

URAC Public Comments

May 28, 2019

**New Jersey Senate Commerce Committee
Trenton, NJ 08625**

**Attn: Kate Millsaps Wolfinger, Senate Democratic Staff; Laurine Purola, Senate Republican Staff
and Distinguished Members of the Senate Commerce Committee**

Re: Assembly No. 3717 Relating to Pharmacy Benefit Managers

URAC is an independent, national quality benchmarking organization focused on improving the care delivered to patients through accreditation, certification, and measurement. URAC was founded in 1990 in response to the growing concern regarding the lack of uniform standards for utilization review. Since our founding, URAC has expanded our services and we 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, and clinical integration, as well as health insurance and workers' compensation utilization management.

We recently changed leadership with the introduction of our new President and CEO, Dr. Shawn Griffin. As a trained family physician who spent years practicing in rural areas, Dr. Griffin has firsthand knowledge regarding the challenges patients and their families face gaining access to affordable drugs. URAC wants to thank Assembly members Raj Mukherji, Joann Downey, Eric Houghtaling, Jamel Holley, Matthew Milam and R. Bruce Land for sponsoring this important piece of legislation. We also want to thank Senators Linda R. Greenstein, Vin Gopal and Bob Andrzejczak, sponsors of the companion bill, S. 728. We greatly appreciate the opportunity to provide comments about URAC and the role of accreditation in driving out the cost of poor-quality care.

URAC is 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 accredits more than 300 licensed pharmacies as specialty pharmacies located across the country. Many of the pharmacies that have achieved URAC Specialty Pharmacy Accreditation are small, community, and regional pharmacies.

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 nor the manner of state regulation of PBMs. URAC generally supports efforts to increase transparency for patients in our healthcare delivery system including efforts to better inform patients about the cost of their prescription drugs and state authority to hold health plans and PBMs accountable for these efforts. For nearly 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, URAC is happy to work with the sponsors, members of this committee, and the Department of Health and Human Services to support their efforts in anyway we can.

Quality Concerns for Patients

URAC has concerns about the impact of the legislation's proposal of new section outlined starting at line 7 of page 4:

A pharmacy benefits manager or third-party payer shall not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to, the federal and State requirements for licensure as a pharmacy in this State.

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 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.

Accreditation vs. Board of Pharmacy Oversight

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 Boards of Pharmacy, is 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 Board of Pharmacy review which is focused on licensure and the environment in which the pharmacy is dispensing drugs. To date, Boards of Pharmacy do 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 proposed language on page 4 line 7 implies that a review by the state’s Board of Pharmacy is sufficient to deliver high-quality care required for those seeking to serve patients prescribed specialty medication. Requirements by the New Jersey Board of Pharmacy 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 New Jersey Board of Pharmacy 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 proposed language would ensure that patients in New Jersey 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.

Commercial payers and their pharmacy benefit managers (PBMs) 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 300 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 your 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. We are happy to work with the sponsors and members of this committee on language that preserves quality best practices while ensuring we meet our shared goal of increasing transparency and protecting residents in New Jersey 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.

	URAC	NABP Model Act	Hospital (Inpatient) Accreditation - Pharmacy Standards
Define Specialty Drug	✓		
Define Specialty Pharmacy	✓		
Onsite Audit	✓	✓	✓
Interactive Demonstration of Compliance	✓		
Staff Qualifications	✓	✓	✓
Clinical Staff Qualifications and Oversight of Specialty Drug Management	✓		
Drug Utilization Review	✓	✓	✓
Specialty Drug Management	✓		
Medication Storage, Dispensing and Disposal	✓	✓	✓
Adverse Event and Medication Error Management	✓	✓	✓
Cold Chain Management	✓		
Patient Education	✓	✓	✓
Medication Adherence Management	✓		
Ongoing Clinical Reassessments for Chronic Specialty Patients	✓		
Outcomes Reporting	✓		