October 16, 2023

Superintendent Adrienne A. Harris
New York State Department of Financial Services
1 Commerce Plaza
Albany, NY 12257
Submitted Via Email: Kristina.magne@dfs.ny.gov

RE: Regulations on Market Conduct Rules for Pharmacy Benefit Managers

Dear Superintendent Harris:

On behalf of the National Association of Specialty Pharmacy (NASP), I write in response to the proposed Pharmacy Benefit Manager (PBM) regulations issued by the Department of Financial Services' Pharmacy Benefits Bureau. NASP supports the state's efforts to address anticompetitive business practices that are negatively impacting patient access to the pharmacy of their choice and specialty pharmacies that support patients in the state. As the state works to finalize its regulations, we would like to provide recommendations specific to specialty pharmacies to ensure the reforms under consideration appropriately recognize the work of specialty pharmacies and ensure a competitive pharmacy marketplace.

NASP represents the entire spectrum of the specialty pharmacy industry, including the Nation's national and regional specialty pharmacies and practicing pharmacists; nurses and pharmacy technicians; pharmacy benefit managers (PBMs); pharmaceutical and biotechnology specialty drug manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies.

NASP supports the state's regulatory efforts to address anticompetitive business practices that have sought to limit specialty pharmacy network participation and access to the specialty pharmacy of a patient's choice. We appreciate a number of provisions in the proposed regulation that would prevent practices by PBMs that have resulted in patient steering to PBM-affiliated pharmacies reimbursing a non-affiliated pharmacy an amount that is less than what is reimbursed to an affiliated pharmacy for providing the same specialty pharmacy medications and services. As the state works toward finalizing the proposed regulation, we recommend a few areas that require further consideration and edit.

Fair Pharmacy Reimbursement

The proposed regulatory requirements included in **456.2(a)(4)(iii)** seek to address retroactive reimbursements to pharmacies after the point-of-sale, which has been a significant concern and led to immense pharmacy closures and acquisitions, limiting patient access to the pharmacy of their choice. NASP agrees with addressing this issue as part of the proposed regulatory framework; however, NASP requests an edit to the proposed regulation to ensure against a loophole in addressing the state's concern, as follows:

"456.2(a)(4)(iii) A pharmacy benefit manager shall not, by contract or otherwise retroactively deny or reduce reimbursement for a claim after returning a paid claim response as part of the adjudication of the claim, ~~unless an adjustment was agreed upon by the pharmacy prior to the denial or reduction~~;"

"Take-it-or-leave-it" contract terms are frequently included in pharmacy contract agreements, prohibiting specialty pharmacies (or other pharmacy types) from objecting to specific terms, particularly terms impacting a pharmacy's reimbursement. NASP urges DFS to strike the highlighted language to ensure against any loophole that would permit a PBM/plan to justify a post adjudication clawback or implementation of other fees after the point-of-sale.

Specialty Pharmacy Reimbursement for Dispensing Services

The proposed regulation includes **Section 456.7 (Pharmacy Reimbursement)**, addressing pharmacy reimbursement:

"A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.18."

NASP strongly supports the state's efforts to set a floor for pharmacy reimbursement to ensure that pharmacies are not reimbursed in a manner that prohibits their participation in a pharmacy network. We are concerned, however, that the proposed dispensing fee, which fits a retail business model of pharmacy does not provide any flexibility for specialty pharmacy dispensing fees to support the ongoing comprehensive patient management handled by specialty pharmacies. Many states support adjusted dispensing fees for specialty pharmacies that take into account the extensive services provided to support smaller groups of patients who have serious and life-threatening conditions that require complex health care management, such as cancer, multiple sclerosis, organ transplantation, rare diseases, HIV/AIDS and cystic fibrosis.

Specialty pharmacies must be accredited as a specialty pharmacy by independent , nationally recognized accreditation organizations and therefore qualify to manage patients with complex medical conditions, and the infrastructure these pharmacies have in place to support these patients is expensive and complex. Specialty prescription medications require significant

patient education and 24/7 monitoring on utilization and adherence. For instance, specialty pharmacies provide: comprehensive treatment assessments; proactive and ongoing patient training on how to administer medications (including infused and injectable medications); ongoing patient monitoring; side effect management and mitigation; and frequent communication and care coordination with caregivers, physicians, and other healthcare providers. The services provided drive patient adherence and proper management of medication dosing. In addition, these services ensure that costly and complex drug therapies and treatment regimens are used correctly and are not wasted.

While all pharmacies provide dispensing services, specialty pharmacies must manage and provide advanced and comprehensive services to support patient drug and disease management and access to drug therapies. The time required on a per-patient basis for a specialty pharmacy to engage a patient is significantly greater than other pharmacies, and represents an acute difference from the traditional retail pharmacy model, which is focused on high patient volume. A low reimbursement for such drug dispensing services that does not appropriately cover the time to deliver high-touch specialty pharmacy services threatens the ability for specialty pharmacies to operate in the state, which would negatively impact a specialty patient from receiving services from the specialty pharmacy of their choice. Without access to their specialty pharmacy, patients could face immense setbacks in their treatment, leading to increased emergency room visits, hospital admissions and other healthcare costs for the patient and the state.

NASP urges DFS to specify that the recommended dispensing fee is meant to support retail pharmacy dispensing costs, and that DFS require that PBMs annually review cost to dispense data provided by specialty pharmacies that are not otherwise owned, controlled or affiliated with a PBM- or plan-owned pharmacy to determine fair reimbursement for the dispensing of specialty drugs. Such data is meant to consider the clinical care and logistics required to support a patient who is prescribed specialty drugs and has been utilized by other states to set forward similar specialty pharmacy dispensing fee requirements. As such, we recommend the following adjustment to **Section 456.7 (Pharmacy Reimbursement)**:

"A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.18 for retail pharmacies and a dispensing fee for specialty pharmacies that is based on cost to dispense survey data provided by non-affiliated specialty pharmacies."

Specialty Pharmacy Definition

To support specialty pharmacy network adequacy in the state and fair consideration of specialty pharmacy patient management/dispensing costs, NASP urges DFS and the Pharmacy Benefit Bureau to define specialty pharmacy in its regulation. NASP offers the following definition for consideration:

> *Specialty Pharmacy Network Participation*
>
> *(a) A health benefit plan or pharmacy benefit manager shall not prohibit a pharmacy from dispensing a specialty drug if the pharmacy meets the definition of specialty pharmacy.*
>
> *(b) A health benefit plan issuer or pharmacy benefit manager shall not exclude a specialty pharmacy from the right to participate in network if the pharmacy agrees to the contract terms, conditions and meets the definition of specialty pharmacy.*
>
> > *1. To be recognized as a specialty pharmacy, a pharmacy must be accredited as a specialty pharmacy by a nationally recognized independent specialty pharmacy accreditation organization.*
> >
> > *b. To participate in network, a health benefit plan issuer or pharmacy benefit manager must require as a condition of a contract with a specialty pharmacy that the pharmacy obtain a single accreditation as a specialty pharmacy from a nationally recognized independent specialty pharmacy accreditation organization.*

NASP respectfully asks that you amend the regulation to protect the practice of specialty pharmacy and the specialty patients that are served in the state. We welcome the opportunity to discuss this further, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila Arquette, R.Ph.
President and CEO