February 2, 2023

Via email: andria.seip@iid.iowa.gov

Andria Seip
Iowa Insurance Division
1963 Bell Avenue, Suite 100
Des Moines, IA 50315

Proposed Rule RE: Amending Chapter 59, "Pharmacy Benefits Manager", Iowa Administrative Code (ARC 6825C)

Dear Ms. Seip:

The National Association of Chain Drug Stores (NACDS) and the National Association of Specialty Pharmacy (NASP) are writing jointly to express appreciation for the Iowa Insurance Division's ("Division") promulgation of rule changes to Chapter 59, "Pharmacy Benefit Managers" ("PBMs") in accordance with 2022 Iowa Acts, House File 2384, Section 22. NACDS represents 14 member companies operating nearly 500 pharmacies in Iowa. NASP is a 501(c)(6) non-profit trade association representing all stakeholders in the specialty pharmacy industry.

Supporting policies that create a fair and open pharmacy marketplace is a top priority for both NACDS and NASP, and our members are encouraged by the steps being taken in Iowa to address anticompetitive PBM practices. We believe that the correct classification of specialty drugs in the implementation of the PBM rule will be critical to ensuring the intent of the underlying law.

For this reason, NACDS proposes that the Division adopt the following definition of "specialty drug":

> "Specialty drug" means a prescription drug that is prescribed for specialized treatment of chronic or rare afflictions that requires special handling, administration, dispensing, or monitoring**. ~~; or that is a high-cost oral or injectable medication for nondiabetic use.~~ ~~As used in this chapter, a specialty drug is not a brand-name or generic drug~~**.

The definition of specialty drugs and the agents that are included in this category continues to evolve and varies widely across health plans. As a method for defining and categorizing specialty drugs, some plans have developed definitions that place drugs on the specialty drugs list when the total monthly cost of that drug exceeds a specified amount. However, some high-cost drugs are not specialty drugs nor dispensed by specialty pharmacies as they lack the need for complex patient management services provided by specialty pharmacies. NASP and NACDS believe that the definition for specialty drugs should be focused on the clinical aspects of these drugs (i.e., route of administration, storage requirements, handling of the product, and the need for trained pharmacy staff supervision), which would allow for more accurate classification and placement on a specialty drug list.

While the cost of specialty drugs continues to be a growing concern, it is not a suitable tool to use for classification purposes. When using cost as a determining factor for classifying specialty drugs, there is significant risk that some drugs will be inaccurately classified as specialty, while others that are truly specialty drugs will be inaccurately excluded. When looking at the number of specialty drugs commonly used to treat complex, chronic, and progressive

medical conditions, several of these drugs would not be included on the specialty drug lists as they would not meet the established cost thresholds.

In addition to removing cost as a qualifier to determine the categorization of specialty drugs, the definition contained in the proposed regulation provides limiting modifiers that would exclude brand or generic drugs from the definition of specialty drugs. Most specialty drugs ARE brand name drugs some are now generic, with more generic or biosimilar specialty drugs expected in the future. Excluding brand or generic drugs from the definition of specialty drugs limits the applicability of the law as it relates to rebate reporting by PBMs. Removing the reporting of specialty brand name drugs or generic drugs, as the current definition in the regulation would allow, will create loopholes in reporting requirements by PBMs, which goes against the intent of the law which states rebates mean "**all** discounts or other negotiated price concessions."

NACDS and NASP thank the Division for this opportunity to share our perspectives on this rule making and overall PBM reform. For questions, please contact Sandra Guckian, NACDS' Vice President, State Pharmacy and Advocacy, at sguckian@nacds.org or Taryn Couture, Director of Government Relations, Powers Pyles Sutter & Verville at Taryn.Couture@PowersLaw.com.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
NACDS President and Chief Executive Officer

Sheila Arquette, RPh
NASP President and Chief Executive Officer

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

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The National Association of Specialty Pharmacy (NASP) is the only national association representing all stakeholders in the specialty pharmacy industry. NASP members include the nation's leading specialty pharmacies, pharmaceutical and biotechnology manufacturers, group purchasing organizations, patient advocacy groups, integrated delivery systems and health plans, technology and data management vendors, logistics providers, wholesalers/distributors and practicing pharmacists, nurses, and pharmacy technicians. With over 170 corporate members and 3,000 individual members, NASP is the unified voice of specialty pharmacy in the United States. Please visit NASPnet.org.