August 7, 2019

Director of Regulatory Affairs
The Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, Maryland 21202

Re: Draft Changes to Title 31 as it relates to Pharmacy Benefit Managers

Dear Director,

Thank you for introducing this important proposed regulation in the continued effort to reduce the cost of prescription drugs. URAC greatly appreciates the opportunity to provide comments about the role of accreditation in driving out the cost of poor-quality care prior to this proposed regulation being published in the Maryland Register.

For background, URAC is an independent, non-profit national healthcare organization focused on improving the care delivered to patients through accreditation, certification, and measurement. As an independent accreditor we believe it would be improper and do not offer any consulting services. URAC was founded in 1990 in response to the growing concern regarding the lack of uniform standards for utilization review. Our board is comprised of experts representing the many diverse stakeholders across health care including physicians, nurses, pharmacists, pharmacy benefit managers, health plans, hospitals, employers and regulators. 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.

As a trained family physician who spent years practicing in rural areas, I have firsthand knowledge of the challenges patients and their families face gaining access to affordable drugs. As the first physician to lead URAC, it is with this perspective that I have sought to ensure we as an organization are promoting high-quality, affordable care.

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 across the country. Many of the pharmacies that have achieved URAC Specialty Pharmacy Accreditation are small, community, and regional pharmacies.

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 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) 962-8801 or sgriffin@urac.org should you have any questions or want to discuss anything in detail.

Sincerely,

Shawn Griffin, MD

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, URAC is happy to work with Maryland Insurance Administration to support their efforts in any way we can.

Quality Concerns for Patients

URAC has concerns about the impact of the draft regulation's proposal of new section outlined at § 04 Noncompliant Contract Terms (A)(4)(a):

> *A. A filing entity may have a contract or amendment to a contract disapproved if the contract or amendment contains or uses any language that:*
>
> *(4) Except when dispensing covered drugs under paragraph (a) of this section, requires a pharmacy to have any type of certification or accreditation standard other than the licensing requirements of the Maryland Board of Pharmacy or Insurance Article § Annotated Code of Maryland.*
>
> *(a) A PBM may require additional certification or accreditation standards to dispense a covered drug to beneficiaries of Medicare or Medicaid, or as required by law to dispense specialty or compounding drug.*

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.

Furthermore, while the proposed language allows for accreditation in the dispensing to beneficiaries of Medicare or Medicaid, this does not cover people who are insured via employer-sponsored insurance which accounts for 56 percent of people in the state of Maryland as of 2017[1]. In fact, in 2017, which is the most recent year for which comprehensive insurance coverage data is available, only 30 percent of Marylanders were covered by Medicare or Medicaid. Limiting the use of accreditation to only this select group could potentially create an inequitable system of care in which one's ability to obtain high-quality services was solely dependent on their type of insurance. Simply put, this requirement as drafted, creates a system where commercially insured patients will receive a lower standard of 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.

[1] Kaiser Family Foundation. (2019). Health Insurance Coverage of the Total Population. Retrieved from https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

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While we support the proposed regulation's allowance for additional accreditation standards to dispense specialty drugs or compounding drugs, this does not account for traditional medications. By their nature, traditional medications typically don't have the same level of inherent risk as a specialty drug but given the prevalence at which they are prescribed, potential errors in their dispensing could have grave consequences. For example, many pharmacies now have the option to mail certain prescriptions, such as those used to treat chronic illness like diabetes. While this option is convenient for patients and usually helps them save money, a mail service pharmacy practice requires several additional key processes to ensure the patient receives the right drug at the right time. For example, mail service pharmacies generally utilize automated technology in the dispensing process. It is key that this machinery and equipment is properly maintained through routine cleaning, calibration, and auditing. Distributing medications through the mail requires additional checks as well. Packaging must ensure that medications remain within the manufacturer recommended temperature range or they risk becoming ineffective. In addition, pharmacies should have the ability to track packages once they leave the pharmacy to ensure delivery and avoid loss or theft and should have processes to manage shipments based on projected delays due to weather. Because patients who use mail service pharmacies do not have the ability for in-person counseling, a mail service practice must also have the ability and availability to provide important medication-related education and answer patient questions.

As such, we urge you to consider the impact of language that determines one's ability to receive care from a pharmacy that has demonstrated their commitment to quality solely based on their insurer and the type of medication they have been prescribed.

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. More specifically, 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 outlined at § 04 Noncompliant Contract Terms (A)(4) implies that a review by the Maryland Board of Pharmacy is sufficient to deliver high-quality care for all patients. Yet, in the next sentence, the Insurance Administration seems to acknowledge that oversight by the Maryland Board of Pharmacy is in fact not enough for Medicare or Medicaid beneficiaries nor in regard to specialty drugs. This proposed regulation would ensure that patients with commercial insurance in Maryland do not receive the same high-quality care that Medicaid and Medicare patients experience.

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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 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.

Role of Mail Service Pharmacy Accreditation

Many pharmacies now have the option to mail certain medications, such as common long-term maintenance medications[2]. While mailing prescriptions saves patients a trip to the pharmacy, there are several inherent risks involved due to the lack of in-person pharmacist-patient interaction. As such, mailing a prescription may involve up to 16 quality checks to ensure accuracy[2]. Many elements of mail-service pharmacies are automated, but some state pharmacy boards require pharmacists to perform a manual check for every single prescription.

Like with specialty pharmacy, URAC's Mail Service Pharmacy Accreditation is structured around delivering the right results for patients and ensuring optimal outcomes. Pharmacies that have achieved URAC's Mail Service Pharmacy Accreditation have demonstrated their ability to validate temperature management throughout the distribution process; manage and track packages to ensure accurate delivery; document maintenance of machinery and equipment including cleaning, calibration, and auditing; and provide 24/7 access to a clinician to answer clinical questions. One of the most seminal components of mail service pharmacy is managing the temperature of medications during the distribution process. Given the potential for rendering the medication ineffective and/or risking severe side-effects if a drug is not maintained at its appropriate temperature, mail-service pharmacies must provide test results that confirm validation that their medication packaging materials and processes maintain proper temperature ranges for different geographic locations and temperature profiles. In

[2] Daily, L. (2019). Should You Switch to a Mail-Order Pharmacy? Here Are the Factors to Consider. Retrieved from https://www.washingtonpost.com/lifestyle/home/should-you-switch-to-a-mail-order-pharmacy-here-are-the-factors-to-consider/2019/01/07/8b56f87a-0ede-11e9-8938-5898adc28fa2_story.html?utm_term=.8106d264e422

addition, a failure on the pharmacy to account for extreme weather or other extenuating circumstances that could result in a delay in distribution, which poses a risk to patient safety and could impact their ability to receive a needed medication. Having a validated distribution process that manages temperature and logistics is only one aspect of mail service, but given the complexities involved, it is a key component of quality.

Accreditation as a Quality Tool

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 and mail service pharmacies across the country. To date, more than 400 pharmacies including many small, community pharmacies have pursued and achieved URAC Specialty Pharmacy Accreditation and another 70 have achieved URAC Mail Service Pharmacy Accreditation.

As highlighted, specialty pharmacy accreditation plays an important role in validating the abilities of pharmacies to effectively manage patients receiving specialty medications. In addition, mail service pharmacy accreditation demonstrates one's commitment to quality in this increasingly popular distribution channel for pharmacy benefit management. 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 specialty pharmacy and/or mail service pharmacy accreditation, any organization regardless of size or practice model that is committed to quality can 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 believes 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. URAC believes any effort to reduce the price of pharmaceuticals should carefully consider the

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risk to patient safety. We are concerned that language restricting the use of accreditation will lead to a lower standard of care being delivered to Marylanders. Accreditation has long been used as a component 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 the respective committees on language that preserves quality best practices while ensuring we meet our shared goal of increasing transparency and protecting residents in Maryland from rising drug costs.

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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	✓		