National Home Infusion Association

NHIA Summary of American Patients First:
The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs
May 11, 2018

On May 11, President Trump outlined an overarching strategy to address prescription drug affordability. Proposals related to Medicare Parts B and D, included in the plan to lower prescription drug prices, may have a direct effect on the home and specialty infusion industry.

Specifics on the President's plan will be communicated over the next few months. At this juncture, it is unclear which proposals will be implemented administratively and which will require legislative action. NHIA will be working to get more specifics on the plan and the various proposals affecting the industry. The official proposals will likely begin as a set of requests for information (RFI). The RFIs will likely have a short comment period (possibly 30 days). This will allow NHIA to weigh in before the Administration formally implements each policy.

To follow are excerpts of the provisions with commentary from NHIA:

Authorize the HHS Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B

This proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D where there are savings to be gained through increased price competition.

NHIA Commentary: This issue could have far-reaching effect on the industry if the Part B Durable Medical Equipment (DME) infusion drugs were in consideration for a move to Part D. There appears to be some stipulations here that are not fully discussed regarding what drugs would be eligible for a move to Part D. The text above specifically notes "where there are savings to be gained." It is unclear what this threshold will be, and how it will be determined.

Increase Medicare Part D plan formulary flexibility

This proposal enhances Part D plans' negotiation power with manufacturers by allowing for additional flexibilities in formulary management. It changes Part D plan formulary standards to require a minimum of one drug per category or class rather than two. It also expands plans' ability to use utilization management tools.

NHIA Commentary: This proposal will limit flexibility in prescribing and it is unclear from the proposal how robust the exception process will be for medical necessity. NHIA commented on this issue as part of the 2019 Annual Part D rule.

Establish a beneficiary out-of-pocket maximum in the Medicare Part D catastrophic phase.
This proposal eliminates beneficiary cost sharing above the catastrophic coverage threshold and increases Part D plan sponsors' responsibility for these costs to 80 percent, with Medicare covering the remaining 20 percent. This will provide beneficiaries with better protection against high drug costs and encourage plans to better manage spending throughout the entirety of the benefit.

NHIA Commentary: For high dollar drugs that are in Part D where beneficiaries reach catastrophic coverage, individuals have a 5 percent copay after they reach this limit. This proposal appears to eliminate that 5 percent copay. The value of this proposal will be different from one drug to the next.

Address abusive drug pricing by manufacturers by establishing an inflation limit for reimbursement of Medicare Part B drugs
Medicare pays most Part B drugs based on 106 percent of the average sales price (ASP). Currently, there is no limit on how much the payment rate for a drug can increase over time. The Budget would place a limit on increases in Medicare's payment rate for a Part B drug based on inflation as measured by the consumer price index.

NHIA Commentary: Considering the 2% sequestration, Medicare payment works out to 1.042 percent of ASP. Given the fact that the Medicare allowable is based on six-month-old ASP data, this cost-plus payment mechanism in effect is an inflation limiter as it does not allow for market forces to set a real time price. This may contribute to new drugs coming to market with an initial high price tag. While there is little extra information on this proposal, NHIA has concerns that if Medicare payments were capped under ASP, acquisition cost could outpace the Medicare reimbursement.

Reduce Wholesale Acquisition Cost (WAC)-Based Payment
The Budget would reduce payments on drugs for which ASP data isn't available, to better approximate the discounts that would be incorporated into average sales prices. For the first two to three quarters a new drug is on the market, it is generally paid at 106 percent of WAC, a price that does not reflect any available discounts. Reducing the WAC add-on from 6 to 3 percent would better reflect the discounts that ultimately are included when payment shifts to use of ASP data.

NHIA Commentary: When home infusion drugs are added to the External Infusion Pump Local Coverage Determination (EIP-LCD) and they have not had an ASP reimbursement rate in the ASP file, WAC pricing is applied. A couple examples of drugs that recently went through this process are HYQVIA and Hizentra. This proposal would reduce the starting for drugs new to the EIP-LCD. Also, ASP is not published each quarter for all Part B DME infusion drug J-codes even though the drug manufacturer is reporting data, examples include Foscarnet and Zerbaxa.

Improve manufacturers' reporting of average sales prices to set accurate payment rates.
The Centers for Medicare & Medicaid Services (CMS) relies on manufacturers to submit ASP data to calculate payment rates for Part B drugs. Manufacturers that do not have a Medicaid drug rebate agreement are not required to submit ASP data. In addition, some manufacturers fail to timely submit required data timely. The Department of Health & Human Services Office of Inspector General found that in 2012, at least one-third of the more than 200 manufacturers of Part B drugs did not submit ASPs for some of their products in the third quarter of 2012, despite being required to do so. Additionally, at least 45 manufacturers were not required to report ASPs for 443 national drug codes in the third quarter. In that quarter, only about half of those manufacturers voluntarily reported data. When payment rates are based on incomplete data, Medicare's payment rate does not accurately reflect price concessions and

other factors that would ensure accurate payment. To address these issues, the Budget would require all Part B drug manufacturers to report ASP data and provide the Secretary with the authority to apply penalties to manufacturers who do not report required data."

NHIA Commentary: NHIA has long stated that ASP pricing data is incomplete and often biased to care settings that have economies of scale that a home infusion provider cannot access. This dynamic suppresses the ASP to rates that in some cases can come below a home infusion provider's acquisition cost. Having more up to date rates from all manufacturers will be a step in the right direction. However, the issue of site of care pricing variations (class of trade variations) will remain. This may be an opportunity for the home and specialty infusion community to discuss this dynamic with CMS and federal legislators.

Further details on the President's proposals will be communicated over the course of the next few months and will likely begin as a set of requests for information (RFI) with a comment period that will allow NHIA to weigh in before implementation of a formal policy occurs. NHIA will continue to follow developments, gain specifics on each proposal, and keep members informed.

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