April 8, 2019

Via electronic filing at www.regulations.gov

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees Proposed Rule (OIG-0936-P)

Dear Secretary Azar:

The National Health Law Program (NHeLP) is a public interest organization working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to comment on the proposed rule, which would remove safe harbor protections for manufacturer rebates to Medicare Part D plans and Medicaid managed care organizations (MCOs), including pharmacy benefit managers (PBMs). The proposal would also create a new safe harbor for point-of-sale (POS) rebates.

We oppose these changes with respect to the Medicaid program, which provides robust coverage of outpatient prescription drugs with guaranteed manufacturers' rebates. Federal law already limits cost sharing for outpatient prescription drugs to nominal amounts for Medicaid beneficiaries. Moreover, the proposal to shift from rebates for MCOs to POS discounts would likely result in higher MCO drug costs and lead to increased Medicaid spending.

Prescription drug coverage in Medicaid

Medicaid coverage of outpatient prescription drugs serves as a lifeline for enrollees, particularly those with serious or chronic health conditions. Although an optional service, all states have elected to provide outpatient prescription drug coverage in their Medicaid programs.[1] Congress recognized that Medicaid enrollees are low income and rarely have other financial means to obtain potentially life-saving medications. Accordingly, Congress requires that state Medicaid prescription drug coverage includes most medications approved by the Food and Drug Administration (FDA) for medically-accepted indications.[2] In exchange for this broad coverage requirement, pharmaceutical manufacturers must provide substantial rebates to states.[3]

Cost sharing protections

Cost sharing can impose a significant barrier to accessing medically necessary services and benefits.[4] Accordingly, Congress limited cost sharing in Medicaid to only nominal amounts for outpatient prescription drugs. In addition, under the Affordable Care Act, Medicaid Alternative Benefit Plans provided to low income adults must meet Essential Health Benefits standards, including no-cost coverage of preventive medications, such as contraception, drugs used to prevent breast cancer, and bowel preparation medicine for colonoscopy procedures.[5]

Federal law allows states to designate "preferred" and "non-preferred" drugs similar to a tiering structure in non-Medicaid formularies.[6] A Medicaid enrollee's income determines the applicable level of cost sharing (as summarized in the chart below), with some populations exempt.[7]

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[1] 42 U.S.C. § 1396d(a)(12); 42 C.F.R. §§ 440.120(a), 440.90, 440.100.
[2] 42 U.S.C. §1396r-8.
[3] *Id*.
[4] *See* David Machledt & Jane Perkins, NHeLP, *Medicaid Premiums and Cost Sharing* (Mar. 26, 2015), http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing.
[5] 42 U.S.C. § 1396a(k)(1); 42 U.S.C. § 1396u-7(b)(5). *See also* CMCS, Alternative Benefit Plan Conforming Changes (Jan, 28, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-28-16.pdf.
[6] 42 U.S.C. §§ 1396o, 1396o-1. States also use Preferred Drug Lists (PDLs) to negotiate supplemental rebates. *See* Medicaid Access and Payment Commission (MACPAC), *Medicaid Payment for Outpatient Prescription Drugs* 9 (May 18, 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
[7] *See* 42 U.S.C. §§ 1396o, 1396o-1; 42 C.F.R. § 447.53.

Medicaid Prescription Drug Cost Sharing			
	≤ 100% FPL	**101% - 150% FPL**	**>150% FPL**
Maximum Allowable Copayments			
Preferred drugs	$4	$4	$4
Non-preferred drugs	$8	$8	20% of the agency's cost of the drug

According to a recent survey by the Kaiser Family Foundation, no states that offer Medicaid eligibility above 150% FPL charge coinsurance for non-preferred drugs."[8]

The administration has touted this proposed rule as providing relief to consumers for the high cost of outpatient prescription drugs.[9] However, Congress has already ensured that low-income Medicaid enrollees have ample protections from high out-of-pocket expenses for outpatient prescription drugs by limiting cost sharing. There is simply no need to address prescription drugs provided through Medicaid in this proposed rule.

Eliminating safe harbor would increase state Medicaid costs

Eliminating the safe harbor for manufacturers' rebates to Medicaid MCOs and the PBMs contracting with Medicaid agencies or MCOs would lead to increased costs, according to HHS' own analysis. The Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) estimates that the proposed rule would increase total Medicaid spending by $1.9 billion over the next ten years, with $1.7 billion in increased federal Medicaid spending and $200 million in increased state Medicaid spending.[10]

The OACT expects that 85% of current Medicaid managed care drug rebates would no longer be negotiated between manufacturers and PBMs on behalf of Medicaid managed care plans.[11]

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[8] Tricia Brooks, Lauren Roygardner, & Samantha Artiga, Medicaid and CHIP Eligibility, Enrollment, and Cost Sharing Policies as of January 2019: Findings from a 50-State Survey, KFF, Table 20 (Mar. 27, 2019), https://www.kff.org/report-section/medicaid-and-chip-eligibility-enrollment-and-cost-sharing-policies-as-of-january-2019-findings-from-a-50-state-survey-tables/.

[9] See, *e.g.*, HHS Press Statement, *Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients* (Jan. 31, 2019), https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html.

[10] Office of the Actuary, Centers for Medicare & Medicaid Services, *Proposed Safe Harbor Regulation* (Aug. 30, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf.

[11] *Id*.

As a result, Medicaid managed care plans would see higher net pharmacy costs under the proposed rule and in turn, states would have to increase their capitation payments to Medicaid managed care plans to account for those higher costs. Down the line, this could lead to states reducing services to preserve their budgets.

The proposed rule could lead to unintended consequences

We echo concerns raised by the Georgetown Center for Children and Families that the proposed rule could lead to unintended consequences. For example, if the proposed rule eventually results in some reduction in the rebates now provided by manufacturers to private insurance, but without a significant reduction in list prices, that could also affect the "best price" requirement in Medicaid. Under the Medicaid Drug Rebate Program, the base rebate is set at the higher of 23.1% of the Average Manufacturer Price (AMP) or the "best price" discount provided to most other payers including in private insurance. (Rebates negotiated by Medicare Part D plans are currently exempt from best price.) That could result in smaller rebates paid to state Medicaid programs and higher net drug costs. While the OACT analysis examines the impact on private insurance from potentially lower list prices, it does not examine how possible changes in private insurance rebates could affect Medicaid.

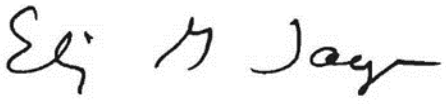
Given the many uncertainties, HHS should fully consider the broader consequences and withdraw this proposal as it applies to Medicaid.

Conclusion

The proposed rule would increase costs to states and the federal government while providing no tangible benefit for the 75 million people enrolled in Medicaid. Moreover, this ill-considered proposal could have far-reaching, unintended effects beyond Medicaid. We urge HHS not to change safe harbor regulations currently in effect for Medicaid.

If you have further questions, please contact Senior Attorney Wayne Turner (turner@healthlaw.org; (202) 289-7661) or Staff Attorney Haley Penan (penan@healthlaw.org; (310) 204-6010).

Sincerely,



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NATIONAL HEALTH LAW PROGRAM