

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

2023 NY Slip Op 34907(U)

September 27, 2023

Supreme Court, Albany County

Docket Number: Index No. 906532-22

Judge: Roger D. McDonough

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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,

Respondent.

Supreme Court Albany County Article 78 Term
Hon. Roger D. McDonough, Acting Supreme Court Justice Presiding
RJI # 01-22-ST2517 Index # 906532-22

Appearances:

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DECISION, ORDER AND JUDGMENT

Roger D. McDonough, Justice

Petitioner challenges the issuance of a “Policy Clarification for Practitioner Dispensing”

issued by respondent on August 10, 2022. The petition sets forth three causes of action: (1) that the August 10, 2022 issuance of the “Policy Clarification”(hereinafter “Clarification” violates the New York State Constitution and SAPA; (2) that the Clarification is unconstitutionally vague; (3) that the Clarification is arbitrary and capricious because it lacks a rational basis; and (4) that the Clarification is an error of law within the meaning of CPLR § 7803(3). Alternatively, petitioner seeks declaratory relief related to the Clarification. The petition also seeks an Order enjoining respondent, during the pendency of this proceeding, from enforcing, seeking to enforce, threatening to enforce, attempting to enforce or otherwise requiring compliance with the Clarification. Respondent opposed the injunctive relief and this Court denied the application for a preliminary injunction. Previously, Justice Mackey had denied the request for a temporary restraining order. Respondent has now answered and the matter is fully submitted.¹

Background

Petitioner is an oncology practice that treats, *inter alia*, New York Medicaid-enrolled cancer patients. On August 10, 2022, respondent issued the Clarification. The Clarification prohibits New York physicians from billing in-office dispensed medications as a Medicaid “pharmacy benefit”. Rather, said medications must be billed as Medicaid “medical benefit”. Petitioner maintains that physicians will no longer be able to dispense medications in their offices to Medicaid patients. The petitioner attributes this inability to the differences in billing complexity for “pharmacy benefits” versus “medical benefits”. Petitioner forecasts that the Clarification will cause physician dispensing to collapse. Further, the petitioner stresses its important role as an independent practice as compared to “large, private equity-backed hospital conglomerates” who typically have “wholly-owned, in house pharmacies”. Accordingly, these competing entities do not rely on physician dispensing.

The Clarification was not filed with the Secretary of State for publication and did not include any public notice of comment period. Petitioner claims that the Clarification was

¹ 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 pleadings or temporary relief submissions. Accordingly, pursuant to 22 NYCRR 202.8-f, the request for oral argument is denied.

therefore illegally promulgated based on the State Administrative Procedure Act (“SAPA”) and New York’s Constitution. Additionally, petitioner argues that the Clarification unconstitutionally vague based on its wholly ambiguous wording. As a result, petitioner claims that chaos and confusion arose in the “physician dispensing ecosystem”. Petitioner also argues that the Clarification lacks a rational basis because it was implemented without any evidence, authority or rationale for its drastic policy revisions to physician dispensing. Finally, petitioner maintains that the Clarification violates the Rehabilitation Act and constitutes an error of law under CPLR § 7803. Specifically, petitioner argues that the Clarification discriminates against disabled cancer patients.

Respondent maintains that the Clarification properly provides interpretive guidance on medication billing in accordance with existing law.

Alternatively, petitioner seeks a declaratory judgment that the Clarification does not preclude a physician dispenser from submitting claims for physician dispensed medication to the pharmacy benefit under Medicaid for otherwise clean claims. As to this alternative relief, respondent maintains that a declaratory judgment is the sole vehicle by which petitioner may challenge the Clarification.

Discussion

First Cause of Action - SAPA and State Constitution

Petitioner maintains that the Clarification is a rule that required compliance with SAPA and the State Constitution. Specifically, petitioner notes that the Clarification dictates a mandatory, non-discretionary outcome as to the billings at issue. Petitioner stresses that the Clarification is nondiscretionary and not dependent on individual facts and circumstances. The petitioner also points to the significant public impact of the Clarification, specifically in the area of public health. Lastly, petitioner maintains that the Clarification is a rule because it altered an existing paradigm without any reliance on corresponding statutory text.

Respondent argues that the rule provisions of SAPA and the State Constitution do not apply because the Clarification constitutes an interpretive statement/guidance. Specifically, respondent claims that the Clarification simply provides direction as to the proper Medicaid reimbursement methods for dispensing physicians/physician groups who are not licensed as a pharmacy. The respondent claims that the interpretation of the process is in accordance with

existing law and the existing reimbursement regime. Respondent further alleges that petitioner's perception of a change in policy only exists because petitioner had been previously seeking Medicaid reimbursement in an improper manner. The respondent further argues that the Clarification is consistent with the Social Services Law and the standards relevant to dispensing rules.

The Court finds that the Clarification is excluded from SAPA and State Constitution rule requirements as it is an interpretive statement/guidance of a preexisting statute (*see, Cubas v Martinez*, 8 NY3d 611, 621 [2007]). Specifically, the Clarification offers guidance as to the proper billing requirements under Social Services Law § 367-a(9). Said section specifically addresses reimbursement for drugs provided by medical practitioners versus drugs dispensed by pharmacies. The Court finds that the Clarification is merely explanatory guidance and without legal effect (*see, Matter of Elcor Services, Inc., v Novello*, 100 NY2d 273, 279 [2003]). Finally, in light of the other pharmaceutical options available to patients in this State and petitioner's apparent success in being properly reimbursed for dispensed medications during the pendency of this proceeding, the Court has not been persuaded that the Clarification has occasioned any meaningful public health impact. Based on all of the foregoing, the SAPA and constitutional challenges to the DOP must be denied.

Second Cause of Action - Vagueness

Petitioner argues that the Clarification is entirely unclear as to its superseding impact on "previous communications on this topic." Specifically, petitioner challenges whether the superseding language applies to one or both of the paragraphs that immediately follow it.

Respondent, relying on their rule definition argument above, contends that a vagueness challenge does not apply to interpretive statements of policy. Alternatively, respondent contends that the argument is without merit and simply not borne out by the actual factual record of how petitioner has been successfully seeking reimbursement.

The Court has held that the Clarification constitutes an interpretive statement/guidance as opposed to a rule. By no reasonable definition is the Clarification a statute or a regulation. Controlling case law solely discusses penal and civil statutes and regulations in applying 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]). Accordingly, the Clarification is not

subject to constitutional vagueness analysis (*see, Id.*). To the extent the Clarification is subject to vagueness analysis, the Court finds that it is not impermissibly vague.

Third Cause of Action - Arbitrary and Capricious

Petitioner argues that the Clarification is wholly lacking in any rationale or justification for its changes to billing methodologies. The petitioner stresses the absence of any record outlining the Clarification's rationale as well as the lack of any relevant studies conducted prior to its issuance. The petitioner also takes issue with respondent's failure to engage with stakeholders prior to issuing the Clarification. Lastly, petitioner re-emphasizes the lack of any link between the Clarification and relevant statutory text.

Respondent initially argues that it is entitled to judicial deference in its interpretation of the statutes and regulations it administers. Further, respondent contends that the Clarification is rational and designed to ensure compliance with existing statutes governing non-pharmacy dispensing.

The Court finds insufficient basis to overrule respondent Department's interpretive guidance of the Social Services Law (*see, Matter of Elcor Services, Inc., v Novello, supra* at 280). As the guidance does not conflict with the plain language of Social Services Law § 367-a(9) and is not arbitrary and capricious nor irrational, this Court will not disturb it (*see, Id.*).

Fourth Cause of Action - Error of Law

Petitioner maintains that it has set forth a clear cause of action that the Clarification constitutes unlawful discrimination under the Rehabilitation Act. Petitioner relies on the theory of associational standing as a rationale for advancing this argument on behalf of its disabled cancer patients.

Respondent contends that the petitioner has not been excluded from participation in any covered federal program. Instead, respondent posits that petitioner has simply been required to utilize proper procedures for medication billing. Further, respondent argues that petitioner has not been discriminated against and may continue to dispense medications directly to its patients. Finally, respondent argues that petitioner's patients are able to secure the necessary medications from licensed pharmacies. In sum, respondent argues that there is simply no meritorious discriminatory claim here.

The Court has not been persuaded that the Rehabilitation Act has any applicability to the

Article 78 record in this matter. There is simply no evidence that the disabilities at issue (cancer/oncological treatment) have resulted in petitioner's patients being in any way denied benefits under any program receiving Federal financial assistance. Accordingly, the Court finds that petitioner's CPLR § 7803 cause of action relying upon 29 U.S.C.A. § 794 must be dismissed.

Fifth Cause of Action - Declaratory Relief

Finally, the Court has not been persuaded that petitioner was required to challenge the Clarification solely through a declaratory judgment action. As the Court has already weighed and decided each of the other four causes of action, the Court need not address the alternative request for declaratory relief. To the extent this Court is required to address the declaratory relief, the Court finds as follows: It is hereby declared that the Clarification precludes dispensing physicians, including petitioner, from submitting claims for physician dispensed medications to the pharmacy benefit under Medicaid for otherwise clean claims.

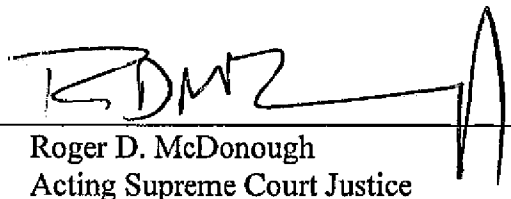
Based upon all of the foregoing, the petition is dismissed and the relief requested therein is in all respects denied.

SO ORDERED, ADJUDGED and DECLARED.

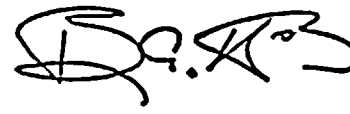
This shall constitute the Decision, Order and Judgment of the Court. The original Decision, Order and Judgment is being returned to the counsel for respondent who is directed to enter this Decision, Order and Judgment without notice and to serve petitioner's counsel with a copy of this Decision, Order and Judgment with notice of entry. The Court will transmit a copy of the Decision, Order and Judgment and the papers considered to the County Clerk. The signing of the Decision, Order and Judgment and delivery of a copy of the Decision, Order and Judgment shall not constitute entry or filing under CPLR Rule 2220. Counsel is not relieved from the applicable provisions of that rule respecting filing, entry and notice of entry.

ENTER

Dated: Albany, New York
September 27, 2023



Roger D. McDonough
Acting Supreme Court Justice



09/28/2023

Papers Considered²:

1. Order to Show Cause executed by this Court (Justice Mackey) on September 9, 2022;
2. Verified Petition, verified on August 31, 2022, with annexed exhibits;
3. Affirmation of Brenda Baddam, Esq., A.A.G., received by NYSCEF on September 2, 2022, with annexed exhibit;
4. Affidavit of Kimberly Leonard, sworn to September 2, 2022, with annexed exhibits;
5. Affirmation of Jason N. Silberberg, Esq., dated September 8, 2022, with annexed exhibits;
6. Affidavit of Rich McMullen, CPA, CMA, CSCA, CHFP, MBA, sworn to September 8, 2022, with annexed exhibit;
7. Decision and Order of this Court (Justice Mackey) executed on September 9, 2022;
8. Petitioner's Counsel's Correspondence to the Court, dated September 15, 2022;
9. Respondent's Counsel's Correspondence to the Court, dated September 19, 2022;
10. Affirmation of Jason N. Silberberg, Esq., dated September 22, 2022, with annexed exhibits;
11. Affidavit of David Eagle, M.D., sworn to September 22, 2022;
12. Affirmation of Jason N. Silberberg, Esq., dated September 29, 2022, with annexed affidavits of: (1) Peter Lande, sworn to September 28, 2022; (2) Christina Shramko-Kibler, sworn to September 28, 2022; and (3) Dorothy Malpica, sworn to September 27, 2022;
13. Respondent's Verified Answer, verified on May 30, 2023;
14. Affidavit of Kimberly A. Leonard, sworn to May 30, 2023, with annexed administrative record.

² The parties also submitted memoranda of law in support of their respective positions. Petitioner added a reply memorandum of law as well.