



February 19, 2019

The Honorable Senator Bill Cassidy
520 Hart Senate Office Building
Washington, DC 20510

The Honorable Senator Mark Warner
703 Hart Senate Office Building
Washington, DC 20510

Dear Senators Cassidy and Warner,

On behalf of the nation's Medicaid Directors, NAMD is writing to express concern with the Patient Affordability Value and Efficiency Act (the PAVE Act). While Medicaid Directors share the goal of promoting new payment models for pharmaceuticals that incentivize value, improve outcomes for patients, and lower costs, we believe the PAVE Act as currently drafted would negatively impact Medicaid's ability to provide the pharmacy benefit in a sustainable manner going forward.

The National Association of Medicaid Directors (NAMD) is a bipartisan, nonprofit, professional organization representing leaders of state Medicaid agencies across the country. Our members drive major innovations in health care while overseeing Medicaid, which provides a vital health care safety net for more than 72 million Americans.

The Medicaid program is unique among health care service payers in how it covers prescription drugs and how those drugs are paid for. Under Medicaid statute, the coverage of prescription drugs is an optional benefit, though all states choose to provide coverage. In order to do so, states must participate in the Medicaid Drug Rebate Program (MDRP), which poses coverage requirements no other payer is subject to.

Unlike commercial payers, the Medicare Part D program, and plans on the Exchanges, Medicaid must cover all drugs approved by the Food and Drug Administration (FDA). States may create prior authorization and utilization management criteria for products, but may not exclude products from coverage entirely.

In exchange for this mandatory coverage, states are guaranteed a number of rebates from manufacturers, including mandatory rebates off of a product's list price which vary based on whether the drug is branded or generic, mandatory rebates if price increases outpace inflation in a given year, and a guarantee that Medicaid is offered the same price paid by another payer

(with exceptions, primarily among other federal payment programs such as the Veterans Health Administration) - the “best price” provision. States are also able to negotiate additional supplemental rebates to enhance these mandatory rebates, though supplemental rebates are contingent on a manufacturer’s willingness to engage in price negotiations.

There are two elements to call to attention in this framework:

- First, the mandatory rebates off list price rely on the calculated Average Manufacturer Price (AMP). Any changes to AMP or what is incorporated into the determination of AMP would impact the mandatory rebates that states receive, and thus the savings accruing to both states and the federal government.
- Second, the best price provision provides an important protection for Medicaid by ensuring scarce state and federal dollars are maximized in the provision of the pharmacy benefit via matching any offer made to private or commercial payers. This is critically important as states continue to grapple with rising costs in providing this benefit, in some instances seeing overall pharmacy spending double over a few short years.

Unfortunately, the PAVE Act would create broad new exceptions to what is considered in both AMP and best price for payment arrangements that are value-based. The Act defines “value-based” in an overly broad manner: any payment arrangement made, in whole or in part, on achievement of measurable outcomes, clinical measures, or relative values of multiple indications would meet the threshold for exclusion from AMP and best price.

Our concern is that such a broad definition of value-based purchasing arrangements creates strong incentives for pharmaceutical manufacturers to enter into nominally value-based arrangements which may benefit an individual payer, but would not enhance value for the Medicaid program or across the health care system writ large. For example, a manufacturer could negotiate a rebate off of a high list price with a single health plan, thereby exempting the payment from AMP and best price calculations and weakening Medicaid’s mandatory rebate structure.

Should a majority of pharmaceutical manufacturers respond to the Act’s incentives in this manner, and industry’s prior actions in pricing suggest they would, the PAVE Act would create conditions under which Medicaid’s primary tools under the MDRP for maintaining the sustainability of the pharmacy benefit are gradually eroded. Medicaid’s mandatory coverage requirements would not be altered, but its mandatory rebates would be lower and lower as more manufacturers create arrangements that are exempted from AMP. Even potentially dramatic shifts in pricing for other payers – for example, a large rebate accrued to a private payer if a product fails to meet its clinical goals – would not be shared with Medicaid due to the



Act's best price exemptions. In fact, manufacturers would have a strong and perverse incentive to not extend the same payment arrangements to Medicaid, since their products will be covered regardless and the mandatory rebates due to states would be reduced by the manufacturer's arrangements with other payers.

It is for these reasons that NAMD and our members urge reconsideration of the PAVE Act's provisions. States share the goal of promoting more effective payment arrangements that reward true value for all stakeholders involved. However, this legislation would exacerbate the already acute challenge of rising pharmacy benefit costs in Medicaid.

NAMD appreciates the opportunity to share our concerns, and we stand ready to work with you to explore other pathways to reduce drug prices and promote sustainability in the Medicaid prescription drug benefit.

Sincerely,

A handwritten signature in blue ink that reads "Judy Mohr Peterson".

Judy Mohr Peterson
Med-QUEST Division Administrator
State of Hawaii
President, NAMD

A handwritten signature in blue ink that reads "Kate McEvoy".

Kate McEvoy
State Medicaid Director
State of Connecticut
Vice President, NAMD