The following are comments received pursuant to Chapter 212, Acts of 2019 as an opportunity for small businesses, nonprofit organizations and other interest parties to review and comment on a draft proposal to adopt new regulations.

Comments were accepted from December 12 through 27, 2025

AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
W:: AdvaMed.org

December 27, 2025

Mr. Bradley Baker
Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, MD 21230-1719

Re: Avoiding Unnecessary Disruptions to Patient Care and Public Health and Adhering Draft COMAR 26.04.14 with Enacting Legislation

Mr. Baker,

On behalf of AdvaMed, the Medtech Association, I am writing regarding the Maryland Department of the Environment's ("Department") draft regulations implementing Maryland's Packaging and Paper Products Producer Responsibility program (Draft COMAR 26.04.14).

While we share the overarching goal of reducing plastic pollution and achieving a circular economy, the proposed regulations present significant legal, operational, and economic concerns that disproportionately impact Maryland's medical technology industry and the patients it serves.

The enacting legislation (SB 901) does not delineate between types of packaging in defining "Covered Materials" and is straightforward in stating that "Covered Materials" do not include "Exempt Materials". It is also clear that all packaging for defined medical devices and medical products are "Exempt Materials" – without exception or limitation. The scope and merits of this exemption was considered as part of the legislative process and the regulation should reflect this provision.

The proposed regulation narrows this exemption to primary packaging alone. The exemption was crafted transparently in the legislature's established policy committee framework. We believe the Department's interpretation exceeds statutory authority, as the law does not impose any qualifiers. Medical device and medical product packaging is a highly regulated and multilayered system, designed to protect product sterility and patient safety. Restricting the exemption jeopardizes

compliance with federal safety standards and risks disrupting the supply chain for life-saving products.

The proposed regulation creates a potential conflict with federal requirements, particularly for packaging that safeguards public health. The U.S. Food and Drug Administration (FDA) requires packaging that ensures the sterility, safety, and efficacy of medical devices. Any regulation that impedes compliance with these federal mandates not only threatens patient health but also creates liability and operational uncertainty for medical device and medical product companies.

Medical device and medical product companies already operate within strict regulatory frameworks for their products and packaging. Disruptions to these frameworks caused by regulatory uncertainty risks reducing access and increasing cost. These costs ultimately impact Maryland's healthcare system, increase the price of critical medical products, create barriers for companies seeking to operate and innovate within the state, and reduce access to novel treatments.

We urge the Department to modify its proposed regulation to adhere to the clear language of SB 901 and maintain the unconditional exemption for medical device packaging and other critical products as provided in the law. Doing so will align with legislative intent, ensure regulatory compliance, and avoid unnecessary disruptions to patient care and public health. AdvaMed remains committed to partnering with the Department to achieve the goals of SB 901 within the enacted language.

Thank you for considering these concerns. We welcome the opportunity to engage further on this matter to ensure the successful implementation of SB 901.

Sincerely,

Bobby Patrick, VI
Senior Vice President, Government Affairs
Head, State Government Affairs
AdvaMed

December 18, 2025

RE: Comments on Proposed Draft COMAR 26.04.14 Packaging and Paper Products - Producer Responsibility

On behalf of the American Forest & Paper Association (AF&PA), thank you for the opportunity to provide comments on the Proposed Draft COMAR 26.04.14 Packaging and Paper Products - Producer Responsibility. We look forward to continued engagement with the Maryland Department of the Environment (MDE) as we refine the approach toward improving recycling. These comments are submitted independently from Abigail Sztein's participation as an Advisory Council member for implementation of SB 901.

AF&PA is a non-profit 501(c)6 organization that serves to advance public policies that foster economic growth, job creation and global competitiveness for a vital sector that makes the essential paper and packaging products Americans use every day. The U.S. forest products industry employs more than 925,000 people, largely in rural America, and is among the top 10 manufacturing sector employers in 44 states. Our industry accounts for approximately 4.7% of the total U.S. manufacturing GDP, manufacturing more than $435 billion in products annually. AF&PA member companies are committed to making sustainable products for a sustainable future through the industry's decades-long initiative — *Better Practices, Better Planet 2030*.

Paper Recycling Works

Paper recycling is essential to our industry's efforts to achieve important sustainability goals and build a more circular value chain. Paper is one of the most widely recycled materials in America, turning used paper into new, essential products Americans rely on. In fact, more than 2/3 of all paper recycled in the U.S. is turned into new products at mills nationwide. In 2024, we recycled around 46 million tons, translating to an overall paper recycling rate of 60%-64%.

Paper recycling is also vital to our national supply chain. AF&PA members own and operate more than 100 materials recovery facilities across the country. About 80% of U.S. paper mills use some recycled paper to make new, sustainable products. Our industry is scaling up the use of recycled paper. U.S. mills used 1.29 million more tons of recycled paper to

make new products in 2024 – that's 32.7 million tons compared to 31.3 million tons in 2023.

Our industry has prioritized recycling for over 30 years, and we are committed to continued progress. AF&PA members are not just participants in the recycling system, we are helping build and improve it through voluntary industry investments that use more recycled paper, create jobs, and innovate in our U.S. manufacturing processes. During 2019-2025, our industry invested in projects at paper mills that will use over 4.5 million additional tons of recycled paper. Companies built new mills, upgraded old ones, and modernized equipment.

The proposed regulations set the baseline for successful program implementation. Please find below our feedback on the Proposed Draft COMAR 26.04.14 Packaging and Paper Products - Producer Responsibility.

Comments

Process

These regulations are wide-reaching and there is a need for meaningful stakeholder input from both the Advisory Council and the public. At multiple Advisory Council meetings following the passage of SB 901, members requested clarity on the timeline for these draft regulations, but agency staff could not give any indication. At the December 2 meeting, just two weeks prior to the release of this draft, agency staff specifically stated that they could not speak on the draft, any comment period that might be given, or the timeline for its eventual release. This lack of transparency inhibits thorough engagement and places every stakeholder – including MDE, tasked with facilitation and implementation – at a disadvantage. The limited time for response and a deadline set during the holiday period limits meaningful feedback on the proposed text, and there is no indication of how stakeholder feedback will be used. This continues a troubling pattern, as MDE previously required the Advisory Council in December 2024 to provide legislative recommendations on EPR in advance of the January legislative session without the benefit of the statutorily required needs assessment under SB 222 (2023), which was not completed until February 2025.

Definitions

"Bound book"

- The definition should be clarified as "a collection of pages that have been assembled and secured together along one edge to form a single volume, with binding methods that include case binding, perfect binding, saddle stitching, and

mechanical binding," as these products are not typically accepted in recycling facilities.

"Compostable"

- The current reference to COMAR 26.04.11.02 ("means the controlled aerobic biological decomposition of organic waste material.") is vague and not based on any certifiable standard. We recommend replacing this definition with a reference to ASTM D6400, ASTM D6868, and ASTM D8410.

"Covered entity"

- The enacting legislation specifically identifies "a public building owned or operated by the state or a local government." The proposed regulations expand this to include parcels of land, parks, state and local highways, and open spaces for the public as identified in local zoning. This is a significant expansion of scope that goes well beyond the enacting legislation. If the enacting legislation had contemplated such an expansion, stakeholder positions might have differed. This proposal appears to legislate via regulation.
- The proposed addition, "an industrial, commercial, or institutional building that source separates paper products for recycling and those paper products do not meet the definition of packaging," is unnecessary and inconsistent with the findings in the Maryland Statewide Needs Assessment (2025), which states:

> "To estimate commercial costs, the Project Team used a similar approach; however, hauler survey responses provided a broad range for commercial recycling routes between $100,000 and $400,000 per route. Survey responses from municipalities provided an average cost of $35 per cubic yard, which the project team ultimately used to estimate the total cost of curbside recycling for commercial material collected through single stream collection**. The operational costs of collecting high quality cardboard and clean office paper on a source separated basis is assumed to have a net cost of $0, as revenues from this commodity stream can be sufficient to offset operations costs.**" (Page 100)

- Including this stream adds administrative burden and program fees that could undermine efficiencies and penalize what should be a model for other materials. MDE should strike this language given its absence in the enacting legislation and the ambiguous definition of "paper products."

- The provision allowing exclusion of portions of buildings not owned, leased or rented by the state and local governments is reasonable. However, MDE should not use its approval authority to expand scope beyond what is included in the enacting legislation.

“Covered material type”

- This should specify that discreet commodity categories align with established commodity markets.

“End Markets”

- Our feedback submitted to the EPR Advisory Council on August 12, 2025, is still applicable and is provided here for reference:

  “We encourage MDE to align and harmonize, where possible, the Responsible End Market (REM) requirements with the other EPR states in the US. MDE should look to Circular Action Alliance (CAA) for guidance as CAA is working to develop a framework to comply with the various REM requirements.

  We support reference to existing industry standards for recyclability and repulpability. In the Approved Program Plan for the State of Oregon, Circular Action Alliance granted domestic paper mills an exemption for paper yield verification. They came to this conclusion based on input from us, the Technical Association of the Pulp and Paper Industry, and Moore & Associates that overall yield performance in the U.S. is never below 60%. Additionally, paper mill operators expressed strong concern that sharing yield information negatively impacts their strategic advantage. We suggest that MDE adopt a similar yield exemption for domestic paper mills.

  We also support the ability to leverage other certification and verification schemes to meet the REM requirements and minimize any duplication of process. We urge MDE to keep in mind that this requirement is not to actively enforce other jurisdictions regulations and laws, it is to review for evidence of violations with the respective competent authorities.”

“Environmental Impact”

- The phrase “compost the covered materials” should be corrected to “compose” to reflect the verbiage of the enacting legislation.

“Exempt material”

- The proposed regulations improperly narrow exemptions by using "primary packaging" instead of "packaging" which the enacting legislation defines to include primary, secondary, and tertiary packaging.
- Subsection (xiii) further disadvantages paper products by adding, "meets the definition of packaging" creating a two-tiered system of treatment for institutional, commercial, or industrial sources. This contradicts the Needs Assessment finding of $0 net cost for paper products and risks forcing already efficient streams to unnecessarily subsidize the program.

"Long-term packaging"

- Subsection (i) requiring resealing is irrelevant. Many long-term packaging options (e.g., pallets or milk crates) do not need to be resealed to serve as long-term packaging.

"Paper products" subsection (b) includes paper products generated by the residential, industrial, commercial, and institutional sectors.

- The Maryland Statewide Needs Assessment (2025) found:

  "To estimate commercial costs, the Project Team used a similar approach; however, hauler survey responses provided a broad range for commercial recycling routes between $100,000 and $400,000 per route. Survey responses from municipalities provided an average cost of $35 per cubic yard, which the project team ultimately used to estimate the total cost of curbside recycling for commercial material collected through single stream collection**. The operational costs of collecting high quality cardboard and clean office paper on a source separated basis is assumed to have a net cost of $0, as revenues from this commodity stream can be sufficient to offset operations costs.**" (Page 100)

- The addition of subsection (b), which was not included in the enacting legislation, appears to be a misguided effort to have paper products, which are processed at a net cost of $0 according to the Maryland Needs Assessment, subsidize the financial burden of program.
- The enacting legislation does not include this language, and MDE should explicitly state that paper products processed through this stream are excluded, mirroring the treatment of "packaging."
- If MDE includes this language in the regulation, it implies the Needs Assessment findings are erroneous. The Needs Assessment serves as the benchmark for

program performance. If the underlying data is not defensible, the program itself is not defensible.

- This language should be substituted with the following:

  "Does not include paper products generated by the industrial, commercial, and institutional sectors"

- This appropriately unifies the program's scope for covered material, rather than bifurcating the program as presented in these regulations.

Recycling

- As reflected in our feedback submitted to the EPR Advisory Council on August 12, 2025, more clarity is needed to define "economic mainstream" and to determine how that economic mainstream might impact marketplace innovation. We also suggest explicitly defining "energy generation" and "fuel production."

.03 Covered Materials

- See previous statements on the inappropriate inclusion of paper products sold, distributed, or intended to be used by industrial, commercial, or institutional use.

.04 Categories of Covered Materials for Registration

(2) Paper

- As reflected in our feedback submitted to the EPR Advisory Council on August 12, 2025, we encourage material categories to harmonize, where possible, with Covered Material Categories lists and the recyclability designations of other EPR states. Contradicting recyclability determinations will create an incredibly confusing and burdensome process for producers and end markets. This could also stymie innovative and new material applications.
- Consistent with feedback provided during public comment at the December 2 Advisory Council meeting, aseptic and gable-top cartons should be a single reporting category due to their relatively small volume.

.05 Exempt and Excluded Materials

- (1)(a-k) – See previous statement on improperly limiting exemptions to "primary packaging" when the enacting legislation made no such qualification. Including these undermines stakeholder engagement that occurred during legislative consideration.

- (1)(k)(ii) – This language reflects the exemption provided in the enacting legislation and should be expanded to include paper products that are not introduced to a person other than the commercial or business entity that receives the paper product.

.07 Registration Requirements and Associated Fees

- D. Delayed registration and reporting - The proposed regulations do not clarify remedies for inequitable treatment of producers who have complied. Because program fees will reflect actual costs, compliant producers will bear higher costs, putting them at a competitive disadvantage in the marketplace to noncompliant producers who avoid participation. Once noncompliant producers are brought in, there must be a mechanism to offset the additional financial burden borne by compliant producers.

.09 Record Keeping, Reporting and Production of Records

- D. Producers (2) – We support the use of prorated national data if state-specific data is not available or feasible.

.10 Timeline

- The timeline for a PRO to have an approved program plan is unclear, making it uncertain if the October 29, 2028, prohibition on the sale, distribution, or import of covered materials is achievable.
- It is also unclear when service providers must register. This is concerning given the disconnect between the timeline for service providers and the fee structure proposed in the enacting legislation.

.12 Producer Responsibility Advisory Council

B. Membership

- The Council consists of no more than 25 and no fewer than 15 members, representing a broad range of stakeholders. The second sentence, allowing the number of members to change with Secretary approval and 30 days' public notice, is ambiguous. It is unclear whether this refers to the Secretary's ability to appoint members (as granted in the enacting legislation) or to amend the membership limits outside the stated 15–25 range. The Secretary's authority should be limited to appointments within these statutory limits.

Elements of Enacting Legislation Requiring Regulatory Clarity

As reflected in our feedback submitted to the EPR Advisory Council on August 12, 2025, there are still many elements from the enacting legislation that are not addressed in this draft regulation. These include:

- Clarity between a "waste producer" and a "resident."
- Clarity on the "optimal level of service" for covered material.
- Clarity on what the "other requirements" established by the Department may be.
- Generalities such as "other factors," "general quality," "sufficient engagement," and "any other criteria" need to be defined.
- Clarity on which market indices will be referenced.
- Clarity around the scope of waste characterization (statewide versus local).
- A definition for "waste reduction."
- Clarity on how many producers are needed to qualify as a "group" to establish a PRO.

Thank you for your consideration of our comments. We appreciate the ongoing collaboration between AF&PA and MDE to advance a sustainable recycling system. We remain available to discuss the feedback herein in greater detail and look forward to your response. Please contact Shoshana Micon, Manager, Recycling and Packaging Sustainability, at shoshana_micon@afandpa.org or Frazier Willman, Manager, Government Affairs, at Frazier_Willman@afandpa.org if you have any further questions.

December 19, 2025

Bradley Baker, Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, Maryland 21230-1719
mde.epr@maryland.gov

The Biodegradable Products Institute (BPI) is North America's leading authority on compostable products and packaging, certifying over 50,000 products from collection bags to food containers. For more than two decades, BPI has given consumers confidence in compostability claims with the backing of science-based standards, while enabling authentically sustainable choices for brands and packagers. BPI champions a systems-wide transition to the circular bioeconomy through rigorous testing, policy advocacy, and industry collaboration, building the infrastructure for "A World Without Organic Waste"—where food scraps and certified compostable packaging become resources. BPI is a non-profit 501(c)(6). To learn more, visit www.bpiworld.org and follow us on LinkedIn.

As an organization, we were involved in the development of SB 901 and supported the language to ensure compost industry representation, rules, infrastructure, and funding. Now in regulation, we appreciate the consideration the Department has given to small businesses, nonprofit organizations, and other interested parties (pursuant to Chapter 212, Acts of 2019). With that said, the period for comment on the proposed regulations, due December 27, does not give our organization or our members sufficient time to properly review and provide comments. In our initial review, BPI has identified some areas of concern with the language in proposed regulation, as well as the associated guidance document, and requests an extension of the deadline to provide thoughtful comments and feedback. Should you not be able to provide an extension, we request confirmation of a subsequent comment period for all parties in the near future.

Please advise,

Alex Truelove
Senior Policy Manager
alexander@bpiworld.org

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December 27, 2025

Mr. Bradley Baker, Resource Management
Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, MD 21230-1719

Re: Comments on Draft COMAR 26.04.14 - Proposed Regulations Implementing Maryland SB 901 – FDA-Regulated Product Packaging Exemptions

Dear Mr. Baker:

On behalf of the Consumer Healthcare Products Association[1], I write to express our serious concerns regarding the Maryland Department of the Environment's ("MDE") proposed interpretation of the exemptions contained in Senate Bill 901 (Chapter 431, Acts of 2025). Specifically, we oppose MDE's proposed reclassification of packaging into primary, secondary, and tertiary categories, with the exemption for Food and Drug Administration (FDA) regulated drugs and medical devices in law applied only to primary packaging.

This narrow interpretation contradicts both the plain language of the statute and the comprehensive regulatory framework governing pharmaceutical and medical device packaging.

The Statutory Language Does Not Support MDE's Narrow Interpretation

The Maryland General Assembly enacted clear exemptions in § 9-2501(L) of the Environment Article for "exempt material," which includes:

> "(4) Packaging for a product regulated as a drug or medical device by the U.S. Food and Drug Administration, including associated components and consumable medical equipment"

The statute uses the broad term "packaging for a product regulated as a drug or medical device"—it does not distinguish between, or limit the exemption to, only primary packaging. Had the General Assembly intended such a limitation, it would have explicitly stated so. Courts consistently apply the principle that when statutory language is clear and unambiguous, it must be given its plain meaning without addition or subtraction.

The phrase "including associated components" further demonstrates legislative intent to encompass all packaging elements associated with FDA regulated products, not merely the immediate container touching the product.

[1] The Consumer Healthcare Products Association is the Washington, D.C. based national trade association representing the makers of over-the-counter (OTC) drugs, medical devices, and dietary supplements.

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Secondary Packaging for Pharmaceuticals and Medical Devices Is Comprehensively Regulated by the FDA

MDE's proposed distinction between primary and secondary packaging fails to recognize that the FDA extensively regulates all packaging components for drugs and medical devices. This regulation is not merely incidental—it is fundamental to product safety, efficacy, and compliance with federal law.

Secondary Packaging Requirements Under Federal Law

Secondary packaging in the pharmaceutical and medical device industries is subject to strict regulatory standards established by various national and international regulatory bodies. The FDA, through its Current Good Manufacturing Practice (cGMP) regulations codified at 21 CFR Part 211, mandates comprehensive requirements for all packaging components, including:

Durability Requirements: Secondary packaging must withstand transportation and storage conditions without compromising the primary packaging or the medication's integrity. These standards are not discretionary—they are mandatory to ensure product quality throughout the distribution chain.

Labeling Requirements: Federal law mandates accurate and clear labeling on secondary packaging, including drug information, dosage instructions, expiration dates, lot numbers, and necessary warnings. This labeling serves critical public health functions and is subject to FDA review and approval.

Tamper-Evidence: Secondary packaging must include features to indicate if it has been opened or tampered with, as required by 21 CFR 211.132. These tamper-evident features are essential for patient safety and are mandated by federal regulations, particularly following the 1982 amendments to the Federal Food, Drug, and Cosmetic Act (FDCA).

Serialization and Track-and-Trace: Under the Drug Supply Chain Security Act, secondary packaging plays a critical role in the pharmaceutical track-and-trace system, requiring specific serialization and data elements that are federally mandated.

The Integrated Nature of FDA-Regulated Packaging

The FDA views packaging as an integrated system, not as discrete, separable components. Secondary and tertiary packaging serve essential functions in maintaining product integrity, providing required information to healthcare providers and patients, and ensuring supply chain security. The agency's regulations at 21 CFR 211.122 specifically address "Materials examination and usage criteria," which apply to all packaging components.

Any state requirement that would force manufacturers to alter secondary or tertiary packaging for FDA-regulated products risks:

- Interfering with federally-mandated packaging requirements
- Compromising the integrated packaging system approved by the FDA
- Creating conflicting state and federal regulatory obligations

- Undermining patient safety protections built into the comprehensive packaging system

GMP Compliance Mandates Comprehensive Packaging Requirements

The FDA's cGMP regulations at 21 CFR Part 211 establish mandatory requirements for all aspects of pharmaceutical manufacturing, including packaging and labeling operations. Section 211.130 specifically requires that:

> "Packaging and labeling operations shall be adequately controlled... to assure that correct labels, labeling, and packaging materials are used for drug products."

These requirements extend to all packaging materials—primary, secondary, and tertiary. The regulations do not permit manufacturers to make unilateral changes to packaging configurations without proper validation and, in many cases, FDA notification or approval. Subjecting secondary or tertiary packaging to Maryland's Extended Producer Responsibility (EPR) requirements could necessitate packaging modifications that would require:

- Revalidation of packaging systems under cGMP
- Potential FDA notification or supplemental applications
- Supply chain disruptions during transition periods
- Increased costs that ultimately impact healthcare affordability

The regulatory burden and potential supply disruptions contradict the public health imperative of maintaining stable, compliant pharmaceutical and medical device supply chains.

The Legislative Intent Was to Exempt FDA-Regulated Healthcare Products

When interpreting statutes, courts seek to effectuate legislative intent. The General Assembly's clear purpose in exempting FDA-regulated drugs and medical devices was to avoid state-level interference with the comprehensive federal regulatory scheme governing these products. This purpose is undermined if the exemption applies only to a portion of the packaging system that federal law treats as integrated and comprehensively regulated.

Moreover, SB 901's definition of "packaging materials" in § 9-2501(N)(3)(ii) separately excludes "any part of a package or container that is sold or supplied in connection with... [a] federally regulated drug, medical device, biologic, diagnostic, or dietary supplement." The phrase "any part of a package" reinforces that the exemption was intended to be comprehensive, not limited to primary packaging alone.

Conclusion and Recommendation

For the reasons outlined above, we respectfully urge MDE to:

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Interpret the statutory exemptions consistent with their plain language, recognizing that "packaging for a product regulated as a drug or medical device" encompasses all packaging components—primary, secondary, and tertiary—associated with FDA-regulated products.

Acknowledge the comprehensive federal regulatory framework that governs all pharmaceutical and medical device packaging, not just primary packaging.

Avoid creating conflicting state requirements that would interfere with federal cGMP compliance and FDA-mandated packaging standards.

Issue regulations that fully exempt all packaging associated with FDA-regulated drugs and medical devices from the EPR requirements established under SB 901.

The health and safety of Maryland citizens depends on a stable, compliant supply chain for essential medications and medical devices. We appreciate your consideration of these comments and stand ready to provide additional information or technical expertise as MDE finalizes its implementation regulations.

Respectfully,

Carlos I. Gutiérrez
Vice President, State & Local Government Affairs
Consumer Healthcare Products Association
Washington, D.C.
202.429.3521
cgutierrez@chpa.org

COALITION FOR PROTEIN PACKAGING

The Hon. Secretary Serena McIlwain
Maryland Department of the Environment
1800 Washington Blvd
Baltimore, Maryland 21230

Monday, December 22, 2025

Dear Secretary McIlwain:
We appreciate the opportunity to provide comments on the Department's draft regulations on statewide recycling needs, and Producer Responsibility (EPR) regulations under Title 26.

The Coalition for Protein Packaging (CPP) is comprised of food packaging producers, major meat and protein processors, resin suppliers, and nationally recognized food brands whose products are widely available in grocery stores across Maryland and the United States.

The Coalition for Protein Packaging is writing to note that the draft regulations do not appear to include exemption language that was explicitly incorporated into the EPR legislation (SB901) enacted by the General Assembly and signed into law by Governor Wes Moore.

Specifically, the statute provides that, *notwithstanding any other law, Section 109 (Statewide Collection Lists) and Section 125 (Petition for the Exclusion of Certain Products) shall not apply to products packaged at establishments under the regulatory jurisdiction of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), including facilities regulated under federal or state meat and poultry inspection laws, as well as cheese, meat, and poultry prepared and packaged at retail locations. The statute further establishes a five-year exemption period, with an optional five-year extension contingent upon the development of recycling, including organics recycling, infrastructure capable of safely managing pathogen-contaminated packaging*[1].

Importantly, the legislative intent underlying this provision is clear and deliberate. The General Assembly explicitly recognized the unique food safety and public health considerations associated with FSIS-regulated products, as well as the current limitations of recycling and organics infrastructure to safely manage pathogen-contaminated packaging. The inclusion of both a defined exemption period and a conditional extension reflect a balanced, forward-looking approach that preserves food safety while allowing time for infrastructure development.[2]

CPP shares the Department's goal of implementing an EPR program that is faithful to statute, protective of public health, and operationally sound.

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[1] https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/SB0901?ys=2025RS
[2] https://mgaleg.maryland.gov/2025RS/bills/sb/sb0901E.pdf

In the spirit of the holiday season, regulatory clarity, and statutory consistency -- we respectfully request the Department incorporate this statutory exemption language into the final EPR regulations to ensure consistency with enacted law and clear legislative direction.

Thank you for your consideration, and please do not hesitate to contact me if additional clarification would be beneficial.

_____

Sincerely,

Erin Hass, Director of the Coalition for Protein Packaging
Senior Director of Government Affairs for the Plastics Industry Association
ehass@plasticsindustry.org
603-738-0291 Mobile

Cc: Angie Webb, Chief Recycled Products & Marketing
Bradley Baker, MBA, PMP, PM Resource Management Materials Administration

Kristie Blumer
to me

Fri, Dec 26, 2:01 PM (3 days ago)

Bradley,

Happy Holidays! I hope you and your family are enjoying this time to celebrate.
I finally had time to do a quick review of these draft policies. These initiatives are sorely needed in the composting world so thank you for the initiative. See my main comments below. If you have any questions, please let me know.

1. This regulation should explicitly require that compostable packaging be labeled on each individual product with the applicable compostability certification standard and/or certifying body. Use of the generic term 'compostable' or a manufacturer name alone is insufficient for verification, enforcement, and acceptance by composting facilities. For our collections and composting, we require products to display an approved compostability certification in order to be accepted. Without clear certification labeling on the individual product, it is not possible to verify compliance once materials enter the collection stream or arrive at a composting program.
2. While ASTM compostability standards establish laboratory performance criteria, they do not address chemical safety concerns such as PFAS, nor do they require field testing, independent audits, ongoing surveillance, or enforcement mechanisms to prevent misleading compostable claims. To ensure environmental protection and program integrity, the regulation should require additional certification or verification beyond ASTM compliance alone (for example: BPI certified, TUV, CMA, Din-Certco, Din-Gepruft, ISO 17088, etc.).

Happy Composting,

Kristie Blumer
Senior Director, Composting
Office: (301) 202-4450
Compost Crew Inc, A Public Benefit Corporation

"Unless someone like you cares a whole awful lot,
Nothing is going to get better. It's not."- Dr. Seuss, The Lorax

Healthcare Distribution Alliance

HEALTH DELIVERED

December 23, 2025

Mr. Bradley Baker, Resource Management
Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, MD 21230-1719

Re: Comments on Draft COMAR 26.04.14 (EPR – Packaging and Paper Products)

Dear Mr. Baker:

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing healthcare wholesale distributors, thank you for the opportunity to provide comments on the Maryland Department of the Environment's draft regulations implementing Maryland's Packaging and Paper Products Producer Responsibility program (Draft COMAR 26.04.14).

We are writing to express our significant concerns regarding the draft Extended Producer Responsibility (EPR) regulations for packaging and paper products, specifically as they relate to FDA-regulated pharmaceutical products, medical devices, and medical equipment. While HDA supports Maryland's goals of improving recycling and reducing waste, we strongly urge the Department to maintain the full EPR exemption for FDA-regulated products as was intended by the legislature upon the enactment of 2025 Senate Bill 901, Chapter 431, including all levels of packaging (primary, secondary, and tertiary).

FDA-regulated medications, devices, and medical equipment are routinely carved out of EPR obligations because of their unique role in ensuring the safety and security of the healthcare system. Every link in the pharmaceutical supply chain has a shared obligation to deliver these products to patients safely, securely, and without delay. In practice, that depends not only on the immediate container, but also on the secondary and tertiary packaging that preserves product quality and compliance, such as insulated shippers, gel packs and other temperature-control materials, protective containers, and other specialized packaging used to prevent damage, contamination, or temperature excursions. Treating these components as anything other than essential infrastructure risks introducing delays and disruption in distribution, undermining continuity of care, worsening patient outcomes, and driving avoidable costs into the healthcare system.

The draft regulations narrow statutory exemptions:
Our concerns stem in large part from the draft regulations' narrowing of statutory exemptions in a manner not supported by the enacted law. SB 901 defines "exempt material" as "a material, or any portion of a material" that is exempt, and includes, among other categories, packaging for FDA-regulated drugs, medical devices, and medical equipment, including associated components and consumable medical equipment. By contrast, the draft regulations redefine these same exemptions as applying only to "primary packaging" for the listed healthcare products, and further create a classification system of primary, secondary, and tertiary packaging that is not defined or contemplated in the statute. The draft then adds an explicit limitation providing that exempt material does not include secondary or tertiary packaging associated with products listed in the exemption.

This approach is inconsistent with SB 901 in two fundamental ways: the statute does not tie exemption eligibility to any packaging tier, instead expressly covering "a material, or any portion of a material," and "packaging for" specified FDA-regulated healthcare products (including associated components and consumables) without limiting the exemption to "primary" packaging; and the draft rule both narrows the exemption and creates internal tension by separately stating that covered packaging includes secondary and tertiary packaging associated with exempt

primary packaging. Together, these provisions would shrink the statutory exemption and expand covered-material obligations beyond what the General Assembly enacted, creating uncertainty about which healthcare packaging is subject to EPR. That uncertainty will ripple through the supply chain, drive up compliance costs, and ultimately jeopardize timely patient access and continuity of care.

Maryland's draft approach also departs from well-established EPR frameworks in other states that generally exempt packaging related to medical products, medical devices, and prescription drugs regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.). Maintaining a consistent, well-understood exemption for FDA-regulated products reflects the widely recognized need to protect regulated healthcare products and the systems that deliver them safely to patients.

Draft regulations impede health care delivery:
The draft also raises serious practical concerns for healthcare delivery in Maryland. By imposing new compliance costs and associated fees across the pharmaceutical supply chain, the proposal would divert critical financial resources away from patient care and add pressure to an already strained healthcare affordability environment. The reporting requirements contemplated for secondary and tertiary packaging would introduce unprecedented administrative burdens for pharmaceutical products while providing no meaningful value to patient care or patient access.

These burdens are particularly problematic in a highly regulated environment where healthcare entities already operate under extensive FDA requirements and state boards of pharmacy oversight; layering additional packaging compliance and reporting obligations on top of existing federal and state mandates creates unnecessary operational challenges, increases the likelihood of regulatory conflict, and raises the risk of disruption in the safe delivery of medicines and medical products.

Draft regulations threaten the stability of healthcare products:
Limiting the exemption to primary packaging only would create avoidable risks to patient safety and the integrity of the supply chain. Healthcare packaging is not ornamental; it often directly supports sterility, tamper evidence, anti-counterfeiting, traceability, temperature stability, safe handling, and regulatory compliance. Secondary and tertiary packaging is frequently integral to maintaining those protections, including preventing temperature excursions and physical damage (for example, cushioning for glass vials, gel packs, and insulated shippers).

Regulatory burdens that introduce delays or disrupt distribution, whether through new reporting requirements, fee allocation complexity, or operational pressure to redesign packaging, can interrupt patient therapy and compromise health outcomes.

Request revisions to protect patient safety:
To ensure the regulations protect patient safety and avoid disruption to continuity of care, *we implore the Department to preserve the full statutory exemption for FDA-regulated products by treating all packaging for those products (primary, secondary, and tertiary) as "exempt material," without additional regulatory limitations.* Any rule that narrows this exemption to primary packaging only would exceed the General Assembly's language, create confusion in the marketplace, impose avoidable costs across the healthcare system, and risk interrupting the safe, timely delivery of life-saving medications and medical products to Maryland patients.

Thank you again for the opportunity to comment and for your consideration. We would be pleased to provide additional information or answer any questions related to these comments.

Sincerely,

Leah Lindahl
Vice President, State Government Affairs

December 27, 2025

Mr. Bradley Baker
Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, MD 21230-1719

Submitted Electronically: mde.epr@maryland.gov

RE: Comments on Proposed Regulations - COMAR 26.04.14 - Extended Producer Responsibility and Request for Exemption of Cold Chain Packaging for Prescription Drugs and Biologics

Dear Mr. Baker:

The National Association of Specialty Pharmacy (NASP) respectfully submits these comments on the proposed amendments to COMAR 26.04.14 regarding Extended Producer Responsibility (EPR) for packaging and paper products in the State of Maryland. NASP urges the Department to clarify and expand the exemption in COMAR 26.04.14 § .02.16(b) to explicitly exempt all primary, secondary, and tertiary packaging associated with cold chain shipments for prescription drugs and biological products.

While NASP appreciates the Department's recognition that primary packaging for FDA-regulated drugs and medical devices merits exemption from EPR obligations, the current regulatory language creates an unjustified and operationally impossible mandate that secondary and tertiary cold chain packaging associated with drug and biologic products be subject to EPR compliance. This proposed approach:

1. Contradicts the statutory intent to exempt medical products from EPR obligations.
2. Fails to account for the mandatory nature of cold chain requirements for specialty pharmacy products.
3. Imposes duplicative and unnecessary regulatory complexity and cost on an already heavily regulated healthcare sector that works to support and carefully manage patients with serious, life-threatening medical conditions.

4. Creates perverse incentives that may increase the risk of temperature excursions and compromise patient safety and drug efficacy.

NASP respectfully requests that the Department revise COMAR 26.04.14 § .02.16(b) to exempt all packaging—primary, secondary, and tertiary—associated with prescription drugs and biological products consistent with the statutory exemption language and the public health imperatives that drive cold chain requirements.

Background On Specialty Pharmacy and Cold Chain Management for Specialty Drugs and Biologics

Specialty pharmacies are highly specialized entities that dispense, deliver and provide patient support services for complex, often high-cost medications used to treat serious, chronic, and rare diseases. These include, but are not limited to:

- Biologic therapies (monoclonal antibodies, recombinant proteins, gene therapies, cell therapies);
- Injectable medications (interferons, growth factors, immunosuppressants);
- Oral chemotherapy agents;
- Antiretroviral medications; and
- Complex injectables requiring patient training and monitoring.

Specialty pharmacies are accredited by national, independent, third-party specialty accreditors (e.g., URAC, ACHC, and JCAHO) and operate under extensive oversight by the U.S. Food and Drug Administration (FDA) and state boards of pharmacy. Cold chain management is not a business choice—it is a regulatory mandate designed to protect patient safety and ensure therapeutic efficacy.

Biologic products differ fundamentally from traditional small-molecule drugs because they are derived from living organisms and contain complex protein or genetic structures that are extraordinarily sensitive to temperature variation. Even brief temperature excursions outside of their required range (exposure to incorrect temperatures for even a few hours) can irreversibly compromise product integrity, efficacy or patient safety in use.

Examples of Temperature-Controlled Specialty Drugs and Biologics

- Humira® (adalimumab): a chronic, patient self-administered biologic medication used to treat a variety of chronic autoimmune and autoinflammatory conditions, such as rheumatoid arthritis, ulcerative colitis, and plaque psoriasis. Humira must be refrigerated at 2-8°C and shipped to a patient home in validated, temperature-controlled packaging to maintain product stability in transit and ensure patient safety and efficacy upon administration.

- Mekinist® (trametinib**)**: an oral medication used for the treatment of unresectable or metastatic solid tumors with genetic mutations for adult and pediatric patients six years of age and older. Mekinist must be stored at 2°C to 8°C, dispensed in the original bottle with the desiccant, protected from moisture and light and not placed in pill boxes to maintain product viability and patient safety.
- Pulmozyme® (dornase alfa): a recombinant enzyme inhalation solution used for the management of cystic fibrosis patients to improve lung function. Pulmozyme ampules must be stored and transported between 2°C to 8°C in their protective foil to protect from light and heat. Once the protective foil pouch is opened, the unused ampules must be kept refrigerated in the protective foil pouch to protect from light and heat. The medication cannot be used if the ampules are exposed to room temperature (22°C to 28°C) for more than a total of 60 hours.

What Cold Chain Packaging Requires

The following represents secondary and tertiary packaging materials that are essential components of FDA-compliant cold chain systems but would NOT be exempt under the proposed regulation: COMAR 26.04.14 § .02.16(b):

A. Thermal Packaging Components

- Styrofoam/Expanded Polystyrene (EPS) Coolers: Rigid foam insulation boxes that maintain temperature stability; irreplaceable for ultra-cold and frozen products.
- Molded Fiber/Pulp Coolers: Paper-based insulation alternatives.
- Reflective Foil-Lined Insulation: Multi-layer insulation wrapping to maintain temperature.
- Vacuum-Insulated Panels: Advanced insulation materials for sensitive products.
- Polyurethane Foam Liners: Additional insulation layer inside coolers.

B. Thermal Conditioning Agents (Packaging Materials Used to Maintain Temperature)

- Gel Ice Packs: Phase-change materials in plastic housings (typically HDPE or PP) that maintain temperature during transport; can hold consistent cold for 24-72+ hours depending on design.
- Dry Ice Packaging: Used for ultra-cold transport (-78°C); sealed in Styrofoam or cardboard containers.
- Liquid Nitrogen Shippers: Specialized containers for cell therapies and gene therapies requiring cryogenic temperatures.

- PCM (Phase Change Material) Liners: Specialized insulation that releases cold gradually.

C. Protective Padding and Void Fill

- Bubble Wrap: Plastic air-filled cushioning to protect medications from temperature shock and physical damage during transit.
- Plastic Air Pillows: Void fill to reduce package movement.
- Kraft Paper Void Fill: Paper-based cushioning.
- Crinkle Paper: Recycled paper packing material.
- Corrugated Cardboard Filler: Carton board used for stacking/spacing.

D. Shipping Containers

- Cardboard Shipping Boxes: Outer container for protection during transport; different grades and coatings required for temperature control.
- Corrugated Mailers: Secondary container for smaller shipments.
- Rigid Plastic Containers: Hard-shell shipping cases for sensitive products.
- Insulated Liners (Plastic/Rubber): Plastic or rubber barriers inside shipping containers.

E. Labeling, Monitoring, and Documentation Packaging

- Temperature Data Logger Packaging: Protective cases for electronic thermometers that track temperature throughout transit.
- Thermal Indicator Labels: Single-use labels that change color if temperature excursions occur (alert systems for pharmacy staff).
- Shipping Labels and Protective Sleeves: Plastic-coated labels and label protectors.
- Desiccant Packets: Moisture-absorbing packets (typically plastic) that prevent condensation inside coolers.
- Oxygen Absorbers: Packages to prevent oxidation of sensitive biologics.

F. Sealing and Closure Materials

- Tape (Paper, Plastic, or Kraft): Used to seal boxes and maintain package integrity.
- Plastic Seals and Security Ties: Tamper-evident packaging.
- Plastic Shrink Wrap: Secondary wrapper around coolers.
- Plastic Film/Wrapping: Protection from moisture and contamination.

Patient Safety Concerns Without Regulatory Exemption

Under the current proposed regulation, secondary and tertiary packaging for drugs is not exempt even though the primary container is exempt. This creates a fundamental regulatory contradiction that undermines the purpose of the statutory exemption, which recognizes that drug packaging must preserve product integrity and meet FDA requirements. While the regulation exempts the primary container (the vial, syringe, or blister pack holding the drug), it does not exempt the secondary and tertiary packaging (ice packs, coolers, insulation) that is equally essential to preventing temperature excursions that would degrade the primary container's contents.

Many specialty drugs and biologics treat rare diseases and extremely small patient populations and are not stocked at local retail pharmacies due to their complex management, high cost, limited shelf life, and low dispensing volume. As a result, these therapies are dispensed through highly accredited specialized pharmacies that primarily operate centralized distribution models, shipping medications directly to patients' homes using validated cold chain packaging, and managing the patient through direct communications during the medication's/biologics' use.

If the regulation is not amended, Maryland's most vulnerable patients could lose access to critical therapies. The state's complex EPR requirements would drastically increase shipping costs and create regulatory uncertainty for specialty pharmacies, making it extremely difficult for specialty pharmacies to continue providing these essential medications. The regulation also risks creating financial pressure on pharmacies to modify cold chain packaging practices in ways that could increase the likelihood of temperature excursions, product loss, or compromised drug integrity. Together, these outcomes threaten patient access to safe and effective treatment and undermine the public health objectives the statute should support.

Volume and Cost Impact: Why This Affects Specialty Pharmacy Disproportionately

Unlike consumer products that are packed once and distributed to many customers, specialty pharmacy medications are typically shipped individually or in small batches directly to patients' homes using temperature-controlled packaging. These shipments require significantly more packaging material by weight due to insulation, refrigerants and monitoring components necessary to maintain validated temperature ranges.

Many specialty pharmacies are clinically specialized to dispense a limited number of therapies or disease states due to the intensive patient management, clinical expertise, accreditation requirements, and infrastructure required to safely support these medications, limiting their ability to diversify services or absorb new regulatory costs. Under the proposed regulation without exemption, these pharmacies would be subject to cumulative producer fees under a per-pound EPR pricing model, along with registration fees, PRO membership fees, administrative costs, and ongoing compliance obligations. For many specialty pharmacies shipping drugs and biologics into Maryland, these combined costs could reach the tens to hundreds of thousands of dollars annually, a level that is unsustainable, particularly for independent specialty pharmacy providers.

Legal and Policy Arguments for Exemption

Maryland's EPR statute (Environment Article 9-2501 et seq.) explicitly exempts "primary packaging for a product regulated as a drug or medical device by the U.S. Food and Drug Administration, including associated components and consumable medical equipment." Cold chain packaging materials (ice packs, insulation, thermal management systems) are "associated components" that are integral to ensuring drugs and biologics reach patients in a safe and efficacious condition.

Interpreting the statutory exemption to exclude secondary/tertiary packaging improperly narrows the exemption in a manner that is inconsistent with the legislative intent, effectively rendering it unworkable for temperature-sensitive drugs and biologics. Federal FDA requirements mandate that drugs and biologics be maintained within specified temperature ranges throughout the entire supply chain, and packaging must be designed to preserve those conditions as temperature excursions would render products non-compliant.

Maryland's state pharmacy regulations similarly presume the use of validated cold chain packaging for temperature sensitive medications. Subjecting required packaging to EPR obligations creates a direct conflict between state pharmacy board requirements, state environmental regulations, and federal drug safety law and regulations. Maryland's EPR regulations should be implemented in a manner that avoids such conflicts and preserves compliance with federal FDA and state patient safety requirements.

Requested Regulatory Revisions

NASP respectfully requests that the Department revise COMAR 26.04.14 § .02.16(b) as follows:

<u>Current Language (to be revised):</u>

"Exempt material means a material, or any portion of a material that is... iv. Primary packaging for a product regulated as a drug or medical device by the U.S. Food and Drug Administration, including associated components and consumable medical equipment..."

"Exempt material does not mean secondary or tertiary packaging associated with products listed in (a)."

Proposed Revised Language:

"Exempt material means a material, or any portion of a material that is... iv. All packaging—primary, secondary, and tertiary—for a product regulated as a drug, biologic, or medical device by the U.S. Food and Drug Administration, including all materials necessary to maintain product stability, temperature control, safety, and efficacy during storage, handling, and distribution to patients, including associated components and consumable medical equipment..."

NASP urges the Maryland Department of the Environment to recognize that cold chain packaging is inseparable from drug efficacy and FDA compliance. Where primary drug packaging is exempt, the packaging materials necessary to maintain validated temperature control during storage and distribution must likewise be exempt to preserve patient safety and therapeutic effectiveness.

Specialty pharmacies already operate under extensive oversight by state boards of pharmacy and are subject to federal requirements governing drug storage, handling, and distribution, as well as rigorous accreditation standards. Imposing additional EPR compliance requirements creates conflict and confusion, unnecessary regulatory duplication, and increases healthcare costs without environmental benefit.

Accordingly, NASP respectfully requests that the Department revise COMAR 26.04.14 § .02.16(b) to explicitly exempt all cold chain packaging (primary, secondary, and tertiary) used for prescription drugs and biologics, consistent with statutory intent and public health considerations.

NASP welcomes the opportunity to work collaboratively with the Department to refine language that protects Maryland's environmental goals while preserving patient access to safe and effective life-saving specialty medications. For additional information please contact me at Sheila.Arquette@naspnet.org.

Respectfully submitted,

Sheila Arquette, RPh
President and CEO

RE: Code of Maryland Regulations (COMAR) 26.04.14 Packaging and Paper Products - Producer Responsibility – December 2025 Draft

Submitted by:

PakTech
Jonathan Levy
Manager, Public Policy and Sustainability

December 24, 2025

Bradley Baker
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 160
Baltimore, MD 21230-1719

RE: Code of Maryland Regulations (COMAR) 26.04.14 Packaging and Paper Products - Producer Responsibility – December 2025 Draft

Dear Mr. Baker,

PakTech would like to thank the Maryland Department of the Environment ("MDE") for giving us an opportunity to share our thoughts related to the *Code of Maryland Regulations (COMAR) 26.04.14 Packaging and Paper Products - Producer Responsibility – December 2025 Draft* ("Draft Regulations"). We congratulate MDE for its work developing these regulations and the countless hours of stakeholder input and feedback it solicited that led to the release of the Draft Regulations. With that in mind, we hope our comments are received in the spirit they were written as we are interested in seeking clarity with some sections while also helping to improve the final draft.

Paktech is a manufacturer of HDPE plastic handles that utilize recycled resin as a feedstock. With facilities located in Eugene, Oregon, PakTech's products are made from post-consumer recycled HDPE resin ("rHDPE") sourced from curbside collection programs. Using rHDPE feedstock is part of our commitment to sustainability and ensuring this material remains in the circular economy. You may be familiar with PakTech's carrier handles as they can be found in retail and neighborhood grocery stores across Maryland where beer and wine are sold. To date, (January to December 2025) we have provided the demand to ensure that over 1.1 million milk jugs have been recycled and turned into recycled resin for our products shipped to Maryland by our customers. In terms of weight, that is 152,594 lbs. of recycled resin. Nationwide, during the same time frame, we have ensured that over 95 million milk jugs have been recycled, which is the equivalent of over 12 million lbs. of recycled HDPE resin being consumed. While our company may be small in size, our consumer footprint is considerable. As such, we are experts when it comes to discussing issues related to recycling programs, the cycles of supply and demand, and having a broad view of how the plastic recycling industry works. The demand we (and other manufacturers) create for rHDPE is the engine that drives the entire plastic recycling industry.

DISCUSSION:

Having read through the draft regulations, we would like to bring up several items that we think should be addressed.

1. Definitions

1.1. Definition of "Component"

In section .03 Covered Materials, we notice that .03(B)(2) makes reference to

"Components and elements that are supplemental, auxiliary, or subordinate and integrated into packaging, including those components and elements that are directly attached to a product and are part of the packaging design functionally or aesthetically, facilitate the packaging function, or facilitate the delivery including through identification of the product. This includes materials used to affix packaging components to one another;"

In reading through the Definitions section of the regulations, we did not see a definition for "Component". As these packaging elements are considered covered materials and producers will be required to report on the types and amounts of components they use in their packaging, we believe that a definition for "Component" is necessary.

We submit for your consideration our suggested language for the definition of "component". You may notice that within our suggested definition, we specifically declare that component manufacturers should not be considered a "producer". We explain our reasoning further within our comments.

"Component" with respect to covered material, means a piece or subpart that is readily distinguishable from other pieces or subparts with respect to its composition or function. Manufacturers of "component" parts are not considered producers and responsibility for such items are the responsibility of the producer of the packaging in which the component part is affixed.

Component parts are by their nature a business-to-business item and only serve their purpose once affixed to a primary package. Once a component is affixed to the primary package, the component manufacturer has no control over how the component will be used. It is this transactional nature that clearly assigns responsibility to the Brand Owner and in these cases should be considered the producer for these items.

From a reporting perspective, the Brand Owner should have the ability to report on the number and types of components it purchases and MDE or the Producer Responsibility Organization ("PRO") can go to the Brand Owner for this information. This reporting information can then be used to ensure the producer of the primary packaging and the components to which it was affixed are dealt with accordingly.

It is our contention that once the extended producer responsibility law goes into full effect, the status of who is and who is not a producer will be hotly debated. We believe that MDE can alleviate much debate by accepting our suggestion and amending the definition of component.

Conclusion

We thank MDE for the opportunity to provide our feedback on the Draft Regulations and look forward to working with all stakeholders in this process to develop rules for the state's Packaging and Paper Products Producer Responsibility Program that will ensure the program works as the Legislature intended and consumer packaging is handled in the most responsible manner possible.

COALITION FOR PROTEIN PACKAGING

The Hon. Secretary Serena McIlwain
Maryland Department of the Environment
1800 Washington Blvd
Baltimore, Maryland 21230

Monday, December 22, 2025

Dear Secretary McIlwain:
We appreciate the opportunity to provide comments on the Department's draft regulations on statewide recycling needs, and Producer Responsibility (EPR) regulations under Title 26.

The Coalition for Protein Packaging (CPP) is comprised of food packaging producers, major meat and protein processors, resin suppliers, and nationally recognized food brands whose products are widely available in grocery stores across Maryland and the United States.

The Coalition for Protein Packaging is writing to note that the draft regulations do not appear to include exemption language that was explicitly incorporated into the EPR legislation (SB901) enacted by the General Assembly and signed into law by Governor Wes Moore.

Specifically, the statute provides that, *notwithstanding any other law, Section 109 (Statewide Collection Lists) and Section 125 (Petition for the Exclusion of Certain Products) shall not apply to products packaged at establishments under the regulatory jurisdiction of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), including facilities regulated under federal or state meat and poultry inspection laws, as well as cheese, meat, and poultry prepared and packaged at retail locations. The statute further establishes a five-year exemption period, with an optional five-year extension contingent upon the development of recycling, including organics recycling, infrastructure capable of safely managing pathogen-contaminated packaging*[1].

Importantly, the legislative intent underlying this provision is clear and deliberate. The General Assembly explicitly recognized the unique food safety and public health considerations associated with FSIS-regulated products, as well as the current limitations of recycling and organics infrastructure to safely manage pathogen-contaminated packaging. The inclusion of both a defined exemption period and a conditional extension reflect a balanced, forward-looking approach that preserves food safety while allowing time for infrastructure development.[2]

CPP shares the Department's goal of implementing an EPR program that is faithful to statute, protective of public health, and operationally sound.

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[1] https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/SB0901?ys=2025RS
[2] https://mgaleg.maryland.gov/2025RS/bills/sb/sb0901E.pdf

In the spirit of the holiday season, regulatory clarity, and statutory consistency -- we respectfully request the Department incorporate this statutory exemption language into the final EPR regulations to ensure consistency with enacted law and clear legislative direction.

Thank you for your consideration, and please do not hesitate to contact me if additional clarification would be beneficial.

_____

Sincerely,

Erin Hass, Director of the Coalition for Protein Packaging
Senior Director of Government Affairs for the Plastics Industry Association
ehass@plasticsindustry.org
603-738-0291 Mobile

Cc: Angie Webb, Chief Recycled Products & Marketing
Bradley Baker, MBA, PMP, PM Resource Management Materials Administration

Restaurant Association of Maryland

December 27, 2025

Bradley Baker, Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, Maryland 21230-1719
Via Email: *mde.epr@maryland.gov*

Re: Comments on Proposed Draft COMAR 26.04.14 Initial Regulations and Draft Guidance Document for Packaging and Paper Products - Producer Responsibility

Dear Mr. Baker:

The Restaurant Association of Maryland appreciates the opportunity to provide some initial comments on the proposed Draft Regulations and Guidance Document for Packaging and Paper Products - Producer Responsibility (EPR).

We are grateful that the new EPR law excludes restaurants from the definition of "producer" if they are headquartered in Maryland and meet the other specified exemption criteria. One of the criteria is that such a restaurant *is not a producer of food serviceware.* The draft initial regulations and guidance copy this language but do not provide any clarification on what this means. It would be helpful if the Department could provide some clarification and examples regarding this.

Most of our members are Maryland-based restaurants. We also have members with Maryland restaurant locations but are headquartered outside the State, and therefore, do not qualify for the restaurant exemption provided in the law. For this reason, we are providing comments and seeking some additional clarifications regarding the draft regulations and guidance.

Under the definitions in Maryland's EPR law, *Packaging includes:*

(ii) Service packaging designed and intended to be filled at the point of sale, including:

1. *Carry–out bags;*
2. *Bulk goods bags; and*
3. *Take–out and home delivery food service packaging*

The draft initial regulations and guidance copy this language, but "including food serviceware" has been added to *take–out and home delivery food service packaging.* No definition of "food serviceware" is provided in the law and draft regulation. On page 28 of the draft guidance document under "Definitions," the Department acknowledges that *there is no specific term defined as "food serviceware,"* and mentions that it is described in the law. It would be helpful if the Department could reference that specific language in the law.

(more)

The Department's draft guidance says that food serviceware also includes (but not limited to) utensils, straws, napkins, condiment packages, and other items. However, these items are not *service packaging designed and intended to be filled at the point of sale* as described in the language of the law (as cited above). This appears to be a very broad interpretation. It would be helpful if the Department could provide the rationale for this broad interpretation.

Thank you for your time and consideration of our comments, and we look forward to the Department's responses and clarifications regarding these issues.

Sincerely,

Melvin R. Thompson
Senior Vice President
Government Affairs and Public Policy

The Recycling Partnership
Building a Better Recycling System

20 F Street NW
7th Floor
Washington, D.C. 20001
recyclingpartnership.org

Bradley Baker, Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, Maryland 21230-1719
med.epr@maryland.gov

Dear Bradley Baker,

Thank you for the opportunity to comment on the draft proposal to adopt new regulations under Code of Maryland Regulations (COMAR) 26.04.14 Packaging and Paper Products – Producer Responsibility.

The Recycling Partnership is a purpose-driven organization committed to building a better recycling system, one that delivers the economic and environmental benefits our communities and the hundreds of thousands of people who work throughout the recycling industry deserve. The Recycling Partnership's team of experts, practitioners, and thought leaders with real-world experience works with its partners to create meaningful change across the recycling system and assist communities, companies, and policymakers in enacting such change. The Recycling Partnership uses its one-of-its kind National Recycling Database that reaches more than 9,000 U.S. recycling programs and develops practical and innovative resources to address critical gaps in the recycling system.

Following our review please find our feedback on the draft regulations below.

.02 Definitions

(11) "Covered materials" - A sub point has been added that was not in the statutory language: "(ii) Packaging or paper products that are multimaterial".

- With the addition of the sub point (11)(b)(i), MDE is including a new term which is not defined elsewhere, packaging materials. We believe this term is duplicative because packaging is already defined within the statute and included in the "covered materials" definition under (11)(a).

- We believe the intent of these additions is to clarify that packaging or paper products that are multimaterial are considered covered materials and we believe that be accomplished without the (11)(b)(i) clarifying language.

- In our opinion, the addition of those sub points could lead some to the conclusion that only packaging or paper products that are multimaterial are covered materials.

(15) "Environmental Impact" – We believe there is a typo under this definition, "beginning with the extraction and processing of the raw materials that *compost* the covered materials through…".

- Within statutory language this says *compose* and not *compost*. We would recommend shifting the language back to match the statutory language.

(21) "Packaging" – A sub point has been added that was not in the statutory language: "(iv) Labels affixed to packaging or products".

- We ask for clarification on the reporting process for producers in regard to labels, within the context of the new multimaterial definition. If a glass jar includes a label that materially affects the recyclability of the jar, if the label is not removed, does that glass jar need be reported in a new multimaterial glass category?

- We would advise that issues with labeling be addressed via other requirements in lieu of introducing new and distinct reporting categories for producers.

(37) "Service provider" – A sub point has been added that was not in the statutory language: "(ii) A private entity that is not contracted with a local government, that provides covered services for covered materials, such as through a subscription model."

- We encourage the use of existing private entities to provide alternative collection programs, funded by the PRO or IPP responsible entity, of certain covered materials to ensure an optimal level of convenience for consumers and collection for those materials. However, we want to ensure that those private entities are not charging consumer-facing fees for the collection and management of covered materials, as that is a PRO responsibility.

- Within statutory language, under Section 9-2505(C)(1)(IX), it is stated that the PRO will pay for the entirety of the program plan without any new or additional consumer-facing fees to members of the public, businesses, service providers, the state or any political subdivisions, or any other person

who is not a producer. Under this language, the only enforcement of additional consumer-facing fees falls upon the PRO.

- We would advise that further regulations include a prohibition on service providers charging any new or additional consumer-facing fees for the collection and management of covered materials.

We thank the Maryland Department of the Environment for the opportunity to provide comments on these draft regulations. The Recycling Partnership stands ready to assist MDE in any way possible throughout the process of regulations and implementation of this extended producer responsibility law.

Please feel free to reach out with any questions.

Sincerely,

Trina Matta
Executive Director, Policy
The Recycling Partnership

December 19, 2025

Mr. Bradley Baker
Resource Management Program Manager
Land and Materials Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 610
Baltimore, Maryland 21230-1719

RE: Draft Proposed Packaging and Paper Products - Producer Responsibility Regulations

Dear Mr. Baker,

Thank you for the opportunity to submit comments on behalf of Upstream regarding the draft proposed packaging and paper products - producer responsibility regulations put forward by the Maryland Department of the Environment (MDE). Upstream is a US-based non-profit and leading change agency for the reuse movement in the US and Canada. We accelerate the transition from our current throw-away economy to one that is regenerative, circular and equitable by normalizing reuse, growing and supporting the reuse industry, and creating an enabling policy environment for reuse.

We strongly support the spirit of Maryland's packaging EPR law and the state legislative intent to reduce waste. We recognize the considerable effort MDE has put into compiling these draft regulations. However, we feel the draft regulations leave room for improvement with respect to reuse. We have outlined our comments in detail below.

Definitions:

We appreciate and support MDE's detailed definitions of reuse and refill in the draft regulations. However, we note that the statute requires the packaging producer responsibility organization (PRO) to establish a target for waste reduction, which is not defined. **We strongly urge MDE to establish a clear definition for waste reduction in the regulations** and suggest referencing Minnesota's definition from SF 3887 (Subd. 39). This definition incorporates refillable covered materials such that producers who convert their products into refillable formats as defined in statute will contribute toward this target.

Producer Reporting:

Strong reporting is essential for building public trust and driving continuous improvements in program outcomes. SB 0901 requires MDE in coordination with the PRO to set reuse rate and return rate targets in the program plan and achieve these targets within five years of plan approval. Within section .09 Record Keeping, Reporting and Production of Records, D (1) outlines which metrics producers must include in documents and records provided to the Department but fails to include reuse rates, return rates, and waste reduction rates. Requiring reporting of reuse rates, return rates and waste reduction rates is pivotal for tracking reusables and refillables in the state. **Please amend the draft proposed regulations to include reuse rates and return rates as well as progress toward waste reduction targets as required metrics for reporting.**

Categories of Covered Materials for Registration:

We further recommend that MDE establish two reporting sub-categories for all covered materials on the registration form that identifies if a covered material is intended for reuse or refill. These sub-categories will help facilitate data collection and will assist in easily tracking progress toward waste reduction, reuse and return targets. Capturing data on reuse and refill should be streamlined such that producers can easily indicate when their packaging supports a reuse or refill model, without requiring producers to complete additional onerous steps to provide this data.

Producer Responsibility Advisory Council:

We appreciate MDE's thoughtfulness in including diverse representation on the Advisory Council. **However, we note that as drafted, the Advisory Council does not explicitly include representation from experts in the reuse sector. This is a problematic oversight given the emphasis on reuse and waste reduction targets and the inclusion of reuse services under covered services.** Recycling and composting service providers are named on the Council and reuse providers should be named as well. Without this expertise, the Council risks overlooking key operational and systems-level considerations unique to reuse and refill models. Washington's packaging EPR codifies at least one member of their advisory board representing an *"an entity that develops or offers for sale covered materials that are designed for reuse or refill and maintained through a reuse or refill system or infrastructure or a statewide or national trade association that represents those entities;"* and Minnesota's packaging EPR law includes two such representatives. **We strongly urge MDE to specify that at least one reuse representative is included on the Advisory Council.**

Thank you for the opportunity to comment on MDE's draft proposed regulations. For any questions, please feel free to contact melissa@upstreamsolutions.org. We look forward to continuing to work with MDE to support the incorporation of a strong reuse vision in Maryland's packaging EPR program.

Sincerely,

Melissa Jung
Policy Officer
Upstream

Sydney Harris
Policy Director
Upstream

VETERAN COMPOST
From Combat to Compost

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December 26, 2025

Maryland Department of the Environment
1800 Washington Boulevard
Baltimore, MD

To Whom It May Concern,

This letter is in response to the public comments requested from small businesses by MDE in regards to proposed EPR regulations. Our company is very interested in these regulations and how they will impact Maryland's Compost Industry. My initial review of the regulations raised a couple of issues which I describe in bold:

- ‘“Compostable” or “compostable products” means packaging or paper products that meet the definition of compostable products as defined in COMAR 26.04.11.02” - **the underlying regulation defining compostables is very vague and outdated. I would suggest that we improve the definition of compostable products and am happy to provide examples of other states with framework we could copy**
- .04B(d) “Paper food service packaging that meets a labeling standard approved by the Department” **Why are paper compostable items being treated differently than other items when it comes to labeling? What is this “approved standard” that the Department will be using?**
- .12C(d) The Council stakeholders shall include, at a minimum: Organics recycling processors; - **We support this 100% Currently - compost collectors and processors are not represented on the Advisory Council**

We are proud to be Maryland's longest-serving food scrap composter. We hope that our small veteran-owned business can help Maryland reach its goal of a circular economy.

Please let me know if you would like any further information, I am happy to help.

Very Respectfully,

Justen Garrity
President
Veteran Compost