January 28, 2020

Representative Michael Schraa  
Senator Jon Erpenbach  
Representative Joe Sanfelippo, Chair, Assembly Committee on Health  
Representative Tony Kurtz, Vice Chair, Assembly Committee on Health  
Distinguished Members of the Wisconsin Assembly Committee on Health  
Madison, WI 53708

Re: Opposition to AB 114 in Relation to Prohibiting Use of Accreditation by Pharmacy Benefit Managers

Dear Distinguished Members of the Wisconsin State Legislature,

On behalf of URAC, thank you for introducing this important piece of legislation in the continued effort to reduce the costs of prescription drugs. URAC appreciates the opportunity to provide comments about the role of accreditation in driving out the cost of poor-quality care.

For background, URAC is an independent, non-profit national healthcare organization that was founded in 1990 in response to the growing concern regarding the lack of uniform standards for utilization review. Since our founding, we have expanded our services and now offer more than two dozen accreditation and certification programs addressing numerous segments of the healthcare market including health plans, pharmacy operations, drug benefit management, medical management, telehealth, mental health parity and utilization management.

URAC has unique insight as it relates to drug benefits and drug benefit management as we are the premier accreditor of pharmacies and pharmacy benefit management (PBM) organizations. The nation’s leading PBMs hold URAC accreditation including CVS Caremark, Express Scripts, OptumRx, and PerformRx. URAC also accredits more than 400 licensed pharmacies as specialty pharmacies located across the country including CVS, Walgreens and your local University of Wisconsin Hospital and Clinics. Many of the pharmacies that have achieved URAC Specialty Pharmacy Accreditation are small, independent, community pharmacies.

We are concerned about the language proposed at § 649.30(2)(b) restricting the use of accreditation as it will risk subjecting patients to substandard care and potentially jeopardize the quality of care provided via lifesaving medications.

As you consider how best to grapple with the rising cost of prescription drugs and the role that PBMs play in the drug supply chain, we encourage you to ensure the highest level of quality is delivered to patients. We look forward to working with you in hopes of finding common ground on this important issue. Please do not hesitate to contact our Vice President of Government Relations and Policy, Aaron Turner-Phifer, at (202) 326-3957 or aturner-phifer@urac.org should you have any questions or want to discuss anything in detail.

Sincerely,

Shawn Griffin, M.D.

Shawn Griffin, M.D.  
President and CEO
Regulating Pharmacy Benefit Managers

As you are aware, Congress, the U.S. Department of Health and Human Services, the National Association of Insurance Commissioners, and nearly every state in the country are focused on the cost of prescription drugs and the role of PBMs. URAC has no position on what constitutes appropriate oversight nor the manner of state regulation of PBMs. URAC generally supports efforts to increase transparency for patients in our health care delivery system including efforts to better inform patients about the cost of their prescription drugs and a state’s authority to hold health plans and PBMs accountable for these efforts. For thirty years URAC has worked with the federal government and state regulators to augment their oversight of managed care organizations and providers. Given our role accrediting the quality of the nation’s leading PBMs and specialty pharmacies, we know it is possible for policymakers to increase their oversight while preserving the highest-standard for quality that patients deserve and expect. URAC is happy to work with the sponsors of this legislation and members of the respective committee considering it to support efforts to ensure quality care for millions of Wisconsinites.

Quality Concerns for Patients

URAC has serious concerns about the impact of the proposed text at § 649.30(2)(b):

2. PROHIBITIONS. A pharmacy benefit manager or a representative of a pharmacy benefit manager may not do any of the following:
   (c) Unless approved by the commissioner after consulting with the pharmacy examining board, require pharmacist or pharmacy accreditation standards or certification requirements in addition to, more stringent than, or inconsistent with any requirements of the pharmacy examining board.

This language is clearly targeted at payer’s and PBM’s use of accreditation for access to specialty drug networks. While there is a legitimate debate that should occur about the use of contracting tools to inappropriately steer patients to PBM-owned pharmacies, accreditation is a quality tool utilized by payers and PBMs to protect patients and ensure every patient receives high-quality, high-value care. URAC urges caution anytime policymakers seek to restrict a payer’s ability to hold network providers to reasonable best practices meant to protect patients from poor quality care. The use of accreditation as a requirement of provider contracts is deployed widely by plans for physicians and facilities to ensure the highest standard of care is provided to patients – pharmacy networks should be treated no different as patients deserve and expect no less.

Accreditation vs. Pharmacy Examining Board Oversight

The Wisconsin Pharmacy Examining Board and other state Boards of Pharmacy are fulfilling their function as a regulator and deciding if a pharmacy meets the minimum threshold to be licensed as a pharmacy and operate in their state. URAC accreditation, building on the foundational oversight of the Pharmacy Examining Board, is 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 (see Appendix).
URAC accreditation is a comprehensive review validating the operations and care management provided by pharmacies based on quality standards defined by national best practices. URAC’s accreditation is specific to those pharmacies dispensing specialty drugs. This differs from the Pharmacy Examining Board review which is focused on licensure and the environment in which the pharmacy is dispensing drugs. To date, the Pharmacy Examining Board does not have a specific definition for specialty drugs or specialty pharmacy as their reviews are broadly applied to all pharmacies regardless of the type of drug being dispensed.

In fact, URAC’s accreditation standards often reference the oversight authority of the jurisdictional Board of Pharmacy. For example, URAC standards require a pharmacy to ensure that its pharmacists are in fact duly licensed by the Board of Pharmacy and that all pharmacy personnel function within the legal limitations of scope of practice.

The language outlined at § 649.30(2)(b) implies that a review by the Wisconsin Department of Safety and Professional Services is sufficient to deliver high-quality care required for those seeking to serve patients prescribed specialty medication. Requirements by the Wisconsin Department of Safety and Professional Services are focused on the baseline environmental and professional qualifications that must be present to operate. However, by their very nature, a “specialty drug” requires a special skill set and technical capabilities that are different than the general approach for traditional drugs. In fact, the Wisconsin Department of Safety and Professional Services does not even have a definition for a “specialty pharmacy” nor does it define those skills required to ensure the safe dispensing of specialty drugs. The legislation’s language would ensure that patients in Wisconsin do not receive the same high-quality care that commercial, Medicaid, and Medicare patients in other states experience.

**Role of Specialty Pharmacy Accreditation**

Given the complexity of specialty medication and the potential for serious side effects, pharmacies must deploy specific competencies in a reliable manner to promote and document positive clinical outcomes. URAC’s Specialty Pharmacy Accreditation is structured around the idea that all pharmacies dispensing specialty drugs must do more than focus on the right patient, the right drug, at the right time. URAC believes the pharmacy should be focused on delivering the right result for patients. 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.

Public and private payers often seek to ensure that pharmacies within their networks are meeting industry standards by requiring accreditation. For example, specialty pharmacies manage and deliver pharmaceuticals that may require special handling, patient education, and clinical monitoring. A failure on the part of the specialty pharmacy to appropriately perform any aspect of the storage, delivery, education, or monitoring of a specialty drug might lead to patient safety issues as well as the inability of patients to receive a life-saving therapy. Therefore, commercial payers are focused on the quality of services delivered within their networks to protect patients and reduce the human and financial costs associated with poor quality. Organizations that fail to achieve accreditation have a greater potential to deliver care that results in real harm to patients as they have failed to demonstrate their ability and capacity to care for complex patients receiving complex drugs. As a tool of quality assurance, PBMs look for
an independent validation of excellence to ensure that their network has the capacity to fully provide these highly specialized services.

URAC prides itself on designing accreditation programs that are accessible to all organizations who wish to demonstrate their commitment to quality regardless of size or business model. URAC’s process for accreditation and pricing considers the varying business models that may be addressed by an accreditation program. Our nearly thirty years of experience evaluating the quality of healthcare organizations has taught us that neither size nor business model is a predictor of quality. This has been true with our experience accrediting specialty pharmacies across the country. To date, more than 400 pharmacies including many small, community pharmacies have pursued and achieved URAC Specialty Pharmacy Accreditation.

Accreditation as a Quality Tool

As highlighted, specialty pharmacy accreditation plays an important role in validating the abilities of pharmacies to effectively manage patients receiving specialty medications. Regardless of how health plans and PBMs build their networks, the value of accreditation does not change in that it is always a validator of quality uniquely focused on the skills and services required to appropriately care for patients.

Further, we acknowledge that the practice of “specialty pharmacy” is not limited to URAC accredited organizations nor is it defined exclusively by URAC or other accreditors. However, given the unique nature of specialty drugs and the potential impact on the life of a patient, we feel strongly that pharmacies that have validated their capabilities via accreditation are the most appropriate and best positioned to manage patients receiving treatment via specialty medications. This applies to any pharmacy regardless of business model. As evidenced by the various types of pharmacies that have achieved accreditation, any organization regardless of size or practice model that is committed to quality has the opportunity to demonstrate that commitment and achieve accreditation.

Accreditation is a rigorous process that requires a resource investment on the part of pharmacies. As such, we do not support redundant requirements that increase the administrative burden pharmacies encounter. URAC does not support the use of audits or additional credentialing criteria conducted by a Part D sponsor that is redundant to the accreditation achieved by the pharmacies. We believe that this function is best performed by an independent, third-party accreditor. To ensure transparency, URAC makes the information required to verify the accreditation status of an organization publicly available via the searchable directory on our website.

Conclusion

We support the Legislature’s efforts to address legitimate concerns about the cost of prescription drugs and the role of PBMs in the system. However, we encourage you to carefully consider any restrictions on a payer’s ability to build quality requirements into their contracts with providers. These efforts have long been allowed for providers who are part of a payer’s medical network and this effort is the foundation for our national efforts to move away from fee-for-service and to value-based care. Further, such a restriction would create a lower tier of quality for Wisconsinites than is delivered to other patients across the country. As such, we urge you to
strike the language outlined at § 649.30(2)(b) as you consider this important piece of legislation. Moving forward, we are happy to continue working with you to ensure we meet our shared goal of increasing transparency and protecting residents in Wisconsin from rising drug costs.
Appendix

URAC's Specialty Pharmacy Accreditation
Comparison Chart

URAC is the nation’s leading pharmacy quality organization and the leading accreditor of specialty pharmacies in the country. URAC’s Specialty Pharmacy Accreditation provides a comprehensive, independent assessment of a pharmacy’s ability to consistently provide high quality care. URAC’s Specialty Pharmacy Accreditation is the industry’s leading indicator of a pharmacy’s ability to manage patients with complex chronic diseases.

Pharmacies, stakeholders, and policymakers often inquire about the intersection between URAC’s Specialty Pharmacy Accreditation, the role of state boards of pharmacy, and the accreditation most hospitals achieve.

The chart below shows major areas of URAC’s Specialty Pharmacy Accreditation compared to the National Association of Boards of Pharmacy (NABP) Model Act on the practice of pharmacy and the general requirements of pharmacy services for hospital accreditation.

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<th>NABP Model Act</th>
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<td>Define Specialty Drug</td>
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<td>Define Specialty Pharmacy</td>
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<td>Onsite Audit</td>
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<td>Cold Chain Management</td>
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