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December 31, 2018

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201

RE: CMS-5528-ANPRM

Dear Administrator Verma:

The National Association of Specialty Pharmacy (NASP) welcomes the opportunity to provide comments on the HHS advance notice of proposed rulemaking (ANPRM) on the International Pricing Index (IPI) Model for Medicare Part B Drugs (83 Fed. Reg. No. 210, October 30, 2018; RIN 0938-AT91). The ANPRM outlines a new drug payment and management pilot program the Centers for Medicare and Medicaid Services (CMS) would like to test through the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) to address the cost of drugs under Medicare Part B. As outlined, the model pilot program would pay private vendors to negotiate drug pricing and manage clinician, hospital and ultimately patient access to Part B drug products. Through this model pilot program, CMS would rely on vendors to reduce pricing for Part B drugs over a five-year period, in an effort to bring pricing to levels comparable to international drug prices when such prices are less than U.S. pricing today.

NASP applauds the administration's desire to reduce Medicare program expenditures and beneficiary cost-sharing for Part B drugs, particularly as it affects access to specialty medications. We agree that a national focus on lowering patient out-of-pocket costs and reducing system efficiencies – whether in Part B or Part D - has the potential to create new alternatives to current systems in a way that strengthens access to needed medications and related services. We encourage the establishment of manageable new pilot programs and regulatory adjustments that seek to improve care quality while reducing system costs. We appreciate the administration's bold thinking in the design of a new model program for Part B drugs; however, we have significant concerns with the feasibility of the approach outlined in the ANPRM and concern over how its design will impact access to essential and life saving medicines for specialty patients that receive their treatment through the Part B program.

NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists to small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans;

and technology and data management companies. With over 100 corporate members and 1,500 individual members, NASP is the unified voice of specialty pharmacy in the United States.

Specialty pharmacies and distributors have unique expertise in the procurement, storage and dispensing of the individual specialty drugs they manage and in providing clinical support, oversight and care management for patients that take specialty drugs. Specialty drugs include oral, injectable, inhalable, and infusible products, for conditions ranging from cancer to rhematoid arthritis to rare autoimmune conditions. The distribution and management of specialty drugs requires significant expertise to protect the authenticity of the drug, and any adjustment to the current processes used to procure, manage, and distribute these drugs requires careful thought and planning by those entities that have demonstrated success in doing so.

The following comments represent NASP's initial review of the administration's proposal for a mandatory Part B pilot demonstration program as outlined in the ANPRM. NASP looks forward to continued dialogue on these and other issues as the administration moves forward with plans to issue a proposed rule on the pilot demonstration in 2019.

NASP Response to ANPRM – Request for Information

Model Vendors

NASP shares the concerns of its members that have expertise in the distribution and management of Part B drugs today that, as outlined in the ANPRM, the competitive acquisition program (CAP) would place extreme burdens on selected vendors, requiring significant investment and differing management systems for drugs that would be managed under the model within the geographic regions selected and drugs that would not be considered under the model or in the model's selected geographic locations.

The proposed CAP does not appropriately consider or address the compensation needed for vendors to assume the risk and costs that would be required to successfully operate a program as envisioned under the pilot model. As specialty pharmacy was outlined in the ANPRM as a potential vendor, NASP considers this from the standpoint of how specialty pharmacy could serve in this capacity with all of the costs needed to address negotiations on pricing with manufacturers; ensuring the integrity of drug products when managed but not in possession by the vendor; managing inventory and allowing for the appropriate distribution of drugs to guarantee timely patient access; collecting and managing patient copays on drugs received, etc.

NASP is also concerned that in testing a new pilot program, the administration does not inadvertently repeat the same mistakes under Part B as with Part D as it relates to the influence of the largest PBMs in the market today that have their own specialty pharmacies. Establishing a new "middleman" into the process in Part B would need to have more advantages than disadvantages. Independent specialty pharmacies today work closely with physicians and hospital outpatient departments to provide for the specialty drug needs of patients served. NASP members have experienced first-hand the anticompetitive abuses by large PBM's with significant implications for Part D beneficiary's access to specialty drugs prescribed by their physicians as specialty pharmacies are shut out of networks and efforts to squeeze costs have no substantive benefit for patients or those in the supply chain other than the middlemen themselves. CMS must also be mindful that any vendor effort to reduce cost must also

be tied to a system driven toward improving quality. The ANPRM mentions the potential for model vendors to allow for indication-specific pricing or outcomes-based arrangements but does not specify which mangagement tools will be permitted or how they should be designed. NASP believes careful evaluation and use of such tools must be managed by CMS. Some existing systems under Part D as they affect specialty drugs today do not fairly evaluate quality as metrics are not aligned with the specialty drugs being dispensed or services offered. Such mistakes must not be inadvertently repeated under Part B with the reforms envisioned by the pilot.

Beneficiary Participation in Pilot Model

CMS proposes to require that all providers and suppliers participate in the pilot program if they are furnishing Part B drugs that are included in the pilot model and are located in a geographic area that is chosen for participation. Beneficiaries would be required to enter the model, disallowing beneficiaries to choose a provider not enrolled in the model regardless of their circumstances (e.g., rural access challenges). NASP supports use of CMMI to test patient-centered, voluntary, small-scale reforms that can be fully evaluated. We are concerned, however, that the pilot model envisioned is a wide-scale demonstration that would be mandatory instead of voluntary and broad-based instead of small-scale, affecting 50 percent of physicians and hospitals serving Medicare Part B beneficiaries today and all beneficiaries within the selected geographic locations.

Access to Specialty Drugs

CMS indicates that it would phase in the group of drug products included in the model over time with an initial focus on single-source drugs and biologics that account for over 50 percent of Part by drug charges. The classes of drugs that would be included in the pilot model program are used to treat vulnerable Medicare beneficiaries whose adherence to their drug regimen is important to their survival and often to saving healthcare dollars and resources. Specialty pharmacy is focused on controlling the total cost of care through medication adherence and patient support services, not only the cost of drugs. NASP is concerned that under the ANPRM, the focus of the pilot program is exclusively on price of drug – not broader quality issues that ultimately impact patient costs and system costs.

The ANPRM does not explicitly discuss whether a vendor would be obligated to supply a drug if it were unable to purchase the drug at a target IPI price envisioned under the pilot model. It is unclear in the ANPRM as to whether vendors would not have to furnish a product if the vendor's purchase price is greater than the IPI target price if a manufacturer did not agree to reduce their price. This situation could result in some products being unavailable in the pilot model areas with concerns about differences in access to drugs in model areas as compared to non-pilot model areas. NASP is significantly concerned about the ability for vendors to appropriately negotiate prices and distribute drugs in a way that does not have a negative affect on patient access for smaller scale populations (e.g., patients with rare disorders) especially when there are no generic drug equivalents available to manage a patient's care. NASP is also ultimately concerned about the impact the model would have on drug innovation and the incentives for manufacturers to produce new drug options and alternatives.

Conclusion

We thank HHS for consideration of NASP's comments on the International Pricing Index Model for Medicare Part B Drugs and look forward to continuing to serve as a resource as the administration plans to put forward a proposed rule for a new Part B drug pilot program. NASP will continue to work with the agency to support policy reforms that can reduce costs to Medicare beneficiaries for specialty drugs and ensure access to the specialty drugs and services needed to improve health and reduce overall health care costs. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila M. Arquette, R.Ph.
Executive Director