NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

July 13, 2026

Maryland Insurance Administration
Attn: Mary Kwei
200 St Paul St #2700
Baltimore, MD 21202

Re: Specialty Drug Definition Comments

Dear Pharmacy Benefits Managers Workgroup,

I am writing on behalf of the National Association of Specialty Pharmacy (NASP) in response to the Pharmacy Benefits Managers Workgroup Meeting #2, during which the definition of a specialty drug was discussed. As the national association representing the full spectrum of specialty pharmacy stakeholders, we appreciate the opportunity to share our perspective and offer feedback informed by our broad experience across the specialty pharmacy landscape.

NASP is a non-profit trade association representing all specialty pharmacy industry stakeholders, including the nation's leading specialty pharmacies and practicing pharmacists; nurses; technicians; pharmacy students; non-clinical healthcare professionals and executives; some pharmacy benefit managers (PBMs); pharmaceutical manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; independent accreditation organizations; and technology, logistics and data management companies.

Specialty pharmacies care for some of the nation's most clinically complex and medically vulnerable patients, including individuals living with cancer, multiple sclerosis, rare diseases, autoimmune disorders, those who have received organ transplants, among others. These patients often require intensive clinical management, ongoing monitoring, comprehensive care coordination, and specialized support to achieve optimal clinical outcomes while ensuring the safe, appropriate, and cost-effective use of high-cost therapies.

As the national voice for specialty pharmacy, NASP believes it is essential that the Workgroup benefit from the perspective of a specialty pharmacy. We noted that the current Workgroup does not include a representative from the specialty pharmacy community, which is an interested party as outlined in the legislation. Given the Workgroup's charge, we believe this perspective is critical to ensuring a comprehensive understanding of what constitutes a specialty drug, the unique role of specialty pharmacies, and the qualifications and capabilities required to safely and effectively dispense these complex therapies. We respectfully request

the Workgroup to include NASP as a member to ensure the specialty pharmacy perspective is represented in its deliberations. In the absence of a specialty pharmacy representative on the Workgroup, we respectfully offer our perspective on the definition of a specialty drug, and the unique role specialty pharmacies play in dispensing specialty drugs and biologics.

Defining Specialty Drug

The Maryland definition of specialty drug adequately addresses the unique needs for a pharmacy to stock and support a patient receiving a specialty drug by discussing who it is prescribed for – "an individual with a complex or chronic medical condition or a rare medical condition" – as well as highlights the need for handling and storage of a specialty drug or biologic and the need for enhanced patient support. NASP supports highlighting those aspects of a specialty drug or biologic.

Where NASP diverges from the existing Maryland language is using a dollar amount to determine if a drug is specialty. While historically, that has been an easy marker for determining if a drug is a specialty drug it fails to recognize that there are an increasing number of generic specialty drug or biosimilars that fall below that cost threshold. Additionally, there are non-specialty drugs whose costs exceed this threshold.

NASP also wants to highlight the challenges of using only a specialty drug to define where a drug should be dispensed. Instead, we encourage Maryland to follow North Carolina's lead in defining specialty drug/biologics and, most critically, move to define a specialty pharmacy. Allowing there to be a definition of specialty pharmacy creates a clearer expectation for what types of services are required and what qualifications are needed for dispensing a specialty drug and supporting the required patient management needs. It also reduces manipulation by some PBMs who may use drug prices or other nebulous definitions of patient support to narrow the network to specific pharmacies that they determine are eligible to dispense specialty drugs.

NASP recommends that Maryland define specialty pharmacy with a clear understanding of the clinical capabilities and operational infrastructure a pharmacy must possess to dispense specialty drugs. We have found that the easiest way to do that is to require that a pharmacy be accredited as a specialty pharmacy by a single, nationally recognized, independent third-party specialty pharmacy accreditation organization. This allows for:

1. Ensuring a pharmacy meets the requirements set forth in Maryland's existing specialty drug definition, including prior authorization support, insurance and financial assistance coordination, shipping and handling standards, and patient management services, as these elements are already required by nationally recognized independent specialty pharmacy accrediting organizations;

2. Eliminating duplicative accreditation requirements imposed by PBMs by recognizing accreditation from a single nationally recognized, independent third-party specialty pharmacy

accrediting organization. PBMs frequently create unnecessary administrative barriers by requiring multiple accreditations, including accreditation programs they own or operate;

3. Allow for any pharmacy that meets the single accreditation requirement to dispense specialty drugs.

Furthermore, this would align Maryland with existing legislation passed in other states, including by North Carolina as recently as 2025 with H.B 163.

Requirements to Dispense a Specialty Drug

During Workgroup Meeting #2, questions were raised regarding the requirements pharmacies must satisfy to participate in a specialty pharmacy network, the rationale for those requirements, and the types of services that constitute "enhanced patient education, management, or support." NASP welcomes the opportunity to provide insight into each of these areas based on our extensive experience representing the full spectrum of specialty pharmacy stakeholders.

Regarding the first question on accreditation requirements, pharmacies seeking specialty pharmacy accreditation must demonstrate that they meet rigorous standards established by a nationally recognized, independent third-party accrediting organization. These standards include utilizing appropriate packaging, shipping, and temperature controls to preserve medication integrity; implementing standardized patient management processes, including initial assessments, routine reassessments, and documented clinical interventions; providing ongoing patient education at the start of therapy and whenever adherence or clinical concerns arise; regularly engaging with the patient's care team to support appropriate medication management; and maintaining the specialized equipment and refrigeration necessary to safely store and dispense specialty medications

Specialty pharmacy accrediting organizations evaluate a pharmacy's ability to meet these requirements through a rigorous initial accreditation survey followed by comprehensive reaccreditation reviews every three years. This process assesses whether the pharmacy consistently meets the operational, clinical, and quality standards necessary to deliver safe, effective, and high-quality specialty pharmacy services. Importantly, accreditation is not a point-in-time achievement. Accredited specialty pharmacies are expected to maintain continuous compliance with these standards between survey cycles and remain subject to ongoing oversight and quality improvement requirements.

With respect to the comprehensive and specialized patient services patient services provided by a specialty pharmacy, NASP considers the following components to be essential:

- Providing benefits investigations and verifications to identify opportunities to support drug affordability for the patient. This includes coordinating with physician offices and often multiple insurers, identifying programs that can support drug affordability, supporting benefits and treatment understanding and choices with patients.

- Coordinating clinical logistics across multiple service providers to manage the delivery of the drug to the patient's site of care (including at home).
- Ensuring all prior authorization and reauthorization requirements are met; providing 24/7 patient support through staff clinicians: testing or other pre-treatment arrangements; drug administration and knowledge of any drug interactions; ability to answer questions on adherence and side effects; and managing timely physician adjustments to medications and/or therapeutic coordination/reconciliation amongst all of the patient's therapies.
- Ongoing patient and caregiver contact and coordination via phone, videoconferencing, text or email.

Due to their inherent capabilities and infrastructure, accredited specialty pharmacies are uniquely situated to manage these complex patients and medications.

In conclusion, NASP respectfully requests inclusion on the Workgroup as the nation's leading organization representing all specialty pharmacy industry stakeholders, or at the very least participation in Workgroup discussions on defining specialty drug. Given NASP's broad membership and deep expertise in specialty pharmacy practice, patient care, accreditation standards, and operations, we believe our participation would provide valuable perspective as the Workgroup continues its deliberations and develops its recommendations.

In addition, we encourage the Workgroup to consider defining specialty pharmacy, rather than focusing solely on the definition of a specialty drug. Establishing clear criteria for both would help ensure that specialty medications are dispensed by pharmacies with the specialized infrastructure, clinical capabilities, and accredited processes necessary to optimize patient outcomes and promote the safe, appropriate, and cost-effective use of these therapies. A clear definition of specialty pharmacy would also reduce the potential for inconsistent network participation requirements and arbitrary or duplicative accreditation standards that can unnecessarily limit patient access to care.

We look forward to continuing conversation. For additional information or questions please contact Taryn Couture at Taryn.Couture@PowersLaw.com.

Sincerely,

Sheila Arquette, RPh
President & CEO