

VIA Electronic Submission

September 13, 2019

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2406-P2
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-2406-P2; RIN 0938-AT41, Medicaid Program; Methods for Assuring Access to Covered Medicaid Services

The National Association of Chain Drugs Stores (NACDS) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) proposed regulation published on July 15, 2019, in the *Federal Register* regarding “Methods for Assuring Access to Covered Medicaid Services,” hereafter (“2019 Proposed Rule”).

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS’ over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries.

The Proposed Rules Fails to Meet Federal Reasoned Explanation for Changing Course Requirements

While CMS has stated that they are repealing the 2015 Methods for Assuring Access to Covered Medicaid Services Final Rule (“2015 Final Rule”)¹ to relieve administrative burden on the states, CMS fails to provide a “reasoned explanation” for changing course from the previously adopted 2015 Final Rule and has neglected to consider alternatives presented in the original rulemaking record. According to the Administrative Procedure Act’s (APA)² “reasoned explanation” requirement, in order to repeal or suspend a regulation, an agency must (1) “display awareness that it is changing position,” (2) show that “the new policy is permissible under the statute,” and (3) show that there are good reasons for the new policy. If CMS is seeking to repeal the intent and requirements of the 2015 Final Rule, CMS must also satisfy additional requirements, including providing

¹ CMS-2328-FC; RIN 0938-AQ54; November 2, 2015; [Federal Register \(80 FR 67576\)](#)

² See 5 U.S.C. § 706

a more detailed justification that includes a reasoned explanation to change its policy approach based on factual findings and not just based on the administrative burden that it may impose on states. As such, the repeal of the 2015 Final Rule would be done in a manner that fails to examine the relevant data and articulate a satisfactory explanation for why states would no longer be held to the standards of compliance with the 2015 Final Rule to ensure patient access standards.

While the intent of the 2019 Proposed Rule is to improve administrative efficiencies in the processes states use to ensure patient access, in addition to failing to adhere to the requirements of the APA, CMS also fails to consider the fact that the original 2011 Methods for Assuring Access to Covered Medicaid Services Proposed Rule (“2011 Proposed Rule”)³ and 2015 Final Rule deliberated and rejected the ‘state burden’ arguments as a factor that would impede state compliance with the access review requirements. However, despite the rejection of these arguments, in the 2019 Proposed Rule, CMS is now using these same arguments as a reason to repeal the previous requirements but is also failing to provide reasoned explanation of why such arguments are now valid, especially given the small overall cost to states.

Importance of Network Adequacy and Patient Choice in the Medicaid Program

In repealing the 2015 Final Rule, CMS is ignoring the principal reason for the 2011 Proposed Rule and 2015 Final Rules – ensuring patient access. The 2011 Proposed Rule was based on “significant” recommendations from the Medicaid and CHIP Payment and Access Commission (MACPAC). Specifically, the March 2011 report to Congress⁴, the MACPAC made specific recommendations on a three-part framework for analyzing access to care. The framework considers, 1) enrollees’ needs, 2) availability of care and providers and 3) utilization of services. Proposing to repeal the regulatory text that sets forth the current required process for demonstrating and ensuring patient access not only removes a standardized and transparent process for setting state access requirements, it also removes any checks and balances to ensure adequate provider payment rates within the Medicaid program that would further ensure patient access to needed providers. NACDS has serious concerns with this proposal, as we believe that access standards provide the necessary oversight and help ensure that patients have adequate access to needed healthcare services. While the overly burdensome administrative requirements can be a barrier to states’ adequately demonstrating access, there is a continuous need for CMS to maintain equal access provisions that serve as a method to direct states on how to meet these requirements.

CMS and states must be mindful of the importance of network adequacy for Medicaid patients; that is, ensuring that there is network adequacy and provider capacity to administer the services that Medicaid beneficiaries need. NACDS supports network

³ CMS-2328-P; RIN 0938-AQ54; May 6, 2011; [Federal Register \(76 FR 26342\)](#).

⁴ [MACPAC 2011 Report to the Congress on Medicaid and CHIP](#)

adequacy standards that promote access based on enrollees' needs, availability of care and providers, and utilization of services. To this end, any changes to state requirements to demonstrate compliance with access standards should include policies to ensure that patients will continue to have access to their current providers and pharmacies of choice.

Medicaid patients should be allowed the freedom to select a pharmacy that best fits their personal health needs and provides the most accessible care. Restrictive provider networks are not appropriate for Medicaid recipients. Medicaid beneficiaries are less mobile than the general population as they rely more heavily on public transportation and have fewer options for traveling to providers that are not conveniently located.

Restricting provider networks result in restricted patient ability to access their healthcare providers and unnecessary disruptions in needed care. As a result, there is the potential for increased overall healthcare expenditures due to the use of more costly healthcare services among Medicaid patients. Therefore, in order to ensure continuity of care and minimize healthcare costs, states should be required to maintain open networks and demonstrate network adequacy that allows patients continued access to providers and community pharmacists they have come to know and trust.

Monitoring Access Through the State Plan Amendment Process

Minimizing state administrative burdens should not take priority over ensuring adequate patient care. CMS must maintain a standardized, transparent process for states to determine if they are meeting federal access requirements. As written, the proposed rule would remove the requirements for states to submit access monitoring review plans (AMRP) that are updated every 3 years, and states would be held to the requirements of Section 1902(a)(30)(A) of the Social Security Act⁵ in which states would still be required to submit information and analysis to demonstrate that provider payment rates should be adequate to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Again, CMS should keep in mind that a major factor driving the 2011 Proposed Rule, 2015 final Rule was that the federal access standard is not one of "sufficient" access, but rather requires Medicaid beneficiary access to healthcare services to be at least comparable to the access enjoyed by the general population in the same geographic area. There is a concern that without a framework and the lack of a standardized process to monitor access, the proposed rule would not only remove the burdensome requirements on states but would also lessen the importance of "sufficient" access.

⁵ 42 U.S.C. Section 1396a(a)(30)(A)

Through the Medicaid Rate Setting Proposed Rule, CMS also proposes to remove the requirement for states to annually conduct access reviews for a subset of services pursuant to the notion that similar information can be provided by the state in the State Plan Amendment (SPA) process. CMS believes that states will be able to adequately demonstrate compliance with the statute through the SPA process without developing and submitting an access monitoring review plan (AMRP). While the information on AMRP can be sufficiently presented as a component of any SPA, there is a concern that limiting access review to the SPA process means that access will only be assessed before rates are cut potentially resulting in the impact of the cuts on access will never be assessed. As a part of the access review demonstrating that access is currently adequate to be included in the SPA, CMS should also require states to provide reliable projections and other data to demonstrate that any proposed reimbursement reductions in the SPA will not harm access in violation of the statute once fully adopted.

In addition to the above concerns, it is unclear if the requirements provide such information applies to the list of services that were specified for access monitoring review under the previously required AMRP. As written, it appears that the 2019 Proposed Rule would still require state SPAs to focus only on primary care services, physician specialist services, behavioral health services, pre- and post-natal obstetric services, and home health services.⁶ NACDS continues to have serious concerns with the lack of monitoring access to pharmacy services. Although states have been given the flexibility to apply these requirements to other services where payment rates have been reduced or restructured, if this requirement still only applies to the list of specified services, there is likelihood that states will continue to neglect considering the impact on patient access to prescription drugs and other pharmacy services when payment rate changes are adopted and implemented. Therefore, we urge CMS to provide clarification of which services are subject to these requirements in the 2019 Proposed Rule and to include pharmacy services to any established list of services for access review in state SPAs to protect patient access to the valuable services that community pharmacies provide.

Public Process to Involve Stakeholders

In the 2011 Proposed Rule, CMS noted the importance of including patients and providers in the process as it leads to greater access, but again CMS in the 2019 Proposed Rule, CMS ignores the value of patient and provider involvement with the proposed repeal of those provisions. As written, it is unclear whether CMS will maintain its efforts to ensure greater transparency and opportunities for public input in efforts to measure access. We continue to believe the ability to have input in this process is critical. We strongly urge CMS to maintain the requirements for states to allow public availability to access studies. We also urge CMS to continue to require states to have a

⁶ [42 CFR Section 447.205\(b\)\(5\)](#)

public review process before SPAs are submitted as well as the continued use of an electronic publication process to notify the public of provider reimbursement changes.

Instead of removing these requirements that help to ensure public input into the sufficiency of access to providers, CMS should work to enhance transparency in its deliberations after SPAs are submitted. Maintaining open communication among beneficiaries, providers, states, and the federal government will lead to improved healthcare services for Medicaid beneficiaries.

Value of Pharmacy in State Medicaid Programs

It is important for CMS to know that ensuring access lowers overall state costs. Non-optimal medication therapy (estimated to cost the healthcare system \$528.4 billion per year)⁷ and medication non-adherence (estimated at \$100-290 billion per year and attributed to 10% of hospitalizations)⁸ results in avoidable and costly health complications. Decreased patient access due to lack of access standards or limited network, or provider capacity imposes unnecessary barriers that directly impact medication adherence.

Without network adequacy and limited access patients are more likely to forgo taking their medications as prescribed and are left to utilize more costly healthcare treatment options. As such, the importance of medication adherence cannot be overstated. Medications are the primary intervention to treat chronic disease and are involved in 80% of all treatment regimens. Yet medication management services are poorly integrated into existing healthcare systems. Without network adequacy and access standards, the rate of medication nonadherence can increase substantially, thus further increasing overall healthcare costs as patients will seek more costly healthcare services, such as emergency room visits and hospitalization.

As CMS considers proposals to lessen administrative burdens on the states, CMS must be mindful the value of community pharmacies and the services they provide in the Medicaid program. As the demand for healthcare services continues to grow, pharmacists have expanded their role in healthcare delivery, partnering with physicians, nurses, and other healthcare providers to meet their patients' needs. Innovative services provided by pharmacists do even more to improve patient healthcare quality of life. Increasingly, pharmacies provide vaccinations, health education, point of care and disease-state testing, disease management, and medication synchronization.

⁷ Watanabe JH, McInnis T, Hirsch JD; "Cost of Prescription- Drug Related Morbidity and Mortality;" *Annals of Pharmacotherapy*; March 26, 2018. <http://journals.sagepub.com/doi/10.1177/1060028018765159>

⁸ Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; August 22, 2013. Shrank WH, Polinski JM; "The Present and the Future of Cost-Related Non-Adherence in Medicare Part D;" *J Gen Intern Med* 30(8):1045-6. Pretorius RW, et al. "Reducing the Risk of Adverse Drug Events in Older Adults;" *American Family Physician*; March 1, 2013. <https://www.aafp.org/afp/2013/0301/p331.html>.

Pharmacists are even more highly valued by those that rely on them most – older Americans, individuals managing chronic diseases, and those in urban, rural, and underserved areas. Pharmacy services improve quality of life and healthcare affordability. Helping patients take their medications effectively and providing preventive services, pharmacists help avoid more costly forms of care and result in greater savings to the state and CMS. Because pharmacy services can help to improve medication adherence and result in overall better patient outcomes, we caution CMS that any changes made to the requirements for states to ensure access standards must not jeopardize patients access to their local pharmacists who are trusted, highly accessible healthcare providers who are deeply committed to providing accurate prescriptions and helping patients take medications as prescribed.

Conclusion

Thank you for the opportunity to share our views. We look forward to working with you to maintain access to prescription drugs and pharmacy services for the Medicaid population.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer