

August 20, 2019

The Honorable Andrew M. Cuomo  
Governor of New York State  
NYS State Capitol Building  
Albany, NY 12224

Re: Opposition to S. 6531/A. 2836A in Relation to Prohibiting Use of Accreditation by Pharmacy Benefit Managers

Dear Governor Cuomo,

On behalf of URAC, I urge you to reconsider signing S. 6531/A.2836 into law as written due to concerns that it poses serious quality concerns for New Yorkers.

For background, URAC is an independent, non-profit national healthcare 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, 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, clinical integration, and health insurance and workers' compensation 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 and Walgreens. In New York alone, we accredit over 50 specialty pharmacies. Many of the pharmacies that have achieved URAC Specialty Pharmacy Accreditation are small, community, and regional pharmacies.

We are greatly concerned about the language outlined at § 280-a (5)(c) because it will almost certainly subject patients to substandard care and potentially jeopardize their ability to obtain lifesaving medications due to its prohibition on the use of accreditation.

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 recognize the pivotal role that accreditation plays as a quality management tool. As detailed in our comments below, we urge you to strike the language at § 280-a (5)(c) and look forward to working with you in hopes of finding common ground on this important issue. Please do not hesitate to contact me at (202) 326-3957 or [aturner-phifer@urac.org](mailto:aturner-phifer@urac.org) should you have any questions or want to discuss anything in detail.

Sincerely,



Aaron Turner-Phifer  
Vice President, Government Relations and Policy

Corporate Member Organizations

- America's Health Insurance Plans
- Academy of Managed Care Pharmacy
- American Association of Preferred Provider Organizations
- American College of Physicians
- American Health Quality Association
- American Hospital Association
- American Insurance Association
- American Medical Association
- American Nurses Association
- American Psychiatric Association
- Blue Cross Blue Shield Association
- Case Management Society of America
- National Alliance of Healthcare Purchaser Coalitions
- National Association of Insurance Commissioners
- Pharmaceutical Care Management Association

Peter Lund, M.D.  
Board Chairperson

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 nor the manner of state regulation of PBMs. We generally support 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 a state's 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 and specialty pharmacies, URAC urges you to reconsider adopting this bill as written to ensure that it does not sacrifice quality care for millions of New Yorkers.

## **Quality Concerns for Patients**

URAC has serious concerns about the impact of the legislation's proposal of new section outlined at § 280-a (5)(c):

*5. Contract provisions. No pharmacy benefit manager shall, with respect to contracts between such pharmacy benefit manager and a pharmacy, or alternatively, such pharmacy benefit manager and a pharmacy's contracting agent, such as a pharmacy services administrative organization:*

*(c) require a pharmacy to meet any pharmacy accreditation standard or recertification requirement inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy.*

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.

## **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 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

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 language outlined at § 280-a (5)(c) implies that a review by New York State Office of the Professions is sufficient to deliver high-quality care required for those seeking to serve patients prescribed specialty medication. Requirements by the New York State Office of the Professions 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 York State Office of the Professions 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 New York 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 General Assembly'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. As such, we urge you to strike the language outlined at §280-a (5)(c) prior to signing 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 New York 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.

	<b>URAC</b>	<b>NABP Model Act</b>	<b>Hospital (Inpatient) Accreditation - Pharmacy Standards</b>
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	✓		