

By electronic submission

January 14, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, MD 21244

Re: Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care, CMS-2408-P

Dear Administrator Verma:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule titled "Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care," which was published in the *Federal Register* on November 14, 2018.¹ NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Together they represent a \$76 billion health care marketplace and employ over 250,000 individuals. Our members are small business owners who are among America's most accessible health care providers.

Independent community pharmacies play a vital role in the Medicaid program; in fact, 17 percent of prescriptions filled by the average independent community pharmacy are covered by Medicaid.² More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved urban and rural areas that are home to many Medicaid recipients, with 75 percent of independent pharmacies serving areas with a population less than 50,000.³ Local pharmacists provide expert medication counseling and other cost-saving services, such as medication synchronization services, compliance packaging, and home or work site delivery to mitigate the estimated \$290 billion spent annually as a result of patient medication nonadherence.

NCPA appreciates CMS' goals with this Proposed Rule to promote flexibility, strengthen accountability, and maintain and enhance program integrity within Medicaid and CHIP managed care. We provide the following comments in an effort to assist CMS in achieving those goals.

¹ 83 Fed. Reg. 57264 (Nov. 14, 2018).

² National Community Pharmacists Association, 2018 NCPA Digest, 6 (2018).

³ National Community Pharmacists Association, 2018 NCPA Digest, 12 (2018).

I. Network Adequacy Standards

CMS proposes revising network adequacy standards by replacing the requirement for states to establish time and distance standards with a requirement for states to establish a quantitative network adequacy standard. While NCPA appreciates CMS' desire to provide states with flexibility in determining appropriate standards that will guarantee adequate access to care for beneficiaries, we have concerns with the proposed removal of time and distance as baseline federal requirements related to network adequacy. NCPA also finds the proposed change to be premature, as several oversight provisions related to network adequacy standards did not go into effect until July 1, 2018.

Under the current Medicaid managed care rules, states are already granted flexibility in determining the exact time and distance requirements that best fit the needs of their beneficiaries, and there are no restrictions on states choosing to require additional quantitative standards. In fact, many states have chosen to take advantage of this flexibility and require managed care organizations (MCOs) to implement network adequacy standards beyond time and distance. The Medicaid and CHIP Payment and Access Commission (MACPAC) recently conducted a review of current network standards in 14 states and found that none of the states failed to meet the existing rule requirements with the flexibility currently allowed.⁴

Time and distance requirements are common metrics for measuring network adequacy and are used in both the private market and in other government-funded programs, such as Medicare Advantage. These requirements are particularly important for pharmacy network adequacy in the Medicaid program, as limited transportation options can be a concern for many beneficiaries, and NCPA encourages CMS to provide guidance to states on aligning their minimum standards with those already in place in other government-funded programs, such as Medicare Advantage and Medicare Part D. Maintaining a specific quantitative federal requirement for network adequacy standards, such as time and distance, and aligning those standards with other government-funded programs also allows states and CMS to more easily compare network adequacy measures across states and develop appropriate benchmarks. NCPA urges CMS to maintain the baseline requirement for states to establish time and distance standards for network adequacy in Medicaid managed care.

NCPA also encourages CMS to closely monitor the network adequacy standards each state sets and ensure the states are properly enforcing those standards among the MCOs with which they contract. Appropriate standards and enforcement of those standards are critical to safeguarding beneficiaries' access to care. One area of specific concern related to appropriate pharmacy network adequacy standards and enforcement is beneficiary access to specialty drugs. In some states, MCOs and pharmacy benefit managers (PBMs) inappropriately categorize certain

⁴ MACPAC December 2018 Public Meeting Tr., 202:11-18, December 2018.

medications as specialty drugs based solely on cost and then force beneficiaries to obtain these medications through a PBM-owned mail order program, when the medications can be readily available at a community pharmacy utilized by the beneficiary. To prevent barriers to access for vulnerable beneficiaries, NCPA encourages CMS to stipulate that states and contracted MCOs and PBMs must follow Medicare Part D regulatory guidance on access to specialty medications.⁵

II. Quality Rating System

CMS proposes to develop a minimum set of mandatory performance measures that will apply equally to federal and alternative quality rating systems (QRS) and to make state and stakeholder consultation in developing these measures more explicit. CMS also proposes to implement cross-program alignment of Medicaid and CHIP QRS with other CMS managed care programs, such as the Medicare Advantage Star Rating System and the QRS for qualified health plans (QHPs), where appropriate. NCPA is committed to ensuring beneficiaries have access to quality pharmacy services and appreciates CMS' intention to align Medicaid QRS mandatory performance measures with other managed care program QRS. As CMS continues to engage stakeholders and develop performance measures, NCPA encourages CMS to ensure the incorporation of medication use-related metrics, especially in the areas of medication safety, adherence, and appropriate use. As a founding member of the Pharmacy Quality Alliance (PQA), NCPA suggests CMS engage with PQA in utilizing and further developing quality metrics related to medication use.

NCPA also urges CMS to take into account numerous industry-wide concerns regarding the current method of evaluation of pharmacy performance in other managed care programs. The quality-based measures being used to measure pharmacy performance were developed for population health measurement at a health plan level, not for use in individual pharmacies with significantly smaller patient populations. Applying health plan level measures to individual pharmacies does not provide an accurate reflection of the individual pharmacy's overall quality. There is also a significant lack of standardization among MCOs and PBMs with respect to these measures, causing an inconsistent application of the definition of "quality" to individual pharmacies from various payers. NCPA suggests CMS define pharmacy quality within the Medicaid QRS and urges CMS to hold MCOs, PBMs, and states accountable for determining standardized, achievable, and proven criteria that appropriately measure individual pharmacy performance, as opposed to criteria that focus on measuring plan performance or criteria which individual pharmacies have little to no opportunity to influence. NCPA recommends CMS engage with PQA on this issue, as efforts are currently underway at PQA to develop quality metrics that can be used at the individual pharmacy level.

⁵ Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf.

III. Delivery System and Provider Payment Initiatives

NCPA supports CMS' proposed changes to directed payments that would reduce the current administrative burden on states. In relation to pharmacy reimbursement specifically, a handful of states have chosen to direct their contracted MCOs to use the Medicaid fee-for-service outpatient drug reimbursement methodology for pharmacy payments under managed care, and the additional flexibility provided by CMS would allow other states to more easily adopt this methodology. NCPA supports utilizing directed payments to adopt this drug reimbursement methodology in Medicaid managed care. Federal statutes require pharmacy reimbursement in the Medicaid fee-for-service program to be "sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population."⁶ However, these requirements are not necessarily in effect for pharmacy services provided under managed care. Medicaid fee-for-service outpatient drug reimbursement is based on actual acquisition costs and reasonable costs of dispensing for medications and is a more stable and accurate standard for drug reimbursement than other methodologies currently being used. Any reimbursement metric that goes below this standard frequently forces pharmacy providers to dispense medications at a financial loss. In the absence of protective federal "guardrails," such as those in Medicaid fee-for-service, MCOs and the PBMs subcontracted by them can significantly decrease reimbursement rates, creating a serious financial burden for pharmacy providers and potential access issues for the Medicaid beneficiaries they serve. For these reasons, NCPA strongly recommends CMS provide guidance to states on adopting the Medicaid fee-for-service outpatient drug reimbursement methodology as a minimum fee schedule or cost-based rate for pharmacy payments in the Medicaid managed care program.

IV. Accountability and Program Integrity in Subcontractual Relationships

CMS proposes to explicitly require reporting to the Transformed Medicaid Statistical Information System (T-MSIS) of the allowed amount and paid amount for claims when submitting financial data from enrollee encounters. NCPA supports this proposal and the efforts being made by CMS to ensure program integrity. NCPA also strongly encourages CMS to provide guidance to states and MCOs on increasing accountability and program integrity in subcontractual relationships between MCOs and PBMs beyond the proposed changes to reporting of enrollee encounter data.

Recently, states have found that an excessive amount of taxpayer dollars remains with PBMs under managed care. Between 2013 and 2017, the amount that Pennsylvania taxpayers paid to PBMs for Medicaid enrollees more than doubled from \$1.41 billion to \$2.86 billion.⁷ In Ohio, the state auditor found that, of the \$2.5 billion that's spent annually through PBMs on Medicaid

⁶ 42 U.S.C. § 139a(a)(13)(A)(2000).

⁷ Pennsylvania Auditor General, Bringing Transparency & Accountability to Drug Pricing 6 (Dec. 11, 2018), available at https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

prescription drugs, PBMs pocketed \$224.8 million through the spread alone during a one-year period.⁸ Kentucky spends \$1.68 billion annually on prescription drugs in the Medicaid managed care program, and evidence suggests PBMs keep as much as \$630 million in spread.⁹ Louisiana found that PBMs retained \$42 million that was incorrectly listed as “medical costs.”¹⁰ Based on these findings, states are beginning to take action to increase PBM transparency and accountability in their Medicaid managed care programs and ensure state oversight. Arkansas and Louisiana have implemented a pass-through pricing model for their Medicaid managed care programs, and Ohio made the same decision after a state-commissioned report showed the move could save the state over \$16 million while increasing pharmacy reimbursement by over \$191 million.¹¹

NCPA is committed to pursuing increased accountability and program integrity in Medicaid managed care. Based on the findings and actions of several states detailed above, NCPA has prepared and offers an attachment (Attachment One) with model contractual language for subcontractual relationships and delegation between state Medicaid agencies, MCOs, and PBMs. NCPA urges CMS to use the language and recommendations in the attachment to provide guidance to states on increasing accountability and program integrity in subcontractual relationships with PBMs.

V. Conclusion

NCPA appreciates the opportunity to share our comments and suggestions with you on the Proposed Rule titled “Medicaid Program; Medicaid and Children’s Health Insurance Plan (CHIP) Managed Care.” If you have any questions, please do not hesitate to contact us.

Sincerely,



Karry K. La Violette

Senior Vice President Government Affairs and Director of the Advocacy Center

⁸ Auditor of State of Ohio, Auditor’s Report: Pharmacy Benefit Managers Take Fees of 31% on Generic Drugs Worth \$208M in One-Year Period, (Aug. 16, 2018), available at <https://ohioauditor.gov/news/pressreleases/Details/5042>.

⁹ Hearing Before the S. Comm. On Health and Welfare, 2018 Regular Session (Ky. Jan. 24, 2018), available at <http://www.ncpa.co/pdf/kentucky-testimony-jan2018.pdf>.

¹⁰ Melinda Deslatte, Task Force: Is Louisiana Medicaid Drug Spending Inflated?, U.S.NEWS & WORLD REPORT (Oct. 26, 2017), available at <https://www.usnews.com/news/beststates/louisiana/articles/2017-10-26/louisiana-spending-on-medicaid-prescription-drugs-questioned>.

¹¹ HealthPlan Data Solutions, LLC, Executive Summary: Report on MCP Pharmacy Benefit Manager Performance, 6 (June 15, 2018).

Attachment One

Provider Agreement Language – Pharmacy

Subcontractual Relationships and Delegation

Pharmacy Benefit Manager (PBM) Agreements. If the MCO enters into a contract or agreement (hereinafter referred to as “PBM agreement”) with a PBM for the provision and administration of pharmacy services, the agreement shall be developed as a pass-through pricing model as defined below. For the purposes of this Agreement, all requirements applicable to a PBM shall also apply to any contract or agreement the MCO has with a Pharmacy Benefit Administrator (PBA).

- i. For the purposes of this Agreement, a pass-through pricing model is defined as a PBM agreement type where:
 1. All monies, including but not limited to, dispensing fees and ingredient costs paid to pharmacies, and all revenue received, including but not limited to pricing discounts paid to the PBM, rebates¹², inflationary payments¹³, and supplemental rebates, are passed through to the MCO;
 2. All payment streams, including any financial benefits such as rebates, discounts, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other payments that the PBM receives related to services provided for the MCO are fully disclosed to the MCO, and provided to the Medicaid department upon request; and
 3. The PBM is paid an administrative fee which covers their cost of providing the PBM services as described in the PBM contract as well as margin.
- ii. The payment model for the PBM’s administrative fee shall be made available to the Medicaid department. If concerns are identified, the Medicaid department reserves the right to request any changes be made to the payment model.
- iii. The PBM agreement shall allow for the MCO to perform a competitive market check every three years or allow the MCO to annually renegotiate its terms.

¹² Rebates include manufacturer fees and administration fees for rebating.

¹³ Inflationary payments refer to any agreement a PBM may have with a manufacturer where the manufacturer agrees to a payment back to the PBM if a drug has inflation above an agreed upon level.

iv. The PBM agreement shall require the PBM to implement a value-based payment model developed by CMS.

v. PBM Agreement Language.

1. The following provisions shall be included in any agreement between the MCO and their PBM:

- a. At least annually, the PBM shall hire an independent third party to complete an audit over the PBM's services and activities. This report shall be provided to the MCO, and information from this audit shall be made available to the Medicaid department upon request.
- b. The PBM shall not steer or require any providers or members to use a specific pharmacy in which the PBM has an ownership interest or that has an ownership interest in the PBM.
- c. The PBM shall report semi-annually to the MCO their list of specialty drugs by National Drug Code, including a report on any drugs that have moved between specialty and non-specialty designation.
- d. The PBM is subject to the medical loss ratio standards described in 42 C.F.R. 438.8.
- e. The PBM shall submit a report containing data from the prior calendar year to the MCO. The report shall be made available to the Medicaid department upon request and contain the following information:
 - i. The aggregate amount of all rebates that the PBM negotiated from all pharmaceutical manufacturers on behalf of the MCO; and
 - ii. The aggregate administrative fees that the PBM negotiated from all pharmaceutical manufacturers on behalf of the MCO.

2. The following provisions shall be addressed in any agreement between the MCO and their PBM:

- a. The ability for the MCO, or its designee that has no ownership or control interest with the PBM, to audit and review contracts or agreements between the PBM and their pharmacies at least annually to ensure correct pricing has been applied. This includes, but is not limited to,

prescription drug claim data, billing records, and other records to ensure the PBM's compliance with the terms and conditions of their agreement.

- b. If there is not a provision in the agreement to restrict the PBM from selling pharmacy data, the MCO shall require a secure process to be included and followed. If any Medicaid MCO pharmacy data is sold, aggregate total amount received by the PBM for the MCO's data shall be reported to the MCO at least semi-annually.
- c. The ability for the MCO, at its discretion, to enter into non-exclusive specialty pharmacy network arrangements when a specialty pharmacy can provide a better price on a drug.
- d. A clause that allows the MCO to terminate the agreement for cause, including conduct that is likely to mislead, deceive, or defraud the public, as well as unfair or deceptive business practices.
- e. A clause specifying that the PBM is a fiduciary to the Medicaid department and must discharge that duty in accordance with federal and state law.
- f. Reimbursements based on a nationally recognized, standardized benchmark (e.g., NADAC).

Subcontractual Relationships and Delegation

Upon request, the MCO shall disclose to the Medicaid department all financial terms and arrangements for payment of any kind that apply between the MCO, or the MCO's FDR, and any provider of a Medicaid service. If the FDR is a PBM or PBA, this disclosure shall include financial terms and payment arrangements for formulary management, drug-switch programs, educational support, claims processing, pharmacy network fees, data sales fees, and all other fees. The Medicaid department acknowledges that such information may be considered confidential and proprietary and thus shall be held strictly confidential by the Medicaid department as specified in this Agreement.

Auditing PBM or PBA Agreements

The Medicaid department or its designee reserves the right to review and audit the Pharmacy Benefit Manager (PBM) or Pharmacy Benefit Administrator (PBA) agreements between the MCO and a PBM or PBA to ensure the PBM or PBA is fulfilling its contractual obligations. The MCO

shall be responsible for ensuring that any findings from these audits are corrected within the timeframe specified by the Medicaid department.

Pricing Analysis of Pharmacies

The Medicaid department or its designee, at least annually, will conduct a pricing analysis to identify trends in payment to chain pharmacies and non-chain pharmacies, including but not limited to, identifying cost trends and payments to chain pharmacies and non-chain pharmacies.

Provider Network Requirements (Pharmacies)

The MCO shall provide or arrange for the delivery of all medically necessary Medicaid-covered pharmacy services. When medically necessary, compounding service and same-day home delivery shall also be provided or arranged. The MCO's pharmacy network shall include at least (X) retail pharmacies in the "geographic area" unless any of the following apply:

1. No retail pharmacies are located in the "geographic area";
2. The MCO has offered the retail pharmacies in the "geographic area" the opportunity to contract with the MCO at similar rates offered by the Medicaid fee-for-service program so it is anticipated that aggregate payment for dispensed drugs will not be less than the aggregate amount reimbursed by the Medicaid fee-for-service program; or

Available retail pharmacies in the "geographic area" fail to meet the MCO's quality or program integrity standards.