



Elizabeth G. Taylor
Executive Director

Board of Directors

Ann Kappler
Chair
Prudential Financial, Inc.

William B. Schultz
Vice Chair
Zuckerman Spaeder LLP

Miriam Harmatz
Secretary
Florida Health Justice Project

Nick Smirensky, CFA
Treasurer
New York State Health Foundation

Arian M. June
Debevoise & Plimpton LLP

L.D. Britt, MD, MPH
Eastern Virginia Medical School

Ian Heath Gershengorn
Jenner & Block

Robert B. Greifinger, MD
John Jay College of
Criminal Justice

John R. Hellow
Hooper, Lundy & Bookman, PC (Ret.)

Michele Johnson
Tennessee Justice Center

Lourdes A. Rivera
Center for Reproductive Rights

Donald B. Verrilli, Jr.
Munger, Tolles & Olson

Robert N. Weiner
Arnold & Porter, LLP

Ronald L. Wisor, Jr.
Hogan Lovells

Senior Advisor to the Board
Rep. Henry A. Waxman
Waxman Strategies

General Counsel
Marc Fleischaker
Arent Fox, LLP

July 20, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to RIN 0938–AT82
Proposed Rule: Medicaid Program; Establishing Minimum
Standards in Medicaid State Drug Utilization Review (DUR) and
Supporting Value-Based Purchasing (VBP) for Drugs Covered
in Medicaid, Revising Medicaid Drug Rebate and Third Party
Liability (TPL) Requirements

Dear Administrator Verma:

The National Health Law Program (NHeLP) has worked to improve health access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals for over 50 years. We appreciate the opportunity to provide comments on the proposed rule affecting the Medicaid Drug Rebate Program (MDRP).¹ However, we object to the 30-day comment period, which is too short given the complicated nature and potential consequences of the proposed rule. If implemented, the rule would likely increase costs for Medicaid outpatient prescription drugs while potentially limiting enrollee access.

We urge the Centers for Medicare & Medicaid Services (CMS) to withdraw the proposed rule and reconsider its provisions.

1. Proposed Changes to “Best Price” Would Undermine the Medicaid Drug Rebate Program (MDRP)

Congress established broad coverage requirements to help ensure access to outpatient prescription drugs for low-income Medicaid enrollees.² States that elect to provide the Medicaid outpatient prescription drug benefit must cover all FDA-approved drugs that are offered by any manufacturer that agrees to provide rebates.³ In exchange for broad Medicaid coverage, manufacturers must allow Medicaid programs to purchase prescription drugs at a significantly lowered cost.⁴

The Medicaid Act establishes rebate levels. For brand name drugs, rebates are set at the greater of 23.1% of the average manufacturer price (AMP); or (2) the difference between AMP and the statutory “best price,” defined, with certain exceptions, as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity within the United States.”⁵ Rebates for generic drug are set at 13% of AMP, with no best price provision.⁶ Manufacturers must pay additional inflation-related rebates for both brand-name and generic drugs if their prices rise faster than general inflation.⁷ States also have the ability to negotiate supplemental rebates with pharmaceutical manufacturers; however, not all states have such agreements and others have only single agreements for supplemental rebates.⁸

¹ U.S. Dep’t of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Proposed Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements, RIN 0938–AT82, 85 Fed. Reg. 37286 - 37322 (to be codified at 42 C.F.R. pts. 433, 438, 447, 456) (June 19, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-12970.pdf> (hereinafter “proposed rule”).

² H.R. Rep. 101-881, 101st Cong. 2nd Sess. 1990, 1990 U.S.C.A.A.N. 2017.

³ 42 U.S.C. § 1396r-8(k)(2)(i).

⁴ 42 U.S.C. § 1396r-8(a)(1).

⁵ See 42 U.S.C. §§ 1396r–8 (c) (describing the general statutory scheme); 1396r–8 (c)(1)(C)(i) (defining “best price”). 42 C.F.R. §§ 447. 504, 505, 508.

⁶ 42 U.S.C. § 1396r-8(c)(3)(B)(iii).

⁷ 42 U.S.C. § 1396r-8(c)(2).

⁸ Ctrs. for Medicare & Medicaid Servs., Medicaid Pharmacy Supplemental Rebate Agreements (SRA) (Updated March 2020), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf>.



The MDRP has proven highly successful, providing Medicaid enrollees access to important, and life-saving prescription medicines, while ensuring that state Medicaid programs pay the lowest possible price. Last year, the Medicaid Access and Payment Commission (MACPAC) released an in-depth analysis comparing the cost of prescription drugs in Medicaid, Medicare, and the commercial market. The conclusions are not surprising. Medicaid offers much broader coverage and pays far less for most drugs when compared to commercial plans and Medicare.⁹ Pharmaceutical manufacturers paid state Medicaid programs and the federal government \$36.2 billion in rebates in FY 2018, lowering Medicaid prescription costs by nearly 60%.¹⁰

The proposed rule would change how drug manufacturers report best price to facilitate more widespread adoption of “value-based” purchasing (VBP) arrangements in the commercial sector. Such changes would enable manufacturers to significantly reduce or delay the rebates they would otherwise have to pay under current law, thereby increasing Medicaid drug costs. For example:

- Changes to the “bundled sale” provision could allow manufacturers to mix VBP and non-VBP prices under different contracts across multiple purchasers.¹¹ Changes could also allow manufacturers to exclude some typical discounts that apply whether they are part of a VBP or not. These changes would have the effect of raising best price and lowering rebate amounts. Moreover, the proposed rule does not explain how manufacturers would report initial prices under a VBP arrangement if those prices vary based on anticipated patient outcomes.
- The “varying best price” provision could bar states from benefiting from the best price under VBP arrangements if a manufacturer chooses to report a range of best prices, as the proposed rule allows. A state’s Medicaid program would benefit from varying best prices only if it has VBP arrangement with that manufacturer.¹² This could gut best price if a manufacturer chooses to exclusively offer the drug through VBP arrangements and refuses to participate in VBP arrangements with state

⁹ Chris Park, Medicaid and CHIP Payment and Access Commission, Findings from Phase 2 of Analysis on Medicaid Drug Formularies: Effects on Utilization and Spending (Sept. 2019), <https://www.macpac.gov/publication/findings-from-phase-2-of-analysis-on-medicaid-drug-formularies-effects-on-utilization-and-spending/>.

¹⁰ Medicaid and CHIP Payment and Access Commission, “MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2018,” December 2019, <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2018-millions.pdf>.

¹¹ 85 Fed. Reg. 37292, 37319.

¹² 85 Fed. Reg. 37292 - 37394, 37320.



Medicaid programs. The varying best price provision should be dropped entirely, as manufacturers would already have available the option to treat VBP arrangements as a bundled sale under the current regulation.¹³

CMS' proposed rule is primarily designed to encourage value-base contracting arrangements in the commercial market. We believe that it is improper for CMS to change Medicaid program requirements to achieve a goal outside of the Medicaid program. Moreover, changes to best price reporting will likely lead to lower discounts and higher prescription drug costs for state Medicaid programs.

2. Medicaid Value-based Purchasing Arrangements Should Protect Enrollee Access

In the proposed rule, CMS seeks to facilitate more widespread adoption of VBP arrangements, not only among commercial insurers, but within Medicaid as well. However, CMS does not demonstrate that VBP arrangements between payers and manufacturers will improve access to outpatient prescription drugs. Rather, the proposed approach offers a cost-containment strategy with no safeguards to ensure that, under VBP arrangements, Medicaid enrollees can continue to access needed outpatient prescription drugs.

a. Cost-effectiveness measures should facilitate, not reduce, access to care

The proposed rule establishes a Medicaid definition for VBP.¹⁴ However, the definition is vague, and CMS provides insufficient explanation on key components of VBP, such as "effectiveness" and "performance." Moreover, CMS fails to include important safeguards to ensure that measures of "cost-effectiveness" are not discriminatory or lead to unlawful health care rationing.

The proposed rule defines VBP as "arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population," through evidence and outcomes-based measures.¹⁵ Evidence-based measures would "substantially link the cost of a drug product to existing evidence of effectiveness;" while

¹³ 42 C.F.R. § 447.502.

¹⁴ 85 Fed. Reg. 37319.

¹⁵ *Id.*



outcomes-based measures would “substantially link payment for the drug to that of the drug’s actual performance in patient or a population.”¹⁶

The proposed rule provides little explanation on evidence- or outcomes-based measures, making it difficult for stakeholders to comment. CMS also invites suggestions on additional measures “to reflect value from a drug therapy,” as well as how to interpret the term “substantially” in the context of its proposed definition.¹⁷ This suggests that CMS should have engaged in a Request for Information process on VBP and more clearly developed concepts and proposals before embarking on formal rulemaking.

If CMS moves forward with Medicaid prescription drug regulations defining VBPs, it should make clear that any analysis of a drug’s “cost effectiveness” should not be based on measures which are discriminatory or lead to unlawful health care rationing. For example, in the wake of the COVID-19 emergency, the HHS Office for Civil Rights (OCR) has taken action in several states, including Pennsylvania and Tennessee, to stop treatment protocols that gave lower priority to patients due to their age or disability.¹⁸

In 2019, the National Council on Disability, an independent federal agency, urged HHS to pursue “best practices on the use of cost-effectiveness to inform benefits and coverage decisions with respect to US national health insurance programs, such as Medicare and Medicaid. ‘Best practices’ in this case refers to a means of utilizing cost-effectiveness research that facilitates greater access to care, and does not reduce access to care for people with chronic health conditions and disabilities.”¹⁹ We agree.

Measures that devalue the lives of persons with disabilities and older adults based upon quality of life or age, should not serve as the basis for any analysis of a drug’s cost-

¹⁶ *Id.*

¹⁷ 85 Fed. Reg. 37292.

¹⁸ See, e.g., HHS Office for Civil Rights, *OCR Resolves Civil Rights Complaint Against Pennsylvania After it Revises its Pandemic Health Care Triage Policies to Protect Against Disability Discrimination* (April 16, 2020), <https://www.hhs.gov/about/news/2020/04/16/ocr-resolves-civil-rights-complaint-against-pennsylvania-after-it-revises-its-pandemic-health-care.html>; HHS Office for Civil Rights, *OCR Resolves Complaint with Tennessee After it Revises its Triage Plans to Protect Against Disability Discrimination* (June 26, 2020), <https://www.hhs.gov/about/news/2020/06/26/ocr-resolves-complaint-tennessee-after-it-revises-its-triage-plans-protect-against-disability.html>.

¹⁹ Nat’l. Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series*, at 14 (Nov. 6, 2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.



effectiveness. CMS should make a clear statement that such measures are discriminatory and that it will not approve any VBP arrangements that rely on such measures.

b. Commercial-style VBP arrangements are inappropriate for Medicaid enrollees who face unique health challenges

Medicaid enrollees already face challenges in obtaining medically necessary prescription drugs, for example, due to step therapy or burdensome prior authorization requirements.²⁰ Standardized care decisions, such as those based on VBP arrangements, create additional barriers to treatments. This can be especially harmful for high need patients who rely on Medicaid, including individuals with chronic illness or complex medical conditions, people with disabilities, and older adults.

Moreover, Medicaid enrollees face a myriad of social and structural challenges that impede medication adherence, impacting outcomes and shaping what evidence is available. For example, food insecurity is a prominent barrier to antiretroviral adherence for people with HIV, at rates significantly higher than those of the general population.²¹ In 2018, the International Food Information Council and Root Cause Coalition found that 32% of Medicaid enrollees often purchase less-healthy food options than they otherwise would because of lack of money, compared to 13% of non-enrollees, and 43% of enrollees skip at least one meal per day due to a lack of food, compared with 28% of non-enrollees.²² Medicaid enrollees disproportionately face other challenges that affect medication adherence, such as utility shutoffs, lack of transportation, and housing instability.²³

²⁰ Keith Loria, *The Impact of Prior Authorizations*, Medical Economics (Feb. 27, 2019), <https://www.medicaleconomics.com/view/strategies-to-rebuild-patient-volumes-in-the-wake-of-covid-19>. See also Andis Robeznieks, *Prior Authorization Needs Fixing. How It's Happening in the States*, American Medical Association (Feb. 4, 2020), <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-needs-fixing-how-it-s-happening-states>, reporting that over one third of patients will abandon treatment due to the complexity of prior authorization.

²¹ See e.g., Pennifer A. Pellowski et al., *The Daily Relationship Between Aspects of Food Insecurity and Medication Adherence Among People Living With HIV With Recent Experiences of Hunger*, 50(6) Ann. Behav. Med. 844-853 (2016).

²² 2018 Food and Health Survey, Food Insight (May 16, 2018), <https://www.foodinsight.org/2018-food-and-health-survey>.

²³ See, e.g., Judith Shinogle & Joshua M. Wiener, *Medication Use Among Medicaid Users of Home and Community-Based Services*, 28(a) Health Care Finance Rev. 103, 104 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194969/>; Rebecca Arden Harris et al., *Housing Stability and Medication Adherence among HIV-Positive Individuals in Antiretroviral Therapy: A Meta-Analysis of Observational Studies in the United States* 74(3) J. Acquir. Immune Defic. Syndr. 309 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5305290/>; Sandra Larson, *Protecting Patients From*



The clinical and health-related social challenges facing Medicaid enrollees interfere with their ability to achieve their optimal level of health. Even if linking prescription payments or prices to evidence- or outcome-based measures reduced costs – a possibility that has no support in current research – the rule does not show how VBP will address these myriad barriers to meaningful access to health-promoting and lifesaving therapies.

c. States already have authority and flexibility to create alternative payment models

States already have considerable flexibility to adopt alternative payment methods, including VBP, “subscription” models, and pay-over-time contracts. Since 2018, CMS has approved State Plan Amendments (SPAs) in a handful of states adopting these approaches.

Five states have implemented SPAs under VBP arrangements.²⁴ The SPAs allow states to negotiate supplemental rebates depending on a drug’s performance. For example, Oklahoma has a number of VBP contracts with manufacturers that link payment to a drug’s performance on measures such as adherence rates or hospitalizations.²⁵ Oklahoma tracks its measures using claims data, rather than clinical data.²⁶ It is unclear how Oklahoma’s measures would fall within the under the proposed rule’s VBP definition.

Energy Insecurity Requires Universal Screening, Health City (Nov. 18, 2019), <https://www.bmc.org/healthcity/policy-and-industry/universal-screening-protect-patients-energy-insecurity>.

²⁴ Ctrs. for Medicare & Medicaid Servs., Approval Letter for Oklahoma State Plan Amendment 18-0008 (June 27, 2018), <https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/OK/OK-18-08.pdf>; Ctrs. for Medicare & Medicaid Servs., Approval Letter for Michigan State Plan Amendment 18-0009 (Nov. 14, 2018), <https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf>; Ctrs. for Medicare & Medicaid Servs., Approval Letter for Colorado State Plan Amendment 18-0044 (Feb. 25, 2019), <https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf>; Ctrs. for Medicare & Medicaid Servs., Approval Letter for Massachusetts State Plan Amendment 19-0001 (July 31, 2019), <https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MA/MA-19-0001.pdf>; Ctrs. for Medicare & Medicaid Servs., Approval Letter for Alabama State Plan Amendment 19-0009 (Dec. 20, 2019), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/AL/AL-19-0009_0.pdf.

²⁵ See Melissa Abbott, Pharmacy Management Consultants, Paying for Value, Institute for Health Policy Forum (Sept. 19, 2019), <https://www.kpihp.org/wp-content/uploads/2019/09/Unpacking-Drug-Value-Forum-Melissa-Abbott-PPT.pdf>.

²⁶ *Id.*



In addition, it is not clear how the new rules will impact other alternative payment arrangements. For example, Louisiana’s “subscription model” for hepatitis C treatment provides Medicaid beneficiaries access to generic version of Epclusa.²⁷ The Louisiana program pays a set price per course of treatment up to an agreed-upon cap.²⁸ After reaching that cap, Louisiana will receive unlimited additional treatment at no cost from the manufacturer through the end of 2024.²⁹ Medicaid enrollees can still access other hepatitis C treatments, but must obtain prior authorization approval.³⁰

We remain concerned that alternative payment arrangements, including Louisiana’s subscription model and the proliferation of VBP, may make it harder for Medicaid enrollees to access needed medications if the drug available through the state’s agreement is not clinically appropriate for them. If CMS does move forward with final rulemaking, it should ensure that measures of value or effectiveness are person-centered and based on based on individual assessment of patient needs. CMS should also make it clear to states that it will reject VBP and other alternative payment arrangements that unduly limit Medicaid enrollee access to medically necessary outpatient prescription drugs.

3. The Proposed Rule Could Unduly Limit Access to Pain Management Treatment and Should Facilitate Access to Substance Use Disorder Treatment

The proposed rule also contains provisions which implement opioid-specific drug use review (DUR) standards with the aim to address the opioid crisis and prevent inappropriate prescription, use, fraud, abuse, or medically unnecessary care involving opioids.³¹ CMS includes proposals to enable states to identify or limit inappropriate prescribing of opioids, implement safety reviews related to medication-assisted treatment (MAT), and identify beneficiaries who should be considered for prescription of naloxone.

²⁷ Ctrs. for Medicare & Medicaid Servs., “CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid,” June 26, 2019, <https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified>.

²⁸ *Id.*

²⁹ *Id.*

³⁰ Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Medication Therapy Worksheet for Louisiana Medicaid Recipients, Louisiana Department of Health: http://www.lah.gov/assets/HealthyLa/PDL/3.2019/Hep_C_DAA_Treatment_Worksheet.52419.pdf.

³¹ 85 Fed. Reg. 37286, 37303-37315 (June 19, 2020) (to be codified at 42 C.F.R. pts. 433, 438, 447, 456).



Overall, these proposals seek to address substance and opioid use disorders by imposing prescription limitations and other protective measures which limit the provision of medications. However, we caution against the imposition of prescription limits in the absence of additional measures to reduce opioid use, such as expansion of coverage of non-opioid alternatives for pain treatment and expansion of coverage of Substance Use Disorders (SUD) and Opioid Use Disorders (OUD) treatment in Medicaid.

a. States should not impose prescription limits in absence of additional measures

In recent years, an increasing number of states have resorted to opioid prescribing limits as a way to address the increase in persons with SUD and OUD, particularly around opioids prescribed for treatment of acute pain.³² However, strict limits on opioid prescription may be counterproductive by increasing opioid dependence and failing to effectively address the need for SUD and OUD treatment. While quantity and other limits on prescriptions for opioids may lead to a decrease in the supply of opioids, there is no guarantee that it will result in a reduction of opioid-related harm, which should be the primary goal of any such measure. This is particularly true where efforts to address OUD fail to adopt alternative measures to treat SUDs and OUDs.

In addition, prescription limits often result in unintended consequences, particularly for low-income Medicaid enrollees and people with disabilities who live with chronic pain. Many of these individuals are currently receiving opioids for pain management. Limiting the quantity of opioid prescriptions permitted under Medicaid coverage may lead providers to curtail medically necessary care and to non-consensually discontinue opioid therapy due to unfounded fears that the patient may develop an OUD.

The authors of the Center for Disease Control and Prevention’s 2016 Guideline for Prescribing Opioids recognized that providers have been misapplying the guidelines by inappropriately cutting patients’ opioid prescriptions.³³ For example, the authors noted the

³² Nat’l Conf. of State Legs., *Prescribing Policies: States Confront Opioid Overdose Epidemic* (June 30, 2019), <https://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>; Marilyn Bulloch, *Opioid Prescribing Limits Across the States*, *Pharm. Times* (Feb. 5, 2019), <https://www.pharmacytimes.com/contributor/marilyn-bulloch-pharmd-bcps/2019/02/opioid-prescribing-limits-across-the-states>.

³³ Deborah Dowell, Tamara M. Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 315 *JAMA* 1624 (2016), <https://jamanetwork.com/journals/jama/article-abstract/2503508> [hereinafter “CDC Guideline 2016”]; Deborah Dowell, et al., *No Shortcuts to Safer Opioid*



inconsistency between the guidelines and the implementation of “inflexible recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician’s practice.”³⁴ The authors also point out that patients have a lower risk of overdose and may even experience reduced pain if they have the opportunity to successfully taper their opioid use, while those who have their dosages abruptly tapered may have adverse psychological or physical outcomes and may seek other sources of opioids.³⁵

CMS policies should allow physicians to make clinical decisions based on each patient’s specific circumstances. Agency guidance should never substitute for clinical judgment, and CMS should not limit medically necessary care. Instead of inappropriately curtailing already established regimes of opioid medications for pain, CMS should make sure providers have a full array of tools available to treat acute and chronic pain. This would include access to opioids when medically necessary but also include Medicaid coverage for non-opioid services to treat pain, such as physical therapy, acupuncture, chiropractic care, and over-the-counter medications.³⁶ We believe CMS should encourage states to expand Medicaid coverage to non-opioid treatment alternatives and to encourage removal of coverage limitations, including prior authorization requirements, to make these services accessible and a reliable option for providers and beneficiaries.

b. CMS should encourage states to remove all barriers to Medication Assisted Treatment (MAT) and naloxone coverage

Additionally, the NPRM contains provisions which seek to connect beneficiaries with additional treatments to prevent opioid abuse and overdose. The proposed rule directs states to implement reviews to indicate when a beneficiary is prescribed an opioid after they had been prescribed Medication Assisted Treatment (MAT) drugs.³⁷ The proposed

Prescribing, 380 N ENGL J MED 2285-2287 (June 13, 2019), <https://www.nejm.org/doi/full/10.1056/NEJMp1904190> [hereinafter “Dowell et al.”]; see also Kurt Kroenke, et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: a Consensus Panel Report*, 20 *Pain Med* 724 (2019), <https://academic.oup.com/painmedicine/article/20/4/724/5301726>.

³⁴ Dowell et al. (citing *CDC Guideline 2016*).

³⁵ *Id.*

³⁶ Casey Ross, *As the opioid crisis grows, states are opening Medicaid to alternative medicine*, STAT NEWS (Jan. 17, 2018), <https://www.statnews.com/2018/01/17/medicaid-opioids-alternative-medicine/>.

³⁷ 85 Fed. Reg. 37321 – 37322, to be codified at 42 C.F.R. § 456.703(h)(1)(vii)(A)).



rule would also require states to establish procedures to identify individuals who are at high risk of opioid overdose and should be considered for a naloxone prescription.³⁸

We encourage CMS to adopt rules which advance the use of MAT and caution against putting in place regulations which will inhibit access to MAT. MAT, particularly treatment with the medications methadone and buprenorphine, is the gold standard of care for treating individuals with SUD and has been proven effective in reducing the burdens associated with SUD and OUD.³⁹ Similarly, the overdose-reversal medication naloxone has been responsible for reverting countless opioid-related overdoses and saving thousands of lives since being introduced.⁴⁰ As such, CMS should encourage states to make these medications easily available for all Medicaid enrollees. This means that states should work to remove all policy barriers that impede coverage of the medications, such as prior authorization requirements, simultaneous counseling requirements, and subjecting individuals to pharmacy “lock-in” programs. These onerous requirements prevent Medicaid enrollees from accessing services that reduce the risk of overdose.

Federal law already makes patient access to MAT difficult. For example, methadone for MAT may only be dispensed from a specially licensed clinic, and patients typically must travel to the clinic daily to take their dose under supervision.⁴¹ These restrictions make it very difficult for many people to receive methadone treatment. Similarly, buprenorphine can only be prescribed by practitioners especially “waivered” to do so; such physicians must complete an 8-hour training or hold certain certifications, and may only treat 30 patients with buprenorphine in the first year.⁴² CMS should work with Congress and other federal agencies to eliminate limitations unduly restrict access to MAT for many people.

³⁸ *Id.*, to be codified at 42 C.F.R. § 456.703(h)(1)(vii)(B)).

³⁹ Corey Davis, Carli Suba, & Amy Lieberman, *Medication-Assisted Treatment for Opioid Use Disorder: The Gold Standard*, NATIONAL HEALTH LAW PROGRAM (May 16, 2018), <https://healthlaw.org/resource/medication-assisted-treatment-for-opioid-use-disorder-the-gold-standard/>.

⁴⁰ Eliza Wheeler et al., *Opioid Overdose Prevention Programs Providing Naloxone to Laypersons – United States, 2014*, 64 MORBIDITY & MORTALITY WEEKLY REP. 631 (2015).

⁴¹ 42 C.F.R. § 8.12 (2018). After a certain period of treatment, patients may qualify for “take-home” doses on weekends or for special occasions, but this is at the discretion of the provider. 42 C.F.R. § 8.12(i) (2018).

⁴² See Shane Shiflett, Hilary Fung, Nicky Forster, and Jason Cherkis, *Not Enough Doctors Are Treating Heroin Addiction With A Life-Saving Drug*, THE HUFFINGTON POST (Dec. 30 2015), <http://projects.huffingtonpost.com/dying-to-be-free-heroin-treatment/opioid-abuse-outpace-treatment-capacity>.

Rules governing the prescription of buprenorphine treatment differ by years of physician experience with the drug and additional rules apply to nurse practitioners and physician assistants. *Id.*



The proposed rule would require states to establish procedures to identify individuals who are at high risk of opioid overdose and should be considered for a naloxone prescription.⁴³ We support efforts by CMS to encourage states to expand use, distribution, and access to naloxone. Many opioid-related deaths could be avoided if persons experiencing overdose had received naloxone, which effectively and quickly reversed most opioid overdoses if administered before the individual experiences cardiac arrest. The CDC estimates that from 1996 to 2014, naloxone distribution programs trained and provided naloxone to over 150,000 laypersons, resulting in over 26,000 drug overdose reversals.⁴⁴ The distribution of naloxone to high-risk individuals has also proven to be cost-effective.⁴⁵ Because medical knowledge is not required to administer naloxone, the expenses involved in training laypersons to use the medication are minimal.

However, existing federal laws and policies create barriers to naloxone utilization. At the federal level, two key barriers to widespread access to naloxone exist: the medication's prescription status and its cost.⁴⁶ The requirement of a prescription for naloxone is a significant barrier, while permitting non-prescription distribution of the medication has the potential to reduce deaths from opioid overdoses. Because the probability of opioid-related harm increases with the amount of time a person remains in opioid-induced respiratory depression, naloxone must be immediately available at the scene of the overdose. As such, in 2018, NHeLP submitted comments in favor of making naloxone available over the counter.⁴⁷ We reiterate here our support for such action and note its importance in increasing naloxone treatment to reduce opioid-related deaths.

In addition, the cost of naloxone has drastically increased in recent years, making it inaccessible to many low-income individuals and community-based organizations. In order to address the cost barrier, CMS's regulations should be amended to expressly ensure that

⁴³ 85 Fed. Reg. 37321 – 37322, to be codified at 42 C.F.R. § 456.703(h)(1)(vii)(B)

⁴⁴ Wheeler et al., *supra* note 40.

⁴⁵ Philip O. Coffin & Sean D. Sullivan, *Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal*, 158 ANNALS OF INTERNAL MED. 1, 6 (2013) (finding that “[n]aloxone distribution to heroin users would be expected to reduce mortality and be cost-effective even under markedly conservative assumptions of use, effectiveness, and cost”).

⁴⁶ See Corey S. Davis & Derek Carr, *Legal Changes to Increase Access to Naloxone for Opioid Overdose Reversal in the United States*, 157 DRUG & ALCOHOL DEPENDENCE 112, 113 (2015), <http://prescribetoprevent.org/wp2015/wp-content/uploads/davis-carr-naloxone-laws-US.pdf>.

⁴⁷ Nat'l Health Law Program, Comment Letter on Notice of Establishment of Public Docket: Joint Meeting of Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee (Docket No. FDA-2018-N-3805) (Dec. 14, 2018), <https://healthlaw.org/resource/comments-to-the-fda-urging-approval-of-over-the-counter-naloxone/>.



both the medication and any necessary training are covered by both Medicare and Medicaid without prior authorization or other barriers.

4. CMS Should Conduct a Regulatory Impact Analysis

The proposed rule would have a significant economic impact and impose a significant burden on state Medicaid agencies, pharmaceutical manufacturers, and the federal government to implement these changes. Yet, inexplicably, CMS designated the proposed rule as not economically significant. CMS should withdraw the rule and conduct a regulatory impact analysis (RIA) on its implications.

The Congressional Review Act (CRA) defines a major rule “as any rule that the Office of Information and Regulatory Affairs [OIRA] of the Office of Management and Budget [OMB] finds has resulted in or is likely to result in —

- (A) an annual effect on the economy of \$100,000,000 or more;
- (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.”⁴⁸

A series of Executive Orders require agencies to provide the public and OMB a thorough analysis of the costs and benefits of all significant regulatory actions.⁴⁹ The current administration requires agencies to “include both a proposed significance determination and a proposed determination of whether the rule is major under Section 804(2).⁵⁰ As noted, OIRA ultimately determines whether a rule meets this definition.⁵¹

⁴⁸ 5 U.S.C. § 804(2). Note that this “term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act” *Id.*

⁴⁹ E.O. 12866 (Sept. 30, 1993), <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>; E.O. 13563 (Jan. 18, 2011), <https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>. (specifically requiring agencies to “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible”).

⁵⁰ Russell T Vought, Acting Director, Office of Management and Budget, Memorandum to Heads of Executive Departments and Agencies, Guidance on Compliance with the Congressional Review Act (April 11, 2019), at 4, <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf>.

⁵¹ 5 U.S.C. § 804(2).



In the proposed rule, CMS acknowledges that a “regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year)” but claims, without explanation, that the proposed rule “does not reach the economic threshold and thus is not considered a major rule.”⁵²

However, when CMS has considered these same issues in earlier rulemakings, it concluded they were major rules and conducted the appropriate regulatory impact analysis. For example, the proposed rule would establish a definition for “line extension.”⁵³ Since at least 2012, CMS has considered, but declined to finalize a definition for line extension drugs.⁵⁴ In 2019, CMS published an interim-final rule, stating that for rebates associated with line extension drugs “CMS Office of the Actuary’s (OACT’s) estimated savings of \$1.64 billion over 5 year and \$3.95 billion over 10 years.”⁵⁵ Establishing a definition for a prescription drug provision accounting for \$1.64 billion in savings meets the threshold of economically significant and warrants a full RIA.

Other aspects of the proposed rule, from changes to best price to DUR, could potentially have enormous impacts on state and federal Medicaid spending, in addition to creating complicated reporting and compliance requirements. CMS should withdraw the rule and conduct a RIA before proceeding further.

Conclusion

The proposed rule would likely increase costs for Medicaid outpatient prescription drugs while potentially limiting enrollee access. We urge CMS to withdraw and reconsider its provisions, or, at the very least, include express protections to ensure that Medicaid enrollees have continued access to medically necessary outpatient prescription drugs.

⁵² 85 Fed. Reg. 31317.

⁵³ 85 Fed. Reg. 37294 – 37295, 37319.

⁵⁴ Ctrs. for Medicare & Medicaid Servs., Medicaid Program; Covered Outpatient Drugs Proposed Rule, 77 Fed. Reg. 5318 – 5367, 5360 (Feb. 2, 2012), <https://www.govinfo.gov/content/pkg/FR-2012-02-02/pdf/2012-2014.pdf>. Rebates on new formulation drugs are estimated at \$2,530,000,000 between 2010-2014. Id. at 5354. See also Ctrs. for Medicare & Medicaid Servs., Medicaid Program; Covered Outpatient Drugs Final Rule with Comment Period, 81 Fed. Reg. 5170 – 5357, 5197 (Feb. 1, 2016) (requesting comments on line extension for future rulemaking) <https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

⁵⁵ Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs Final Rule and Interim Final Rule with Comment Period., 84 Fed. Reg. 12130 - 12137, 12135 (April 1, 2019) <https://www.govinfo.gov/content/pkg/FR-2019-04-01/pdf/2019-06274.pdf>.



Please feel free to contact me at (202) 289-7661 or turner@healthlaw.org if you have questions.

Yours truly,

A handwritten signature in dark ink, appearing to read 'W. Turner', followed by a long horizontal line extending to the right.

Wayne Turner
Senior Attorney

