

April 1, 2024

Senator Virginia “Ginny” Lyons  
Chair  
Senate Committee on Health and Welfare  
115 State Street  
Montpelier, VT 05633-5301

**RE: H.B. 233 – An Act Relating to Licensure and Regulation of Pharmacy Benefit Managers**

Chair Lyons,

On behalf of URAC, thank you for the opportunity to provide comments in response to H.B. 233 related to the licensure and regulation of pharmacy benefit managers (PBMs). We appreciate your interest in addressing very meaningful concerns related to the cost of and access to prescription drugs in Vermont. However, we write today to comment on a provision in the legislation that exceeds the scope of appropriate PBM regulation and has serious implications for the quality of care provided to the people of Vermont by eliminating important tools for ensuring safe, quality care is provided by pharmacies.

The language in proposed new Section 3631(e) of Subchapter 4 related to pharmacy requirements goes beyond traditional PBM regulation and restricts a critical quality component in pharmacy accreditation that has been a longstanding tool for driving quality improvement and patient safety. Payers routinely require certain pharmacies to achieve accreditation from nationally recognized accreditors in order to validate quality and ensure their ability effectively handle complex drugs and patient cases. Prohibiting the use of accreditation will not further the goals of reducing costs or enhancing access to care. It serves only to weaken existing patient safety protections and quality improvement initiatives that benefit all Vermonters. We ask that the following be deleted from the bill:

(e) A pharmacy benefit manager shall not restrict, limit, or impose requirements on a licensed pharmacy in excess of those set forth by the Vermont Board of Pharmacy or by other State or federal law, nor shall it withhold reimbursement for services on the basis of noncompliance with participation requirements.

URAC is the independent leader in promoting health care quality through accreditation, measurement, and innovation. As an independent entity, URAC is not owned or controlled by a PBM in any way. URAC is a non-profit organization that uses evidence-based measures and develops standards through inclusive engagement with a range of stakeholders committed to improving the quality of health care. URAC accreditation is a symbol of excellence for organizations to showcase their validated commitment to quality and

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accountability. As the nation’s premier accreditor of pharmacies and PBMs, URAC has unique insight into the potential impacts and unintended consequences of laws regulating PBMs and, in particular, those that impact the role of accreditation in ensuring safe, quality care is delivered to patients.

## **I. The Critical Role of Specialty Pharmacy Accreditation**

As written, proposed new Section 3631(e) of the legislation would effectively prohibit using the accreditation process to implement any quality standards or safety programs for pharmacies beyond the basic requirements for licensure from the Vermont Board of Pharmacy. URAC values the critical role that state Boards of Pharmacy play in ensuring the delivery of quality care and medications to patients, but this role and its scope differs greatly from those of accreditation. While Boards of Pharmacy fulfill functions as a regulator and determine whether pharmacies meet minimum licensure thresholds, URAC accreditation builds on the foundational oversight of Boards of Pharmacy by adding a far more comprehensive review of a pharmacy’s ability to deliver quality services and care management to patients receiving complex, expensive medications in a consistent and reliable manner.

Unlike minimum licensure standards, URAC accreditation validates the operations and care management provided by pharmacies based on quality standards defined by national best practices. This differs from Boards of Pharmacy that focus on a much more limited scope of issues addressing licensure and the environment in which the pharmacy is dispensing drugs. Board of Pharmacy licensure standards on their own are insufficient to deliver high-quality care. In comments to a legislative study group studying pharmacy accreditation, America’s Health Insurance Plans wrote, “URAC’s accreditation standards, for example, include ensuring access to appropriate drugs, measuring consumer satisfaction, protecting consumer health information, patient adherence programs, and patient care quality measures. These accreditation standards enhance consumer protection and encourage pharmacy programs to improve operations and regulatory compliance activities.”<sup>1</sup> **The gap that exists between accreditation and minimum licensure represents meaningful steps that result in improved quality and safety.**

## **II. Accreditation Language Exceeds PBM Reform**

H.B. 233 is a response to a legitimate debate about regulating the practices of PBMs in areas such as access to therapies in different settings or from different pharmacies. As an accrediting entity, URAC has no position on what constitutes effective state regulation of PBMs nor the best manner of doing so. Some of the provisions of H.B. 233 may ultimately serve to benefit the people of Vermont

<sup>1</sup> North Carolina Department of Insurance, *Specialty Pharmacy Stakeholder Workgroup Report* (2022). <https://www.ncdoi.gov/documents/legislative-services/legislative-reports/specialty-pharmacy-report/open>.

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and strengthen access to prescription drug benefits, but we believe that proposed Section 3631(e) should be stricken as it exceeds the bounds of appropriate PBM regulation and effectively regulates non-PBM entities such as accreditors. We do not believe that the prohibition on accreditation requirements contained in the bill is a provision that will increase transparency, reduce costs, or improve safety. Rather, the likely effect of such a prohibition is a decrease in quality and safety. There is a legitimate debate that should occur as part of PBM regulation about the use of contracting tools, but this debate does not extend to accreditation. **Accreditation is a quality tool utilized to protect patients and ensure that every patient receives high-quality, high-value care. It does not address or relate to the concerns that the bill seeks to address with PBMs, it only serves to improve quality and safety for the people of Vermont.**

The goal of appropriately regulating PBMs is a laudable one, but we urge caution whenever legislators seek to restrict the ability to hold providers to reasonable best practices meant to protect patients from poor quality care. The result of such efforts is likely to be a state in which quality and safety are diminished when compared to neighboring states that have adopted PBM laws that do not include the prohibition on accreditation. For that reason, **many states have considered and rejected a prohibition against pharmacy accreditation standards.** For example, in 2021, the North Carolina General Assembly considered and rejected a similar prohibition in favor of a study that ultimately highlighted “the need for achieving accreditation to validate a specialty pharmacy’s commitment to consistent quality of care for patients on specialty medications.”<sup>2</sup> Rather than prohibiting the use of accreditation, the North Carolina study showed the importance of specialty pharmacy accreditation and its role in ensuring quality care.

### **III. Accreditation Ensures High-Quality Pharmacy Care**

The impact of such a prohibition is magnified in areas such as specialty pharmacy, where accreditation plays a critical role in ensuring access to safe and effective specialty pharmacy services. Given the complexity of specialty medications and the potential for serious side effects, pharmacies must deploy specific competencies in a reliable manner to promote and document positive clinical outcomes. Those pharmacies that have achieved URAC Specialty Pharmacy Accreditation have demonstrated their ability to safely dispense and effectively manage the care of patients who require increasingly complex medications. “Accreditation provides an independently validated recognition which demonstrates your organization’s commitment to high-quality patient care,” according to Rebecca Yoon, PharmD, with Vanderbilt University Medical

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<sup>2</sup> North Carolina Department of Insurance, *Specialty Pharmacy Stakeholder Workgroup Report* (2022). <https://www.ncdoi.gov/documents/legislative-services/legislative-reports/specialty-pharmacy-report/open>.

Center.<sup>3</sup> Others support this notion. Alicia Verret, PharmD, with Ochsner Health noted, “Accreditation is our organization’s external stamp of approval validating the quality of our services.” State regulators, payers, pharmacies, and patients all derive tremendous value from the accreditation process. **Organizations that achieve accreditation are less likely to deliver care that results in harm to patients as they have demonstrated their ability and capacity to care for complex patients receiving complex drugs.** Eliminating this important tool will provide no meaningful benefit to the people of Vermont, instead potentially subjecting them to ineffective care or care that results in harm.

We appreciate your willingness to take our views into consideration. However, we urge you to eliminate the language contained in proposed new Section 3631(e) that prohibits the use of accreditation standards in contracts between PBMs and pharmacy providers. Removing this language would be a meaningful step toward ensuring that H.B. 233 does not exceed the scope of appropriate PBM regulation or inadvertently jeopardize patient safety and the quality of pharmacies in Vermont. If you have any questions, please contact URAC’s Director, State Relations, Joshua Keepes at [jkeepes@urac.org](mailto:jkeepes@urac.org).

Sincerely,



Shawn Griffin, M.D.  
President and CEO of URAC

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<sup>3</sup> Rushabh Shah, *Digging Into Specialty Pharmacy Accreditation: Value, Credibility and Challenges*, American Society of Health System Pharmacists Official Podcast (2022), <https://www.ashp.org/Professional-Development/ASHP-Podcasts>