January 22, 2016

Jolie Matthews
Senior Health Policy Advisor and Counsel
National Association of Insurance Commissioners
444 North Capitol Street, NW
Suite 700
Washington, DC 20001

RE: NACDS Comments on the Health Carrier Prescription Drug Benefit Management Model Act

Dear Ms. Matthews:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide commentary to the National Association of Insurance Commissioners’ (NAIC) as you consider possible revisions to the Health Carrier Prescription Drug Benefit Management Model Act. We understand that NAIC has yet to propose specific changes, but has identified several general areas of potential changes to the model act.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS’ chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

Formulary Transparency, Accuracy and Disclosure

The first areas in which NAIC’s possible changes will focus are transparency, accuracy, and disclosure regarding prescription drug formularies and formulary changes during a policy year.

NACDS supports increased transparency between plans and participating neighborhood pharmacies, such as including in contracts clearly defined drug pricing methodologies, routinely updating drug pricing, and allowing pharmacies to contest changes in their reimbursement. Contract pricing terms should be clear, objective, and consistent with both marketing and pricing practices. Such rules would encourage pharmacy participation, meaning increased access and options for patients, ultimately leading to improved health and reduced healthcare costs.

To address concerns with transparency in pricing, NACDS suggests that NAIC consider the following language for Section 5 of the Model Act (Requirements for the Development and Maintenance of Prescription Drug Formularies and Other
Pharmaceutical Benefit Management Procedures) for establishing drug formularies and transparent dealings with participating pharmacies:

(A) For the setting of prescription drug reimbursement benchmarks, including maximum allowable cost (MAC) lists, the health carrier shall include in contracts with pharmacies information regarding which of the national compendia or other drug pricing source is used to obtain pricing data used in the calculation of the reimbursement amount and shall:

1. Make price adjustments at least twice a month and shall provide pharmacies with prompt notification of any changes or additions made to reimbursement lists and rates at that time, except when a price for a drug changes by more than 100%, in such cases the price adjustment for that drug shall be made within three business days of the change in price; and

2. Provide a process for a pharmacy provider to comment on, contest, or appeal the prescription drug reimbursement amount, including a process to allow pharmacy providers to submit 200 claims per appeal, in an Excel file, containing all National Drug Codes (NDCs) within the Generic Product Identifier (GPI). The right to contest should be limited in duration and shall provide for retroactive payment in the event it is determined that the reimbursement amount has been calculated incorrectly.

   i. If the challenge is successful, the health carrier shall make an adjustment in the drug price to the date of the originally challenged claim, and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the managed care organization or pharmacy benefit manager, as appropriate.

   ii. A network pharmacy retains the right to collect or not collect additional appropriate co-payments from a patient after adjustments in the drug price after a successful challenge.

3. The health carrier shall make all applicable price lists, including all changes in the price of drugs, available to network pharmacies upon request in a readily accessible and usable format, such as Excel, CSV, TXT, or Comma Delimited file which contains a complete list of the drug name, NDC, package size, per unit price, strength of drug, GPI, and Generic Code Number (GCN). In the event there are multiple reimbursement lists under the same contract, the contract shall identify which lists are appropriately applicable.

(B) A health carrier shall also include in contracts with pharmacies a process for no less frequent than once a week updates to pharmacy product pricing files used to calculate prescription prices that will be used to reimburse pharmacies.
(C) Generic Predictability: A health carrier shall provide a contractual commitment to deliver a particular average reimbursement rate for generics. The average reimbursement rate for generics (e.g., “generic effective rate”) shall be calculated using the actual amount paid to the pharmacy (such as through patient co-pays and health carrier reimbursement), excluding the dispensing fee, and shall not be calculated solely according to the amount allowed by the plan and shall include all generics dispensed, regardless of whether they are subject to MAC pricing. The health carrier shall disclose to the network pharmacy the methodology used in determining the generic effective rate.

(D) A health carrier may not charge a transaction fee, or any fees associated with processing or adjudicating a claim transaction that are not specified in the contract, for claims submissions provided in an electronic format by a healthcare provider.

(E) For purposes of this Act:

1. “Maximum Allowable Cost (MAC) price” means a maximum reimbursement amount for a group of therapeutically and pharmaceutically equivalent multiple source drugs that are listed in the Food and Drug Administration’s (FDA) “Approved Drug Products with Therapeutic Equivalence Evaluations” (Orange Book), and for which there are no fewer than three nationally-available equivalent drug products. For the purposes of this definition, nationally available shall mean that such products are available for purchase by pharmacies or chain operated warehouses in sufficient supply from national pharmaceutical wholesalers and are not obsolete or temporarily unavailable. Obsolete means that such products may be listed in the national pricing compendia but are no longer actively marketed by the manufacturer or labeler. Temporarily unavailable means that such products are experiencing short term supply interruptions for which only inconsistent or intermittent supply is available in the current marketplace.

2. A MAC shall be:

   i. Established for any drug with at least three (3) or more therapeutically equivalent, multiple source drugs as determined by the FDA or when only two products are available during a generic exclusivity period as defined by Federal statute at 21 USC §355 with a significant cost difference; and

   ii. Determined using comparable drug prices obtained from multiple nationally recognized comprehensive data sources including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are nationally available and available for purchase locally by multiple pharmacies in the state. A MAC shall be established for a product using only equivalent drugs as determined by the FDA.
Requiring fair and transparent contractual terms related to pharmacy pricing will benefit both pharmacy providers and patients by providing a clearer understanding of prescription drug costs.

NACDS has advocated for, and continues to support formulary transparency to consumers within the context of the Medicare Part D program and the health insurance exchanges. We encourage NAIC to continue with their current transparency efforts, as well as aligning their transparency efforts with those embodied within Part D and the health insurance exchanges.

We believe it is important for NAIC to continue with its policy to require health carriers to use formulary lists that are up-to-date, accurate, and include a complete list of all covered drugs. We support NAIC in continuing to make formulary lists easily accessible and understandable to consumers in an electronic format, and in writing, upon request.

We urge NAIC to consider requiring health carriers to include within their formularies information on any drug tiering structure that the plan has adopted and any restrictions on the manner in which a drug can be obtained. Moreover, health carriers should also be required to develop an electronic tool for customers to determine their prospective cost sharing for a given customer’s drug regimen, similar to the Medicare Part D plan finder tool and the formulary lookup tool for exchange plans. We believe these changes would improve transparency and make it easier for consumers to choose the best coverage available to them.

**Tiered Formularies and Discriminatory Benefit Design**

As NAIC addresses the issue of tiered formularies, we support the use of four drug tiers: generic, preferred brand, non-preferred brand, and specialty drugs. These are fairly standard drug tiers within the industry.

Focusing on preventing discriminatory benefit design, we support the efforts that CMS has taken within the context of the exchanges in preventing discriminatory drug benefits designed to discourage those with chronic diseases from obtaining coverage. We encourage NAIC to align their efforts with those of CMS. Accordingly, insurance regulators should be empowered to perform an outlier analysis in which plans are compared and flagged when identified as outliers. Outliers would be plans with an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia (USP) category and class.

Second, insurance regulators should be given the authority to review plans’ prescription drug coverage to analyze the availability of drugs recommended by nationally-recognized clinical guidelines used in the treatment of specific listed medical conditions. CMS, for example, has focused on the following conditions: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia. In addition to analyzing the appropriate coverage of drugs recommended
by the clinical guidelines, any review should also analyze cost-sharing requirements associated with these drugs so that they are not used to dissuade consumers with such conditions from enrolling in a given plan.

Third, insurance regulators should have the power to conduct reviews of plans’ tier placement of prescription drugs that are recommended for treating certain chronic and high-cost medical conditions. Such a review would address situations when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Regulators should have the authority to review plan tier placement to determine whether plans are consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

NACDS supports these three measures to ensure that patients with costly, chronic illnesses have access to the medications that they need. We believe that greater access to drugs will lead to better patient healthcare outcomes.

Defining and Categorizing Specialty Drugs

It is important that NAIC take care in defining specialty drugs. The definition of specialty drugs and the agents that are included in this category are evolving and vary widely across health plans. As a method for defining and categorizing specialty drugs, most states and plans develop definitions that will include drugs on the specialty drugs list when the total monthly cost of that drug exceeds a specified amount. Community pharmacies have concerns with proposed definitions of specialty drugs that are based on monthly prescription cost, and believe that the definition for specialty drugs should be primarily focused on the clinical aspects of these drugs (i.e. route of administration, storage requirements, handling of the product, and the need for medical staff supervision), which would allow for more accurate classification and placement on a specialty drug list.

While the cost of specialty drugs is 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 an increased risk that either some drugs will be inaccurately classified as specialty, or others that are truly specialty drugs will be inaccurately excluded.

As states and plans attempt to define and categorize specialty drugs, they should also adopt a process to allow for stakeholder review and comment on the specialty drug definition and lists prior to the adoption for use. The adoption of a review and comment period allows stakeholders the ability to provide valuable input, which can serve as a critical step to ensuring and maintaining patient access to specialty drugs and to ensuring that drugs are adequately and appropriately placed on specialty drug lists.

Access to retail community pharmacies is vitally important for patients with complex, chronic, and progressive medical conditions. These patients often have an increased need
for follow-up and often the community pharmacist is the most readily accessible provider for them. Although patients have come to trust and rely on the accessibility of these drugs and the knowledge of community pharmacists, some payers have created strong financial incentives for patients to use mail order instead of their local community pharmacy, and often mandate that their enrollees obtain specialty or high cost drugs through a mail order program. While there are many available options to control prescription drug spending, it is imperative to maintain continuous patient access to these medications by allowing patients to use the provider of their choice for their prescription drug needs.

Community pharmacies are the face of neighborhood healthcare and are integral to providing patients with convenient, cost-effective, innovative, and healthcare outcome directed patient care service. As such, community pharmacies believe that there should be a standard as to how specialty drugs are defined and how it is determined which drugs are included on specialty drug lists. As the number of beneficiaries using specialty drugs increases, it will be more important that patients have continuous access to community pharmacists to ensure patients are correctly taking their medications. Therefore, we must protect the patient’s right to choose the pharmacy provider that best suits their healthcare needs.

**Conclusion**

In conclusion, we ask that you take our thoughts and suggestions into consideration as you address potential changes to the model act language.

Sincerely,

Kevin N. Nicholson, R.Ph., J.D.
Vice President
Public Policy and Regulatory Affairs