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Delivered via email: jmatthews@naic.org

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RE: NAIC Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Ms. Matthews,

On behalf of URAC, thank you for the opportunity to provide comments in response to the National Association of Insurance Commissioners' (NAIC) November 7 draft Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators. URAC applauds the NAIC for its ongoing commitment to advancing an important national dialogue on the role of PBMs and the appropriate regulatory response from state insurance departments. We are proud to have engaged with the NAIC on the issues of PBM accreditation and specialty pharmacy accreditation in recent years, discussing the value of accreditation and its critical role as a supplement to state regulation. While we appreciate the NAIC's desire to provide state insurance departments with effective guidance on issues related to PBM regulation, we write today to comment on a provision in the draft guidelines that encourages restrictions on the accreditation of specialty pharmacies despite the clear connection between specialty pharmacy accreditation and patient safety and quality. Specifically, we are concerned about the decision to include the pharmacy accreditation language found in Section 5(G)(4)(d) of the draft guidelines given that a majority of states have declined to adopt such restrictions due to the critical safeguards provided by the accreditation of specialty pharmacies. Recommending that states prohibit important patient safety standards such as specialty pharmacy 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 patients who rely on accredited pharmacies to provide high-quality care. We ask that the following be deleted from the draft guidelines:

> ~~(d) A pharmacy benefit manager may not require a pharmacy or pharmacist, as a condition for participating in the pharmacy benefit manager's network, to obtain or maintain accreditation, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or other relevant federal or state standards.~~

URAC is the independent leader in promoting health care quality through accreditation, measurement, and innovation. 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 accountability.

As written, the draft guidelines encourage states to effectively prohibit PBMs from using the accreditation process to implement any quality standards or safety programs for pharmacies beyond the basic requirements for licensure from the relevant state 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, specialty pharmacy 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, specialty pharmacy 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 required for those seeking to serve patients prescribed specialty medications. **The gap that exists between accreditation and minimum licensure represents meaningful steps that result in improved quality and safety.**

As an accrediting entity, URAC has no position on what constitutes effective state regulation of PBMs. Many of the provisions included in the NAIC's draft guidelines may ultimately serve to benefit patients and strengthen access, but we believe that proposed Section 5(G)(4)(d) should be stricken. We do not believe that the prohibition on accreditation requirements contained in the draft guidelines 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 in states choosing to adopt the language. For these reasons, a majority of states have chosen not to enact a specialty pharmacy accreditation restriction similar to the one contained in the NAIC draft regulation guidelines. URAC has been supportive of alternative approaches to ensuring that pharmacies have access to PBM networks while also assuring that PBMs have the ability to take steps to ensure patient safety and quality. States such as North Carolina have considered limits on accreditation requirements that prohibit requirements for multiple specialty pharmacy accreditations, but maintain the important role of specialty pharmacy accreditation by permitting PBMs to implement safety and quality measures that include requirements for accreditation from a single national accreditor. 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 the value of 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.**

The goal of appropriately regulating PBMs is a laudable one, but we urge caution whenever legislators or regulators 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. Accreditation is intended to be a supplement to basic regulation and

provides necessary oversight in many areas that are simply unaddressed by Board of Pharmacy requirements. As one example, in an article published in 2024 by the New York Times entitled "Hot Summer Threatens Efficacy of Mail-Order Medications," the potential effects of heat exposure on medications were highlighted. The report noted that increasing temperatures have exacerbated the long-term problem of ensuring that medications reach their intended patient at the appropriate temperature range, but highlighted that Boards of Pharmacy were ill-equipped to address this challenge. Conversely, accreditation standards provide enhanced standards for medication shipping and temperature control that supplement traditional regulatory approaches. Other areas where accreditation plays a meaningful role in supplementing Board of Pharmacy requirements include ensuring accurate and detailed communication with patients, as well as applying standards for medication distribution and performance measurement.

The impact of a prohibition against accreditation standards 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. **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.** As a tool of quality assurance, payors look to accreditation as an independent validation of excellence to ensure that their pharmacy network has the capacity to fully provide these highly specialized services. Eliminating this important tool will provide no benefit to patients, instead potentially subjecting them to ineffective care or care that results in harm.

We appreciate your willingness to take our views into consideration as well as your interest in addressing legitimate concerns about the role of PBMs. However, we urge you to eliminate the language contained in Section 5(G)(4)(d) of the draft guidelines 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 the draft guidelines do not exceed the scope of appropriate PBM regulation or inadvertently jeopardize patient safety and the quality of specialty pharmacies. If you have any questions, please contact URAC's Director, State Relations, Joshua Keepes at jkeepes@urac.org.

Sincerely,

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