National Home Infusion Association
Providing solutions for the infusion therapy community

Submitted Electronically to: www.regulations.gov

July 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Comments on RIN 0991-ZA49 "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"

Dear Administrator Verma:

The National Home Infusion Association (NHIA) submits the following comments on the Department of Health and Human Services' (HHS') request for information (RIN) entitled *"HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs".* NHIA members include a cross section of home infusion providers, suppliers, manufacturers, and other industry stakeholders that assist or provide home infusion.

NHIA appreciates the opportunity to comment on your proposal to lower drug prices and reduce out-of-pocket costs. As inferred in the proposal a national focus on lowering drug prices and out-of-pocket costs is necessary for the economic future of our health system. NHIA supports these goals and offers the comments below on your proposals.

Our comments follow the RIN's structure and are not listed in priority order.

NHIA Comments

B. Better Negotiation

Part B Competitive Acquisition Program

The RIN requests comments regarding the reestablishment of the Competitive Acquisition Program for Part B drugs. NHIA has concerns with a program that may reduce the number of eligible home infusion providers in the Medicare Part B program. As part of section 5004(b) of the *21st Century Cures Act* Congress barred competitive bidding of Medicare Part B home infusion drugs. The Centers for Medicare and Medicaid Services (CMS) recently implemented this policy as part of the interim final rule entitled *"Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50*

Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas" (CMS-1687-IFC). It is clearly Congressional intent that Part B home infusion drugs should not be subject to competitive bidding or other competitive acquisition programs.

Part B to D

The President's Budget requested the authority to move some Medicare Part B drugs to Medicare Part D. The RFI requests thoughts on which drugs or classes of drugs would be good candidates for moving from Part B to Part D; how could this proposal be implemented to help reduce out-of-pocket costs for the 27% of beneficiaries who do not have Medicare prescription drug coverage, or those who have Medicare supplemental benefits in Part B; and what additional information would inform how this proposal could be implemented and operated.

The current Medicare Part B drug reimbursement methodology of 106 percent of average sales price (ASP) does not reflect true market dynamics for home infusion providers due to many factors. Because ASP pricing includes all sites of care and provider types the economies of scale and negotiating power of large health systems reduces ASP often well below acquisition cost of a home infusion provider. Other factors also make ASP pricing not reflective of a true market driven reimbursement for home infusion providers such as the applied sequestration cut and the time lag from when manufacturers report pricing to when this data is used to update the ASP benchmark. These issues are discussed later in this document in the section entitled "Improve manufacturers' reporting of average sales prices to set accurate payment rates". Any changes to the current reimbursement structure warrants careful consideration so that home infusion providers are able to treat beneficiaries in the optimal site of care and without delay.

The current ad hoc and fragmented home infusion payment structure is a prime example of why comprehensive and thoughtful reform is necessary. Infusion therapy consists of three components of care: the infusion drug; the supplies and equipment necessary to deliver that drug; and the professional services required to safely and effectively provide the therapy. Rather than seeking treatment for serious conditions in hospitals, nursing homes, and hospital outpatient departments, home infusion allows patients to resume a normal lifestyle and work activities. In doing so, home infusion provides them with the opportunity for a better quality of life.

Historically, neither Medicare Part B or D has covered the professional service component of delivering home infusion drugs. Necessary services may include preparation of the drug; care management; lab review; a visit by a home care nurse to set up the infusion treatments; training caretakers and patients on proper administration and maintenance of equipment' checkup visits; and 24/7 on-call services. Since 2003, the average wholesale price (AWP) for Part B durable medical equipment drugs had often been sufficient to cover the costs associated with home infusion services, but the *21st Century Cures Act* (P.L. 114-255) made significant changes that caused several unintended consequences for beneficiaries and providers. We applaud Congress for its ongoing efforts since then to provide necessary relief to the industry.

As the agency is aware, Congress changed the Medicare program payment for Part B durable medication equipment (DME) home infusion medications to 106 percent of ASP to reflect more accurately the true costs of these medications starting in 2017. In addition, recognizing that there are unique clinical service requirements necessary to deliver infusion drugs in the home, Congress also created a new Medicare payment for home infusion professional services, but that provision does not take effect until 2021 thus creating a four-year gap. To address the unintended consequences created by this gap in home infusion services coverage, Congress passed Section 101 of the *Medicare Part B Improvement Act of 2017/ the Medicare Home Infusion Therapy Access Act of 2017* (H.R.3178/ S.1738) as part of the *Bipartisan Budget Act of 2018 (*P.L. 115-123), which the agency is now working to implement in January 2019.

After a period of uncertainty, we are extremely appreciative that the law passed to provide a transitional services reimbursement for Part B DME infused drugs two years earlier than planned in *the 21st Century Cures Act*. Unfortunately, we have strong concerns with the parameters of the home infusion requirements in the recent CMS proposed rule entitled: *"Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations (CMS-1689-P)"* and fully intend to submit comments by the August 31 deadline. The lack of a robust definition of professional services associated with home infusion in the rule is particularly troubling. By solely defining professional services as nursing services provided in the home on the day of a drug administration, CMS has greatly restricted the value of this benefit for Medicare beneficiaries. We urge the agency to continue to prioritize the implementation of both the transitional and permanent services payment structure as Congress intended. In doing so, the Medicare program will realize savings as beneficiaries receive continuous care in less costly settings. We urge CMS to examine the impact of any reimbursement changes on patient access and patient safety.

Should the agency consider including Part B home infusion drugs in a shift to Part D, NHIA cautions that the *21st Century Cures Act's* and the *Bipartisan Budget Act of 2018's* provisions regarding home infusion services and drugs hinge upon these drugs being reimbursed within the Part B program. An effort to move these drugs to Part D would render the provisions of the *21st Century Cures Act* and the *Bipartisan Budget Act of 2018* statutorily immaterial. If an effort was made to shift Part B home infusion drugs to Part D, considerable legislative action would be necessary to ensure the provisions of the *21st Century Cures Act* and the *Bipartisan Budget Act of 2018* would remain applicable to these drugs.

C. Create Incentives to Lower List Prices

Pharmacy Price Concessions

The RFI requests comments regarding how beneficiaries are negatively impacted by incentives. NHIA has concerns regarding the growing use of pharmacy price concessions, known as direct and indirect remuneration (DIR).

In recent years, DIR fees have become increasingly problematic for home infusion pharmacies for several reasons. DIR fees are often applied retroactively. This causes beneficiaries to pay a higher copayment that does not reflect a reduction once DIR fees are assessed retrospectively to the pharmacy. Essentially, a beneficiary's copayment is based on a higher rate than the actual cost of the drug for the plan. Pharmacies are adversely impacted because they cannot determine their actual reimbursement rate until well after they have dispensed the medication. Further, for Medicare Part D and other government-funded drug coverage programs, DIR fees lead to inaccurate information on the drug costs that are reported because of differences in costs reported by plans and the amounts paid by the plans after DIR fees are taken into account.

For these reasons we urge CMS to eliminate DIR fees from Medicare and Medicaid. This approach would generate savings for the Medicare and Medicaid programs, provide cost-sharing relief for beneficiaries, and restore fair business practices to pharmacies.

E. Additional Feedback

The RFI does not reference several proposed policies that were included in the President's *"American Patients First"* blueprint to lower drug prices. While these issues are not included in the RFI, NHIA is compelled to comment on the policies in response to the RFI.

Increase Medicare Part D plan formulary flexibility

The blueprint proposes to change 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.

The proposal will constrain flexibility in prescribing and it is unclear from the proposal how robust the exception process will be for medical necessity. Home infusion drugs are unique because of the route of administration. Many drugs that are considered pharmacologically equivalent may not be equivalent for the beneficiary. In some cases patients my have life threatening reactions to certain drugs in category or class, but be able to utilize another drug in the same class or category. Should a policy move forward that only requires a single drug per category or class rather than two, there must be a robust exemption process to ensure beneficiaries are not harmed by the policy.

Recent drug shortages, specifically shortages of home infusion drugs, have also pointed to the need for a Medicare exceptions process for beneficiaries when a drug is not available to the home infusion pharmacy. If a pharmacy does not have access to a particular drug that is the only drug in a preferred tier due to a national shortage, the pharmacy may be forced to dispense another drug in the same category or class at the expense of the Medicare program and the beneficiary. In the circumstance where medical necessity is documented or a preferred tier drug is not available, beneficiaries should have access to the lowest cost sharing tier.

Address abusive drug pricing by manufacturers by establishing an inflation limit for reimbursement of Medicare Part B drugs

The President's blueprint discusses possibly limiting increases of ASP to inflation. Medicare pays most Part B drugs based on 106 percent of the ASP. Currently, there is no limit on how much the payment rate for a drug can increase over time. The proposal 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.

Considering the two percent sequestration reduction, Medicare reimbursement for Part B drugs is 104.2 percent of ASP. The Medicare allowable is also based on six-month-old ASP data. The cost-plus payment mechanism currently in effect is an inflation limiter on its own as it does not allow for market forces to set a real time price. The current payment policy contributes to new drugs coming to market with an initial high price tag. NHIA has concerns that if Medicare payments were subject to inflationary adjustments of ASP the acquisition cost could outpace the Medicare reimbursement thus leaving many providers perpetually underwater on their margin between acquisition cost and the ASP reimbursement in the Part B program.

Reduce wholesale acquisition cost (WAC)-based payment.

The President's blueprint proposes reducing payments on drugs for which ASP data isn't available. The proposal states that this policy would better approximate the discounts that would be incorporated into ASP later on. For the first two to three quarters a new drug is on the market, it is generally paid at 106 percent of WAC. WAC pricing does not reflect any available discounts. The proposal states that 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.

When home infusion drugs are added to the External Infusion Pump Local Coverage Determination (EIP-LCD) WAC pricing is applied. A couple examples of drugs that recently went through this process are HYQVIA and Hizentra. The President's proposal would reduce the starting reimbursement for drugs new to the EIP-LCD. This proposal will also affect drugs that may not be new to the market, but ASP is not published. Each quarter for all Part B DME infusion drug J-codes CMS publishes the ASP for each drug, even though the drug manufacturer is reporting data the file may not include certain drugs. Recent examples of this phenomenon include Foscarnet and Zerbaxa. NHIA has concerns with this proposal because it could disincentivize innovation and entry into the market for new drugs.

Improve manufacturers' reporting of average sales prices to set accurate payment rates

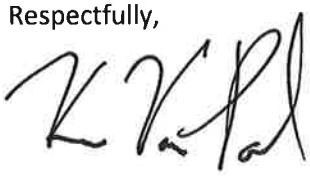
CMS relies on manufacturers to submit ASP data to calculate payment rates for Part B drugs. Manufacturers that do not have a Medicaid drug rebate agreement are not required to submit ASP data. In addition, some manufacturers fail to timely submit required data timely. When payment rates are based on 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 President's blueprint 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 has further concerns with ASP pricing. As noted in the blueprint the data is often incomplete. Furthermore, the ASP rate is 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 be below a home infusion providers acquisition cost. Having more up to date rates from all manufactures will be a step in the right direction. However, the issue of site of care pricing variations (class of trade variations) will remain. NHIA urges CMS consider altering the calculation of ASP to reflect site of care variations. For example the home infusion ASP rate for a specific drug could be higher or lower than in a physician office or hospital outpatient clinic because ASP would be calculated for the site of care separately from ASP data for other sites of care.

NHIA thanks the President and HHS for making the price of prescription drugs and the solvency of our federal health care programs a priority. NHIA has long argued that providing care to beneficiaries in the appropriate setting can not only garner savings to the federal government, but also provide beneficiaries with better care and quality of life.

Please feel free to have your staff contact me at kendall.vanpool@nhia.org or 703-838-2664 should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Respectfully,



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