May 18, 2016

Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period [RIN 0906-AA89]

Dear Commander Pedley,

On behalf of the nation’s Medicaid Directors, NAMD is pleased to submit comments on HRSA’s reopened comment period on the proposed rule 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation. We respond here to two of the issues reopened for comment, and we also wish to reiterate a request made in our initial comment letter on this proposed rule that HRSA identify a mechanism to permit state Medicaid agencies direct access to 340B ceiling price information.

Ceiling Price for a Covered Outpatient Drug Exception
HRSA requested additional comments on its proposal to set the ceiling price of a drug at one cent in instances where the calculated 340B ceiling price resulted in an amount less than one cent. NAMD supports HRSA’s initial proposal in this area. Under the recently finalized Medicaid covered outpatient drug rule, the Centers for Medicare and Medicaid Services (CMS) requires states reimburse 340B entities for 340B drugs in fee-for-service (FFS) delivery systems under an actual acquisition cost (AAC) methodology. In subsequent guidance, CMS indicated that the state’s reimbursement methodology must not exceed the 340B ceiling price. We believe it is appropriate in instances where the calculated 340B ceiling price is less than a cent for the penny pricing model to prevail, as doing so will produce significant savings for the Medicaid program compared to the approaches suggested by other commenters.
New Drug Price Estimation
HRSA requested comments on a proposed methodology for calculating the 340B price for new drugs at wholesale acquisition cost (WAC) minus the applicable rebate percentage that would apply for the drug class under the Medicaid drug rebate program (MDRP), rather than having the manufacturer estimate the 340B ceiling price for the first three quarters a new drug is on the market and reconciling with covered entities beginning in the fourth quarter, as initially proposed.

NAMD supports the newly proposed methodology, with the caveat that the calculation should be made in a manner that is identical to that used under the MDRP – that is, average manufacturer price (AMP) minus the applicable rebate percentage, rather than WAC. This approach is consistent with existing statute and regulation governing both the MDRP and the 340B program. Additionally, this approach would ensure consistency between the 340B ceiling price and the MDRP price for the first three quarters a new drug is on the market, reducing administrative burden on state Medicaid programs and minimizing the potential for Medicaid’s need to reconcile reimbursement to covered entities in instances where the estimated ceiling price differs from the actual ceiling price. This approach would also provide certainty around the 340B ceiling price for new drugs for purposes of implementing the final Medicaid covered outpatient drug rule’s 340B reimbursement requirements.

Sharing 340B Ceiling Price Information with States
As we have referenced above, the final Medicaid covered outpatient drug rule imposes new requirements on states to develop FFS reimbursement methodologies for 340B covered entities that reflect acquisition costs and do not exceed the 340B ceiling price. In order to meet these requirements, states need to have a means of ascertaining the 340B ceiling price for a given drug in a manner that complies with federal law and regulation regarding the confidential nature of these prices.

We request that HRSA work with CMS and the states to identify a mechanism allowing this information to be shared such that states may meet all necessary regulatory standards. We believe agreements could be structured to protect pricing information, and note states are subject to similar agreements under the MDRP. NAMD stands ready to partner with each agency to develop this process, with the goal of producing a streamlined mechanism for sharing information that does not pose additional administrative burdens for states.

We thank HRSA for the opportunity to comment again on the 340B ceiling price regulation, and look forward to continued collaboration to improve the administration of the 340B program and its intersection with states’ responsibilities under the Medicaid statute.
Sincerely,

Thomas J. Betlach  
Arizona Health Care Cost  
Containment System Director  
State of Arizona  
President, NAMD

John B. McCarthy  
Director  
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