FROM THE NAIC CONSUMER REPRESENTATIVES

December 18, 2020

To: Regulatory Framework (B) Task Force and Ms. Jolie Matthews

RE: Consumer Representatives' Comments on the Pharmacy Benefit Manager Licensure and Regulation Model Act

On behalf of the undersigned Consumer Representatives to the National Association of Insurance Commissioners (NAIC), we appreciate the opportunity to provide comments to the NAIC's Pharmacy Benefit Manager Licensure and Regulation Model Act. Pharmacy benefit managers (PBMs) play a critical role in the drug pricing, access, and delivery system. As such, their actions have a profound impact on consumer access and affordability.

While we appreciate the opportunity to participate in the subgroup's process, we are concerned that the Model Act alone will not provide states that wish to go further in their regulation of PBMs, direction and options that may be available to them. We recommend a deeper discussion of these issues among regulators and welcome the opportunity to participate in development of a white paper (which was suggested during the PBM subgroup process) and in other NAIC venues that seek to identify regulatory solutions to prescription drug price, access, and affordability challenges. To facilitate this process, we urge the B Committee to allow the PBM Regulatory Issues (B) Subgroup to continue its work, with a modification of its existing charge to reflect that the Subgroup's work would go beyond the development of a Model Act.

Please see below for recommendations for inclusion in the final version of the model law as well as recommendations for how the NAIC can continue its work in this important area.

The PBM Subgroup Should Reconvene to Discuss Implications of the Draft Model Law in Light of the Supreme Court Decision in *Rutledge vs. Pharmaceutical Care Management Association*

The much anticipated decision by the U.S. Supreme Court in *Rutledge vs. Pharmaceutical Care Management Association* on December 10, 2020 changes the dynamics of state regulation of PBMs. The NAIC model law should, therefore, go back to the PBM subgroup to discuss implications of that decision and potential changes to the model. Throughout the model law process, the breadth of PBM regulatory options available to states was largely unknown as the Supreme Court grappled with what actions are preempted by ERISA. In *Rutledge*, the Supreme Court – in a unanimous eight to zero decision – upheld Arkansas's PBM law, which requires PBMs to pay pharmacies at least as much as what the stores pay to wholesalers to obtain drugs. The Court held that the Arkansas law is "merely a form of cost regulation" and thus not preempted by ERISA. The implications of the decision are significant, not only for states that have or are considering adopting similar reimbursement protections for pharmacies, but for a wide range of regulatory interventions that clamp down on a range of questionable PBM business practices.

The NAIC Should Undertake Development of a White Paper on PBM Regulation and Create More Opportunities for Discussion of Medication Access and Affordability Policy Solutions

Regardless of how the *Rutledge* decision affects the trajectory of the model law, it was clear from the subgroup discussion and resulting final product that there is not currently national consensus on the approach to PBM regulation, particularly in the areas and topics relegated to the optional regulation provisions in Section 8. It is important that the NAIC continue to work on this issue as legislative and regulatory approaches to rein in drug pricing emerge. We urge NAIC to take up a suggestion made at the outset of the PBM model law process to

undertake development of a white paper. The white paper would allow the NAIC to better analyze and assess the role that PBMs play in the provision of prescription drug benefits and to identify and describe emerging state regulatory approaches that curb the PBM practices that contribute to high drug prices and insurance affordability challenges. The white paper should address the breadth of topics that were ultimately left out of the NAIC PBM model law, including transparency and reporting requirements; fiduciary duty and other business practices provisions; and consumer cost sharing and access. In addition, given the NAIC's commitment to addressing disparities in healthcare access based on race and ethnicity, a white paper should also assess policy solutions that address the disproportionate impact of high drug prices on communities of color. The process for developing the white paper should include a range of perspectives and expertise, including consumer voices.

The Following Additional State Citations Be Added to the Drafting Note in Section 8

We appreciate the inclusion of examples of state legislative and regulatory approaches to PBMs in the drafting note to Section 8. In addition to the statutes and regulations listed in the draft model law, we believe the following should be added:

- Washington PBM law, RCW 74.09.215 and Connecticut PBM law, CT Public Act No. 18-41 (2018) (providing examples of transparency provisions, including annual PBM reporting requirements to regulators and/or state legislative bodies).
- Connecticut PBM law, CT Public Act No. 18-41 (2018) (providing an example of enforcement mechanisms and penalties for statute violations).
- Nevada PBM law, NRS 439.915 (2017) (regulating PBM "business practices," including requiring a duty for PBMs to act in good faith and in the best interest of any third party with whom it has contractual relationship, including health plans).

Finally, we very much support the broader work of the NAIC – through the B Committee's Health Innovations Working Group and the Regulatory Framework Task Force – to delve deeper into state regulatory responses to the growing drug pricing and affordability challenges faced by consumers, including highlighting innovative solutions that balance price, patient access, and affordability. The PBM subgroup's decision to limit the scope of the model law should be revisited, particularly following the *Rutledge* decision and growing urgency to rein in prescription drug costs as the recession worsens. This must include perspectives from a diverse set of regulator and non-regulator stakeholders on some of the more challenging ideas presented during the model law process, which were not fully discussed. Though it may not have been appropriate to allow discussion of ideas and provisions raised by the range of non-regulator interested parties – including the Consumer Representatives – given the eventual limited scope of the model PBM law, we believe that these ideas and voices should be considered in future venues as the NAIC continues to grapple with this issue.

For any questions, please contact Amy Killelea (akillelea@nastad.org).

Sincerely,

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