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October 16, 2023
Superintendent Adrienne A. Harris
New York State Department of Financial Services
One Commerce Plaza
Albany, New York 12257
Kristina.Magne@dfs.ny.gov

Re: NY DFS Proposed Consolidated Rulemaking for Insurance Regulations 219, 224, and 226-229 that would regulate the operation of Pharmacy Benefit Managers ("PBMs") in New York

Dear Superintendent Harris,

The New York Health Plan Association ("HPA") represents 27 health plans across New York. HPA's member health plans provide coverage of comprehensive health care services to nearly 11 million adults, children and seniors. These people include those enrolled through their employers as well as a variety of government-sponsored programs and individuals who shop for coverage through the state's official Marketplace or directly from plans. HPA is submitting these comments in response to the Proposed Consolidated Rulemaking for Insurance Regulations 210, 224, and 226-229 (the "Proposed Regulations") that would regulate the operation of Pharmacy Benefit Managers ("PBMs") in New York.

Both Governor Hochul and Superintendent Harris have made clear that their primary objective is to protect consumers against the high cost of health care and especially the high cost of pharmaceuticals and pharmacy coverage. Similarly, the authority that the Legislature granted to the Department of Financial Services (the "Department" or "DFS") was focused on protecting consumers. HPA agrees that protecting consumers should be the objective of the Department's Proposed Regulations. Unfortunately, the Proposed Regulations are profoundly anti-consumer. They would increase the cost of pharmacy coverage for employers, union benefit funds, insurers, and individual consumers – many of whom are medically vulnerable or seniors – by an enormous amount that, in the aggregate, would be in the billions of dollars annually. The cost impact of the proposal is not speculative or subject to actuarial debate. It is basic arithmetic that is easily calculated.

In addition to a range of substantive flaws set forth below, the Proposed Regulations exceed the statutory authority granted to the Department by the State Legislature and disregard federal laws that preempt State regulation of self-insured employee benefit plans as well as Medicare Advantage and Medicare Part D plans. While the Department has sought to avoid the reach of the federal preemption provisions, there is ample precedent – including the recently decided *Mulready* decision – that demonstrate that the Proposed Regulations cross the line both under the Employee Retirement Income Security Act ("ERISA") preemption and Medicare preemption.

The Department faces a stark choice: it can move forward with the Proposed Regulations and impose enormous new costs on health insurance consumers, or it can pull back the Proposed Regulations – as we urge – and work with stakeholders to achieve a more balanced approach. Such an approach would focus initial licensure standards that build from the robust registration process DFS is already implementing coupled with common sense oversight of certain PBM practices. We would welcome the opportunity along with other stakeholders to achieve a pro-consumer vision that decreases, not increases, the cost of pharmacy coverage.

A. The Proposed Regulations Would Drive Up the Cost of Prescription Drug Coverage

If promulgated, the Proposed Regulations would increase the cost of prescription drug coverage for those enrolled in HPA member health plans in New York by an enormous amount. A subset of HPA plans have estimated that just the introduction of a minimum dispensing fee of $10.18 and the requirement to pay pharmacies no less than the national average drug acquisition cost ("NADAC") would increase costs for their members by more than $740,000,000 dollars annually, with the greatest share of these costs impacting senior citizens enrolled in Medicare Part D.[1]

Such increases would flow through directly to New York's consumers in the form of increased premiums and higher costs at the prescription counter.[2] To the extent the overall cost of a drug increases, consumers must spend more to meet their deductible and coinsurance obligations in addition to paying higher premiums. New York's employers, already struggling to balance health care costs and wages in a challenging economy and labor market, would have to choose whether to bear these additional costs, shift them to their employees (via increased premium contributions and cost-sharing), leave New York or shut down. Self-insured employers and union benefit funds would face the same challenge. For benefit funds, the Proposed Regulations would hurt workers by diverting funds that could otherwise be used for wages or other benefits. These increased costs will most likely be borne by workers, as employers do not have unlimited health care budgets and will almost certainly need to pass on cost increases to enrollees.

Specifically, the Proposed Regulations would drive up prescription drug coverage through the following provisions:

1. Imposing a "Floor" for Drug Prices

The Proposed Regulations would set a "minimum" price for drugs at no less than the national average drug acquisition cost ("NADAC") price. There is no question that setting a "minimum" or "floor" for prescription drug reimbursement places upward pressure on claims costs (as well as premiums and member cost-sharing) because pharmacies and PBMs lose the ability to negotiate lower prices or rely on a different pricing index without adjustments. A subset of HPA member health plans estimate the annual impact of this provision alone will be an increase in costs borne by their members of nearly $590,000,000.

The Department's press release for the Proposed Regulations touts ensuring access to affordable prescriptions and making healthcare more accessible and affordable. Similarly, Governor Hochul has repeatedly stressed her goal of making New York a more affordable state. And yet, setting a floor for drug prices is directly and indisputably contrary to this objective.

Importantly, there is no provision in the PBM legislation that authorizes the Department to set prices. The underlying statute allows the Department to create licensure requirements and establish other defined requirements, but that express authority does not come close to allowing the Department to set prices. It is well-established New York law that a State agency's rulemaking may not exceed the scope of authority granted to the agency.[3] In addition, because the NADAC proposal is contrary to the explicit objective of making health care more affordable, it is arbitrary and capricious.

2. Imposing a Minimum Dispensing Fee

The proposed minimum dispensing fee of $10.18 per fill is a $7 to $8 increase over existing dispensing fees negotiated in the commercial market. A subset of HPA member health plans estimate this provision alone will increase costs to employers, consumers and union benefit plans enrolled in these plans by over $150,000,000 annually. This increase does nothing that even remotely benefits consumers. It is simply a transfer of dollars from the ultimate purchasers of pharmacy coverage to pharmacies.

Here too, there is no legislative authority for DFS to impose a minimum dispensing fee. For example, Section 280-a(2)(b) of the Public Health Law provides authority to prescribe rules concerning PBM administrative fees. However, "administrative fees" are defined to include payments to compensate a PBM for its services. Claims payments to pharmacies for covered care are not administrative fees, and this subdivision does not provide authority to set drug prices. Similarly, Section 2906(b)(5) of the Insurance Law provides authority to address the "pricing model" but it does not provide authority to set the minimum price for each drug. And, while other provisions speak more generally to PBM requirements, the legislative history makes clear that the Legislature did not intend to give DFS authority to regulate pricing. That is not surprising because the Legislature was focused on registration and certain specific PBM practices, not the general contractual relationships or payments between two commercial parties – pharmacies and PBMs or PBMs and health plans or IPAs.

In addition, when the Legislature has sought to address pharmacy payment terms, it has been careful to require that payments be on similar terms to existing contract requirements but did not impose higher terms – precisely because it was concerned about increasing the cost of pharmacy coverage. This restriction is also nonsensical because many payors could, in theory, shift contracts to non-PBM entities and bring the contracts with pharmacies outside the scope of the regulation.

Moreover, and similar to the discussion above, the dispensing fee requirement is contrary to the Governor's and Department's objective of reducing the cost of pharmacy coverage. It is arbitrary and capricious to declare that the purpose of a regulation is to make coverage more affordable and then propose a regulation that makes coverage substantially more costly.

3. Pharmacy Network Provisions Increase Costs and Undermine Quality

The proposed network adequacy standards would force PBMs to include many more pharmacies in their networks (even as compared to current fully-insured commercial or Medicare standards) to meet onerous time and distance standards while disregarding the availability of mail

order pharmacies and prohibiting health plans from directing or encouraging covered individuals to use affiliated pharmacies. The standards would effectively mandate PBMs to contract with every rural pharmacy and 24-hour pharmacy without regard to quality or cost and to do away with existing preferred network and specialty drug programs designed to contain costs and ensure quality. If promulgated, these requirements would govern a central matter of health plan administration by dictating the benefit design for fully insured and self-insured health plans including which pharmacies may be used and the level of cost-sharing that would be applied. Further, the standards would be inconsistent with the network adequacy standards imposed by the Department and the Department of Health on fully-insured commercial policies.

Moreover, many other provisions of the Proposed Regulations also appear to be designed to permit pharmacies to join and retain participation in pharmacy networks including: i) provisions to prohibit PBMs from charging application fees to join pharmacy networks; ii) notice requirements and appeal rights tied to credentialing denials; iii) restrictions and appeal rights tied to the non-renewal or termination of pharmacies from networks; and iv) rules that would make it difficult for PBMs to revise credentialing standards. Finally, there are rules that prohibit dispensing restrictions based on volume, therapeutic class, or the dispensing practices of other pharmacies that would also make it difficult for a health plan to rely on preferred or specialty pharmacies.

Taken together, these proposed rules would effectively force PBMs to include any willing licensed pharmacy in their pharmacy networks, despite the fact that the Legislature enacted Chapter 128 of the Laws of 2022 which removed a requirement in the initial law that PBMs must include all licensed pharmacies in their networks. Over many years, the Legislature has repeatedly and consistently rejected "any willing provider laws" that force the inclusion of providers in networks because such provisions are prohibitively expensive for health plans and the employers and members they serve.

While broadening the choice of pharmacies may seem to enhance consumer choice, guaranteeing broader pharmacy networks also comes at an enormous cost to consumers, especially where there already is access to a convenient pharmacy. If PBMs cannot limit their networks and deliver volume to network pharmacies, they lose the power to negotiate favorable pricing to the detriment of employers and consumers. Further, Medicare explicitly allows preferred pharmacy networks in Part D so long as the full network meets the access standards and network adequacy requirements set by the Centers for Medicare & Medicaid Services ("CMS") and some of the provisions above would impermissibly impact Medicare Part D.

4. The Proposed Limits on the Use of Specialty Pharmacies Also Will Increase Costs

The Proposed Regulations prohibit a PBM from restricting a pharmacy from dispensing a drug to a member based on therapeutic categories. Further, the Proposed Regulations would restrict a PBM's ability to direct, incentivize or require members to go to a particular pharmacy to obtain specialty drugs, even if such restrictions are incorporated into the health plan's benefit design. Specialty networks are of critical importance given that specialty medications are the largest and fastest-growing segment of the U.S. pharmacy market. While only 4% of Americans use specialty drugs, they account for 65% of total drug spend and 19% of total health care

spend. Currently, some clients may receive specialty medicines exclusively through a specialty network. However, the Proposed Regulations would prevent PBMs and health plans from adopting that approach as a means of reducing costs to the consumer and the employer. A single PBM affiliated with an HPA member plan has estimated the cost of these provisions for the members they serve in New York to range between $200,000,000 and $236,000,000 annually.

Specialty drug programs should be supported, as opposed to prohibited, as they provide members with access to specialty pharmacists and condition-specific and potentially life-saving advice to assist members managing chronic or complicated conditions, typically at a savings. The Proposed Regulations would prohibit such programs absent an appeal to the Pharmacy Benefit Bureau. Federal law preempts this provision for self-funded ERISA and Medicare plans because such programs most certainly "relate to" the design of the underlying health benefit program. Similarly, to apply such a restriction to a fully-insured health plan, the State legislature would need to introduce a mandate to be enforced by the DFS' Health Bureau during its review and approval of policy forms.

We also recommend that the Department include a carve-out for member-specific requirements tied to, for example, opioid seeking behavior. On certain occasions, a health plan will require a member to use one pharmacy when it is determined that the member is using the network to mask certain prohibited behavior. Utilizing the appeals process contemplated by the Proposed Regulations to obtain Department approval of such an exception would be onerous under circumstances where a member's health and safety are in jeopardy.

5. Formulary Restrictions

The Proposed Regulations provide that a PBM shall not remove a drug from a formulary, move a drug to a higher cost sharing tier, or add utilization management restrictions to a drug unless such changes occur at the time of enrollment, issuance, or renewal of coverage. HPA opposes this provision. The Legislature has addressed this issue. Chapter 99 of the Laws of 2022 was expressly limited to fully-insured plans. Additionally, amendments were negotiated to state that the law does not supersede the terms of a collective bargaining agreement. Including this provision serves the sole purpose of regulating self-insured benefit plans and Medicare plans contrary to federal preemption and reaching certain fully-insured programs that were intentionally exempted by the State Legislature. The Department does not have the authority to regulate benefit design in this way and is acting beyond the legislative intent and authority of the law. Further, this requirement is in direct conflict with Medicare's extensive formulary and utilization management rules.

Additionally, pursuant to the Proposed Regulations, the formulary would be "frozen" beginning on the date on which a plan year begins through the end of such plan year. This is impractical. While HPA is strongly opposed to these formulary restrictions because they increase the cost of prescription drugs by preventing the marketplace from responding to changes in drug pricing, at a minimum, changes in the formulary should be tied to the calendar year. Plan years vary for every plan such that no plan within the scope of this law would be able to leverage a standard formulary. Therefore, changes to plan years would add significant, unnecessary administrative costs without benefits for pharmacies or consumers.

6. The Proposed Regulations Could Result in Fraudulent and Abusive Billing

Contrary to the Department's statutory responsibility to reduce fraudulent billing, the Proposed Regulations could encourage fraudulent and abusive billing by imposing stricter rules on audits and limiting recoupment of payments for inappropriate billing. The Proposed Regulations add a new Part 459 that adds requirements for audits and investigations of pharmacies. As a preliminary matter, the authority to regulate pharmacy audits is vested to the Commissioner of Health pursuant to Public Health Law § 280-c, and we do not believe that the Department has the authority to promulgate regulations relating to audits. With respect to audits and payment recoupment, ERISA fiduciary rules require plan oversight and any requirements that limit a plan's rights are preempted by ERISA. While HPA opposes this section generally, of particular concern, is the limitation that PBMs would be prohibited from withholding future payments before the final audit or investigation for any audit below a $25,000 threshold; and if it meets the threshold, not more than 10% of each monthly payment to the pharmacy may be withheld until the final determination. If plans cannot collect any of the cost or only a small percentage of the cost prior to completing an audit, plans would be at risk of losing a significant amount of money due to fraud.

Similarly, the Proposed Regulations would limit probability sampling, which is hard to understand because the Department frequently uses probability sampling in its own audits. There are numerous other examples of how the Proposed Regulations would inappropriately restrict legitimate efforts to reduce fraud and abuse rather than adopt a balanced approach to audits of pharmacies – indeed an approach that is similar to what the Office of the Medicaid Inspector General employs in its audits of providers.

B. The Proposed Regulations Would Exacerbate Health Disparities

In a recent Centers for Disease Control and Prevention ("CDC") survey, a significant percentage of adults ages 18-64 (8.2%) reported not taking medications as prescribed due to cost,[4] a practice that contributes to more serious illnesses and the need for more costly medical interventions. Even more troubling, the survey revealed large health disparities with vulnerable populations sacrificing their health due to the cost of prescription drugs to a much greater degree.

Specifically, many more adults with disabilities (20%) reported rationing prescriptions than adults without disabilities (7.1%). Adults in poor health (18%) are three times as likely to forego medications as adults in good health (6.3%). Those with lower incomes (200% - 400% FPL) (9.9%) are two and one-half times more likely to ration prescriptions than those with higher incomes (at or above 400% FPL) (3.9%). Additionally, Black (10.4%) and Hispanic (9.7%) populations are more likely to forego medication than Asian (6.8%) or White (7.4%) populations, and women (9.1%) are more likely than men (7.0%), to ration necessary prescriptions due to cost.

Although the CDC did not survey senior citizens, most adults over age 65 report taking four or more prescription drugs each year[5] and we think it is fair to assume that seniors on fixed incomes may be making similar compromises. In view of these findings, it is concerning that the Department would risk driving up the cost of prescription drugs and further increasing existing health disparities.

Addressing health disparities has been a priority of both the Governor and the Superintendent. Thus, it is distressing and arbitrary that the Department would propose regulations that so directly and materially increase costs for vulnerable populations.

C. Provisions of the Proposed Regulations Are Preempted by Federal Law and further Should Be Applied only to Fully-Insured Health Plans Sitused in New York

The Proposed Regulations apply to self-insured employee health plans (including the New York State Health Insurance Program ("NYSHIP")), Medicare Advantage and Medicare Part D plans (subject to select exceptions), the Federal Employee Health Benefit Plan ("FEHBP") as well as fully-insured employer policies issued in other states. As we have raised in previous comments, the statutes governing Medicare Advantage and Part D articulate broad preemption of state laws and guidance. *See* 42 U.S.C. § 1395w-26(b)(3) and § 1395w-112(g). Similarly, federal law includes explicit federal preemption provisions for employee benefit plans that are not fully-insured and FEHBP. *See* 29 U.S.C. § 1144(a) and 5 U.S.C. § 8902(m)(1). As such, imposing requirements related to PBM arrangements involving Medicare Advantage, Medicare Part D, self-insured employee benefit plans or FEHBP would go beyond the authority of the State and conflict with such business arrangements as well as federal governance of these matters.

The provisions cited above are preempted by the very broad "complete preemption" of state laws that relate or refer to Medicare Advantage or Medicare Part D. Significantly, DFS recognized that Medicare preemption would preclude the application of certain provisions. But the Department seemingly concluded that the NADAC requirement and the dispensing fee are permissible. However, these types of pricing requirements are precisely why Congress enacted Medicare preemption. There is much evidence to show that Congress did not want states increasing the cost of the federally-funded Medicare program through state laws. That is also why Congress preempted state laws that imposed taxes or fees on Medicare coverage. If individual states were permitted to set dispensing fees and prescribe a pricing benchmark, then federal costs will go up without any federal input or approval. The importance of stable Part D premiums for seniors cannot be over-emphasized.

Similarly, although *Rutledge v. Pharmaceutical Care Mgmt. Assoc.*, 592 U.S. ----, 141 S. Ct. 474 (2020), found that ERISA's express preemption clause will not necessarily preempt *all* state regulation of PBMs, state laws which go beyond mere cost regulation and refer or "relate to" ERISA plans remain preempted. Here, the state statute expressly referred to employee benefit plans so there is no doubt that this prong of ERISA preemption is satisfied. A state law impermissibly "relates to" ERISA when the impact of the regulations affects a central matter of plan administration, such as network design, or when the state law interferes with nationally uniform plan administration. Notably, the United States Court of Appeals for the Tenth Circuit recently applied *Rutledge* to invalidate an Oklahoma statute which contained similar provisions to the Proposed Regulations. *See Pharmaceutical Care Mgmt. Assoc. v. Mulready*, 78 F.4th 1183 (10th Cir. 2023). While the Arkansas statute challenged in *Rutledge* targeted **only** the reimbursement rates set by PBMs, the Oklahoma law at issue in *Mulready* instead imposed network restrictions which impacted the basic ability of PBMs to administer plans. The Tenth Circuit specifically found that the Oklahoma pharmacy access standards and prohibitions on the use of cost-sharing discounts impermissibly impacted the ability of PBMs to design and administer

their own networks using their choice of two-tiered networks, mail-order pharmacies, and specialty pharmacies.

Finally, the Proposed Regulation should be revised to apply only to fully-insured health insurance business situsued in the State of New York or otherwise subject to the Department's oversight by virtue of the review and approval authority set forth in Section 3201(b) of the Insurance Law and Regulation 123.

D. Timing

Most of the provisions of the Proposed Regulations would apply to contracts amended on or after January 1, 2024 and any conflicting provision of a contract would be deemed void and unenforceable on and after January 1, 2025. This will cause the unwinding of existing complex multi-year contractual arrangements. As discussed, disrupting multi-year contracts mid-term to include the requirements of the Proposed Regulations (including minimum price requirements) will impair existing contracts and place upward pressure on rates prior to an opportunity for the health plan to renegotiate the contract in good faith to ensure that the entire agreement makes sense in the revised regulatory environment. Additionally, if the Proposed Regulation is not amended to eliminate costly provisions, employers and other consumers must be given time to budget for increased coverage costs. Further, the added costs will impact premium rates and, for fully-insured plans, a process must be put in place to allow for adjustment of premium rates approved by the Health Bureau of the Department. The effective date should be amended to allow sufficient time for implementation and health plan contracts with PBMs should not be disrupted prior to their renewal.

Conclusion

HPA appreciates the opportunity to comment on the Proposed Regulations as well as the Department's efforts to seek comments from interested parties in advance of the issuance of the proposal. More detailed health plan comments specific to the regulatory provisions are attached. Given the breadth of issues – and the possibility of litigation – we recommend that the Department amend the Proposed Regulation, following a process that complies with the State Administrative Procedure Act, to reduce consumer harm. Additionally, after the promulgation of the final regulations, health plans PBMs and their policyholders and clients will need time to implement any standards that are ultimately included.

Sincerely,

Eric Linzer
President & CEO

HPA Comments Related to Specific Regulatory Provisions:

11 NYCRR 450.1, Definitions

Subsection (a) elaborates on **t**he definition of health plan and includes all lines of business (including Medicare for dispensing fees and other significant provisions) that have 50% or more beneficiaries who work or reside in the state. PBMs have no way to identify members that work within New York. The PBM will have difficulty tracking and reporting changes in the group (e.g., employees moving in and out of New York). This will effectively result in an obligation for fully-insured and self-insured health plans to track changes in residency and worksite in order to alter the prescription drug benefit based on workplace location and residency. Further, the regulation does not clarify how mid-year changes should be handled.

- **Preemption.** Over and above the issues cited previously, the regulations should clarify that the definition of health plan excludes self-funded employee welfare plans, FEHBP and Medicare plans (including fully-insured or self-insured employer group waiver or "EGWP" plans) due to federal preemption.

- **Extra-territorial jurisdiction.** The definition should be revised to exclude fully-insured policies sitused in other States consistent with the treatment of such policies under the Insurance Law to minimize disruption, particularly for small groups. The State Legislature has consistently rejected attempts to revise the Insurance Law to assert jurisdiction over out-of-state policies issued to employer groups that cover New York residents. Therefore, particularly since this results in a health plan obligation, the Department should not define "health plan" to exceed its jurisdiction over health plans as set forth in Section 3201(b) of the Insurance Law and in Regulation 123.

- **Employer Disruption.** At a minimum, relatively smaller groups sitused in other states should be exempted. Otherwise, minor changes in the employer's workforce or the residency of their employees could force significant disruption. Using an example of a New Jersey employer with four employees, the regulation would currently assert jurisdiction if more than one of those employees resides in New York. As structured, a New York resident working for the New Jersey employer could see significant increases in their coinsurance obligations because a co-worker also moves into New York. Additionally, it would be troubling to New York if neighboring states promulgated similar regulations affecting fully-insured employer plans sitused in New York. Because New York's PBM regulations carry meaningful costs (e.g., NADAC pricing plus a minimum $10.18 dispensing fee), the regulation could discourage employers from hiring New York residents.

In addition to excluding self-funded ERISA plans, FEHBP and Medicare Advantage and Medicare Part D plans, we recommend exempting fully-insured plans sitused outside of New York unless the Department has jurisdiction over the forms and rates pursuant to Section 3201(b) of the Insurance Law and Regulation 123. If the Department does not align the PBM regulations with Regulation 123, at a minimum, small employer groups with less than 100 employees sitused in other states should be exempted to reduce, but not eliminate, member disruption. Additionally, the percentage of beneficiaries residing in New York should be increased to 75% or more to focus on the employer groups with a more significant presence in New York than in their home jurisdiction.

This can be accomplished with modifications to the definition set forth in Subsection (a). Lastly, DFS will need transitional rules (e.g., jurisdiction over the group should be determined at inception and its status should not be disrupted mid-year or at the time of renewal absent a substantial change in circumstances).

The definitions of "Rebate Aggregator" and "Switch Company" in Subsections (l) and (m) should be deleted, as the reason for their inclusion is unclear.

11 NYCRR 450.7, Applicability

The Proposed Regulations in their entirety should not apply to Medicare Advantage plans, Medicare Part D plans, Medicare employer group waiver plans, FEHBP or self-insured benefit plans (including NYSHIP) due to federal preemption. Currently, Section 450.7 of the Proposed Regulations indicates that certain provisions do not apply to Medicare Part D plans, but it fails to address Medicare Advantage or fully insured or self-insured employer group waiver plans at all. Additionally, as discussed above, the Proposed Regulations should not apply to fully-insured health plans situsedoutside of New York unless the policy forms and rates are subject to DFS jurisdiction pursuant to Section 3201(b) of the Insurance Law and Regulation 123.

In addition, it appears that the provisions would apply to the PBM handling the State's Medicaid program as well as PBMs performing services related to the Child Health Plus program or the Essential Plan. If this is the case, the regulation should so specify and the costs should be accounted for in the State budget. Similarly, please clarify the implications for workers compensation programs and whether there are any lines of business exempt from the requirements of the regulation.

11 NYCRR 456.1, Applicability

Subsection (a) provides that the rule applies to *any* contract issued, assigned, renewed, recredentialed, extended, amended, or otherwise modified on or after January 1, 2024. Additionally, any provision in a contract between a PBM and a pharmacy that conflicts with the regulatory requirements shall be deemed void and unenforceable on and after January 1, 2025.

Many relevant contracts extend for 3 years or more and, as of January 1, 2025, the regulation will impair such contracts and result in unnecessary costs and disruption for payers that do not renew until after that date. For such contracts, requiring mandated pricing to be applied as of January 1, 2025 will force the PBM to meet minimum pricing and other requirements prior to an opportunity to renegotiate the contract to attempt to off-set increased costs and ensure that the agreement makes sense in the revised regulatory environment. Further, the Health Bureau of the Department has already approved premium rates applicable for 2024 and such rates are difficult to amend mid-year to address added costs. The PBM-health plan payer contracts should be allowed to run their course subject to the rates upon which those contracts were negotiated. At a minimum, we recommend that the regulation be revised to remove the January 1, 2024 effective date for any contract in favor of applicability to contracts delivered, issued, or renewed on or after January 1, 2025 or at least one full year following the promulgation of the final regulation. Health plans and

self-insured benefit plans should be given sufficient time to budget for increased costs or otherwise decrease or adjust benefits and cost sharing to address them. Similarly, DFS' processes must allow for such costs to be incorporated into premium rates.

Subsection (b) includes a definition of pharmacy benefit manager that includes any representative, subcontractor, affiliate, subsidiary, or other individual or entity acting on behalf of a pharmacy benefit manager. This expanded definition of a PBM should be deleted as the Department does not have the authority to expand a key definition set forth in statute. The definition in the regulation should mirror the definition in the law.

11 NYCRR 456.2, Contracting Standards

Fees. Subsection (a) provides that a PBM shall not, by contract or otherwise charge a pharmacy a fee related to enrollment or participating in a network (including an application fee, a credentialing or re-credentialing fee, a change of ownership fee, or fee for the development or management of claims processing services or claims payment services). Similarly, the standards provide that a PBM shall not charge a fee related to the adjudication of a claim (including for the submission, receipt, or processing of the claim).

Elimination of these fees will cost PBMs, plans and ultimately consumers – as yet another cost that will trickle down to hurt New York's employers and consumers and seemingly benefit only pharmacies. While HPA agrees that fees must be balanced and reasonable, we oppose the outright elimination of fees. Many health plan contracts with pharmacies contain agreed upon transaction fees for providing pharmacies with claims processing and transaction services. These service fees provide the contracting parties with transparency as to costs and are preferable to spread pricing. If the Department must do something on fees, we would prefer that the Department prohibit them unless contractually agreed upon, or cap fees at a reasonable amount, and/or limit the provisions to low volume pharmacies.

The PBM statute provides the Department with the authority to develop standards and practices for use in pharmacy contracts, not to dictate material contract terms such as fees. The Legislature has made no policy decision about whether a PBM charging fees for services is deceptive or unfair conduct, particularly when a pharmacy contractually agrees to such fees.

Certain costly tasks must be completed to review change of ownership, credentialing, and re-credentialing applications. Just as the State includes a fee of $345 to process and validate PBM information, it is necessary to account for these fees. Specified fees provide transparency and deter the submission of applications that do not have merit.

Lastly, these provisions could potentially run into major conflicts with any new federal legislation related to Medicare.

Payments to affiliated pharmacies. Paragraph (3) of subsection (a) prohibits reimbursing a pharmacy less than a PBM's affiliate pharmacy for the same services. The provision will reduce ability for commercial plans to develop value-driven pharmacy networks.

The Department should provide standards and practices for contracting with network pharmacies and not dictate exactly how parties are required to interact when doing business. At a minimum,

HPA recommends removing the language "on a per unit basis using the same generic product identifier or generic code number paid to the pharmacy benefit manager owned or pharmacy benefit manager affiliated pharmacy." These are clinical classifications that do not result in meaningful comparisons or reflect how business is conducted. Better indicators should be employed following discussion with the relevant stakeholders.

Retroactive payment adjustments. Paragraph (4) of subsection (a) prohibits retroactive denials or reductions in reimbursement after a claim has been paid unless there had been an instance of fraud, the adjustment is completed to correct errors identified on audit, or the adjustment is agreed upon by the pharmacy prior to the denial or reduction.

Health plans oppose this provision as there should be more flexibility to permit a PBM to recoup overpayments that are not a result of fraud and are not identified pursuant to a full audit. Allowing pharmacies to maintain overpayments made in error unjustly enriches pharmacies at the expense of health plans and consumers. Health plans and PBMs will likely be forced to respond to such a limitation by applying more resources up-front to review claims in advance of processing reimbursement, a result which could disrupt pharmacy cash flow. Further, we believe this provision is beyond the scope of the law and jurisdiction of the Department, as Section 280-c of the Public Health Law provides the Department of Health with jurisdiction over pharmacy audits.

Affirmative obligations. Subsection (b) requires PBMs to transmit all pharmacy contracts to the effective pharmacy on or prior to the effective date of the contract, regardless of whether the PBM also requires a PSAO or other agent to transmit such pharmacy contract to the pharmacy. PBMs cannot be responsible for PSAO oversight as the PSAO is selected by the pharmacy to act as its contracting agent. Obligating the PBM to transmit all pharmacy contracts to the pharmacy and the PSAO, drives up costs without benefits to health plans or consumers.

Paragraph (3) of subsection (b) should be limited to unilateral "material" changes.

Paragraphs (6)-(9) require a PBM to notify the pharmacy of a denial of its application for participation in a pharmacy network, in writing, within 30 days from submission of a complete network application, including a detailed explanation for denial. Then, the PBM must allow the pharmacy to reapply within a year of the denial if the pharmacy documents that the reason for the denial has been cured or no longer applies. Similarly, PBMs that exercise right of non-renewal must provide detailed notice and an opportunity to reapply within one year.

Requiring a detailed explanation when a PBM denies network participation or declines to renew a pharmacy contract, and also providing the pharmacy a right to reapply within the year, implies that if a pharmacy cures the missing element, the pharmacy may then become a participant in the network. Such requirements make little sense when there is no requirement to allow a pharmacy to participate in the first place and, in fact, the Legislature rejected a requirement that all licensed pharmacies be included in networks. Further, the Proposed Regulations would create an imbalance where a pharmacy could choose not to renew without cause, but a PBM could not. If the contract is not desirable for one or more parties, either should have the ability to leave the relationship in accordance with the contract terms.

We recommend requiring a PBM to apply objective criteria when creating a pharmacy network instead of driving up administrative costs by requiring detailed written explanations be provided to every single pharmacy. Health plans and, by extension, their PBMs have varying reasons not to allow all pharmacies to participate in a particular network (including network size, health plan's member population, utilization patterns, etc.) and many are designed to reduce rising drug costs. One of the key reasons for having a restricted network is to drive volume to the pharmacies willing to accept lower rates in exchange for that volume. The Department and the State have a common interest in ensuring that consumers have access to high quality and affordable pharmacies that are reputable and have processes in place to avoid patient safety hazards.

11 NYCRR 456.3, Credentialing, Recredentialing and Accreditation Requirements

Subsection (b) requires a PBM to notify a pharmacy in writing of any credentialing requirements for enrollment in a pharmacy network within 14 days of a request and any recredentialing requirements 30 days prior to recredentialing. Subsection (d) requires written notice of any certification or accreditation requirements used by the PBM within 30 days of a request. These provisions appear conflicting. Additionally, subsection (d) indicates that a PBM may not change its accreditation requirements for a pharmacy that has requested them until at least 12-months from the date the PBM provided such written notice. This 12-month restriction would make it extremely complicated for PBMs to alter accreditation requirements on a systematic basis that applies to all pharmacies since exceptions would always be needed for pharmacies that have made a recent request.

Credentialing is an important part of managing a network. Binding a PBM to certification or accreditation requirements for network participation limits its ability to pivot in a rapidly changing environment. If the Department is insistent on limiting changes, then it should be across the board for all pharmacies during a 12-month period to avoid administrative burden.

11 NYCRR 456.4, Termination of a Pharmacy from a Network

This section prohibits immediate termination of pharmacy contracts subject to certain exceptions. These requirements greatly limit the PBM's ability to manage a network for healthcare payers by weeding out bad actors or enforcing contractual provisions because the provisions do not allow for immediate termination due to a material breach of contract. If the Department imposes this list of exceptions, we recommend adding exceptions for material breach of contract, public safety and welfare issues (e.g., imminent harm to patients"), debarment from a government program, loss of required insurance without replacement, and reasonable belief of fraud, waste or abuse.

The Proposed Regulation requires 60-days written notice for a pharmacy termination by registered mail. We recommend allowing trackable methods other than registered mail.

We recommend removing the requirement to provide a rational basis and a detailed explanation and the requirement to allow a pharmacy terminated "for cause" back into the network. Under existing law, either party may terminate without cause – with no harm and no foul. Requiring PBMs to name the cause and then allow the pharmacy to reapply within the year implies that PBMs must allow bad actors back into the network. Even if bad actors cure the most apparent defect, PBMs can still reasonably hesitate to continue to work with the pharmacy. Further, the vagueness

related to this requirement would set regulated PBMs up for potential litigation with these pharmacies. It appears that the Department is seeking a back-door means of including all licensed pharmacies in the network, regardless of behavior, but language guaranteeing all licensed-pharmacies the ability to participate in the network was specifically deleted from Chapter 828 of the Laws of 2021 when modified by Chapter 128 of the Laws of 2022. Not being able to terminate the pharmacies without cause if they show signs of fraud, waste or abuse is irresponsible, will harm people physically and financially, and will drive up costs for health plans.

11 NYCRR 456.5, Contracts with Parties

Subsection (a) provides that the Department can request copies of terms and conditions between a PBM and any other party relating to PBM services for health plans. We recommend that the Department remove the broad language "any other party" and replace with "a health plan" to limit to relevant contracts.

The provision further provides that PBMs are prohibited from including confidentiality provisions and shall not require approval of the other party prior to disclosure. In the event the Department requires proprietary and/or competitive information to be submitted, PBMs should be permitted to classify them as confidential, and they should be protected from public records disclosure. Any public disclosure will lead to increased costs and lower competition in the marketplace. In addition, PBMs should be provided with notice if the contract is sought by a competitor or other person/entity who is not a party to the contract.

Additionally, the provision would require PBMs to transmit such contracts within 15 business days, unredacted. This provision is problematic because there are portions of PBM contracts that are not responsive (e.g., another state's Medicaid contract) and PBMs should be able to remove them.

Lastly, if the State requests a large volume of contracts or information, then the 15 business days would be unreasonable. Turn-around times should be correlated to the volume of information requested.

Subsection (b) provides that any PBM that contracts with a subcontractor, affiliate, subsidiary or other entity to perform PBM services shall include an authorization in its contract for the Department to request information directly from the third party and an agreement for the third party to cooperate with the Department. There is no underlying statutory authority for Department to regulate these entities. In fact, legislation granting the Department such authority was pending last session and was not enacted. All such communications should be handled through the regulated health plan or PBM.

11 NYCRR 456.6, MAC List and Appeals

Subsection (b) requires, when placing a drug on a MAC list, a PBM must ensure the drug has at least two equivalent multi-source generics or at least one generic drug available from at least one manufacturer available for purchase by pharmacies. We object to this provision because the Department lacks the authority to regulate MAC appeals. MAC appeals have been in the Public Health Law under the jurisdiction of DOH since 2015. While Chapters 828 of 2021 and 128 of 2022 amended the MAC appeals law, it still resides in the Public Health Law under DOH

jurisdiction. While the Superintendent has authority to regulate, in consultation with the Commissioner of DOH, that regulatory authority is limited to paragraph 280-a(1)(a) and subdivision 280-a(2) & 280-a(3) and does not include Public Health Law §§ 280-a(4) or (5). Likewise, Insurance Law § 2911, does not do away with the due process protections of Public Health Law §§ 12, 12-a and 12-b. In other words, Insurance Law § 2911 says a PBM cannot violate the Public Health Law, and the Superintendent has authority to revoke or suspend a PBM license, but it does not say the Superintendent can determine when there has been a violation of the Public Health Law. That determination must be made by DOH through the notice and hearing process.

The statutory requirement (also included in the proposed rules) to name a wholesaler where a drug subject to a denied appeal can be purchased for less than the MAC reimbursement is impossible to comply with if registered wholesalers will not provide their price lists to PBMs. PBMs do not have access to wholesaler prices which is why multiple sources are used to determine price for multi-source generic drugs. It would not be in anyone's interest to provide a path to incentivize PSAOs/Wholesalers to increase wholesale prices knowing that PBMs are going to be required by the Department to pay those higher prices. A mechanism is needed to ensure some level of price protection for pharmacies that also prevents unlimited price hikes by wholesalers. The Department should work with DOH to gain access to wholesaler drug pricing information or require that wholesalers provide the prices lists to PBMs.

11 NYCRR 456.7, Pricing Models

Subsection (a) sets forth a minimum price for prescription drugs. Specifically, a PBM may not reimburse a pharmacy less than NADAC plus a professional dispensing fee of $10.18 for each drug dispensed. If NADAC is unavailable, the PBM is required to pay the wholesale acquisition cost plus $10.18.

As discussed previously, HPA strongly opposes this provision due to increase plan costs, member premium, and cost-sharing, and costs to the State and federal government. Mandating NADAC reimbursement plus a minimum dispensing fee is not aligned with any policy decision made by the Legislature. This provision will increase drug costs for all New Yorkers and it serves solely to benefit pharmacists. Additionally, NADAC is a relatively unreliable price point that is retrospective and not truly reflective of real time marketplace conditions and pricing, and it is dependent on pharmacies self-reporting prices.

HPA recognizes that other states have implemented the NADAC pricing and dispensing fee provisions; however, this policy was set through action by their state legislatures and under marketplace conditions that differ from New York. In addition, this same proposal was rejected by Medicaid for years prior to the carve out given the financial impact.

It should be noted that some plans have quality programs which are designed to improve member adherence for specific generic drugs, and pharmacies who participate in such program forego or provide low dispensing fees for such drugs. A mandatory dispensing fee would not only result in significant out of pocket cost increases for members but would effectively render these quality programs obsolete.

HPA suggests elimination of the mandatory minimum dispensing fee. At the very minimum, this provision should be amended to exclude self-funded plans, public sector employers, workers' compensation plans, Medicare plans, fully-insured plans sitused out of state and not subject to DFS' jurisdiction under Insurance Law § 3201(b), and be limited to low volume, rural pharmacies defined as ten or more miles away from nearest pharmacy.

11 NYCRR 456.8, Prohibition on Certain Dispensing Restrictions

A PBM is prohibited from restricting a pharmacy from dispensing a drug to a member based on:

(1) Volume of claims as measured by number of claims, quantity dispensed or dollars paid;

(2) Therapeutic categories; or

(3) Dispensing rates of other pharmacies.

As previously discussed, the Department should be aware that specialty networks are of critical importance given specialty medications are the largest and fastest-growing segment of the U.S. pharmacy market. At the very least, specialty drugs should be carved out from any pharmacy network benefit design restrictions as it would prohibit plans from accessing the lowest cost, highest quality, specialized care for vulnerable patients with chronic and complex conditions.

Specialty drug programs should be supported, as opposed to prohibited, as they provide members with access to specialty pharmacists and condition-specific and potentially life-saving advice to assist members managing chronic or complicated conditions, typically at a savings. The regulation would prohibit such programs absent an appeal to the pharmacy benefit bureau pursuant to Subsection (b). Federal law preempts this provision for self-funded ERISA and Medicare plans. Similarly, to apply such a restriction to a fully-insured health plan, the State legislature would need to introduce a mandate.

We also urge that the Department should consider including a carve out for member specific requirements tied to, for example, opioid seeking behavior. Utilizing the appeals process contemplated by the regulation to obtain Department approval of such an exception would be too onerous under circumstances where a member's health and safety are in jeopardy. Additionally, it is unclear what the impact of this provision would have on Medicare plans.

Part 457

11 NYCRR 457.2, Prior Approval Required for Acquisition of Control of Licensed PBM

The Proposed Regulation requires prior approval by the Superintendent for an acquisition of control of a PBM. Legislation was adopted this year that would require notice to the Department of Health for certain acquisitions (i.e., material transactions). Similarly, the Plans request that the Department consider a notice requirement in lieu of prior approval.

Part 458

11 NYCRR 458.1, Definitions

Refers to the definitions of pharmacy and PBM from Part 456. As previously mentioned, the definition of PBM includes any representative, subcontractor, affiliate, subsidiary, or other individual or entity acting on behalf of a pharmacy benefit manager. This expanded definition of a PBM should be deleted as the Department does not have the authority to expand a key definition set forth in statute. The definition in the regulation should mirror the definition in the law.

11 NYCRR 458.2, Prohibited Market Conduct Practices

Subsection (b) sets forth prohibited market conduct practices, including unfair trade practices. HPA requests that the Department provide clarity and additional detail/examples regarding what is an unfair, deceptive, or abusive act or practice. It is costly for Plans to defend against baseless complaints, and providing clarity of the scope would be cost effective and more efficient.

Subsection (c)(1) provides that a PBM shall not engage in marketing, advertising or promotional activities to members or prescribers for the purpose of gaining business and PBM affiliated pharmacies without the members' knowledge or understanding that their pharmacy choices are not restricted. PBMs may include a PBM affiliated pharmacy in communications to members regarding network pharmacies and prices, provided the PBM includes information regarding all nonaffiliated pharmacies. The regulation should include an exception for members purchasing drugs exclusively through a mail order pharmacy. For example, a health plan may require use of a mail order pharmacy, therefore PBMs should be able to advertise the home delivery pharmacy option. Similarly, specialty drug programs should be carved-out so that such programs may continue to be relied upon to reduce costs and improve care. Health plans should also have the freedom to communicate with their members as they deem appropriate as it exceeds the scope of DFS' jurisdiction to dictate the terms of such communications. Communications sent at the health plans' request should be expressly carved out from this requirement. In addition, restrictions regarding outreach to prescribers could impact patient care if affiliated pharmacies are considered to be acting on behalf of the PBM (because of the expanded definition of PBM in these rules) such that a clear exception should be included.

Subsection (c)(2) provides that materials, including ID cards, may not include the name of any pharmacy unless it includes the names of all pharmacies in the network. Since it is unrealistic and infeasible to include *all* pharmacies on an ID card, alternatives should be considered (e.g., include at least two unaffiliated pharmacies based on zip code).

Subsection (c)(4) provides that a PBM may not require a member to purchase drugs exclusively through a mail order pharmacy unless contractually required to do so by the health plan. This exception, for limitations authorized by the health plan, should be carried over to all provisions set forth in subsection (c).

Subsection (c)(5) provides that a PBM may not penalize a member, including by requiring full cost for a drug, when the member chooses not to use a PBM affiliated pharmacy. Similarly (c)(6) prohibits incentivizing a member to use an affiliate pharmacy. At the very least, specialty drugs

should be carved out from any pharmacy network benefit design restrictions as it would prohibit plans from accessing the lowest cost, highest quality, specialized care for vulnerable patients with chronic and complex conditions. Alternatively, specialty drugs could be carved out if it is contractually required by the health plan. The language should also be revised to clarify that mail order programs authorized by a health plan are carved out. One health plan has advised that removal of exclusive specialty and exclusive mail order programs could cost up to $105.00 per member, per year.

Subsection (d) provides a PBM shall not require a member to pay an amount greater than the lesser of: (1) the cost share under the terms of the health plan; (2) the maximum allowable cost ("MAC"); or (3) the cash price. Cash price is incorrect, it should be the pharmacy submitted usual and customary charge. Additionally, in Medicare, there is no way for plans and PBMs to monitor or oversee this requirement, as we do not have visibility into every pharmacy's cash price for drugs. This is especially problematic for common generic drugs.

Subsection (e) provides that violation of any of the above provisions (Section 458.2) is deemed to be a commission of a fraudulent, coercive, or dishonest practice for purposes of Insurance Law section 2907 (dealing with insurance fraud). We recommend removing this language because unintentional violation may not be deemed fraudulent, coercive or dishonest.

11 NYCRR 458.3, Consumer Resources

Subsection (a) provides that PBMs come into compliance with formulary mandates by July 1, 2024, although the rest of the proposed rules become effective upon renewal following January 1, 2024, or as of a date certain on January 1, 2025. We seek clarification regarding the different date is used for these formulary provisions (as well as the network directory provisions). The earlier applicability of this provision will complicate the repricing because the restrictions on formulary actions will have an impact on client financial guarantees.

Subsection (a)(2) provides that except as provided in paragraph (4), a PBM shall not (i) remove a drug from formulary; (ii) move a drug to a higher cost sharing tier; or (iii) add utilization management restrictions to a drug, unless such changes occur at the time of enrollment, issuance, or renewal of coverage. HPA strongly opposes this provision. New York's Frozen Formulary law (Chapter 99 of 2022) was expressly limited to fully-insured plans. Additionally, amendments were negotiated to expressly state the law does not supersede the terms of a collective bargaining agreement. Including this provision serves the sole purpose of impacting self-insured ERISA plans and Medicare Plans subject to federal preemption and reaching fully-insured programs that were intentionally exempted by the State legislature. The Department does not have the authority to regulate benefit design in this way and is acting beyond the legislative intent and authority of the law. Further, this requirement is in direct conflict with Medicare's extensive formulary and utilization management rules.

Additionally, pursuant to Subsection (a)(3), the prohibitions in Subsection (a)(2) apply beginning on the date on which a plan year begins through the end of such plan year. This is impractical. While HPA is strongly opposed to frozen formularies because they increase the cost of prescription drugs by preventing the marketplace from responding to changes in this dynamic industry, if promulgated, HPA would strongly advocate to tie changes in the formulary to the calendar year.

Otherwise, because plan years vary by plan, no plan within scope of this law would be able to leverage a standard formulary.

Subsection (a)(4) provides that a PBM that manages a tiered formulary (i) may move a drug to a tier with a higher cost share if an AB rated generic equivalent or interchangeable biological product for such prescription drug is added to the formulary at the same time; (ii) may remove a drug from formulary if the FDA determines it should be removed from the market; and (iii) may move a drug to a larger cost share during the plan year, provided the change is not applicable to a member who is already receiving such drug or has been diagnosed with a conditioned on or prior to the start of the plan year that is treated by such a drug that would be a part of their regimen. Medicare plans are required to follow Medicare's formulary rules and this provision appears to apply to Medicare. If this is the case, PBMs and plans would need to manage separate formularies for individual states creating a significant burden for plans participating in the Medicare program. It is unclear that would be operationally feasible, but it would increase PBM, plan, and federal government costs across the board. If this provision is not deemed to be preempted, it is unclear what role CMS would play in formulary reviews and approvals. It is possible CMS would need to hire additional staff to review plan formularies against the requirement of every individual state's laws and there may be added complications if a state specific formulary does not comply with specific federal Medicare formulary requirements (e.g., non-discrimination rules).

Subsection (a)(5) provides that PBMs must provide notice to members of its intent to remove a drug from formulary or alter the cost share in the next plan year 90 days prior to the start of the plan year. A PBM may meet this obligation if it co-signs on a similar health plan notice. We recommend altering the timeframe for notice because the 90-day notice is too long for members to reasonably be expected to engage with prescribers. Further, in Medicare, it is unclear whether this timeline would afford enough time to submit and get CMS approval of formularies.

Subsection (b)(1) requires PBMs to publish an up-to-date, accurate, and complete list for each health plan for which the PBM performs services. The list must identify each pharmacy with which the PBM has a direct/indirect contractual relationship and be posted on the PBM's public website and in a manner that is easily accessible to covered individuals and prospective insureds. These requirements create unnecessary burdens. The general public does not need access on a public website to the network directories of hundreds or thousands of plans sponsored by private employers, each of which could have a custom network. The general public does not purchase health plans from PBMs so there is no reason for a PBM to publish these network directories. Further, there are already Insurance Laws that require health insurers to provide this kind of information to insureds and prospective insureds. At a minimum, these provisions should be limited to health insurance policies only, and should avoid any overlap with requirements already existing in the laws applicable to health insurers (see for example, Insurance Law § 3217-B). To ensure accuracy for covered members, the Department should allow for a member to login to access the appropriate health plan directory. Also, some pharmacies do not provide PBMs with public-facing email addresses, so the requirement to publicize such emails should be removed.

Further, the proposal requires a PBM to verify and update the pharmacy directory information included on its public website for each health plan within two business days of the addition or termination of a pharmacy from a health plan's network. HPA believes this requirement should

be deleted in its entirety but, at a minimum HPA requests two days be amended to five days, as a weekly update should be sufficient given that pharmacy networks are relatively stable.

11 NYCRR 458.4, Network Adequacy

The proposed regulations require PBMs to offer a pharmacy network that would provide in-state members access to a least one 24-hour pharmacy within 30 minutes travel time unless none are located within the state, and at least three pharmacies within 30 minutes travel unless none are located within such distance. Mail order pharmacies may not be considered in meeting these standards. These requirements would effectively mandate that each PBM contract with every rural pharmacy, dictating benefit design by determining where prescriptions may be filled and at what cost-sharing amount.

The geo reporting to ensure 30-minute access would be overly burdensome. Also, industry standard software does not contain public transportation information. Further, the standards are inconsistent with the standards that are applied to fully-insured commercial products reviewed and approved by the Health Bureau of DFS and/or the Department of Health ("DOH"). It is unclear how the Health Bureau of DOH's review process would interact with network adequacy reviews at the PBM level.

Self-funded plans should be exempted from these provisions due to federal pre-emption. For fully-insured plans, HPA requests that the Department consider an alternative time and distance standard (e.g., aligned, as appropriate, with either the existing commercial insurance standards or Medicare access standards – which consider the percentage of beneficiaries living in close proximity to a pharmacy and include standards that vary for urban, suburban and rural areas. Medicare also uses miles versus minutes).

In addition, if PBMs must put any pharmacy in the network as long as it's open 24 hours, PBMs will be unable to ensure quality adherence. The 24-hour requirement is problematic because there are not many 24-hour pharmacies in many regions (there are approximately 60 in NYC, but few elsewhere). However, many in-network pharmacies have extended hours to service members' needs.

This section also provides that a PBM must not require members to only use PBM affiliated pharmacies for all prescriptions, refills or specialty drugs regardless of number of days' supply. This provision will operate to prohibit reliance on existing preferred network and specialty drug programs to the detriment of consumers. At a minimum, similar to other sections in the regulation, this language should be amended to add, "unless contractually required to do so by the health plan."

11 NYCRR 458.5, Investigation of Complaints

Upon receipt of a Department complaint, the regulation would require a PBM to file a response within five business days of receipt. The response would be considered filed only if it addresses all matters raised. The five-day timeframe is too short, as PBMs must determine what plan and program is involved (often with little information), whether there is any validity to the complaint,

and how it should be addressed. Plans request that the Department align the turnaround time standards with other programs (i.e., Medicare/Medicaid).

This section also prohibits a PBM from requiring the Department to use any external email or other system to read responses. Pharmacy complaints often contain PHI and/or proprietary information, such that PBMs might opt to use a secure portal to address HIPAA and other privacy concerns.

11 NYCRR 459.1, Requirements for Audits and Investigations of Pharmacies

The proposed regulations add a new Part 459, to provide requirements for audits and investigations of pharmacies. Presently, the authority to regulate pharmacy audits is vested to the Commissioner of Health pursuant to Public Health Law § 280-c and we do not believe that the Department has the necessary authority to promulgate regulations relating to audits. Further, the proposed regulations by the Department would violate the due process protections afforded by Public Health Law §§ 12, 12-a, 12-b. While the Plans oppose this section in its entirety; of particular concern, is the limitation that PBMs would be prohibited from withholding future payments before the final audit or investigation for any audit below a $25,000 threshold; and if it meets the threshold, not more than 10% of each monthly payment to the pharmacy may be withheld until the final determination. If Plans cannot collect any of the cost or only a small percentage of the cost prior to completing an audit, Plans would be at risk of losing a significant amount of money due to fraud. In addition, the prohibition against a PBM using a fax to send a pharmacy notice of an audit or investigation is problematic, because many pharmacies have fax as their preferred communication preference.

11 NYCRR 459.2, Audits and Investigations Conduct

The Proposed Regulations provide that a PBM shall conduct no more than one audit/investigation per calendar year per pharmacy unless initiated to address an identified problem, or upon reasonable suspicion of fraudulent activity/other intentional or willful misrepresentation. Plans recommend changing the timeframe from a 12-month period to 6-month period due to the volumes of claims that can be filled/processed with no ability for a pharmacy auditor to identify suspicious activity because of the limitations. There should also be an exception where audit findings suggest high levels of abnormal activity and fraud is not necessarily suspected. There are issues other than fraud that yield abnormal usage.

Citation correction: 459.2(b)(5) – Public Health Law section 280-c(2)(d) should be 280-c(2)(e).

[1] Estimates represent a sampling of HPA member plans and do not reflect the added costs that would be incurred by all HPA plans nor by non-HPA plans. The data includes estimates from a majority of HPA members, but does not include estimates from some HPA members that have significant New York market share. Thus, HPA expects that the total impact on the members served by HPA member health plans would be far greater than $790,000,000. Additionally, because self-insured plans who rely on HPA member plans for administrative services frequently contract directly with PBMs, the numbers below do not reflect the full impact of the dispensing fees or NADAC minimum on self-insured employer and union welfare fund clients.

Plans were asked for an estimate of the cost impact of a mandated dispensing fee of $10.18 as well as an estimate of the difference between existing drug costs and estimated costs to transition to the national average drug acquisition cost (NADAC) as the reimbursement floor, where applicable. Plans were not asked to account for other changes (in pricing practices or benefit design) that might be implemented in response to these requirements. Cost estimates were based on claims for the 2022 plan year and the chart below presents the impact by lines of business.

LOB	Dispensing Fee Difference (current vs $10.18)	Drug Costs Difference (current vs NADAC floor)	Total Impact Dispensing Fee + Drug Cost
Self-insured/ERISA	$ 28,286,973	$ 5,465,924	$ 33,752,897
Commercial (fully-insured)	$ 135,679,570	$ 41,343,284	$ 177,022,854
Medicare Part D	$ 340,476,858	$ 73,866,685	$ 414,343,543
Essential Plan	$ 76,167,261	$ 23,885,391	$ 100,052,652
CHPlus	$ 8,150,698	$ 5,940,284	$ 14,090,982
Total	**$ 588,761,360**	**$ 150,501,568**	**$ 739,262,928**

[2] For example, if the cost of a drug increases by $20 and the consumer has a 25% coinsurance obligation (the amount that applies to Medicare Part D), that consumer will be obligated to pay an additional $5 to obtain the drug. If the consumer has not yet met their deductible, they would bear the full $20 increase. Additionally, premiums (paid by the consumer, their employer or a public program) would also increase.

[3] "It is well established that in exercising its rule-making authority, an administrative agency cannot extend the meaning of the statutory language to apply to situations not intended to be embraced within the statute[.]" *Trump-Equitable Fifth Ave. Co. v. Gliedman*, 57 N.Y.2d 588, 595 (1982); *see, e.g., Kahal Bnei Emunim & Talmud Torah Bnei Simon Israel v. Town of Fallsburg*, 78 N.Y.2d 194, 204 (1991) ("Indeed, an administrative agency cannot promulgate a regulation that adds a requirement that does not exist under the statute."); *Health Ins. Ass'n of Am. v. Corcoran*, 154 A.D.2d 61, 67 (3d Dep't 1990) ("holding agency regulations must be consistent with and have a basis in the statute itself"), *aff'd*, 76 N.Y.2d 995 (1990)

[4] *See* NCHS Data Brief, No. 470, June 2023.

[5] Kaiser Family Foundation. Data Note: Prescription Drugs and Older Adults, August 9, 2019; accessed at https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.