

**Matter of North Shore Hematology-Oncology Assoc.,  
P.C. v New York State Dept. of Health**

2023 NY Slip Op 34708(U)

February 27, 2023

Supreme Court, Albany County

Docket Number: Index No. 908289-21

Judge: Roger D. McDonough

Cases posted with a "30000" identifier, i.e., 2013 NY Slip Op 30001(U), are republished from various New York State and local government sources, including the New York State Unified Court System's eCourts Service.

This opinion is uncorrected and not selected for official publication.

STATE OF NEW YORK  
SUPREME COURT                      COUNTY OF ALBANY

---

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.

---

Supreme Court Albany County Article 78 Term  
Hon. Roger D. McDonough, Acting Supreme Court Justice Presiding  
RJI # 01-21-ST1946    Index # 908289-21

Appearances:

FRIER & LEVITT, LLC  
Attorneys for Petitioner<sup>1</sup>  
(Jason N. Silberberg, Esq., of Counsel)  
84 Bloomfield Avenue  
Pine Brook, NY 07058

LETTIA JAMES  
Attorney General of the State of New York  
Attorney for Respondents  
(Kostas D. Leris, Esq., A.A.G., of Counsel)  
The Capitol  
Albany, New York 12224

**DECISION/ORDER/JUDGMENT**

---

<sup>1</sup> Petitioner's attorneys also made the motion filings on behalf of the amici.

Roger D. McDonough, Justice

Petitioner challenges respondent NYSDOH's definition of Oncologic Protocol ("DOP") as: (1) a violation of the New York State Constitution and the State Administrative Procedure Act ("SAPA"); (2) lacking in a rational basis; and (3) unconstitutionally vague in its failure to rationally or reasonably differentiate between certain medications. Accordingly, petitioner seeks an Order and Judgment annulling the DOP. Respondents moved to dismiss based on service/jurisdictional issues. Respondents withdrew their dismissal motion and served an answer to the petition. Therein, respondents oppose the requested relief in its entirety. Petitioner has served reply papers and the matter is fully submitted. Subsequently, petitioner brought two motions for leave to file amicus curiae affidavits on behalf of Community Oncology Alliance ("COA") and Hematology-Oncology Associates of Central New York, P.C. ("HOACNY") respectively. Respondents have opposed both amicus motions.<sup>2</sup>

### Background

Petitioner is a medical practice specializing in oncology. The petitioner's patients include New York residents enrolled in Medicaid. Respondent NYSDOH is involved in the administration of New York State's Medicaid Program. Respondent NYSED is a state agency governed by and involved in the administration of the New York Education Law, including § 6807.

Petitioner contends that respondents inappropriately added the DOP to the New York State Medicaid Pharmacy Manual ("Manual"). The Manual was issued in June of 2021. The definition concerns the practice of oncology in New York State. § 6807 prohibits New York's physicians and other defined prescribers, who are not owners of a pharmacy, from dispensing more than a seventy-two hour supply of drugs. However, the statute contains certain exceptions including the dispensing of drugs pursuant to an oncological protocol. The petitioner contends

---

<sup>2</sup> The Court has reviewed the request for oral argument. Said request came solely from the petitioner. In the absence of novel legal issues or some other compelling factor, this Court has adopted a procedure of not granting oral argument when it is requested by only one party. No novel legal issues or other compelling factors have been presented in any of the submissions herein. Accordingly, pursuant to 22 NYCRR 202.8-f, the request for oral argument is denied.

that the DOP was the first time any definition of oncological/oncologic protocol was issued by a New York State agency. The DOP states that an oncologic protocol “does not include protocols that cover drugs prescribed to relieve side effects of these therapies or to relive distressing symptoms (such as nausea or pain).” The referenced therapies are chemotherapy, immunotherapy, hormone therapy and targeted therapy.

### **Discussion**

#### **Amici Motions**

The Court finds that the proposed amici have adequately met their burden for Court consideration of the proffered affidavits (*see generally*, Matter of Norse Energy Corp. USA v Town of Dryden, 108 AD3d 25, 30 [3<sup>rd</sup> Dept. 2013]).

The amici focused their arguments on the reality that oncological protocols regularly include concomitant supportive care prescriptions. They further maintain that there is no sound clinical reason for deeming these prescriptions to be outside the oncologic protocol. Additionally, the amici provided specific examples of differing approval treatments for identical drugs.

#### **Respondents’ Timeliness Challenge**

Respondents acknowledge that the DOP was published in the Medicaid Manual on June 24, 2021. The petition in this matter was clearly filed within four months of said date. However, respondents maintain that the subject definition was actually included on NYSDOH’s website in January of 2021 and a link to said section was specifically emailed to the petitioner in February of 2021. Respondents contend that the four month limitations period began to run in January or February of 2021. Accordingly, they seek dismissal on a timeliness basis.

Petitioner raises various arguments in opposition. First and foremost, petitioner argues that the DOP did not become binding and actionable until June of 2021. It was at this time, along with the publishing of the DOP in the Medicaid Manual, that petitioner began receiving claims denials for the impacted prescriptions.

The Court finds that respondents have not met their timeliness burden. Specifically, respondents did not establish that petitioner’s “actual concrete injury” from the DOP occurred prior to June of 2021 (*see*, Matter of Silvestri v Hubert, 106 AD3d 924, 925 [2<sup>nd</sup> Dept. 2013]).

Accordingly, the timeliness argument must be rejected.

**1<sup>st</sup> Cause of Action - Alleged Violations of SAPA and the State Constitution**

Petitioner argues that the DOP is a rule under New York law and that respondents were required to comply with the rule making provisions of SAPA. As to the State Constitution, petitioner argues that Article IV, § 8 required respondents to file the DOP in the office of the department of state. Specifically, petitioner contends that the DOP substantially altered New York's Medicaid coverage for medications dispensed by oncologists.

Respondents principally argue that the DOP is not a rule, but rather constitutes a clarification and reasonable interpretation of the existing Education Law statute. Accordingly, they argue that the first cause of action should be dismissed in its entirety.

In reply, respondents re-stress that the DOP clearly meets the controlling case law definition of a rule. In particular, respondents contend that the DOP is non-discretionary and compels certain actions/denials on the part of respondents. Accordingly, petitioner maintains that the DOP is not merely interpretive or a statement of general policy and must be treated as a rule for SAPA and constitutional purposes. In support of the rule definition, petitioner also stresses the significant public impact of the DOP on patients receiving oncological medical care. Finally, petitioner notes that the DOP has no basis in preexisting statute or regulation. Specifically, petitioner points to the absence of any discussion of side effect treatments or supportive therapies in any relevant statute or regulation.

The Court finds that the DOP is excluded from SAPA and constitutional rule notice requirements as it is an interpretive statement of a preexisting statute (*see, Cubas v Martinez*, 8 NY3d 611, 621 [2007]). § 6807 already allows for non-pharmacy owners/employees to dispense more than a 72 hour supply of drugs pursuant to an oncological protocol. The DOP interprets the statutory language as having no applicability to drugs prescribed to relieve the side effects of the oncological therapies of chemotherapy, immunotherapy, hormone therapy and targeted therapy. Accordingly, the Court finds that the DOP is merely explanatory and without legal effect (*see, Matter of Elcor Services, Inc., v Novello*, 100 NY2d 273, 279 [2003]). Finally, in light of the 72 hour emergency prescription provisions and the absence of any meaningful proof that petitioner's patients are experiencing any actual difficulties in obtaining their necessary prescriptions through

pharmacies, the Court has not been persuaded that the DOP has occasioned any meaningful public health impact. Based on all of the foregoing, the SAPA and constitutional challenges to the DOP must be denied.

**2<sup>nd</sup> Cause of Action - Rational Basis**

Petitioner challenges the DOP as lacking a rational basis as it solely relies on a subpart of § 6807 of the Education Law. The petitioner contends that this subpart does not distinguish between medications in the manner set forth by respondents. Additionally, petitioner notes that respondents failed to cite any independent studies supporting respondents' definition of oncologic protocol.

Respondents contend that there was no need to cite any medical/scientific studies because the DOP merely constitutes a clarification of an existing statute. Further, respondents argue that the DOP was necessary to address physicians using the oncological protocol to dispense drugs that were beyond the limits of New York's Education Law. The respondents maintain that this clarification was adopted after consultations with NYSED. Further, respondents state that the DOP was necessary to: (1) prevent patient steering and lack of pharmacy choice; and (2) guide physicians who might be subjecting themselves to professional discipline for failure to comply with the relevant prescribing/dispensing legislation. The respondents also maintain that they utilized their administrative and interpretative expertise in clarifying the protocol definition. Accordingly, they maintain that this Court should extend the appropriate deference to the DOP.

In reply, petitioner again cites the absence of any reasonable scientific due diligence prior to promulgating the DOP. As such, they again maintain that respondents are not entitled to any agency expertise deference. More specifically, petitioner focuses upon respondents' failure to consult with any oncologists and ignored the authoritative texts/treatises on oncology.

The Court finds that respondents' interpretation of the Education Law § 6807 does not conflict with the plain language of the statute and is not irrational (*see, Matter of Elcor Health Servs. v Novello, supra* at 280). The possibility that the statute could be interpreted as having a broader definition of oncological protocol prescriptions does not render respondents' interpretation irrational (*see, Id.*). Further, the Court finds that respondents have adequately explained how the interpretation is necessary to prevent patient steering and lack of pharmacy

choice for consumers.

**3<sup>rd</sup> Cause of Action - Vagueness**

Petitioner contends that the DOP fails to offer any guidance on distinguishing oncologic protocol drugs from drugs prescribed to relieve side effects of chemotherapy, immunotherapy, hormone therapy and targeted therapy. Additionally, petitioner argues that the confusion that has arisen from the DOP could have been addressed had respondents properly followed the legally required rule making procedures.

Respondents first argue that the vagueness challenge has no applicability to an interpretive statement of policy. In any event, they contend that the DOP has a clear, core meaning that can reasonably be understood and applied. Accordingly, respondents ask the Court to reject the vagueness argument.

In reply, petitioner maintains that respondents failed to even address the proffered factual and legal assertions of vagueness. Additionally, petitioner re-stresses and expands upon the arguments raised in their initial submissions. \

The Court has held that the DOP constitutes an interpretive statement as opposed to a rule. Respondents' own classification of the DOP is that of an interpretive statement without legal effect. The Court finds that the DOP cannot be classified as a statute or regulation subject to constitutional vagueness analysis (*see, Matter of Independent Ins. Agents & Brokers of N.Y., Inc. v New York State Dept. of Fin. Servs.*, 39 NY3d 56, 63-64 [2022]). Controlling Court of Appeals case law solely discusses penal and civil statutes and regulations in applying vagueness analysis (*see, Id.*).

The parties' remaining arguments and requests for relief have been considered and found to be without merit and/or unnecessary to reach in light of the Court's findings. Specifically, respondents' conditional request to respond to the amici submission has been rendered moot by the Court's findings.

Based upon all of the foregoing, it is hereby

**ORDERED and ADJUDGED**, that the motions for leave to file amici affidavits from COA and HOACNY are hereby granted and said affidavits have been considered by the Court; and it is further

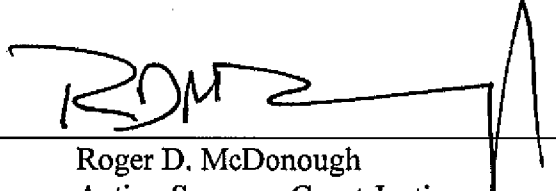
**ORDERED and ADJUDGED**, that the petition is hereby dismissed and the relief requested therein is in respects denied.

**SO ORDERED AND ADJUDGED.**

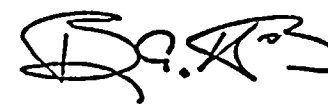
This shall constitute the Decision, Order and Judgment of the Court. This Decision, Order and Judgment will be forwarded to the Albany County Clerk by the Court. A copy of the Decision, Order and Judgment is being forwarded to all counsel of record. The signing of this Decision, Order and Judgment and delivery of the same to the County Clerk shall not constitute entry or filing under CPLR 2220. Counsel for the respondents is not relieved from the applicable provisions of that rule with respect to filing, entry, and notice of entry of the Decision, Order and Judgment. As this is an E-FILED case, there are no original papers considered for the Court to transmit to the County Clerk.

**ENTER**

Dated: Albany, New York  
February 27, 2023

  
Roger D. McDonough  
Acting Supreme Court Justice

7



02/27/2023



Papers Considered<sup>3</sup>:

1. Notice of Petition, dated September 22, 2021;
2. Verified Petition, verified on September 21, 2021, with annexed exhibit;
3. Respondents' Notice of Motion, dated September 27, 2021;
4. Affirmation of Kostas D. Leris, Esq., A.A.G., filed on September 27, 2021, with annexed exhibit;
5. Affirmation of Aaron M. Baldwin, Esq., dated September 27, 2021, with annexed exhibit;
6. Affirmation of Kerry-Ann Lawrence, Esq., dated September 27, 2021;
7. Affidavit of Danny McDonald, sworn to September 27, 2021;
8. Court Order granting withdrawal of respondents' Motion to Dismiss, executed on October 28, 2021;
9. Respondents' Verified Answer, dated November 8, 2021;
10. Affidavit of Suzanne Sullivan, sworn to November 8, 2021, with annexed exhibits;
11. Affidavit of Monica M. Toohey, sworn to November 8, 2021, with annexed exhibits;
12. Affirmation of Jason N. Silberberg, Esq., dated February 14, 2022, with annexed exhibits;
13. Notice of Motion to File Amicus, dated May 19, 2022;
14. Affidavit of Mark E. Thompson, M.D., sworn to May 18, 2022, with annexed exhibits;
15. Notice of Motion for Leave to File Amicus, dated August 1, 2022;
16. Affidavit of M. Daniel Bingham, M.D., sworn to August 1, 2022, with annexed exhibits.

---

<sup>3</sup> The parties also submitted several memoranda of law in support of their respective positions on the petition and the related motion practice.