June 14, 2024

BY E-MAIL

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Re: 2024 NADAC Methodology Changes

Dear Secretary Becerra and Administrator Brooks-LaSure:

The National Association of Chain Drug Stores ("NACDS"), representing traditional drug stores, supermarkets, and mass merchants with pharmacies, urgently requests that you examine more carefully CMS's recent changes to the National Average Drug Acquisition Cost (NADAC) price benchmark, which have dramatically reduced pharmacy reimbursement in Medicaid and some Medicare plans beginning mid-April. The NADAC changes threaten access to care under Medicaid, especially in underserved areas. Furthermore, as discussed below, these changes are arbitrary and capricious and did not proceed through the necessary rulemaking process nor did CMS seek public feedback and comments as historically done.

The significant changes to NADAC prices first appear in the April 17, 2024 NADAC file. Since then, pharmacies have experienced, in aggregate, as much as a 19% average decrease in NADACs for generic drugs, with some NADACs down 60%, followed by an additional decrease in May. In the 10 years that CMS has been calculating NADAC rates, pharmacies have never experienced as strong a shift in reimbursement due to NADAC rate updates as they are experiencing today. Pharmacy reimbursement issues—including those related to pharmacy benefit manager practices—are destabilizing the pharmacy industry, forcing store closures and threatening Americans' convenient access to needed medications and healthcare services. The drastic NADAC changes increase risks for pharmacies and those they serve, especially in underserved communities.

CMS's explanation of the changes to NADAC rates has been so limited that it is difficult to precisely know what caused this pricing benchmark to plummet. CMS told NACDS that it increased the number of pharmacies it surveyed from 2500 to 4000 and that shift contributed to the decline in NADAC prices. CMS has not

explained in any further detail why the number 4,000 was selected or how many responses resulted.[1] At the same time, CMS implemented a new methodology for *calculating* the NADAC rates. The agency points to its February 2024 NADAC methodology document as constituting adequate notice, yet this document fails to adequately explain this new methodology, nor has the agency been forthcoming with how this methodology has ultimately impacted NADAC rates. CMS provided no opportunity for stakeholder comment.

NACDS requests that CMS pause the changes and utilization of the new NADAC methodology until stakeholders have been offered an opportunity to review the new methodology, provided the justification for such methodology, and given an opportunity to comment; or halt utilization of the new methodology and return to the previous methodology used to calculate rates prior to the publication of the April 17, 2024 NADAC rate file. In addition, CMS should explain when the increase in the number of surveyed pharmacies took effect, the reason for the increase, and seek comment from stakeholders regarding such change.

The NADAC Methodology Change Undermines CMS's Commitment to Medicaid Beneficiaries' Access to Care, Especially Among the Underserved

The manner in which CMS reduced Medicaid pharmacy reimbursement undermines CMS's commitment to promoting access to care for Medicaid beneficiaries and is inconsistent with the agency's statutory obligation to ensure Medicaid reimbursement rates are "consistent with efficiency, economy, and quality of care and are sufficient 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."[2] As you have acknowledged throughout the recent final rule on access to services in Medicaid, restructuring Medicaid payment rates affects Medicaid beneficiaries' access to care.[3] You recognize that inadequate Medicaid reimbursement rates make it less likely providers will accept Medicaid patients and could even impact beneficiaries' self-reported health.[4] By promulgating the new NADAC calculation and survey methodology with no warning or explanation, and no consideration of its impact on the adequacy of rates and access to care, CMS fails to meet its end of the bargain in "the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act."[5]

The Agency's Change to the NADAC Methodology Is Arbitrary and Capricious.

The NADAC methodology change is arbitrary and capricious because CMS provided no explanation of its decision to increase the survey size, nor did it even announce that a change had occurred. In a recent conversation, NACDS asked CMS when the change was implemented, but CMS could not recall. Rather than explain its methodological change and the data relied upon (and why), CMS made a policy decision in

[1] NACDS has filed a request under the Freedom of Information Act seeking (1) copies of all CMS documents created from April 1, 2023, to the present related to any changes in the NADAC price survey and the NADAC calculation methodology; and (2) copies of all written communications from January 1, 2023 through the present between CMS and Myers and Stauffer LC regarding changes to the NADAC survey or methodology.
[2] Social Security Act § 1902(a)(30)(A).
[3] Medicaid Program; Ensuring Access to Medicaid Services, 89 Fed. Reg. 40542, 40548 (May 10, 2024).
[4] *Id*. at 40844.
[5] *Id*. at 40548.

conclusory terms.[6] CMS has failed to show that it "reasonably considered the relevant issues and reasonably explained the decision," and has failed to show that there is a rational connection between the data it used and the policy decision that it made, so its action is arbitrary and capricious.[7] Further, CMS has departed from prior practice, and its change is an "unexplained inconsistency."[8]

CMS's decision to increase the survey size is also arbitrary and capricious because the agency has not attempted to measure the change's material impact on pharmacy reimbursement. In changing the NADAC methodology and expanding the survey size without notice, CMS has "entirely failed to consider an important aspect of the problem": the effect of its change on the amount payable to pharmacies under federal law, as well as the amount that will be payable by CMS to the states under federal law.[9] The pharmacy industry is experiencing the negative impact of the changes in NADAC rates on a daily basis. By failing to consider the effects of the change, CMS's action is arbitrary and capricious.

The Agency Failed To Provide Notice and an Opportunity for Public Comment Prior to Issuing the Change to the NADAC Methodology.

CMS's decision to change the NADAC methodology constitutes a rulemaking under the Administrative Procedure Act (APA) that requires notice-and-comment via publication in the Federal Register. Because most states[10] use NADAC as part of their Medicaid pharmacy reimbursement methodology established for determining "medical assistance" for covered outpatient drugs "under the State plan," CMS's changes to the methodology for calculating NADAC can change the amount payable to pharmacies under federal law, as well as the amount that CMS will pay states under federal law.[11] Therefore, when CMS changes the methodology for calculating NADAC it is changing the amount of medical assistance, and thereby federal financial participation that is payable under federal law. This is a "rule" in the terms of the APA: "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," and "includes the approval or prescription for the future of rates … [or] prices … or practices bearing on any of the foregoing."[12] While not every rule is a legislative rule that must comply with the APA's requirement for notice-and-comment rulemaking, none of the exceptions apply here.[13]

---

[6] *Cf.* Baystate Med. Ctr. v. Leavitt, 545 F. Supp. 2d 20, 48-49 (D.D.C. 2008) (holding that the CMS Administrator's reliance on a policy decision to ignore certain data despite acknowledged errors required remand to determine whether certain data had been excluded and to allow the Administrator to provide a reasoned explanation for why other available data were not the "best available data" to incorporate).

[7] F.C.C. v. Prometheus Radio Project, 592 U.S. 414, 423 (2021).

[8] Nat'l Cable & Telecomms. Ass'n v. Brand X Servs., 545 U.S. 967, 981 (2005).

[9] *Cf.* Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

[10] CMS, Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/medicaid-covered-outpatient-prescription-drug-reimbursement-information-state/index.html (2022).

[11] Social Security Act §§ 1905(a)(12), 1903(a)(1), 1927(b)(1)(B).

[12] 5 U.S.C. § 551(4).

[13] Although this matter arguably relates to public "benefits," which could place it outside the APA's requirement for notice-and-comment rulemaking, the Secretary has voluntarily agreed not to use this APA exception, and that decision binds CMS. Public Participation in Rule Making, 36 Fed. Reg. 2532 (Feb. 5, 1971); Clarian Health West, LLC v. Hargan, 878 F.3d 346, 356-57 (D.C. Cir. 2017). "Interpretive" rules are exempt but those only "advise the public of the agency's construction of the statutes and rules

Further, HHS and CMS have used notice-and-comment rulemaking in the past when adjusting pharmacy reimbursement methodology for Medicaid drugs.[14]

***

We urgently request that CMS and HHS halt the implementation of the new standard until there is better clarity around the specific changes to NADAC rate calculations, CMS's rationale for implementing modifications to the survey and process, and why stakeholders were not given an opportunity to comment. We are open to a meeting to discuss this further. Thank you for your prompt attention to this matter.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

B. Douglas Hoey, Pharmacist, MBA
Chief Executive Officer
National Community Pharmacists Association

which it administers," as opposed to having the "force and effect of law." Azar v. Allina Health Servs., 587 U.S. 566, 573 (2019) (internal quotations omitted). Here no statute or rule is being interpreted in changing the NADAC methodology, which has the force of law in determining the amount payable under federal law. Rules of agency procedure are also exempt, but "the critical feature of a procedural rule is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 250 (D.C. Cir. 2014). The NADAC methodology clearly alters the rights and interests of pharmacies.

[14] *See, e.g.*, Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5169 (Apr. 1, 2016); Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs, 75 Fed. Reg. 69591 (Nov. 15, 2010).