SUPREME COURT OF THE STATE OF NEW YORK
ALBANY COUNTY

In the Matter of the Application of

NORTH SHORE HEMATOLOGY-ONCOLOGY ASSOCIATES, P.C. d/b/a NEW YORK CANCER & BLOOD SPECIALISTS,

Petitioner,

For a Judgment Under Article 78 of the CPLR,

- against –

NEW YORK STATE DEPARTMENT OF HEALTH, and NEW YORK STATE EDUCATION DEPARTMENT,

Respondents.

**AMICUS CURIAE AFFIDAVIT OF M. DANIEL BINGHAM, M.D., ON BEHALF OF HEMATOLOGY-ONCOLOGY ASSOCIATES OF CENTRAL NEW YORK, P.C.**

**Index No.: 908289-21**

**M. Daniel Bingham, M.D., representative of the amicus curiae Hematology-Oncology Associates of Central New York, P.C. ("HOACNY"), being sworn, deposes and says:**

1. I am a New York State licensed physician, board certified in internal medicine and medical oncology and hematology. I graduated from medical school from the University of North Carolina at Chapel Hill in 1992, and completed my residency at Duke University Medical Center in 1995. Later, I completed my fellowship in medical oncology and hematology at UNC Hospital in 1998. Currently, I serve as the President for HOACNY, and I have practiced medical oncology for 24 years.

2. I submit this Affidavit on behalf of HOACNY, which is to serve as HOACNY's amicus curiae submission in the above-captioned litigation.

3. I have reviewed the pleadings and motion papers filed on the docket in this case. As a

prefatory matter, HOACNY, having reviewed the Community Oncology Alliance's ("COA")[1] Motion for Leave to File an Amicus Curiae Submission, see NYSCEF No. 64-70, agrees with the substantive points raised by Dr. Mark E. Thompson[2] in his proposed amicus filing, and incorporates the arguments and authorities set forth therein into this Affidavit, as if set forth herein at length.

4. HOACNY is a New York hematology-oncology practice, which employs 14 New York-licensed oncologists, who practice out of one or more of HOACNY's three different locations, including East Syracuse, Onondaga Hill and Auburn, in addition to two New York hospitals, at which they maintain privileges.

5. HOACNY is not a parent, subsidiary, or affiliate of the Petitioner[3] in this matter. It is a fully independent oncology practice, and makes this submission as such.

6. HOACNY has a diverse patient population, including patients who are insured commercially, through Medicare, New York fee-for-service Medicaid, and New York Managed Medicaid.

7. Because HOACNY is comprised of New York oncologists who treat patients enrolled in New York fee-for-service Medicaid ("NYS FFS Medicaid") and Managed Medicaid plans, HOACNY has a vested interest in the outcome of this matter, as the Respondents' definition of the so-called "oncologic protocol" (the "DOP") prohibits HOACNY oncologists from in-office dispensing supportive therapies to these patients.

8. It is HOACNY's earnest hope that this filing – submitted by an independent, New York

[1] HOACNY is a member of COA. Anticipating the State's response to this point, HOACNY avers that COA does not control HOACNY's decision-making, nor does HOACNY control that of COA.
[2] See NYSCEF No. 65.
[3] The Petitioner, North Shore Hematology-Oncology Associates, P.C. d/b/a New York Cancer & Blood Specialists, hereafter referred to as "NYCBS". Respondents New York Department of Health ("NYDOH") and New York State Education Department ("NYSED") shall hereafter be referred to in the collective as "Respondents" or the "State".

oncology practice with its own unique perspective on this matter – will assist the Court in rendering a decision on the DOP's lawfulness.

9. Specifically, HOACNY submits this Affidavit to express its strong disapproval of the DOP and to advocate for its nullification. The DOP has affected and will continue to affect HOACNY's and other New York oncologists' ability to offer in-office dispensing of supportive therapies to a patient population that is arguably among the most vulnerable in all of our State: Medicaid patients suffering from cancer. Notably and, in HOACNY's view, unjustly, in-office dispensing of supportive therapies is generally not prohibited under Medicare or commercial plans. Thus, not only does the DOP result in comparably suboptimal care, but it also, in effect, punishes New York's impoverished and/or disabled Medicaid population from receiving the care that is available to their wealthier and less-burdened co-citizens. Such a result is, respectfully, a clinical, political, and legal travesty.

10. The egregiousness of the DOP's effects is unsurprising given the egregiousness of its provenance: per our review of the docket, the State has failed to submit a single Affidavit by an oncologist (or any other type of physician) in support of the rule's drafting, nor cited to a single page of authoritative medical literature that might begin to explain, let alone justify, its implementation.

11. What's more, HOACNY believes that the DOP fits a wider pattern of unchecked and unlawful agency rule-making in the oncology space, promulgated as a (poorly-disguised) policy, without any opportunity for the statutorily requisite public notice and comment period.

12. For these reasons and those that follow, HOACNY respectfully submits that the Court ought to grant NYCBS' Petition and deny the State's Motion to Dismiss.

## *I. From a Clinical Perspective, the DOP is Unworkably Vague.*

13. As this Court is by now well aware, the DOP creates a distinction between medications

dispensed for the "treatment of cancer or tumors[,]" on the one hand, and "drugs prescribed to relieve side effects of these therapies or to relieve distressing symptoms[,]" on the other. A true and accurate copy of the DOP is attached hereto as **Exhibit A**. This distinction is inconsistent with the clinical practice of oncology, with the medical literature, and, respectfully, does not appear to have a logical or rational basis.

14. Indeed, as indicated in Dr. Thompson's filing, the DOP makes it virtually impossible for the average oncologist to determine which drugs and modalities fall within it and which fall outside of it – and the same goes, necessarily, for any State bureaucrat or New York Managed Medicaid plan ("MCOs") attempting to enforce it. See NYSCEF No. 65 at, e.g., ¶5. ¶13.

15. By way of example but not limitation, there are medications, such as pegfilgrastim (Neulasta), that are designed to raise a patient's white blood cell count prior to chemotherapy, so that the patient's immune system is not overly-suppressed following chemotherapy.[4] This medication is not designed for the "treatment of cancer or tumors[,]" but it is integral to permitting a patient to safely undergo treatments that plainly are. Likewise, it is unclear whether it would be accurate to characterize such medications as being prescribed to "relieve [the] side effects . . . or to relieve the distressing symptoms" of a "treatment of cancer or tumor[,]" as to do so would be to characterize the prevention of fatal, post-chemo infections as a "side effect" or "distressing symptom[]" of chemotherapy. Such a position would be, with respect, absurd on its face. This underscores just how unworkable and unclear the DOP is.

16. Moreover, HOACNY can report that some MCOs have rejected claims by HOACNY submitted for the dispensing of pegfilgrastim (Neulasta) as being outside of the DOP, whereas other MCOs have not.

17. It is likewise unclear whether drugs indicated to treat the pharmacological extensions from

[4] Neulasta Prescribing Information. Onpro®(pegfilgrastim) injection. Amgen 2021.

chemotherapy – including drugs such as Allopurinol, often prescribed to counteract the elevations in uric acid levels resulting from the killing of cancer cells[5] – are "reliev[ing] side effects . . . or . . . distressing symptoms" – fall within in the ambit of the DOP, when, in the absence of such drugs, patients may develop potentially fatal complications, including Tumor Lysis Syndrome and hyperuricemia.

18. Similarly, it is unclear whether a drug like Apixaban – often prescribed to reduce the risk of clotting,[6] which risk may be increased both by the cancer itself, in addition to certain treatment modalities, including certain forms of chemotherapy – is designed to "relieve side effects" or "distressing symptoms[,]" where the distressing symptom could be a fatal blood clot and may derive from the underlying cancer itself, rather than the treatment thereof.

19. To underscore the clinically confounding nature of the DOP, we note that the National Cancer Institute, ("NCI") administered by the National Institute of Health ("NIH"), defines "Concomitant Agent" to mean: "Supportive care and essential ancillary medications required by a treatment regimen should be clearly identified." https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&version=21.06e&code=C70902&ns=ncit. In other words, the NCI construes an oncological treatment regimen to include concomitant or ancillary medications, which can include supportive therapies. Indeed, a search of www.clinicaltrials.gov, a database also administered (in part) by the NIH, revealed over 1,234 oncological treatment protocols including prednisone, an oral

[5] Zyloprim (Allopurinol) tablets. Prescribing Information. Casper Pharmaceuticals 2018. See Indications- "the management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels."

[6] Fernandez- Ruiz I. Apixaban therapy is effective and safe for cancer-associated VTE. Nature Reviews Cardiology 2020;17:322. "Apixaban therapy is as effective as low-molecular-weight heparin (LMWH) therapy for the prevention of recurrence of venous thromboembolism (VTE) in patients with cancer, with no increase in major bleeding events." See also Agnelli G, et al. Apixaban for the Treatment of Venous Thromboembolism Associated With Cancer. New Engl J Med 2020;382:1599-1607.

corticosteroid that the DOP would (presumably) preclude. In other words, New York's DOP – a so-called "policy" affecting the scope of the practice of oncology – runs contrary to a federally-recognized authority on the treatment of cancer.

## II. *Patients Who Cannot Avail Themselves of the Benefits of In-Office Dispensing Face Risks and Challenges that Affect Their Ability to Optimally Fight Their Disease.*

20. The DOP has caused and will continue cause Medicaid enrollees with cancer to seek out pharmacies – often specialty and/or mail order pharmacies – to obtain the supportive therapy medications they require under the relevant oncological regimen. This is not a small inconvenience.

21. It is no secret that, from time to time, pharmacies lose prescriptions; pharmacies dispense the wrong medication prescribed or the wrong form of the medication prescribed;[7] and, in the case of out of state mail order pharmacies, deliveries can be substantially delayed, or medications lost in the mail all together. Indeed, in my experience as a practicing oncologist, it is not atypical for a patient to have to wait at least 1-2 weeks to receive their medications.

22. HOACNY has found that, as a result of the DOP, certain MCOs have been denying claims for the dispensing of certain oral oncolytic medications, including Everolimus, Imatinib, Scemblix, Lenvima, Xeloda, Lonsurf, Verzenio, Xtandi and Tagrisso. Why this has occurred is unclear – these drugs are undeniably indicated for the "treatment of cancer and tumors" and yet the MCOs are so confounded in their efforts to comply with the DOP, that they have denied claims for their dispensing anyway. If these drugs cannot be dispensed in-office, they must, almost without exception, be secured from an out of state, mail order pharmacy. The administrative errors causing delays in delivery described above are compounded significantly in such instances, as is the corresponding potential danger to the patient, who loses precious time in fighting the disease with

[7] Goldspiel B, Hoffman JM, Griffith NL, et al. ASHP Guidelines on Preventing Medication Errors With Chemotherapy and Biotherapy. Am J Health System Pharm 2015;72:e6-35. See also Cohen Michael R., Medication Errors, 2nd edition. (Washington, DC: American Pharmaceutical Association, 2007), 55-66.

the appropriate medication.

23. Delay in receipt of drugs, be they oral oncolytics or supportive therapies, is also highly problematic, since, in my view, the optimal standard of care for the treatment of many cancers is to prepare all drugs required by an indicated oncological regimen (often referred to as an "Order Set") ***before treatment begins***.[8] This is why, as Dr. Thompson noted, many electronic health records systems prepopulate Order Sets for a given oncological treatment protocol to include all relevant medications, including supportive therapies such as prechemotherapy antiemetics. See NYSCEF No. 65 at ¶9.

24. The real world result of this is that patients must rush to find third-party pharmacies to dispense supportive medications immediately after or concurrent with receiving treatment – treatments which, as the DOP itself recognizes, can often have painful and debilitating side effects, such as chemotherapy-induced nausea and vomiting ("CINV") or serious infection. And many well-established oncological treatment protocols do, in fact, require that supportive medications be taken concurrently with (or immediately after) taking medications indicated for the "treatment of cancer or tumors[,] such as chemotherapy.[9,10] By way of example, the treatment protocol recognized by the National Comprehensive Cancer Network ("NCCN") for the treatment of Non-Hodgkin's lymphoma, often referred to as the CHOP protocol, calls for prednisone to be given together with the chemotherapy itself (as well as afterwards) to treat the inflammatory side effects of the

[8] Keefe S, Kambhampathi S, Powers B. An Electronic Chemotherapy Ordering Process and Template. Fed Pract 2015;32(Suppl 1):21S-25S. ("Depending on the chemotherapy regimen chosen, prechemotherapy antiemetics are prepopulated in both order sets, based on emetogenic potential. For a more complex patient, (i.e., one with multiple myeloma), the Kansas City VAMC order set includes type and dose of bisphosphonates, antiviral and antibacterial prophylaxis desired, anticoagulant therapy (aspirin vs warfarin vs other), and a reminder to consider erythropoiesis-stimulating agents for anemia.").

[9] NCCN Guidelines Version 1.2022. Management of Neutropenia See also NCCN G-CSFs for Prophylaxis of Febrile Neutropenia and Maintenance of Scheduled Dose Delivery (MGF-B).

[10] Matera RM, Relias V, Saig MW. Safety and Efficacy of Same-Day Administration of Pegfilgrastim In Patients Receiving Chemotherapy For Gastrointestinal Malignancies. Cancer Med J. 2021;4;6-11.

chemotherapy.[11] It is not reasonable, fair or, indeed, humane, to force a patient who is suffering from the debilitating effects of chemotherapy to rush to find a third-party pharmacy to get this medication filled because the State's so-identified "policy" says so.

25. Once a prescription leaves a practice, the provider loses control over the entire prescription event, including the processing and dispensing and delivery of the drug to the patient. Unless an oncologist is in-office dispensing supportive therapies, there is no way for him or her to ensure this process proceeds optimally, speedily and in a manner most consistent with the applicable oncological treatment protocol. The DOP has and will continue to ensure that this loss of control is, in effect, codified in law, to the detriment of thousands of highly vulnerable New York Medicaid-enrolled cancer patients. This is unacceptable on a medical, clinical, and human-level.

26. As an oncologist who has physician-dispensed supportive therapies in my practice, I would also note that my ability to ensure patient-adherence to medication regimens is greatly increased. Every time he or she visits with me, I, as their provider, can ensure they receive the medications they require – be they supportive or otherwise. Without this provider-to-patient linkage in the drug dispensing chain, there can be – as has been documented – "prescription abandonment" issues by patients.[12] This prescription abandonment is especially problematic for oral chemotherapy drugs.[13] They may forget to pick up the medications, or forget to pick them promptly enough to be taken pursuant to the patient's indicated oncological treatment protocol. Or the patient may feel too sick or weak to regularly and timely travel to the pharmacy. These issues are not present where patients may avail themselves of in-office dispensing by their trusted provider.

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[11] NCCN Guideline Version 5.2022. Treatment of Non-Hodgkin Lymphoma.
[12] Shank WH, Choudhry NK, Fischer MA, Avorn J, Powell M, Schneeweiss S, Liberman JN, Dollear T, Brennan TA, Brookhart MA. The epidemiology of prescriptions abandoned at the pharmacy. Ann Int Med 2010;153:633-40.
[13] Toich L. Large Portion of Oral Cancer Drugs Abandoned at Pharmacy Due to Out-of-Pocket Costs. Pharmacy Times. 2018; https://www.pharmacytimes.com/view/large-portion-of-oral-cancer-drugs-abandoned-at-pharmacy-due-to-out-of-pocket-costs.

III. ***The DOP Targets New York's Impoverished and/or Disabled Medicaid Population For the Provision of Comparatively Subpar Oncological Treatment.***

27. The diverse benefits associated with in-office dispensing supportive clinical therapies, an otherwise standard oncological practice now prohibited by the DOP within New York Medicaid, are generally available to patients enrolled in Medicare[14] and commercial plans.[15] HOACNY can confirm this from its own clinical and billing experience, as the practice has, historically, regularly in-office dispensed supportive therapies to its Medicare and commercially-insured patients without issue from Medicare or the relevant commercial plans, both of which regularly reimbursed HOACNY for such dispensing.

28. As a corollary to the above, the DOP's negative clinical effects – resulting from its requirement that cancer patients seek all supportive therapies (and even some oral oncolytics) from third-party pharmacies[16] – solely and specifically impact New York's Medicaid cancer patient population, which is to say, the deeply impoverished and/or significantly disabled.

29. Thus, as a law, the DOP is plainly a discriminatory and an unseemly one. HOACNY, a medical practice made up of oncologists, other healthcare professionals, and conscientious human

[14] See, e.g., MCPM Chapter 17 Section 80.2.2.

[15] See, e.g., Blue Cross Blue Shield. available at https://www.bluecrossnc.com/providers/medical-policies-and-coverage/search-medical-policy/medical-oncology-program (indicating that it will pay for regimens published in the literature, or published in Guidelines from organizations such as NCCN or NCI. As indicated above, many of these regimens include supportive therapy); see also Cigna Pathwell Specialty℠ Drug List, available at https://static.cigna.com/assets/chcp/resourceLibrary/pharmacyResources/pharmSpecialityPharmListing/cigna-pathwell-specialty-drug-list.html (providing in pertinent part that, for patients using a specialty medication to treat a complex medical conditions including cancer, "certain medications have to be administered by a provider in the Cigna Pathwell Specialty Network *or* ordered from an in-network specialty pharmacy to be covered."); see also Pharmacy Resources and Physician Administered Drugs, United Health, available at https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html (providing that "[s]pecialty pharmacy medications covered under the member's medical benefit may be provided through various sources – home infusion providers, outpatient facilities, physicians or specialty pharmacy.").

[16] See previous section, supra.

beings, takes the (hopefully) uncontroversial position that the State should not be in the business of punishing the poor and the disabled. While we presume the DOP's discriminatory impact was inadvertent and not by design, regardless of whether it resulted from nefariousness or incompetence, it is an impact that the State is now aware of (thanks, in part, to this litigation), and must correct. Unfortunately, however, by all accounts, the State is presently uninterested in doing so. Indeed, Respondents have expended valuable State time and resources to oppose the instant Article 78 Petition, and even to oppose COA's Motion for Leave to File an Amicus Submission. See, e.g., NYSCEF No. 71. Given the above, it is respectfully submitted that it is incumbent upon New York's independent judiciary, applying well-established law and common sense, to nullify the DOP with all practicable haste.

30. The issue of the lack of parity of quality of care for Medicaid enrollees as compared to Medicare and commercial insureds is not new. By way of example, the American Society of Clinical Oncology, or ASCO – a preeminent non-profit organization founded to "'conquer cancer through research, education, and promotion of the highest quality of care' [and whose] . . . annual meetings are among the largest and most prominent cancer conferences worldwide[17] – authored a paper in the preeminent "Journal of Clinical Oncology" entitled "[ASCO's] Oncology Policy Statement on Medicaid Reform" in 2014.[18] The paper laid out a series of enumerated principles and policy recommendations for Medicaid reform, including:

- "Patient with cancer who have Medicaid should receive the same timely and high-quality cancer care as patients with private insurance[;]" and
- "Medicaid payments should be sufficient to ensure that Medicaid patients can have access to quality cancer care." (collectively, the "ASCO Medicaid Principles").

31. The DOP's negative clinical effects and the State's unwavering championing thereof run

[17] Fergus v. Immunomedics, Inc., 2019 WL 1435917, at *2 (DNJ 2019).
[18] See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4879717/.

contrary to these principles, as blocking oncologists' ability to in-office dispense supportive therapies for Medicaid patients creates an asymmetry in those physicians' ability to optimally care for them as compared to those patients enrolled in Medicare or commercial plans who generally face no such hurdles. Stated another way, Respondents' promulgation and support of the DOP is irrational, arbitrary and capricious, presuming (perhaps wrongly) the State's goal is to affect positive change for the quality of care of Medicaid recipients. This conclusion is yet further bolstered given that well-documented studies have frequently found, as a general proposition, a disturbing trend of lower quality of care with regard to patients suffering from certain forms of cancer enrolled in Medicaid at the time of their diagnosis. [19,20]

32. For these reasons, HOACNY supports Petitioner's efforts to nullify the DOP.

### *IV. The DOP is Part of a Wider Pattern of Poor Rule-Making Unchecked by the Requisite Notice and Comment Period.*

33. As correctly noted in Petitioner's Verified Complaint, the DOP was promulgated in the absence of the statutorily required public notice and comment period because Respondents have taken the position that it is a mere "policy" rather than a rule with legal effect. See NYSCEF No. 1, at FN8; ¶34-41. Specifically, in lieu of notice and comment, Respondents simply slipped the DOP into the June 2021 New York Medicaid Fee-For-Service Program Pharmacy Manual Policy Guidelines (the "Medicaid Manual"); see also Verified Petitioner, NYSCEF No. 1, at ¶10.

34. But the DOP was not the only such rule-disguised-as-policy casually dropped into the Medicaid Manual by the State. In the Medicaid Manual, the State also shoehorned in a rule providing that only those pharmacies enrolled in NYS FFS Medicaid could lawfully dispense medications to Medicaid enrollees. See a true and accurate copy of the Medicaid Manual, attached hereto as

[19] See Parikh AA, Morris CR, Kizer KW. Disparities in quality of cancer care. Medicine 2017;96:50(e9125).
[20] See Parikh AA et al. The effect of health insurance status on treatment and outcomes of colorectal cancer. J Surg Oncol 2014;110:227-32.

**Exhibit B**. at 19-21 ("Who May Dispense" section). At the same time, the State expressly stated that, with regard to practitioner dispensers (i.e., physicians who wish to dispense medications in-office): "The [NYS] FFS [Medicaid] program ***currently does not enroll Practitioner Dispensers; however, the Department is working to facilitate this enrollment option***." Id. at 20 - 21 (emphasis supplied). In other words, by way of alleged "policy[,]" the State declared that medications for Medicaid enrollees may only be dispensed by providers enrolled as practitioner dispensers in NYS FFS Medicaid, ***and that enrollment was to take place through a process which does not yet exist***.[21] HOACNY respectfully submits that this bureaucratic catch-22 is, on its face, arbitrary and capricious, and totally lacking in rational basis.[22][23] This thinly-veiled rule is part and parcel with the DOP insofar as it is, like the DOP, a disturbingly unchecked and abusive exercise of unlawful quasi-legislative rule-making – without public notice and comment or input from the entities and individuals it purports to regulate.

35. By way of further example (but not limitation), the Medicaid Manual also arbitrarily and capriciously limits the scope of the practice of pharmacy in New York State under certain circumstances. Specifically, the Manual provides that any medications dispensed by a physician must be "***hand[ed] . . . to the patient directly[i.e., no physician dispensed medications may be] .***

[21] The State has since removed any representation that it is actively working to create an enrollment option for Practitioner Dispensers in the April 2022 version of the Medicaid Manual attached hereto as Exhibit C. See id. at 20.

[22] To add insult to injury, the Medicaid Manual goes on to state that practitioner dispensers were free to dispense under Medicaid, so long as the drugs were dispensed "***free of charge***[.]" Exhibit B at 20 (emphasis supplied). In another unviable solution, the State has since added that Practitioners may engage in billing the medical benefit for these drugs, despite not having been administered by the physician or the practical reality that medical benefit coverage for medications often differs than the pharmacy benefit coverage for a particular plan. Exhibit C at 20.

[23] The State recently doubled-down on this position in December 2021 and April 2022 versions of the Medicaid Manual which directs practitioners to dispense these drugs without any reimbursement for the acquisition costs associated with obtaining these necessary medications. A true and accurate copy of the December 2021 Medicaid Manual is attached hereto as Exhibit D. See id. at 20; Exhibit C at 20.

*. . delegated to another person[, the handoff] must be completed by only the dispensing physician*." Exhibit B at 20 (emphasis supplied). But as an oncology practice, HOACNY can attest that it is not unusual for larger practices in our field to employ clinical pharmacists, often in the form of Board Certified Oncology Pharmacists ("BCOPs"), to assist in dispensing/providing medications to patients. Pharmacists are, by law – and, ironically, specifically by the New York Education Law – to handle and dispense medications. See N.Y. Educ. § 6803; 6801. And nothing in Section 6807 of that law – which, per Respondents, is what the DOP is predicated upon[24] – prohibits a physician dispenser from directing a duly-licensed New York pharmacist working in that physician's practice to "hand" the physician-dispensed medications to a patient. See, generally, N.Y. Educ. § 6807. To provide or state otherwise, as the Medicaid Manual does, is to clearly encroach upon and narrow a New York statute governing the scope of the practice of a highly-regulated profession (in this case pharmacy), and doing so no less in the form of a so-called "policy"[25] is either the height of agency arrogance or agency negligent "policy"-making.

36. The DOP thus fits a wider pattern of highly problematic agency overreach by the Respondents and, in the absence of judicial intervention, HOACNY fears the State will continue to inadeptly tinker with the regulation of our and other highly-regulated healthcare professions, doing so without input from the public and, perhaps most importantly, from the professionals themselves.

## CONCLUSION

37. For all of these reasons, HOACNY respectfully submits, as a friend of the Court, that the Court should take action to check Respondents' unlawful rulemaking, and do so by, among other things, granting Petitioner's Verified Petition, denying Respondents' Motion to Dismiss, and

[24] See Exhibit B at 20.
[25] As repeated above, for the avoidance of doubt, it is HOACNY's position that the DOP is not a policy, but, rather, an agency rule.

nullifying the DOP.

Respectfully submitted,

M. Daniel Bingham, M.D.
President

State of New York
County of Onondaga

Sworn before me, the undersigned notary public, on the 1st day of August in the year 2022

Christine A Smith

CHRISTINE A. SMITH
Notary Public, State of New York
No. 01SM6286868
Qualified in Onondaga County
Commission Expires August 5, 2025