State of New York
Supreme Court, Appellate Division
Third Judicial Department

Decided and Entered: April 3, 2025 CV-23-2119

In the Matter of NORTH SHORE HEMATOLOGY-ONCOLOGY ASSOCIATES, P.C., Doing Business as NEW YORK CANCER & BLOOD SPECIALISTS,

Appellant,

v

NEW YORK STATE DEPARTMENT OF HEALTH,

Respondent.

OPINION AND ORDER

Calendar Date: February 20, 2025

Before: Garry, P.J., Lynch, Reynolds Fitzgerald, Fisher and McShan, JJ.

Frier Levitt, New York City (*Michael N. Sheflin* of *Frier Levitt*, Pine Brook, New Jersey, of counsel, admitted pro hac vice), for appellant.

Letitia James, *Attorney General*, Albany (*Kate H. Nepveu* of counsel), for respondent.

Garry, P.J.

Appeal from a judgment of the Supreme Court (Roger McDonough, J.), entered September 28, 2023 in Albany County, which dismissed petitioner's application, in a proceeding pursuant to CPLR article 78, to review a determination of respondent clarifying certain billing practices for practitioner dispensing.

This is the second proceeding between these parties to come before us concerning physician dispensing of prescription drugs, a practice explained fully in our decision on the prior appeal (*Matter of North Shore Hematology-Oncology Assoc., P.C. v New York State Dept. of Health*, 233 AD3d 97 [3d Dept 2024]). Pursuant to the state budget for fiscal year 2020-2021, pharmacy benefits for individuals receiving Medicaid were to be transitioned from the Medicaid managed care program – whereby respondent, as the agency charged with administering Medicaid in this state, pays an external managed care organization (hereinafter MCO) a fee for each enrolled member and the MCO then pays providers for covered services – to the Medicaid fee-for-service program – whereby respondent pays providers directly.[1] In preparation for that transition, slated to begin in April 2021 but later delayed to April 2023, respondent undertook a general review of pharmacy claims processed by MCOs. Somewhat unrelated to the transition, that review revealed that a small number of non-pharmacy Medicaid practitioners – fewer than 12 of the more than 116,000 of such practitioners – were submitting claims to their patients' pharmacy benefit, as opposed to their medical benefit. In other words, that small group of medical practitioners had been submitting and receiving reimbursements for dispensed drugs under the statutory methodology for drugs dispensed by pharmacies, which receive payment not only for the drugs that they dispense, as medical practitioners do for the drugs that they provide,[2] but also a professional pharmacy dispensing fee. Those medical practitioners included petitioner, an oncology practice that engages in physician dispensing.

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[1] Transitioning pharmacy services from the managed care program to the fee-for-service program was a cost savings measure, providing the state with increased visibility into the cost of prescription drugs and centralizing negotiation power for the purchase of said drugs, among other things (*see* Department of Health, *Understanding the Move from Managed Care to FFS: History and Objectives*, available at https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/pharmacy_transition/consumers/history.htm [last accessed Mar. 3, 2025]).

[2] At that time, medical practitioners received payment for "the actual cost of the drugs to the practitioners" (Social Services Law § 367-a former [9] [a], as added by L 1994, ch 170, § 456). Effective October 1, 2024, payment to medical practitioners considers benchmark prices, as has been the case for pharmacies, subject to a floor (*see* Social Services Law § 367-a [9] [a] [i], [iii], as amended by L 2024, ch 57, part I, §§ 5, 6). Petitioner makes no mention of this change.

As it regularly does, respondent then took steps to clarify appropriate billing practices. This included issuance of the July 2022 edition of its official newsletter of the New York State Medicaid Program – Medicaid Update. In a section entitled "Policy Clarification for Practitioner Dispensing" (hereinafter the clarification), which purported to "supersede[ ] previous communications on this topic," respondent stated that the state Medicaid program reimburses for drugs furnished by practitioners to their patients on the basis of the acquisition cost to the practitioner and that additional registration or ownership of a pharmacy is not required. The clarification went on to provide that practitioners billing for medications dispensed to its fee-for-service patients should use the medical claim format and that practitioners still participating in managed care should check with the patient's health plan to determine the billing policy for prescription drugs dispensed directly to patients. Reportedly confused by the alleged change in billing practice, petitioner subsequently contacted respondent for further clarification. In response, respondent reiterated that a practitioner that dispenses drugs to their patients is not considered a pharmacy under either statutory or enrollment requirements and therefore should not be enrolled or billing as a pharmacy provider.

Petitioner then commenced this CPLR article 78 proceeding to annul the clarification as an unpromulgated rule, unconstitutionally vague, irrational and violative of section 504 the Rehabilitation Act of 1973 (*see* 29 USC § 794). Citing anticipated financial losses for expenses attendant to medication dispensing, that is, beyond the acquisition cost of the drugs, petitioner argued that respondent's alleged new rule would force it to cease its physician-dispensing services altogether, thereby both irrationally depriving cancer patients from effective treatment and discriminating against them by effectively precluding them from meaningful access to the provider of their choice. Supreme Court rejected each of petitioner's arguments, and petitioner appeals.

The challenged clarification is not a rule. A "rule" for purposes of notice and filing requirements includes "the whole or part of each agency statement, regulation or code of general applicability that implements or applies law" (State Administrative Procedure Act § 102 [2] [a] [i]). However, specifically exempted from the definition of a rule under the State Administrative Procedure Act are "forms and instructions, interpretive statements and statements of general policy which in themselves have no legal effect but are merely explanatory" (State Administrative Procedure Act § 102 [2] [b] [iv]). As we recently reiterated, "the primary difference between a rule or regulation and an interpretive statement or guideline is that the former set standards that substantially alter or, in fact, can determine the result of future agency adjudications while the latter simply provide additional detail and clarification as to how such standards are met by the public and

upheld by the agency" (*Matter of North Shore Hematology-Oncology Assoc., P.C. v New York State Dept. of Health*, 233 AD3d at 100 [internal quotation marks, brackets and citations omitted]).

Medicaid is implemented in this state by Social Services Law article 5, title 11. Social Services Law § 367-a (9) provides that payments for drugs authorized under the title shall be made at the amounts specified in that subsection. Social Services Law § 367-a (9) (a) governs "drugs provided by medical practitioners and claimed separately by the practitioners," whereas Social Services Law § 367-a (9) (b) governs "drugs dispensed by pharmacies." Both medical practitioners and pharmacies are entitled to payment for the drug itself, whether presently measured by the wholesale acquisition cost or benchmarks adopted by the Legislature (*see* Social Services Law § 367-a [9] [a], [b]), but only pharmacies are further entitled to a "professional pharmacy dispensing fee for each such drug dispensed" (Social Services Law § 367-a [9] [d]). The challenged clarification, conveying the statutory payment methodology for medical practitioners and directing that they use the medical claim format – and, thus, that they not submit claims for payment under the statutory methodology for drugs dispensed by pharmacies – does no more than implement the governing statute through billing guidance, and it is therefore not a rule (*see Matter of Board of Educ. of the Kiryas Joel Vil. Union Free Sch. Dist. v State of New York*, 110 AD3d 1231, 1234-1235 [3d Dept 2013], *lv denied* 22 NY3d 861 [2014]). Whether certain MCOs incorrectly accepted a relatively small number of prior claims for payment beyond what was contemplated by the Legislature does not alter our conclusion (*see Matter of North Shore Hematology-Oncology Assoc., P.C. v New York State Dept. of Health*, 233 AD3d at 101).

Petitioner next maintains that the clarification is unconstitutionally vague as applied to it. In petitioner's view, the clarification's directive that it "supersedes previous communications on this topic" fails to qualify whether that applies to all or only part of what follows in the clarification, in addition to failing to specify the range of said previous communications. Petitioner's argument is nearly entirely premised on its continued mischaracterization of the clarification as a rule. Nonetheless, assuming without deciding that the clarification, with no independent legal effect of its own, may be subject to a void for vagueness analysis, we do not find it to be vague in any legitimate respect. First, the complete language regarding the impact of the clarification – that "[t]he following guidance supersedes previous communications on this topic" – makes clear that it applies to the clarification in its entirety. As described above, the clarification has two subsections: one regarding fee-for-service billing for practitioner dispensers and one regarding managed care billing for practitioner dispensers. With respect to fee-for-service

billing, the clarification is plainly intended to supersede previous communications from respondent concerning the lack of a mechanism for practitioner dispensers to bill for medications dispensed to their fee-for-service patients, providing the format and codes so that said practitioners may now do so. The section on managed care billing similarly reflects the evolving circumstances prior to the April 2023 implementation of the transition. In our view, it would be entirely unreasonable for petitioner, or any other practitioner dispenser, to assume that literally all other policies, manuals, bulletins, etc. concerning practitioner dispensing as a whole would be null in the face of this update.

We are also unpersuaded by petitioner's argument that the clarification is arbitrary, capricious or irrational. Unlike the circumstances presented in our prior case (*Matter of North Shore Hematology-Oncology Assoc., P.C. v New York State Dept. of Health*, 233 AD3d at 102-103), study and/or consultation with stakeholders was entirely irrelevant here, where respondent has merely effectuated the clear payment scheme established by the Legislature. Petitioner's true quarrel appears to be with the statute, to which there is no challenge before us.

Lastly, petitioner has failed to demonstrate a violation of the Rehabilitation Act on associational standing grounds as there is no record proof that any of its patients have actually been denied any benefit of a federally funded program.

Lynch, Reynolds Fitzgerald, Fisher and McShan, JJ., concur.

ORDERED that the judgment is affirmed, without costs.

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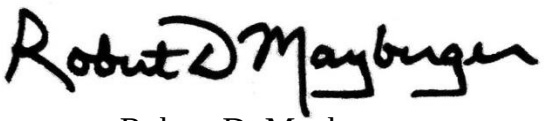

Robert D. Mayberger
Clerk of the Court