

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.

VERIFIED PETITION

**ORAL ARGUMENT
REQUESTED**

Index No.

Plaintiffs, NORTH SHORE HEMATOLOGY-ONCOLOGY ASSOCIATES, P.C. d/b/a NEW YORK CANCER & BLOOD SPECIALISTS, LLC (“NYCBS” or “Petitioner”), for its Verified Petition for judgment pursuant to Article 78 as against Respondents the NEW YORK STATE DEPARTMENT OF HEALTH (“NYDOH”) and the NEW YORK STATE EDUCATION DEPARTMENT (“NYSED”) (collectively, the “Respondents” or the “State”) states as follows:

THE PARTIES

1. Petitioner is an independent, New York oncology practice that treats, among others, New York Medicaid-enrolled cancer patients.
2. NYDOH is a New York state agency involved in the administration of New York State’s Medicaid program.
3. NYSED is a New York state agency governed by and involved in the administration of the New York Education Law, including New York Education Law § 6807, of relevance to this matter.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this controversy pursuant to, among other law, CPLR 7801 and 7803.

5. Venue is proper in this Court under CPLR 7804(b) and 506(b) because the Respondents are both located in Albany, New York.

PRELIMINARY STATEMENT

6. In June of this year, the NYDOH and NYSED quietly slipped a *de facto* agency rule into a New York State Medicaid Pharmacy Manual, which, without fanfare or legal authority, created out of whole cloth a definition of the practice of oncology in New York State, and did so in such a narrow and restrictive way as to interfere with New York oncologists' ability to manage the care of their own (Medicaid) patients. Constructing an entirely new legal definition of any medical specialty, let alone oncology, without public notice and comment is a breathtakingly irresponsible abuse of agency authority and one that must be corrected by the Court. The matter is all the more egregious given that this new definition does not exist within Medicare and, thus, its adverse consequences are felt only by New York's highly vulnerable and "categorically needy" Medicaid population.¹

7. Through this action, Petitioner seeks an Order nullifying this *de facto* rule as: an arbitrary and capricious violation of (1) the New York State Administrative Procedure Act ("SAPA") and (2) Article IV, § 8 of the New York State Constitution for lack of public notice and comment; (3) and as unconstitutionally vague.

¹ Roach v. Morse, 440 F.3d 53, 59 (2d Cir. 2006). ("The Medicaid program requires states that participate to cover the cost of care for the 'categorically needy,' which the statute defines as those individuals who are unable to cover the costs of their basic needs and already receive or are eligible for certain forms of public assistance.") (internal citation omitted).

BACKGROUND

A. Physician Dispensing In New York State and the “Oncological Protocol”.

8. Broadly, physician dispensing refers to the process through which a physician dispenses medications to a patient at the point of care, rather than providing the patient a prescription to be filled at a separate, third party pharmacy.² It has obvious advantages – particularly in the oncology context. The dispensing physician can coordinate all aspects of the patient’s medication management, in addition to providing counseling to the patient upon dispensing, enhancing the effectiveness of a drug regimen and a patient’s adherence to it.³ Under this model, sickly patients don’t have to try their luck at random retail or mail-order pharmacies, where dispensing mistakes can occur, where wait times can be extensive, and where administrative red-tape and confusion are often the rule rather than the exception.⁴ Moreover, in the oncology setting, patients are often taking multiple prescriptions at the same time, some of which cause severe side effects, and others of which mitigate them. Receiving all cancer care – oncolytics and supportive medications – from the same source has immense benefits for patients and caregivers alike.

9. New York generally limits physician dispensing by statute, with certain exceptions. Specifically, New York Education Law § 6807, prohibits physicians and other New York prescribers “who [are] not the owner[s] of a pharmacy” from “dispens[ing] more than . . . seventy-two hour supply of drugs[.]” Id. at 6807(2)a. This prohibition is then followed by a finite list of exceptions,

² While, upon information and belief, there is nothing unlawful about a medical practice owning a pharmacy in the State of New York, as a practical matter, it is Petitioner’s understanding that this is generally disallowed by the State. This reality is reflected by the fact that, to Petitioner’s knowledge, neither the New York Board of Pharmacy nor the NYSED, Office of the Professions more broadly, grant pharmacy licenses to physician practices. Thus, for all intents and purposes, physician dispensing is a physician practice’s only option should it wish to dispense in-office to its patients.

³ See, e.g., <https://www.ncoda.org/wp-content/uploads/bp-attachments/7218/ajmcpa032016inofficedispensingcontinuityofcarebynancyegerton.pdf> (last accessed 9/14/21) at S100-202.

⁴ See Id. at S101.

among which, at § 6807(2)(a)(9), is the following: physicians may “dispens[e] . . . drugs pursuant to an oncological or AIDS protocol.” This is the only mention of oncology in § 6807. See, generally, id.

10. The term “oncological protocol” or “oncologic protocol”⁵ is nowhere defined within the New York Education Law or, per our research, anywhere else in New York law – be it statutory, regulatory or the common law. And, as discussed below, no New York agency had ever issued guidance on its meaning, until the *de facto* rule at issue in this matter was surreptitiously included in a June 4, 2021 copy of the New York Medicaid Fee-For-Service Program Pharmacy Manual Policy Guidelines (the “Medicaid Manual”).⁶

B. Publication of the June 4, 2021 New York State Fee-for-Service Program Pharmacy Policy Guidelines Without Notice and Comment.

11. On or about June 4, 2021, a link to the Medicaid Manual was published on the NYDOH website. See https://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm (last accessed on 9/14/21).⁷

12. Page 20 of the Medicaid Manual provides a definition of the Oncologic Protocol, which, on information and belief, was crafted by both the NYDOH and the NYSED (the latter of which is charged with administration of the New York Education Law and associated regulations). The definition provides:

“Policy

Practitioners who choose to dispense outpatient drugs to a NYS Medicaid FFS or Managed Care member must:

- be actively licensed as a practitioner authorized to prescribe and in good standing with NYS;
- be actively enrolled as a practitioner;

⁵ For reasons unknown, the State appears to use the terms “oncologic protocol” and “oncological protocol” interchangeably. Compare Exhibit A at 20 with New York Education Law § 6807(a)(9).

⁶ A true and accurate copy of the Medicaid Manual is attached hereto as Exhibit A.

⁷ Note that clicking on the “NYS MMIS Pharmacy Provider Manual” hyperlink on this webpage redirects readers to <https://www.emedny.org/providermanuals/> (last accessed 9/14/21), which contains a listing of “Provider Manuals,” among which is the Medicaid Manual.

- have software available to monitor for drug allergies or other complications;
- dispense only to their own patients;
- label, hand the drug to the patient directly (cannot be delegated to another person, must be completed by only the dispensing physician), and counsel patient according to NYS Education Department guidance;
- maintain records of drugs dispensed and circumstances (i.e., emergency);
- ***limit dispensing of drugs according to law including but not limited to:***
 - ***An oncologic protocol is written set of instructions to guide the administration chemotherapy, immunotherapy, hormone therapy, targeted therapy to patients for the treatment of cancer or tumors. It does not include protocols that cover drugs prescribed to relieve side effects of these therapies or to relieve distressing symptoms (such as nausea or pain). [Education Law §6807]***
 - An acquired immunodeficiency syndrome (AIDS) protocol is a written set of instructions to guide the administration antiretroviral drugs to patients for the treatment of HIV infections or AIDS. It does not include protocols that cover medications prescribed to provide relieve side effects of these therapies or distressing symptoms (such as nausea or pain). [Education Law §6807]"

[Id. (emphasis supplied) (hereafter, the “Oncologic Protocol” or the “*de facto* Rule”].

13. Thus, as the bolded language suggests, the NYDOH and the NYSED, took it upon themselves to define, in a highly restrictive fashion, the term “oncologic protocol,” decoupling from it any medications prescribed by an oncologist to ease the often brutal pain, nausea or infections that may arise as a result of therapies prescribed in the “treatment of cancer or tumors.” Indeed, Respondents took it upon themselves to determine what the “treatment of cancer or tumors” means and what it does not. Effectively, therefore, this so-called “[p]olicy”⁸ defines the practice of oncology.

14. Other than the citation to the New York Education Law § 6807, there is no authority, legal, medical or otherwise, cited in support of the Oncologic Protocol’s newly-crafted definition.

15. There is, in fact, no statute, regulation or case that defines the Oncologic Protocol.

16. Respondents do not cite to any independent scientific or medical study supporting the definition of the Oncologic Protocol.

17. Respondents do not cite to any study undertaken by either the NYDOH or the NYSED, or, for that matter, to a study by any other New York State agency defining or attempting to define the

⁸ In fact, as discussed in greater detail below, the definition of the Oncologic Protocol is not a policy – it is a rule.

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