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PHARMACY

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Mr. Bradley Baker
Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, MD 21230

Submitted electronically: mde.epr@maryland.gov

RE: Producer Responsibility Packaging and Paper Products Regulations - Public Comment

Dear Mr. Baker:

The National Association of Specialty Pharmacy (NASP) respectfully submits these supplemental comments regarding the proposed COMAR 26.04.14 – Packaging and Paper Products – Producer Responsibility, implementing Maryland’s Extended Producer Responsibility (EPR) framework.

Since submitting our initial comments on December 27, 2025, NASP conducted additional outreach to our cold chain packaging provider members to better understand the operational and regulatory implications of the proposed language. These comments reflect that additional stakeholder engagement and incorporate technical feedback from entities directly responsible for implementing pharmaceutical cold chain systems across state lines.

NASP continues to urge the Department to clarify § .02.16(b), which addresses the definition of exempt materials, to ensure that packaging systems used for FDA-regulated prescription drugs, biologics, and medical devices are treated consistently within the exemption framework. While the regulation appropriately exempts primary packaging, the proposed language continues to distinguish secondary and tertiary packaging from exempt materials. That distinction creates great concern for cold chain packaging systems that require secondary and tertiary packaging to maintain drug safety, stability, efficacy, and to ensure regulatory compliance.

Specialty pharmacies dispense complex, high-cost, and often temperature-sensitive medications used to treat serious, chronic, and rare diseases. Many of these products are biologics, gene therapies, oncology treatments, and other injectables. Throughout the storage and distribution processes, most of these must be maintained within validated temperature ranges which is commonly 2–8°C. Cold chain packaging systems do not function as simple shipping materials. Manufacturers engineer and validate these systems as integrated configurations under pharmaceutical quality standards. Validation typically includes thermal modeling, seasonal lane testing, operational qualification, and real-world performance verification, often conducted through ISTA-certified laboratories. Secondary and tertiary packaging components, such as insulation systems, refrigerants, monitoring devices, and outer containers, function together to maintain product stability and sterility. It is not sufficient for Maryland to simply



exempt primary packaging for drug packaging and transport. The state must recognize that some drugs require secondary and tertiary packaging to protect drug integrity and patient safety and well-being.

NASP recognizes that sustainable packaging alternatives and patient safety are not inherently in conflict. Validated recyclable and compostable insulation materials, optimized refrigerant configurations, and dimensional redesign strategies are increasingly used in pharmaceutical distribution without compromising thermal performance. NASP supports continued innovation that advances environmental objectives while maintaining rigorous pharmaceutical quality standards. Our concern is not with the EPR policy generally, but with regulatory language that may be interpreted to distinguish between exempt primary packaging and non-exempt secondary or tertiary components within validated cold chain systems.

In addition, regulatory ambiguity regarding the treatment of secondary and tertiary packaging creates unintended operational and cost pressures for specialty pharmacy supply chains. For many specialty pharmacies, particularly smaller providers, these additional costs could affect their ability to continue serving patients in Maryland. Specialty medications frequently treat rare and life-threatening conditions and are often not readily available through traditional retail pharmacies. Disruptions to these distribution models could create barriers to patient access, and therefore, negatively impact treatment adherence for patients who depend on these medications.

NASP Regulatory Recommendations

Certain provisions of the proposed rule create uncertainty regarding how the exemption applies in practice, including the reference in .03 Covered Materials to “secondary and tertiary packaging associated with exempt primary packaging,” and the use of “primary” packaging terminology within § .02.16(b) and related sections when describing exempt materials.

To eliminate ambiguity and ensure the regulation reflects how pharmaceutical packaging systems function in practice, NASP requests the following revisions:

1. Strike (11) under .03 Covered Materials
Remove the provision referencing “secondary and tertiary packaging associated with exempt primary packaging,” as this creates a distinction between packaging levels within validated pharmaceutical cold chain systems.
2. Revise references to “primary” packaging within .05 Exempt and Excluded Materials and §B(16) Exempt Material
Strike references to “primary” packaging or replace them with “all packaging” so the provision reads “All packaging...”
3. Add a clarifying subsection under .05 Exempt and Excluded Materials
NASP recommends adding subsection (m) stating:



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“Exempt material does include primary, secondary, or tertiary packaging associated with products listed in .05(A)(B) of this regulation.”

4. Revise §B(16)(b)

NASP recommends revising this provision to read:

“Exempt material does include primary, secondary, or tertiary packaging associated with products listed in §B(16)(a) of this regulation.”

NASP recognizes that EPR programs are generally implemented through producer responsibility organizations and assess fees based on reported covered material quantities, often using weight-based or eco-modulated structures. Our comments are not intended to mischaracterize the program’s structure, but to ensure that implementation does not inadvertently conflict with validated pharmaceutical distribution systems required under federal and state law.

Specialty pharmacies operate under extensive federal and state oversight to ensure safe storage, handling, and distribution of prescription drugs and biologics. Cold chain packaging systems are inseparable from drug stability, efficacy and regulatory compliance. Clarifying COMAR 26.04.14 to confirm the treatment of packaging systems used for FDA-regulated products will provide certainty to regulated entities, avoid unintended compliance ambiguity, preserve patient safety and therapeutic integrity, and support continued sustainability innovation within validated pharmaceutical systems.

NASP welcomes continued collaboration with the Department to ensure Maryland’s environmental objectives are advanced in a manner that also safeguards public health and patient access to essential specialty therapies.

For additional information, please contact Sheila.Arquette@naspnet.org.

Respectfully submitted,

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