

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

Decided and Entered: October 17, 2024

CV-23-0517

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 et al.,
Respondents.

OPINION AND ORDER

Calendar Date: September 3, 2024

Before: Garry, P.J., Pritzker, Lynch, Fisher and Powers, JJ.

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

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

Garry, P.J.

Appeal from a judgment of the Supreme Court (Roger D. McDonough, J.), entered February 27, 2023 in Albany County, which, among other things, dismissed petitioner's application, in a proceeding pursuant to CPLR article 78, to review a determination of

respondent Department of Health adopting a definition of oncological protocol established by respondent State Education Department.

In order to address the potential conflict of interest that arises when a medical professional, such as a physician, acts as both a prescriber and seller of prescription drugs (*see* Governor Approval Mem, Bill Jacket, L 1989, ch 777 at 15), licensed healthcare providers who are legally authorized to prescribe drugs are generally prohibited from also dispensing more than a 72-hour supply of those drugs to their patients (*see* Education Law § 6807 [1] [b]; [2] [a]). There are a number of statutory exceptions to that general prohibition (*see* Education Law § 6807 [2] [a]; *see also* L 1990, ch 18), including, as relevant here, when the drugs are being dispensed "pursuant to an oncological . . . protocol" (Education Law § 6807 [2] [a] [9]). Petitioner, an oncology practice, engages in physician dispensing, including for its patients enrolled in Medicaid. Respondent Department of Health (hereinafter DOH) is the agency charged with administering Medicaid in this state. As the result of its review of certain Medicaid pharmacy claims handled by managed care organizations (hereinafter MCOs), DOH concluded that physicians were submitting claims for drugs falling outside of the oncological protocol exception, including drugs to treat nausea and pain, vitamins, antibiotics and antipsychotics. DOH then took a number of steps to clarify its position – to both physician dispensers and MCOs – regarding the exception. Those steps included communication with respondent State Education Department (hereinafter SED), the agency charged with implementing the Education Law, for the purpose of obtaining SED's interpretation of the exception. DOH ultimately adopted SED's interpretation, with one relatively minor change not at issue here. In its June 2021 update to the New York State Medicaid Fee-For-Service Pharmacy Manual Policy Guidelines, DOH published its definition of oncological protocol – "a written set of instructions to guide the administration of chemotherapy, immunotherapy, hormone therapy, [or] targeted therapy to patients for the treatment of cancer or tumors" that does not extend to "protocols that cover drugs prescribed to relieve side effects of these therapies or to relieve distressing symptoms (such as nausea or pain)."

Petitioner subsequently commenced this CPLR article 78 proceeding, asserting that, in or around the time of the June 2021 publication, it began receiving claims denials from MCOs for "supportive care" medications that had previously been reimbursed. Petitioner argued that DOH's new, allegedly more restrictive definition of oncological protocol constituted an unpromulgated rule and that said rule lacked a rational basis and was unconstitutionally vague. Respondents answered, and amici curiae were permitted to file affidavits in support of petitioner. Supreme Court ultimately dismissed the petition,

concluding that the challenged definition was merely a rational interpretive statement of preexisting statutory language. Petitioner appeals.

We initially reject petitioner's claim that DOH's definition of oncological protocol is an unpromulgated rule being applied without having been adopted through the procedure set forth in the State Constitution and State Administrative Procedure Act (*see generally* NY Const, art IV, § 8; State Administrative Procedure Act § 202). 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, "interpretive statements and statements of general policy which in themselves have no legal effect but are merely explanatory" are expressly exempted from the definition of a rule (State Administrative Procedure Act § 102 [2] [b] [iv]; *see Matter of Elcor Health Servs., Inc. v Novello*, 100 NY2d 273, 279 [2003]). Although "there is no clear bright line between a 'rule' or 'regulation' and an interpretative policy" (*Cubas v Martinez*, 8 NY3d 611, 621 [2007]), "[t]he 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 Plainview-Old Bethpage Congress of Teachers v New York State Health Ins. Plan*, 140 AD3d 1329, 1331 [3d Dept 2016] [internal quotation marks, brackets and citations omitted], *appeal dismissed* 28 NY3d 1168 [2017], *lv denied* 29 NY3d 910 [2017]; *see Matter of Elcor Health Servs., Inc. v Novello*, 100 NY2d at 279; *Matter of Board of Educ. of the Kiryas Joel Vil. Union Free Sch. Dist. v State of New York*, 110 AD3d 1231, 1233-1234 [3d Dept 2013], *lv denied* 22 NY3d 861 [2014]).

In pertinent part, Education Law § 6807 provides that "no prescriber who is not the owner of a pharmacy or who is not in the employ of such owner, may dispense more than a [72-hour] supply of drugs, except for . . . the dispensing of drugs pursuant to an oncological . . . protocol" (Education Law § 6807 [2] [a] [9]). DOH's definition of oncological protocol, which is not defined in the statute, imposes no additional limitation on prescribers beyond that already imposed by the Education Law. Rather, the challenged definition aims to provide clarification as to how prescribers can comply with the statute. We do not agree with petitioner's characterization of the subject definition as "redefining" oncological protocol merely because MCOs had, to some unknown extent on prior occasions, paid out claims for medications arguably beyond that contemplated by the Legislature (*see Matter of Pharmacists Socy. of State of N.Y., Inc. v Pataki*, 58 AD3d 924, 925-926 [3d Dept 2009], *lv denied* 12 NY3d 710 [2009]; *cf. Matter of HMI Mech.*

Sys. v McGowan, 277 AD2d 657, 659 [3d Dept 2000], *lv denied* 96 NY2d 705 [2001]; compare *Matter of Homestead Funding Corp. v State of N.Y. Banking Dept.*, 95 AD3d 1410, 1412-1413 [3d Dept 2012]; *Matter of SLS Residential, Inc. v New York State Off. of Mental Health*, 67 AD3d 813, 816 [2d Dept 2009]). Thus, as the subject definition has no independent legal effect (see *Matter of United Jewish Community of Blooming Grove, Inc. v. Washingtonville Cent. Sch. Dist.*, ___ NY3d ___, ___ 2024 NY Slip Op 03377, *4 [June 20, 2024]), we agree with Supreme Court that it is an interpretive statement not subject to rulemaking procedures (see *Matter of Pharmacists Socy. of State of N.Y., Inc. v Pataki*, 58 AD3d at 925-926; *Matter of UCP-Bayview Nursing Home v Novello*, 2 AD3d 643, 645 [2d Dept 2003]; see also *Matter of Board of Educ. of the Kiryas Joel Vil. Union Free Sch. Dist. v State of New York*, 110 AD3d at 1234; *Matter of Neighborhood Cleaners Assn.-Intl. v New York State Dept. of Env'tl. Conservation*, 299 AD2d 790, 793 [3d Dept 2002]).

However, we agree with petitioner that DOH's definition, adopting SED's interpretation, is irrational. In opposition to the petition, respondents submitted an affidavit by the Executive Secretary to the State Board for Nursing, housed within SED's Office of the Professions, who drafted the subject definition. In 2016, the Executive Secretary developed practice guidance for nurses, including related to certified nurse practitioners' authority to dispense drugs pursuant to Education Law § 6807 (2) (a) (9). In developing the guidance, she "consulted with SED staff, . . . conducted legal research and researched standards relevant to dispensing and oncologic protocols." No further explanation is provided regarding those consultations or medical standards. Guided by her assessment of the Legislature's goals to prevent the prescribing of unnecessary drugs and/or the charging of excessive prices while ensuring patient access to drugs for special medical conditions, the Executive Secretary elected to exclude from the definition of oncological protocol drugs that can be obtained through traditional fulfillment methods. The only other proof submitted by respondents to support the rationality of the subject definition was an affidavit by the Pharmacy Manager of DOH's Office of Health Insurance Programs. The Pharmacy Manager merely offered that DOH had conferred with SED regarding the oncological protocol exception on several occasions.

To the extent that respondents maintain that they are entitled to deference in this case, their argument is misguided. It has long been the practice in this state that, "where the statutory language is special or technical and does not consist of common words of clear import, courts will generally defer to the agency's interpretative expertise unless that interpretation is unreasonable, irrational or contrary to the clear wording of the statute" (*Kennedy v Novello*, 299 AD2d 605, 607 [3d Dept 2002] [internal quotation marks and

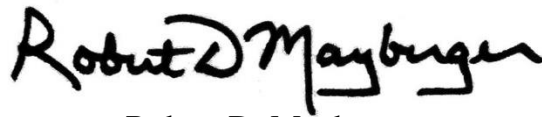
citations omitted], *lv denied* 99 NY2d 507 [2003]; *see Kurcsics v Merchants Mut. Ins. Co.*, 49 NY2d 451, 459 [1980]; *see also Matter of Leggio v Devine*, 34 NY3d 448, 460 [2020]; *Matter of Rosen v Public Empl. Relations Bd.*, 72 NY2d 42, 47 [1988]). Here, although the relevant statutory language touches upon technical healthcare matters, there is no evidence that any such expertise was genuinely exercised by either agency in arriving at the subject definition. Thus, although we agree with Supreme Court that the challenged definition does not conflict with the plain language of the statute (*see Matter of Elcor Health Servs., Inc. v Novello*, 100 NY2d at 280), we do not find that any deference in interpreting that language is warranted (*compare Kennedy v Novello*, 299 AD2d at 607-608).

As the Executive Secretary alluded to, there was a dual intent behind the oncological protocol exception: to minimize the financial incentive for a physician to narrow a patient's therapeutic choices (*see* Senate and Assembly Introducers' Mem in Support, Bill Jacket, L 1989, ch 777 at 5) but also "ensure that adequate health services can be provided in those instances when it is reasonable for physicians to dispense" (Senate and Assembly Introducers' Mem in Support, Bill Jacket, L 1990, ch 18 at 5, 7; *see* Governor Approval Mem, Bill Jacket, L 1989, ch 777 at 15). The record before us is replete with evidence of industry guidelines and authoritative medical literature strongly suggesting that respondents' definition may inhibit the provision of adequate healthcare to oncology patients. This includes evidence of the need for ancillary or concomitant administration of medications presumably excluded from the definition in order to enhance the effects of cancer treatments and/or prevent fatal complications arising therefrom. That evidence also clearly contemplates supportive care medications being administered as part of cancer treatment regimens in order to address the often debilitating side effects of such treatment. Given the complete absence of any medical basis for the line drawn here, and guided by the Legislature's intent to ensure that its general prohibition against prescriber-dispensing did not unreasonably impede the provision of adequate healthcare services in the context of oncology, we cannot find that the definition of oncological protocol before us is rational. In light of this conclusion, petitioners' remaining arguments are academic.

Pritzker, Lynch, Fisher and Powers, JJ., concur.

ORDERED that the judgment is reversed, on the law, without costs, and petition granted.

ENTER:

A handwritten signature in black ink that reads "Robert D. Mayberger". The signature is written in a cursive style with a large, prominent "R" at the beginning.

Robert D. Mayberger
Clerk of the Court