February 19, 2019

Seema Verma
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC, 20201

RE: CMS-9926-P

Dear Administrator Verma,

On behalf of URAC, I respectfully offer our comments in response to the proposed rule updating the benefit and payment parameters for qualified health plans (QHPs) participating on the Exchanges as established under the Patient Protection and Affordable Care Act (ACA).

URAC is a nationally recognized, non-profit accreditation organization focused on advancing healthcare quality and protecting consumers as advocates for patient care. Our standards help to assure that patients have access to high quality care and that the organizations that serve them have the foundational operations in place to provide such. We have nearly three decades of experience accrediting managed care and provider organizations, including those providing pharmacy services. URAC is a deemed accreditor of QHPs and the nation’s leader in pharmacy quality. We accredit the top pharmacy benefit managers (PBMs) in the nation including CVS Caremark, Optum Rx, Express Scripts, and Prime Therapeutics LLC. As the leading accreditor of pharmacy quality management, URAC has unique expertise as it relates to the management of both medical and pharmacy benefits.

URAC supports CMS’s efforts to reduce regulatory burden, increase flexibility and improve affordability. We are encouraged by the continued efforts of HHS to address rising prescription drug costs while ensuring consumers have access to high quality care. URAC recognizes that the increased flexibility for issuers to modify their formularies during the plan year may help reduce unnecessary expenditures on prescription drugs, but this change in policy must maintain existing protections for patients. Our experience setting standards in this area has shown that there is the potential to disrupt patient care plans whenever a formulary change occurs. This disruption could occur under the guise of a decision to add or drop a drug from coverage or a change in a formulary tier. These disruptions hold the potential to adversely affect patients and as such, it is important that enrollees, their prescribers and pharmacies receive sufficient advance notice prior to any formulary changes.

Given our expertise, URAC is confident that mid-year formulary changes can be made in an effective manner, however, it is important that the criteria by which formulary changes are enacted first and foremost consider the safety of patients. PBMs should have a clearly defined process to review the clinical appropriateness of making a generic substitution in a timely manner. URAC urges HHS to consider requiring issuers to include a disclosure notice in their plan materials at the start of the plan year informing enrollees that mid-year formulary changes are permitted. This notice should disclose that beneficiaries may be subject to different cost-sharing arrangements as a result of changes to the formulary and more broadly, inform enrollees about what factors are considered when designing a formulary.

Peter Lund, M.D.
Board Chairperson
Shawn Griffin, M.D.
President and CEO
URAC’s accreditation standards require drug therapies to first be evaluated for their safety and efficacy as this is the most important component of formulary design. Only after therapeutic appropriateness has been established may an organization consider the economic implications of placing a certain drug therapy on the formulary. URAC encourages CMS to explicitly state in the final rule or subsequent guidance that financial factors can only be considered after a drug has been deemed safe and medically appropriate to ensure consumer protection.

URAC supports the proposal to require issuers to provide written notification to plan enrollees at least 60 days prior to removing a brand-name drug from a formulary or moving it to a different cost-sharing tier. Furthermore, we encourage HHS to consider requiring a 60-day notification to prescribers and all in-network pharmacies prior to the effective date of the change. This is consistent with the National Association of Insurance Commissioners (NAIC) Health Carrier Prescription Drug Benefit Management Model Act (Model Act) which was last revised in 2018. The NAIC Model Act requires all notices for changes in formularies that impact prescription drug benefit coverage or PBM administration to include in plain language the potential for formulary changes to modify out-of-pocket costs and the need to consider medically appropriate alternatives. Additionally, NAIC’s suggested notice upon change in formulary design also includes information encouraging enrollees to periodically review their health plan’s formulary.

URAC’s experience has taught us that patients, caregivers, and providers must be clearly informed about how to request coverage of their original prescription through an appeal or exception process. Notification of access to the appeal and exception processes should be included as part of the advance notice of a formulary change and should include explicit time frames for each stage of the resolution. This information should be clearly communicated by the issuer when notice of an impending formulary change is made. While disruption may occur, we have found that timely notification coupled with access to the appeal and exception processes is the best way to protect patients from poor quality and adverse events.

While not addressed in the proposed rule, URAC believes that PBMs should have the ability to make immediate changes to a formulary when there is a concern for patient safety without the 60-day advance notice period. The ability to make changes to the formulary in response to identifying urgent patient safety concerns like a recall by the U.S. Food and Drug Administration (FDA) is of utmost importance. While an advance notice is preferred, there may be instances in which it is not practical given the imminent risk to patient safety. In response to urgent safety concerns, issuers should have the ability to make formulary changes and send a notice to all affected patients, pharmacies and prescribers in a timely fashion.

URAC believes that there needs to be a balance between access to high quality care and the management of costs. We support the increased flexibility proposed for issuers to incentivize the use of generics when coupled with advance disclosure notices and access to the appeal and exception processes. Given our role as advocates for high quality patient care, we want to ensure that any changes made to the current prescription drug benefit structure considers the impact that it will have on patients. As HHS continues to explore ways to manage the growing costs of prescription drugs, please do not hesitate to call on URAC as a resource. We stand ready and willing to assist.

Sincerely,

[Signature]

Shawn Griffin, M.D.
President and CEO