing fees outlined in Section 5160-9-05(E)(1)(a)-(e). Lastly, we are asking ODM to provide details as to when a pharmacy is considered "located outside of Ohio" and how that applies to chain pharmacies operating both in and outside of the state.

Impact on Patient Access

More broadly, on the issue of patient access, we believe that any changes in reimbursement that would ultimately result in pharmacy payments that are below cost would be inconsistent with the efforts by CMS to ensure that rate setting in the Medicaid program can sustain beneficiary access. We have concerns that the currently proposed tiered dispensing fees would set reimbursement levels that are inconsistent with efficiency, economy, and quality of care. These proposed changes could leave overall reimbursement levels too low to enlist a sufficient number of providers to ensure that services are available to program recipients at the same level as those services are available to the general population as required by §1902(a)(30) of the Social Security Act. This is also extremely concerning when it potentially jeopardizes availability and access to care and providers. This could have a detrimental effect on overall Ohio Medicaid program costs as beneficiaries who are not able to access prescription drugs on a timely basis or access them at all will be forced to seek higher cost care such as more frequent visits to hospitals, emergency rooms, and doctors' visits.

Chain pharmacy recognizes the tremendous budgetary challenges that the state of Ohio is facing and the subsequent need to control Medicaid program costs to help balance the state budget. However, the average net profit margin for pharmacies is just 2 percent, a profit margin that has been continuously shrinking due to increasing product, labor, and administrative costs. The implementation of below-cost tiered dispensing fees on the heels of already reduced reimbursement rates will pose a real threat to Ohio pharmacies continued financial viability and, in turn, to the ability of low-income Ohio residents to access prescription drugs and pharmacy services. We urge ODM to reconsider the proposed methodologies to avoid any compromises to patient access to prescription drugs. In addition, we urge ODM to make the necessary adjustments to ensure that Ohio pharmacy access is maintained at the levels required under federal law.

Conclusion

Community pharmacies fully understand the level and complexity of changes that are required for states to fully accommodate the requirements of the Medicaid Covered Outpatient Drugs Final Rule. We remain committed to preserving Medicaid beneficiary access to their needed medications and the ability of our members to provide services to this important population. We strongly support CMS' goal that chain pharmacies receive fair and adequate reimbursement that is based on the cost of acquiring and dispensing prescription drugs in the Medicaid program. We will continue to work with ODM as it makes the necessary changes to adopt cost-based reimbursement methodologies that are required by the Final Rule. We believe that if implemented properly, cost-based reimbursement methodologies can lead to fair and adequate payment levels that reflect the cost of providing needed healthcare services to Medicaid beneficiaries.

On behalf of chain pharmacies operating in Ohio, we thank JCARR for the opportunity to present our views and we welcome the opportunity to respond to any questions you may have.

Sincerely,

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