NAMD
National Association of Medicaid Directors

April 8, 2019

Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue S.W.
Washington, DC 20201

Dear Inspector General Levinson,

On behalf of the nation's Medicaid Directors, NAMD is pleased to offer comments in response to the proposed rule concerning removal of safe harbor protections for rebates involving prescription pharmaceuticals and creation of new safe harbors (OIG-0936-P). While we agree with the overall goals of controlling the growth of prescription drug costs, this rule would have highly variable impacts across the states which are difficult to predict. Unintended consequences could include lower rebates for states, increased Medicaid pharmacy spending, and restructuring of the pharmacy benefit. As such, a careful reconsideration of the inclusion of Medicaid managed care organizations and their contracted pharmacy benefit managers in this rule, and at minimum a delay of the planned effective date to January 1, 2021, is necessary.

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. Medicaid statute creates significant cost-sharing protections for Medicaid beneficiaries receiving prescription drugs, such that out-of-pocket costs for these individuals are either negligible or nonexistent. Instead, states receive mandatory rebates from manufacturers participating in the Medicaid Drug Rebate Program (MDRP) in exchange for coverage of all drugs approved by the Food and Drug Administration (FDA).

States have the ability to negotiate additional rebates on top of the MDRP's mandatory rebates. These are known as supplemental rebates. Supplemental rebates may be negotiated directly by

the state with manufacturers, or by a contracted third party on behalf of the state. For states electing to include the pharmacy benefit in their managed care contracts (known as "carving in"), the state may benefit from any rebates negotiated by the contracted Medicaid managed care organization (MCO) or the MCO's contracted pharmacy benefit manager (PBM). These rebates (referred to hereafter as "market shift rebates") differ from the mandatory and supplemental rebates collected by the state under the MDRP, and any savings the state accrues from them are more likely to be reflected in lower capitation rates paid by the state to the MCO to reflect the MCO's lower pharmaceutical spending net rebates. It is these MCO and PBM rebates which would be eliminated under this proposed rule, with potentially significant consequences for states.

First, this proposal is premised on the assumption that the market shift rebates negotiated between Medicaid MCOs and/or PBMs and manufacturers are the primary driver of high list prices, and that eliminating rebates will necessarily result in a reduction in list prices. This is not necessarily the case. Indeed, previous experience on pricing issues from the pharmaceutical industry – such as increasingly high prices for newly introduced therapies and persistent overall price inflation in generic drugs, as well as numerous examples of significant increases in prices for long-existing therapies – indicates a persistent willingness to set prices at a level the market will bear, regardless of the long-term sustainability of a given price point.

Second, even if this proposal results in reduced list prices, there is no guarantee that these reductions will be at a level that maintains current Medicaid spending on pharmaceuticals after rebates, much less present cost savings to the program. The Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT) analysis accompanying the release of this rule reflects this assumption. The OACT analyses assumes that manufacturers will retain 15 percent of current rebates, with the remaining rebate amount split between a point of sale chargeback reduction (75 percent) and reduced list prices (25 percent). Since Medicaid beneficiaries are protected from virtually all out-of-pocket costs for pharmaceuticals under statute and regulation, the point of sale chargebacks present little to no value for states – though including chargebacks in the MDRP's best price calculation could potentially alleviate this concern.

OACT's analytical assumptions are only one of many possible scenarios, and it is just as possible that manufacturers elect to retain more rebates, favor more chargebacks, or otherwise find arrangements that do not result in substantially reduced list prices. In fact, testimony from various pharmaceutical company executives on February 26, 2019 before the Senate Finance Committee suggests this is the likely outcome. In this hearing, executives stated in questioning that their companies would reduce list prices only if rebates were eliminated in the commercial

market as well as Medicare. If this testimony is indicative of the overall industry view, then this proposal as written would not impact list prices as significantly as would be desired.

A further nuance for Medicaid programs and overall list prices relates to how the MDRP's mandatory rebates are calculated. The MDRP derives a Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP) of a product, which is itself impacted by the list price and other factors. Lower list prices would reduce AMP, which would reduce the URA, and therefore reduce the mandatory rebate states receive. While this scenario presents value for states which only collect a mandatory rebate on a given product, states carving in the pharmacy benefit and relying on MCO-negotiated market shift rebates face a different challenge. It is possible that MCOs or their PBMs successfully negotiate robust rebates on specific products such that they could not be matched by a lower list price and lower mandatory rebate, but no accompanying market shift rebate or supplemental rebate. In this circumstance, the state would end up spending *more* on a given product under the proposed rule, not less.

In addition to the potentially negative interactions between list price, mandatory rebates, and nullified market shift rebates, carve-in states will also likely see an increase in their contracted MCO rates to make up the MCO's lost rebates. This presents a further cost increase for the state.

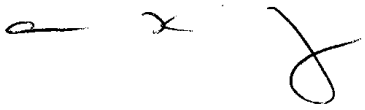
We wish to emphasize that states are continually working to identify new strategies to enhance the transparency and value of the Medicaid pharmacy benefit. This includes leveraging their managed care contracting authority to require more reporting on charges and prices paid by PBMs to MCOs and to dispensing pharmacies. In some states this work has identified "spread pricing" practices, under which PBMs pay a lower amount to the pharmacy than they charge to the MCO and retain the difference as profit. States are assessing the degree to which these practices exist in their programs, and in some cases have required alternative pricing arrangements to ensure PBMs are passing on any savings to the MCO and the state. NAMD supports these state efforts. However, we do not believe that eliminating the role of Medicaid MCOs and PBMs in negotiating market shift rebates is a necessary or helpful step in promoting overall value in the pharmacy benefit. If states see value in having MCOs and PBMs participate in the rebate negotiation process, that tool should remain available.

Lastly, if this rule is finalized as proposed, current carve-in states may reconsider their overall approach to the pharmacy benefit. Careful actuarial analysis would be required to assess spending trends, and the state may elect to assume direct responsibility for supplemental rebate negotiations or carve the benefit entirely out of managed care. These steps would require potential state-level statutory and regulatory change, which themselves impose costs in both dollars and scarce staff time. The proposed rule's contemplated effective date of January 1, 2020

would be insufficient for states to conduct appropriate analyses and make these changes. At minimum, an additional year – an effective date of January 1, 2021 – would be necessary.

Given the unique challenges Medicaid faces under this proposed rule, we urge careful reconsideration of the inclusion of Medicaid MCOs and their contracted PBMs in this proposal. NAMD and our members are committed to working with HHS to explore sustainable solutions to the challenge of continually increasing drug costs.

Sincerely,



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