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,

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[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/ajmcpan032016inofficedispensingcontinuityofcarebynancyegerton.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 meeting, 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;

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[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.

Oncologic Protocol.

18. Respondents provide no description or discussion of why the definition of the Oncologic Protocol is necessary or helpful from a "[p]olicy" standpoint.

19. Upon information and belief, Respondents did not file a regulatory impact statement in connection with the potential adverse effects of defining the Oncological Protocol as Respondents have done.

20. Notwithstanding its utter lack of basis, legal or otherwise, this "[p]olicy," which is actually a poorly-veiled rule, directly and adversely impacts those members of New York's deeply vulnerable Medicaid population who are stricken with cancer, by precluding their oncologists' ability to dispense supportive medications while the patient is in-office, disruptively forcing these patients to search for third party pharmacy alternatives.

21. Notably, federal law recognizes the value of physician dispensing, going so far as to create safe harbors for the Stark Law and Federal Anti-Kickback Statute so that providers (under certain circumstances) may bill Medicare for medications dispensed in-office without facing liability for what might otherwise be deemed self-dealing. See 42 C.F.R. 431.55(b); 42 C.F.R. 1001.952(p)(4).

22. What's more, the definition of the Oncologic Protocol ("DOP") is plainly inconsistent with the ordinary practice of oncology in that it attempts to decouple supportive care, such as the dispensing of pain medication, anti-emetics or anti-biotics, from the "treatment of cancer or tumors[,]" as though they were clinically unrelated.

23. The National Comprehensive Cancer Network ("NCC") is an institution recognized as "an expert body in the field of clinical oncology," whose clinical care "Guidelines" are widely accepted as "authoritative in the field." See Zeneca Inc. v. Eli Lilly & Co., 1999 WL 509471, at *23 (SDNY 1999); see also Reimann v. Anthem Ins. Company, Inc., 2008 WL 4810543, at *6 (S.D.IN 2008) (accord). Such acceptance extends to the Centers for Medicare and Medicaid Services ("CMS"), which

has recognized the NCCN Guidelines as an authoritative source for use in determination of medically accepted indications for many aspects of the practice of oncology in connection with rendering Medicare coverage decisions. See, e.g., www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R96BP.pdf (last accessed 9/14/21).

24. The NCCN's Guidelines contain a multitude of best practices for oncologists with respect to oncology "Supportive Care," including: "Adult Cancer Pain, Antiemesis, Cancer-Associated Venous Thromboembolic Disease, Cancer-Related Fatigue, Distress Management, Management of Immunotherapy-Related Toxicities" and "Palliative Care," among others. See https://www.nccn.org/guidelines/category_3 (last accessed 9/14/21). This is entirely inconsistent with Respondents' *de facto* Rule, which would excise from the Oncologic Protocol these recognized categories of oncological care to the extent they call for the prescribing of medications not for the "treatment of cancer or tumors," such as, per Respondents, drugs falling within the "Antiemesis" Supportive Care Guidelines.

25. In short, the DOP was issued without rationale, need or serious study. It is unsurprising, then, that Respondents failed to file it with the Secretary of State for publication in the state register or afford the public with an opportunity to submit comments to it as proposed rule, in violation of SAPA and the New York State Constitution, among other laws.

C. Health Plans' and PBMs' Confused and Chaotic Implementation of the De Facto Rule.

26. In or around the time that the Medicaid Manual was published, NYCBS began receiving claims denials for "Supportive Care" medications, such as injectafer and venofer, from New York Managed Medicaid plans (the "MCOs"), all of which were administered by the same Pharmacy

Benefits Manager (the "PBM").[9] The stated basis for the claims denials was that the "Practice [was] Not Contracted With Plan On Date of Service[,]" despite the fact that NYCBS was, in fact, in contract with both the MCOs and the PBM. Markedly, some of the MCOs denied claims for these medications regularly and other did not, even though the stated reasons for the rejections remained the same.

27. Counsel for NYCBS spoke with counsel for the PBM in an effort to determine the cause of the denials. The PBM advised that the NYDOH had directed the MCOs to deny all claims for medications that fell outside of the DOP and that the MCOs, in turn, had advised the PBM of the new NYDOH-issued directive. This subsequently led to confusion on the MCOs' part in terms of what, in fact, fell within the ambit of the DOP and what did not, which, in turn led to disparate determinations from individual MCOs – some finding that, for example, injectafer and venofer were not within the DOP and others finding that they were.

28. Upon information and belief, to date, these claims denials have resulted in the denial of hundreds of claims, valued at hundreds of thousands of dollars. More importantly however, this has created a highly problematic and disruptive environment for NYCBS' oncologists, who can no longer dispense Supportive Care medications in-office to their New York Managed Medicaid patients with

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[9] For clarification on the relationship between these entities, note the following: "PBMs manage the pharmacy benefit of group health plan sponsors, such as HMO plans, self-insured employers, indemnity plans, labor union plans, and plans covering public employees. When an enrollee in one of these plans purchases a drug at a retail pharmacy, he or she presents a health plan card identifying the source of insurance coverage. The pharmacy will transmit the insurance coverage information to the PBM, which verifies coverage and determines if the plan covers the prescribed drug, what the plan owes as direct payment to the pharmacy, and what the enrollee's co-payment will be (if any). The PBM transmits this information back to the pharmacy, logs the payment information on its system, and transmits the billing information to health insurers. These insurers then remit payment to the PBM, which forwards payment to the retailer. This process, known as claims adjudication, is handled electronically. Ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM." Improving Health Care: A Dose of Competition, A Report by the Federal Trade Commission and the Department of Justice, 2004 WL 1685795, at *136 (2004).

cancer.

29. To be clear, prior to the implementation of the DOP, NYCBS and many other New York oncology practices regularly dispensed Supportive Care medications in-office to their cancer patients, which claims were reimbursed without issue by all MCOs (assuming the claims were otherwise clean).

30. The DOP-based claims denials continue through the date of this writing, as does the disparate treatment of those claims by various MCOs, all of which appear to be interpreting the meaning of the DOP differently.

31. Additionally, by its own terms, the DOP affects physician dispensing both within the "Managed Care" context, as described above, and within "NYS Medicaid F[ee-for-Service.]" This means that the DOP will affect oncologists' ability to dispense to patients directly enrolled in New York's Medicaid program, rather than through an intermediary MCO.

32. These are unacceptable results both for NYCBS and its Medicaid patients with cancer.

FIRST CAUSE OF ACTION AGAINST THE RESPONDENTS
(The DOP Violates SAPA and the New York Constitution)

33. NYCBS incorporates the preceding paragraphs as if set forth herein.

34. While Respondents attempt to characterize the DOP as mere "[p]olicy[,]" it is, in fact, a rule under New York law and, as such, Respondents' failure to file a notice of proposed rule making with the secretary of State for publication in the state register or to provide for a public notice and comment period renders the rule unlawful and unenforceable under SAPA and the New York State Constitution. It follows that the DOP was made in violation of lawful procedure, was arbitrary and capricious, and was affected by an error of law under CPLR 7803(3).

35. Article IV, § 8 of the New York Constitution provides that "[n]o rule or regulation made by any state department, board, bureau, officer, authority or commission, except such as relates to the organization or internal management [thereof] . . . shall be effective ***until it is filed in the office of the department of state***." Id. (emphasis supplied); see also New York Executive Law § 102(1).

36. The "SAPA requires submission of notice of a proposed rule making to the Secretary of State for publication in the state register, followed by a public comment period, a public hearing (where applicable), and the filing and publication of a notice of adoption of the rule. Only after the foregoing is completed is the rule deemed effective." Kahrmann v. Crime Victims Bd., 827 N.Y.S.2d 817, 820 (Alb. Cty. 2006) (citing to NY State Adm Pro §§ 202-203).

37. SAPA defines the term "Rule" to mean: "the whole or part of each agency statement, regulation or code of general applicability that implements or applies law . . . or practices bearing on any of the foregoing whether of general or particular applicability." NY State Adm Pro § 102(2)(a).

38. Rules in the guise of agency guidance, policy or interpretation, are still rules under SAPA and the New York Constitution if they "set standards that substantially alter or, in fact, can determine the result of future adjudications." In the Matter of Alca Industries, Inc. v. Peter W. Delaney, Commissioner of the NY State Office of General Services, 686 N.Y.S.2d 356, 358 (Ct. App. 1999). Stated another way, a "fixed, general principle to be applied by an administrative agency without regard to other facts and circumstances relevant to the regulatory scheme of the statute it administers constitutes a rule or regulation[.]" In the Matter of Pallette Stone Corporation v. State of New York Office of General Services, 665 N.Y.S.2d 457, 459-460 (Ct. App. 1997).

39. Here, the DOP substantially alters or determines the result of whether New York Medicaid (or, by extension, one of its contracted MCOs) will cover or not cover a particular medication dispensed by an oncologist by applying the fixed inquiry of whether the medication is to be used for "chemotherapy, immunotherapy, hormone therapy, [or] targeted therapy for the treatment of cancer or tumors[,]" or, alternatively, whether medication is to be used "to relieve [the] side effects of these therapies or to relieve distressing symptoms (such as nausea or pain)." See Exhibit A at 20. The State has already implemented the application of this principle by directing its MCOs to comply with it and, upon information and belief, by applying it to Medicaid fee-for-service coverage

determinations.[10] Given the foregoing, the DOP is plainly a rule within the meaning of the New York Constitution and SAPA.

40. Because the Respondents failed to file the DOP with the Secretary of State for publication in the state register or provided for a public comment period or notice of adoption, the DOP was promulgated in violation of New York law, namely, Article IV, § 8 of the New York Constitution, and Sections 202 and 203 of the SAPA.

41. Respondents' unlawful promulgation and implementation of the DOP proximately damaged (and continues to damage) NYCBS financially, in addition to disrupting NYCBS' ability to provide its New York Medicaid patients with all of the benefits of in-office physician dispensing.

SECOND CAUSE OF ACTION AGAINST THE RESPONDENTS
(The DOP is Arbitrary and Capricious Because Its Promulgation Lacked a Rational Basis)

42. NYCBS incorporates the preceding paragraphs as if set forth herein.

43. Respondents' promulgation of the DOP lacks any rational basis and should be annulled as such.

44. Notwithstanding any principles of agency deference that might ordinarily apply to a rule making, a rule[11] that lacks rationality and is marked by arbitrariness should be annulled as unlawful. See Law Enforcement Officers Union, Dist. Council 82, AFSCME, AFL-CIO by Seide v. State, 647 N.Y.S.2d 916, 919-920 (Alb. Sup. Ct. 1996).

45. An agency rule lacks a sufficient rational basis where it is unreasonable and is unsupported by any evidence, which may be discerned by the absence of "credible and more than insubstantial"

[10] Upon information and belief, the NYDOH has denied providers the ability to enroll with Medicaid fee-for-service as physician dispensers due to administrative delay and error. Notwithstanding, the DOP itself makes clear that it applies with equal force to both Medicaid Managed Care and fee-for-service Medicaid. See Exhibit A at 20. If Respondents have not yet implemented the *de facto* Rule with respect to fee-for-service coverage determinations, therefore, they will be doing so imminently.

[11] As discussed at length above, the DOP is a "rule" despite labeling itself a "[p]olicy."

evidence supportive thereof. Brodsky v. Zagata, 646 N.Y.S.2d 188, 190 (App. Div. 3rd Dep't 1996).

46. The only evidence or authority cited in support of the DOP by Respondents is New York Education Law § 6807. See Exhibit A at 20.

47. Section 6807 references oncology in only one subpart, namely, § 6807(2)(a)(9), which provides that a physician may dispense medications "pursuant to an oncological or AIDS protocol." The statute says nothing further about an oncologic or oncological protocol.

48. In construing an enabling statute, courts should be mindful that "questions of pure legal interpretation of statutory language do not warrant judicial deference to administrative expertise." Matter of Toys 'R' Us v. Silva, 89 N.Y.2d 411, 419 (Ct. App. 1996).

49. Here, the language of § 6807(2)(a)(9) – providing that physicians may dispense "pursuant to an oncological or AIDS protocol[] – does not support the position, taken by Respondents, that the Oncologic Protocol distinguishes between medications dispensed for "chemotherapy, immunotherapy, hormone therapy, [or] targeted therapy for the treatment of cancer or tumors[,]" and those medications dispensed "to relieve [the] side effects of these therapies or to relieve distressing symptoms (such as nausea or pain)." See Exhibit A at 20.

50. Further, in support of the DOP or as evidence for its lawful promulgation, Respondents fail to cite or reference any independent scientific or medical study supporting the definition of the Oncologic Protocol. Nor do Respondents reference or cite to any study undertaken by either NYDOH or NYSED or any other New York State agency, which defines or attempts to define the Oncologic Protocol. Nor have Respondents provided any discussion or indication as to why the particular definition contained in the DOP is at all necessary or helpful from a "[p]olicy" perspective, medical perspective or, indeed, a legal perspective.

51. Upon information and belief, there was no regulatory impact statement filed in connection with the potential effects of publishing and implementing the DOP.

52. In fact, authoritative compendia on the practice of oncology, such as the NCCN Guidelines, directly contravene the substance of the DOP in that they do not distinguish between the practice of oncology (or the following of an oncological protocol) and the provision of supportive care, such as the dispensing of anti-emetics, pain medications and/or antibiotics, among others.

53. In light of the above, it is plain that Respondents have not met even the relatively generous "credible and more than insubstantial" evidence standard and, as a consequence, it is equally plain that promulgation of the DOP lacked a rational basis.

54. The DOP is therefore arbitrary and capricious and affected by an error of law within the meaning of CPLR 7803(3).

55. Respondents' arbitrary and capricious promulgation of the DOP has proximately damaged (and continues to damage) NYCBS financially, in addition to disrupting NYCBS' ability to provide its New York Medicaid patients with all of the benefits of in-office physician dispensing.

THIRD CAUSE OF ACTION AGAINST THE RESPONDENTS
(The DOP is Unconstitutionally Vague)

56. NYCBS incorporates the preceding paragraphs as if set forth herein.

57. "The void-for-vagueness doctrine employs a rough idea of fairness, and applies to regulations as well as statutes." Matter of Gurnsey v. Sampson, 57 N.Y.S.3d 855, 865 (Ct. App. 2017).

58. A two-part test applies in evaluating a vagueness challenge. First, a court must determine whether the regulation is "sufficiently definite so that individuals of ordinary intelligence are not forced to guess at the meaning of [regulatory] terms" Matter of Kaur v. New York State Urban Dev. Corp., 15 N.Y.3d 235, 256 (Ct. App. 2010), and have fair notice of the conduct is prohibited. See People v. Nelson, 69 N.Y.2d 302, 307 (Ct. App. 187). Second, the court must determine whether the regulation provides "clear standards for enforcement so as to avoid resolution on an *ad hoc* and subjective basis." People v. Stephens, 28 N.Y.3d 307, 312 (Ct. App. 2016). In sum, a regulation that "invites . . . misunderstanding by a person of ordinary intelligence [and] . . . arbitrary enforcement by plaintiff[,]"

is unconstitutionally vague. Matter of Sullivan Farms IV, LLC v. Village of Wurtsboro, 21 N.Y.S.3d 450, 455 (App. Div, 3rd Dep't 2015).

59. Here, the DOP purports to differentiate between medications to be used for "chemotherapy, immunotherapy, hormone therapy, [or] targeted therapy for the treatment of cancer or tumors[,]" on the one hand, and medications "to relieve [the] side effects of these therapies or to relieve distressing symptoms (such as nausea or pain)[,]" on the other. See Exhibit A at 20. But it offers no guidance on how a dispensing oncologist or the NYDOH is to make this determination – and a medication that might have pain relieving, anti-emetic or anti-biotic effects may be necessary for the "treatment of [the] cancer or tumors[,]" as such treatment may only proceed or succeed if the patient remains reasonably healthy.

60. NCCN "Guidelines for Management of Immunotherapy-Related Toxicities," for example, are designed to "provide guidance on the management of immune-related adverse events (irAEs) resulting from cancer immunotherapy." https://jnccn.org/view/journals/jnccn/17/3/article-p255.xml (last accessed 9/14/21). These Guidelines recommend various treatments to be used to maintain the health of a patient undergoing immunotherapy for cancer, which can result in harmful toxicities such as "dermatological toxicity" or "musculoskeletal toxicity[,]" conditions for which the Guidelines suggest medications such as "oral antihistamines" or steroids such as "prednisone". Are these medications managing a potentially life-threatening "side effect[,]" in the words of the DOP, of immunotherapies utilized to treat cancer or are they an integral part of it, and how is NYDOH to make this determination in any given case? Similarly, can the use of antiemesis to manage Chemotherapy Induced Nausea and Vomiting, which can cause "dehydration, malnutrition, electrolyte imbalances, esophageal tears, fractures, wound dehiscence and deterioration of physical and metal status[,]" legitimately be decoupled from the chemotherapy itself, if chemotherapy cannot be safely administered in its absence? https://www.uspharmacist.com/article/chemotherapyinduced-nausea-

and-vomiting (last accessed 9/14/21). The DOP provides no reasonable guidelines for providers or NYDOH to make such determinations.

61. Upon information and belief, the above-described[12] disparate coverage determinations made by the MCOs at the Respondents' direction resulted from the confusion inherent in the DOP's failed effort to differentiate treatment of cancer from supportive care integral to it.

62. A person of ordinary intelligence could not make a meaningful, let alone clinical, distinction between medications for the "treatment of cancer or tumors" and medications to "relieve [the] side effects of these therapies or to relieve distressing symptoms[.]"

63. Respondents, manifestly, cannot make a meaningful, let alone legal or clinical, distinction between medications for the "treatment of cancer or tumors" and medications to "relieve [the] side effects of these therapies or to relieve distressing symptoms[,]" as is evident from NYDOH's bungled efforts to direct MCOs to deny claims for medications outside of the DOP.

64. The unreasonable difficulty in differentiating between these two poorly-described categories is heightened by contravening authoritative guidelines that do not so differentiate.

65. Had Respondents followed lawful procedure and filed the DOP with the Secretary of State and provided for a meaningful notice and comment period, this substantive issue could have been addressed by members of the public with expertise in oncology and pharmacy-related matters, but Respondents failed to do so.

66. Promulgation and implementation of the unconstitutionally vague DOP by Respondents is a violation of NYCBS' rights to due process under the 14th Amendment to the United States Constitution.

67. Because Respondents have, in the form of the DOP, promulgated a rule[13] that is

[12] See discussion, supra, at ¶26-31.
[13] See discussion, supra, at ¶34-39.

unconstitutionally vague in violation of the 14th Amendment to the United States Constitution, the agency decisions to craft it in its current form were arbitrary and capricious and affected by an error of law under CPLR 7803(3).

68. Respondents' promulgation of the unconstitutionally vague DOP has proximately damaged (and continues to damage) NYCBS financially, in addition to disrupting NYCBS' ability to provide its New York Medicaid patients with all of the benefits of in-office physician dispensing.

PRAYER FOR RELIEF

WHEREFORE, NYCBS respectfully requests that the Court enter an Order pursuant to CPLR 7806 and other applicable law,

1. annulling the DOP as being made in violation of lawful procedure, as arbitrary capricious, and/or as affected by an error of law due to Respondents' violation of the SAPA and the New York Constitution in their failure to file it with the Secretary of State and follow required notice and comment procedures pursuant to SAPA, among other laws; and

2. annulling the DOP as being arbitrary and capricious and/or affected by an error law because its promulgation and substance lacks a rational basis; and

3. annulling the DOP as unconstitutionally vague in its failure to rationally or reasonably differentiate between those medications dispensed for the "treatment of cancer or tumors" and those medications to "relieve [the] side effects of these therapies or to relieve distressing symptoms[.]"; and

4. providing for such other relief that the Court deems equitable and just.

Respectfully submitted,

/s/ Jason N. Silberberg
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Dated: 9/20/2021

VERIFICATION

JEFFREY VACIRCA, M.D., a principal and officer of the Petitioner in this action, hereby states that:

I have read the foregoing Verified Petition and know the contents thereof. The same are true to my knowledge, except as to matters therein stated to be alleged on information and belief and, as to those matters, I believe them to be true.

Dated: 9/21/2021

Respectfully submitted,

(Signature and Notary Public)

STATE OF NEW YORK
COUNTY OF SUFFOLK
DAWN C. SAVARESE
REG. # 01SA6060861
TERM EXPIRES 7/2/2023

Jeffrey Vacirca, M.D., Principal
North Shore Hematology-Oncology Associates, P.C.
d/b/a New York Cancer & Blood Specialists

SWORN AND SUBSCRIBED TO ON THIS TWENTIETH DAY OF SEPTEMBER, 2021

EXHIBIT A TO VERIFIED PETITION

NEW YORK STATE
MEDICAID FEE-FOR-SERVICE PROGRAM

PHARMACY MANUAL

POLICY GUIDELINES

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This Policy Manual applies to the Medicaid Fee-for-Service Program. While some provisions apply to Medicaid Managed Care (MMC) plans per statute, specific questions regarding MMC requirements should be directed to the applicable MMC plan. The manual applies to the Medicaid Pharmacy Program for pharmacy claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format.

Section I - General Pharmacy Policy

Required Prescribing Information

In accordance with NY State Education Law, all prescriptions written in New York State by a person authorized by New York State to issue such prescriptions shall be transmitted electronically directly from prescriber to pharmacist in a licensed pharmacy. Official New York State prescription forms or an oral prescription are accepted when exceptions exist as noted in law.

All prescriptions and fiscal orders must bear:

- The name, address, age and client identification number (CIN) of the patient for whom it is intended. If the CIN does not appear on the order, the prescription should only be filled if the CIN is readily available in the pharmacy records;
- The date on which it was written;
- The name, strength, if applicable, and the quantity of the drug prescribed;
- Directions for use, if applicable; and
- The name, address, telephone number, profession, DEA Number (if applicable) and signature of the prescriber who has written or initiated the prescription or fiscal order.

  If a pharmacist is certain that the prescription is from a legitimate prescriber and the prescriber's license number or eMedNY provider identification number is readily available in the records of the pharmacy, it is not necessary to record the license number or eMedNY provider identification number on the prescription or fiscal order.

For **non-controlled substance prescriptions**, the pharmacist may record on the prescription:

- The address, age and CIN of the Medicaid member,

If the address, age or CIN of the Medicaid member are missing, the pharmacist is not required to enter any of these items on the prescription if the information:

- Is otherwise readily available in the records of the pharmacy and the pharmacist knows the person who is requesting that the prescription be filled, or
- The pharmacist is otherwise satisfied that the prescription is legitimate.

Prescriptions written for **controlled substances** must meet the requirements of Article 33 of the Public Health Law. In accordance with New York State Department of Health Codes, Rules and Regulations Title 10, Part 80, pharmacists are permitted to add or change only certain information on controlled substance prescriptions.

Prescription Drug Orders

Prescription drugs can be obtained by an electronically transmitted prescription, a signed written order, facsimile (on an Official NY State Prescription form) when allowed by law, or oral prescription from a qualified prescriber. Faxbacks are not considered original prescriptions and are not allowed.

Quantities for prescription drugs shall be dispensed in the amount prescribed, taking into consideration those drugs should be ordered in a quantity consistent with the health needs of the Medicaid member and sound medical practice.

Non-Prescription Drug Orders

Non-prescription drugs, also known as over-the-counter (OTC) drugs, can be obtained by an electronically transmitted prescription or a signed written order (fiscal order) from a qualified prescriber.

A fiscal order written on an Official NYS Serialized Prescription Form and faxed to the pharmacy provider will be considered an original order. When an order for non-prescription drugs not written on the serialized official prescription form has been telephoned or faxed to the pharmacy provider, it is the pharmacy provider's responsibility to obtain the original signed fiscal order from the prescriber within 30 days.

If the ordering practitioner does not request a quantity that corresponds to the prepackaged unit, the pharmacist may supply the drug in the pre-packaged quantity that most closely approximates the amount ordered.

Medical/Surgical Supply Orders

Medical/surgical supplies can be obtained by an electronically transmitted prescription or a signed written order (fiscal order) from a qualified prescriber.

A fiscal order written on an Official NYS Serialized Prescription Form and faxed to the pharmacy provider will be considered an original order. When an order for medical/surgical supplies not written on the serialized official prescription form has been telephoned or faxed to the pharmacy provider, it is the pharmacy provider's responsibility to obtain the original signed fiscal order from the prescriber within 30 days.

If the ordering practitioner does not request a quantity that corresponds to the prepackaged unit, the pharmacist may provide the item in the pre-packaged quantity that most closely approximates the amount ordered.

Serial Number and Origin Code Requirement

The serialized number from the Official NY State Prescription (ONYSRx) **must** be used when submitting claims for prescriptions written in New York State on an Official New York State Prescription form. The table below describes other situations in which a prescription would be dispensed by a pharmacy with the Department approved ONYSRx serial number replacement. In addition to the serial number requirement, all claims for prescriptions require an accurate Origin Code. The table below lists the Origin Codes with the appropriate corresponding serial number.

ORIGIN CODE Field 419-DJ	CORRESPONDING SERIAL Field 454-EK	DESCRIPTION
1	Unique ONYSRx #	Written - Prescriptions prescribed in NY will be on Official New York Prescription forms with a designated serial number to use.
1	ZZZZZZZZ	Written - Prescriptions prescribed from out-of-state practitioners or by practitioners within a federal institution (e.g., US Department of Veterans Affairs) or Indian Reservation.
2	99999999	Telephone - Prescriptions obtained via oral instructions or interactive voice response using a telephone.
2	SSSSSSSS	Telephone – Fiscal orders for supplies obtained via oral instructions using a telephone. *
3	EEEEEEEE	Electronic - Prescriptions obtained via SCRIPT or HL7 standard transactions, or electronically within closed systems. **

4	Unique ONYSRx #	Facsimile – ONYSRx Prescriptions obtained via fax machine transmission.
4	SSSSSSSS	Facsimile – Fiscal orders for supplies not on a ONYSRx obtained via fax machine transmission. *
4	NNNNNNNN	Facsimile - Prescriptions obtained via fax machine transmission for **nursing home** patients (excluding controlled substances) in accordance with written procedures approved by the medical or other authorized board of the facility.
5	TTTTTTTT	Pharmacy - this value is used to cover any situation where a new Rx number needs to be created from an existing valid prescription such as traditional transfers, intra-chain transfers, file buys, software upgrades/migration, and any reason necessary to give it a new number. ***
5	99999999	Pharmacy - this value is appropriate for "Pharmacy dispensing" when applicable such as non-patient specific orders, BTC (behind the counter), Plan B, established protocols, etc.
5	DDDDDDDD	Pharmacy - this value is used to cover prescriptions dispensed as Medically Necessary during a Declared State of Emergency (excluding controlled substances).

***** Dispensing provider is required to obtain the original signed fiscal order from the ordering practitioner within 30 days.
** Fail-over electronically transmitted prescriptions that come to the pharmacy as a facsimile are **invalid**.
Reference: http://www.op.nysed.gov/prof/pharm/pharmelectrans.htm
******* Remember to use original date prescribed as “written date” when processing prescription transfers. Transfers are not allowed for controlled substances in New York State. All other laws regarding prescription transfers apply.

Prescription drug orders received by the pharmacy as a facsimile must be an original hard copy on the Official New York State Prescription Form that is manually signed by the prescriber, and that serial number represented on the form must be used. Prescriptions for controlled substances that are submitted electronically but fail transmission **may not** default to facsimile.

Multiple Drug Orders

For drugs administered in a nursing home, multiple drug orders for **non-controlled** prescription drugs can be ordered on a single prescription document. Pharmacies providing services under contract to nursing homes are not required to obtain separate prescriptions for these drugs. The dispensing pharmacy must be employed by or providing services under contract to the nursing home.

All prescriptions written for controlled substance medications must be electronically transmitted by a qualified prescriber or written on an Official New York State Prescription Form in order to be dispensed by a pharmacy. Multiple drug orders are **not** allowed on prescriptions for controlled substances.

Refills

A prescription or fiscal order may not be refilled unless the prescriber has indicated on the prescription or fiscal order the number of refills. No prescription or fiscal order for a drug or supply may be refilled 180 or more days after it has been initiated by the prescriber. In addition, no more than five (5) refills are permitted for prescriptions or fiscal orders with the exception of oral contraceptives, for which no more than 11 refills are permitted when prescribed for family planning purposes.

All refills of prescription drugs must be in accordance with Federal and State laws and bear the prescription number of the original prescription. Refills of non-prescription drugs and medical/surgical supplies must also be appropriately referenced to the original order by the pharmacy.

Faxed refill authorization requests are not allowed under the Medicaid Program.

Transfers

Transfers are allowed for a refill when all other state laws and Medicaid policies are adhered to. This includes using the original written date of the original order; and only one refill at a time may be transferred. In addition to the serial number and origin code requirements as stated above in section Serial Number and Origin Code Requirement, transferred prescriptions/OTC orders must be filled within 180 days of the original written date. Changing a written date to bypass the edit is considered fraudulent billing and is subject to audit.

Automatic Refill

Automatic refilling is not allowed under the Medicaid program. Automatic-refill programs offered by pharmacies are not an option for members. Faxbacks are also not allowed.

Requests for a refill: A member or designated caregiver may contact the pharmacy to request necessary refills.

Provider inquiry: A pharmacy/DME provider may initiate contact with a member by phone or electronic means (e.g. text message) to determine if a refill is necessary. Documentation of th3e member's response on the need for each refill shall be maintained in the patient record and must include the date and time of contact,

Medicaid member or designated caregiver's name and contactor's identification. This documentation must be available for audit purposes. Billing claims before the member has requested or consented to the filling of the drug/DME item is considered inappropriate billing and not allowed.

Reminder: Compliance with HIPAA privacy guidelines is mandatory.

Lost or Stolen Prescriptions

If a Medicaid member has experienced a loss or theft of medication, pharmacy providers should instruct members to contact their prescriber. The decision to honor a member's request for authorization of a replacement supply is based on the professional judgement of the prescriber.

Prescribers may initiate a prior authorization request for a lost or stolen medication by contacting the eMedNY Call Center at 800-343-9000. Replacement, if granted, will be approved for up to a 30-day supply of medication.

Vacation Requests

Medicaid ensures an ample medication supply to accommodate for most temporary absences. Members that do not have an adequate supply of medication due to a temporary absence should make alternative arrangements, such as relying on a trusted friend or family member.

Pick up / Receipt

Pharmacies/DME providers must obtain a signature from the Medicaid member, their caregiver or their designee to confirm receipt of the prescription drugs, over-the-counter products, medical/surgical supplies, and DME items when picked up from the provider. The pharmacy must have documentation confirming the prescription number(s), date of pick-up and signature. One signature is sufficient for multiple prescriptions being picked-up at one time. Claim submission is not proof that the prescription or fiscal order was actually furnished.

Delivery

Delivery of prescription drugs, over-the-counter products, medical/surgical supplies, and durable medical equipment (DME) is an optional service that can be provided to Medicaid member's home or current residence including facilities and shelters. Pharmacies/DME providers must obtain a signature from the Medicaid member, their caregiver or their designee to confirm receipt of the prescription drugs, over-the-counter products, medical/surgical supplies, or DME items. Claim submission is not proof that the prescription or fiscal order was actually furnished.

Providers offering delivery must implement and operate a distribution and delivery system that reflects “best practices”.

If a provider chooses to provide this optional service to their customers, all the criteria listed below will apply:

For all Deliveries:

1. A signature of the recipient or authorized agent is required at the time of delivery, including facility/provider deliveries.
2. A single signature of the recipient or authorized agent verifying receipt will be sufficient for all of the medications in the delivery.
3. A waiver signature form is not an acceptable practice, and such forms will not serve as confirmation of delivery. Waiver signature forms are defined by delivery industry standards.
4. Delivery industry tracking receipts that contain a signature of the recipient or authorized agent (e.g., FedEx tracking receipts) qualify as a signature for receipt of delivery.
5. Electronic signatures of the recipient or authorized agent for receipt or electronic tracking slips for delivery are permitted only if retrievable on audit.
6. Documentation confirming delivery must also include the list of prescription number(s) and date the medication(s) was/were delivered.
7. Delivery confirmation must be maintained by the pharmacy for six years from the date of payment and must be retrievable upon audit.
8. All shipping and delivery costs are the responsibility of the pharmacy.
9. Medicaid members cannot be charged for delivery if Medicaid reimburses for all or any portion of the item being delivered.
10. The pharmacy is accountable for proper delivery of intact, usable product; the pharmacy is liable for the cost of any item damaged or lost through distribution and delivery. The Medicaid Program does not provide reimbursement for replacement supplies of lost, stolen or misdirected medication, medical/surgical supply or DME deliveries.
11. The pharmacy must ensure proper storage is available and authorized agent or recipient is aware of requirements before delivery.
12. All Medicaid claims for drugs that were not deliverable must be reversed within 60 days.

For Home Deliveries:

1. The pharmacy should inform the member or their designee of the pharmacy’s delivery schedule, verify the date and location for the delivery, and notify the member that a signature will be required at the time of delivery.
2. The number of times a pharmacy attempts to deliver is left to the discretion of the pharmacy.

3. The pharmacy must advise the member or their designee, either verbally or in writing (e.g., a patient information leaflet) of the correct handling and storage of the delivered prescriptions.
4. When applicable the pharmacy must confirm an appropriate administration plan is in place for home deliveries.

Pharmacy Dispensing of Drugs That Require Administration by a Practitioner

NYS Medicaid recognizes the need for certain drugs requiring administration by a practitioner to be available to members by way of both the Medical Benefit and Pharmacy Benefit. Drugs are evaluated to determine if they are eligible for coverage under the pharmacy benefit using the following criteria:

1. The drug must be able to be billed in the NCPDP format.
2. The drug must be able to be delivered directly to the place of administration.
3. The drug must be available from a dispensing pharmacy that is enrolled in FFS Medicaid.
4. The drug must either fit into an existing category within the PDL, DUR, or CDRP **OR** have a potential for inappropriate use outside of FDA approval or Compendia support that can be avoided using clinical editing.
5. In certain circumstances, the DUR Board may need to review the drug before clinical criteria may be applied. Drugs will be evaluated on a case-by-case basis to determine if they are appropriate to add to the pharmacy formulary.

Practitioner-administered drugs are listed on the Medicaid Pharmacy List of Reimbursable Drugs and may be billed directly to the Medicaid Fee-for-Service (FFS) program by a pharmacy. **Nothing in this policy is meant to suggest that practitioner-administered drugs must be dispensed as a Pharmacy Benefit.** The policy regarding practitioner-administered drug billing is addressed in the Physician's Manual found here: https://www.emedny.org/ProviderManuals/Physician/index.aspx. Practitioner-administered drugs dispensed as a Pharmacy Benefit must be delivered by the pharmacy directly to the site of administration. This is considered "white bagging" and is acceptable under the following guidelines:

1. Drugs should only be dispensed by the pharmacy directly to the patient when they are to be self-administered. The policy surrounding self-administered drug delivery is found in section titled *Delivery* above.
2. Prior to delivery of a practitioner-administered drug the dispensing pharmacy must confirm the delivery address, that the member still requires the drug, that an appointment has been scheduled and confirmed for its administration. **Automatic refills are not permitted**. The policy surrounding refills is found in the section titled *Refills* above.
3. Delivery charges may not be billed to the member or Medicaid.
4. The pharmacy is responsible for preparing and delivering the drug in accordance with administration guidelines in the package insert, as well as the replacement of

improperly stored, lost, or stolen drugs until confirmed receipt by the authorized agent.
5. The pharmacy must confirm an appropriate administration plan is in place for home deliveries.
6. The pharmacy is required to obtain documentation of delivery by the receipt of a signature of a recipient or an authorized agent at the site of administration.
7. All Medicaid claims for drugs that were not deliverable must be reversed within 60 days.
8. Once delivered and signed for, the site of administration is responsible for replacement of improperly stored, handled, lost, or stolen practitioner-administered drugs.

Practitioner-administered drugs dispensed directly to a patient by the pharmacy to bring to their practitioner's office for administration is considered ***"brown bagging,"*** and causes concern regarding proper storage or handling, which can affect the drug's efficacy. Brown bagging is not acceptable under NYS Medicaid.

This policy refers to any drug being dispensed by a pharmacy for practitioner-administration to a Medicaid FFS member, including those billed as a secondary payment.

Unused Medication

Under certain situations, returns of unused medications by a long term care facility to the pharmacy may be returned per the Rules of the Board of Regents Part 29; the vendor pharmacy to which drug products are returned shall reimburse or credit the purchaser of such drug products for the unused medication that is restocked and re-dispensed and shall not otherwise charge any individual resident or the State, if a resident is a Medicaid member or member of a State-funded program, for unused medication or drug products returned for reimbursement or credit, per Title 10 NYCRR 415.18(f).

Nursing homes and pharmacies providing pharmacy services to nursing homes are encouraged to review their protocols to assure these requirements are met:

- Drug products returned must be sealed in unopened, individually packaged, units and within the recommended period of shelf life for the purpose of re-dispensing.

- Drug products returned should show no obvious sign of deterioration.

- Drug products packaged in manufacturer's unit-dose packages may be returned provided that they are re-dispensed in time for use before the expiration date, if any, indicated on the package.

Drug products repackaged by the pharmacy into unit-dose or multiple-dose "blister packs" may be returned for re-dispensing provided that:

- The date on which the drug product was repackaged, its lot number and expiration date are indicated clearly on the package;
- Not more than 90 days have elapsed from the date of the repackaging;
- A repackaging log is maintained by the pharmacy.
- Partially used blister packs may be re-dispensed only as returned.
- Partially used blister packs may not be emptied and repackaged.
- Additional units of medication may not be added to partially used blister packs.
- No drug product dispensed in bulk in a dispensing container may be returned.
- No medication or drug product defined as a controlled substance may be returned.

Frequency, Quantity and Duration (F/Q/D) Limits

Prescription, non-prescription drugs and medical/surgical supplies may have fixed limits in the amount and/or frequency that can be dispensed. NY Medicaid considers Frequency, Quantity, and Duration (F/Q/D) recommendations made by the Drug Utilization Review (DUR) Board. Some of the drugs/drug classes affected by F/Q/D editing are also included in the Preferred Drug Program (PDP). Therefore, drugs/drug classes that have a preferred status can also be subject to F/Q/D editing.

System messaging has been developed to help guide the pharmacists to appropriately submit the claim or to refer to the prescriber.

For certain medical/surgical supplies, if the limit on an item is exceeded, prior approval must be requested with accompanying documentation as to why the limit needs to be exceeded. Quantity and frequency limits are available in the OTC and Supply Fee Schedule section of this manual:
https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx

Questions on medical/surgical supplies may be referred to the eMedNY Call Center at 800-342-3005.

The following links have been provided as helpful resources for information on the PDP, F/Q/D and Step Therapy Programs: https://newyork.fhsc.com/ and http://www.health.ny.gov/health_care/medicaid/program/dur/index.htm.

Questions on prescription Frequency, Quantity and Duration (F/Q/D) Limits may be referred to the NY Medicaid Clinical Call Center at: 877-309-9493.

Generic Drug Substitution Policy

All Medicaid pharmacy providers must comply with all State requirements adopted pursuant to NY State drug substitution laws. Additionally, as a result of the Medicaid Mandatory Generic Drug Program, prior authorization must be obtained for most brand-name drugs with an "A-rated" generic equivalent before dispensing.

Prior Authorization Programs

The Medicaid program requires prior authorization for certain drugs under the following programs:

- Preferred Drug Program (PDP)
- Brand When Less Than Generic Program (BLTG)
- Dose Optimization Initiative
- Clinical Drug Review Program (CDRP)
- Drug Utilization Review (DUR) Program
- Mandatory Generic Drug Program (MGDP)

Prescribers may need to obtain prior authorizations for certain drugs. General information on the prescription drug prior authorizations, including the above programs, can be found at the following website: https://newyork.fhsc.com.

Note: If a prior authorization number has not been obtained by the prescriber and the pharmacist is unable to reach the prescriber, the pharmacist may obtain a prior authorization for up to a 72-hour emergency supply of a multi-source brand-name or non-preferred drug, subject to state laws and Medicaid restrictions. Once a 72-hour supply prior authorization number is given and a 72-hour supply is dispensed, the prescription is no longer valid for the remaining quantity and refills. The pharmacist is expected to follow-up with the prescriber to determine future needs.

Pharmacy Program information is available on the Medicaid Pharmacy Program website at: https://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm.

PAXPRESS

Medicaid enrolled prescribers can initiate prior authorization requests using a web-based application. PAXpress is a web-based pharmacy PA request/response application accessible from the eMedNY website at https://www.emedny.org as well as the NY Medicaid Pharmacy Prior Authorization Program website at: https://newyork.fhsc.com/.

The PAXpress website provides a single point of entry for prescriber access to announcements, documents and quick links to important program information.

A user manual is accessible from the eMedNY website and provides information for using the PAXpress application: https://www.emedny.org/info/paxpress/PAXpress_User_Manual.pdf.

Pharmacists are not authorized to submit for a Prior Authorization except for the 72-hour emergency supply as mentioned above.

Pharmacists as Immunizers

Reimbursement is provided to Medicaid enrolled pharmacies for vaccines and anaphylaxis agents administered by certified pharmacists within the scope of their practice within all Medicaid polices.

A link to the latest billing information can be found on the following website under "Pharmacists as Immunizers": https://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm

Service Limits

Selected items of medical/surgical supplies have limits in the amount and frequency that can be dispensed to an eligible Medicaid member. If a member exceeds the limit on an item, prior approval must be requested with accompanying documentation as to why the limits need to be exceeded.

For more information, please refer to the Fee Schedule at: https://www.emedny.org/ProviderManuals/DME/index.aspx

Medicaid/Medicare Reimbursement

Pharmacies enrolled in the *Medicaid* Program as a billing provider are required to demonstrate participation in the *Medicare* Program. Medicaid pharmacy enrollment

information can be accessed online at: https://www.emedny.org/info/ProviderEnrollment/index.aspx.

Medicare benefits must be maximized prior to billing Medicaid. Services covered by both Medicare and Medicaid must first be billed to Medicare. Pharmacy providers can bill Medicaid only after payment information is received from Medicare. For audit purposes, payment information must be retained for a minimum of six years following the date of payment.

For information on the reimbursement methodology of dual eligible individuals, please refer to the June 2015 Medicaid Update, found at: https://www.health.ny.gov/health_care/medicaid/program/update/2015/jun15_mu.pdf

Medicare Part A

Medicare Part A covers inpatient care, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). It also covers hospice care and some home health care. Members must meet certain conditions to receive these benefits.

Medicare Part B

Medicare Part B covers doctors' services, outpatient care and some other medical services that Part A does not cover. Information regarding Medicare Part B outpatient covered drugs can be found here: https://www.medicare.gov/coverage/prescription-drugs-outpatient Medicare Part B covers certain drugs such as:

- Drugs used with an item of durable medical equipment
- Some antigens
- Injectable osteoporosis drugs
- Erythropoiesis-stimulating agents
- Blood clotting factors
- Injectable and infused drugs
- Oral End-Stage Renal Disease (ESRD) drugs
- Parenteral and enteral nutrition (intravenous and tube feeding)
- Intravenous Immune Globulin (IVIG) provided in the home
- Vaccinations
- Immunosuppressive drugs following a Medicare paid transplant
- Oral cancer drugs
- Oral anti-nausea drugs
- Self-administered drugs in hospital outpatient setting.

For Medicaid/Medicare crossover claims, even for a procedure that would have required Medicaid prior approval, prior approval is not required since Medicare approved and paid for a service and/or procedure.

The total Medicare/Medicaid payment to the pharmacy provider will not exceed the amount that the pharmacy provider would have received for a Medicaid-only patient. If the Medicare payment is greater than the Medicaid fee, no additional payment will be made.

***Note*:** The Medicare and Medicaid payment (if any) must be accepted as payment in full. Per State regulation, a pharmacy provider of a Medicare Part B benefit cannot seek to recover any Medicare Part B deductible or coinsurance amounts from Medicare/Medicaid Dually Eligible Individuals.

Medicare Part D

Medicare members who also have Medicaid, also known as dual-eligible, must be enrolled in a Medicare Part D prescription drug plan in order to maintain their Medicaid coverage. Medicaid does not cover any class of drugs covered under Medicare Part D for full-benefit dual eligible members. Members and their prescribers must work together to find an appropriate drug that is covered by the Part D plan or, if necessary, use the Part D plan's exception and appeals process to obtain coverage for necessary prescriptions not listed on the plan's formulary.

Under the Medicare Part D prescription drug benefit most drug costs are paid for by Medicare. Medicaid only pays for drugs from the List of Medicaid Reimbursable Drugs where the drug class is specifically excluded by law from being covered under the Part D plans, such as:

- Select prescription vitamins; and
- Certain non-prescription drugs.

All claims for dual-eligibles submitted to Medicaid are subject to Medicaid rules, including prior authorization.

For more information regarding Medicare Part D benefit, refer to the DOH website at: https://www.health.ny.gov/health_care/medicaid/program/medicaid_transition/index.htm.

Home Infusion

The New York State Medicaid Program does not provide a bundled payment to cover drugs, supplies and services associated with home infusion treatments. Home infusion drugs and supplies must be billed as a pharmacy or medical benefit.

The list of Medicaid reimbursable drugs available as a pharmacy benefit may be accessed at:
http://www.emedny.org/info/formfile.html.

The Centers for Medicare and Medicaid Services (CMS) requires coverage of home infusion drugs under Medicare Part D that are not currently covered under Parts A and B of Medicare. Information on Medicare coverage of home infusion can be found here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html.

Monitoring

Federal regulations require that pharmacy providers be monitored in order to assure that reimbursement for drugs is made at the lowest possible level, consistent with accurate cost information. This monitoring will consist of on-site and data reviews to verify that the pharmacy is submitting accurately priced claims.

Section II - General Guidelines

Pharmacy Provider Enrollment

Pharmacy Types

New York State Medicaid enrolls in-state and bordering state pharmacies under one of three pharmacy provider types. Bordering states include New Jersey, Vermont, Massachusetts, Pennsylvania, and Connecticut. Listed below are the three types of pharmacies, the applicable Category of Service (COS), and a brief description of the characteristics of each.

Pharmacy (COS 0441)
Pharmacies that have a separate and distinct location that meet the one of the descriptions below are classified as a COS 0441:

- Outpatient dispensing, community-based pharmacies that include:
  - Independently owned;
  - Chain; and
  - Those owned by a non-profit entity whose physical space is separate and distinct from the physical space of other healthcare services provided by the non-profit entity (e.g., does not share a waiting room with another office or clinic, patients do not need to walk through an office area to present to pharmacy); and/or

- Pharmacies that are contracted with and provide drugs to NY Medicaid members residing in NY Medicaid enrolled facilities; and/or

- Pharmacies that provide drugs to NY Medicaid members to the site where they are being administered or infused by a practitioner.

Note, pharmacies that are embedded or located (not separate and distinct) within a healthcare facility, physician's office or group, or in a hospital setting, are not classified under COS 0441.

Clinic Pharmacy (COS 0161)

- Owned and operated by a clinic;

- Services only the patients of the clinic;

- Physically adjacent to or embedded within the clinic it serves; and

- Able to submit claims for medication orders and/or patient-specific orders to Medicaid.

Hospital Pharmacy (COS 0288)

- Owned and operated by the hospital;

- Services patients in the hospital and may also provide outpatient services;

- Physically adjacent to or embedded within the hospital it serves; and

- Able to submit claims for medication orders and/or patient-specific orders to Medicaid.

Enrollment Policy

COS 0441

Medicaid will accept applications for pharmacy enrollment for those located in NY state or the bordering states listed above when criteria under "Medicaid Enrolled Pharmacies" below is met at time of application submission.

Medicaid will accept applications for limited pharmacy enrollment for pharmacies outside of NYS and outside of the bordering states, when criteria under "Medicaid Enrolled Pharmacies" below is met at time of application submission and when there is an unmet need such as:

- the pharmacy serves a NY Medicaid member that lives outside of NY state or outside of the bordering states (e.g. a NY Medicaid enrolled foster care child); or
- the pharmacy has an exclusive arrangement to dispense a drug on the Medicaid

Pharmacy List of Reimbursable Drugs.

Medicaid Enrolled Pharmacies (COS 0441, 0161, 0288):

- have a Medicaid enrolled Supervising Pharmacist;
- are fully operational, open, and dispensing medications;
- are fully enrolled in Medicare as a participating provider with the submission of form CMS-460 and both CMS-855B (allows drug claim billing to Medicare Part B) and CMS-855S (allows diabetic supplies and enteral nutrition billing to Medicare Part B);
- maintain inventory of commonly dispensed medications and supplies (e.g. diabetic), that are applicable to the patients they serve;
- maintain adequate hours of operation, as needed for the Medicaid members that they serve;
- are able to respond to urgent or emergent issues that occur after normal operating hours;
- follow all federal and NYS laws, regulations and policies;
- maintain applicable State registration(s) including Medicaid enrollment and registration in state of service location and NY non-resident registration; and
- applicant pharmacy submitted all required forms and information.

More information about the Pharmacy provider enrollment application process can be found here:
https://www.emedny.org/info/ProviderEnrollment/pharm/index.aspx.

Who May Dispense

Enrolled Pharmacies

Drugs and medical/surgical supplies may be dispensed to Medicaid members by pharmacists/pharmacies which are licensed and currently registered by the New York State Education Department, and which are enrolled in the New York State Medicaid Program.

Practitioners Dispensing Pharmacy Outpatient Drugs:
Drugs may be provided by a prescribing practitioner under certain circumstances.

Practitioners who are authorized to prescribe may dispense pharmacy outpatient drugs, however, they must do so per the criteria described by the NYS Education Law Article 137 §6807(1)(b) and (2)(a) and NYS Public Health Law §2312. Dispensing within the Education Law noted above is limited and intended to be narrow in scope, whereas dispensing within Public Health Law is more common. The FFS program currently does not enroll Practitioner Dispensers; however, the Department is working to facilitate this

enrollment option. In the interim, practitioners that choose to dispense may provide the drug free of charge or the provider may write a prescription for dispensing at the enrolled pharmacy of the member's choosing.

The NYS Medicaid Program has a large number of enrolled pharmacies, most of which are available seven days a week, open beyond normal business hours and some provide 24-hour service options. Additionally, NYS Medicaid enrolled pharmacies have access to a wide variety of drugs and receive regular shipments to accommodate outpatient prescriptions for Medicaid members.

Note: Practitioners are reminded, Medicaid members are entitled to obtain pharmacy services from any qualified provider enrolled in the Medicaid program, pursuant to 18NYCRR Section 360-6.3.

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;
- 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]

Notes:

Practitioners may not submit an office visit claim for the sole purpose of dispensing a drug that the member can obtain at a NYS Medicaid enrolled pharmacy.

All Federal, State, and NYS Medicaid polices regarding dispensing, billing and record keeping apply.

Nothing in this policy is meant to suggest, encourage or otherwise require that any practitioner administered, or dispensed drug be billed to the Program under the pharmacy benefit. Practitioner administered drugs will continue to be billed as a NYS Medicaid medical benefit.

Questions regarding this policy may be directed to the Medicaid Pharmacy Policy unit at 518-486-3209 or ppno@health.ny.gov.

Who May Prescribe

Practitioners authorized to prescribe by New York State must be enrolled in the Medicaid Program in order to prescribe to NY Medicaid members. Enrollment information may be found here: https://www.emedny.org/info/ProviderEnrollment/index.aspx.

All prescriptions/fiscal orders must comply with relevant State Education Law requirements.

Additionally, other requirements include:

- Enrolled Registered Physician Assistants (RPAs) may prescribe orders subject to any limitations imposed by the supervising physician. The Medicaid member must be under the care of the physician responsible for the supervision of the RPA.

Exemptions from Enrollment Requirements for Prescribers

Interns, Residents and Foreign Physicians in Training — Unlicensed Physicians

In accordance with NYS Education Law Article 131 § 6526, unlicensed physicians who are residents, interns and foreign physicians participating in training programs, are authorized to prescribe. NYS Medicaid recognizes the authority under which these unlicensed providers may prescribe; however, these physicians are not eligible for enrollment into the Medicaid program without a license. Medicaid Provider Enrollment Compendium (MPEC) allows unlicensed physicians to provide ordering/prescribing/referring/attending (OPRA) services to Medicaid members. The State Medicaid Agency (SMA) is not required to enroll a provider type, such as unlicensed physicians, for the purpose of complying with 42 of the Code of Federal Regulations (CFR) § 455.410(b) or § 455.440, when the provider type ***is ineligible*** to enroll in the NYS Medicaid Program.

Billing Guidance

To allow claims by unlicensed physicians who are authorized to prescribe pharmacies may use the following billing guidance:

Claims prescribed by an unlicensed OPRA provider will initially reject for National Council for Prescription Drug Programs (NCPDP) Reject code **"56"** *(Non-Matched Prescriber ID).* This means the prescriber is ***not*** enrolled in Medicaid.

The following information must be included on the claim to override the above rejection for unlicensed residents, interns, or foreign physicians in training programs:

- Field 439-E4 (Reason for Service Code): enter **"PN"** *(Prescriber Consultation*)
- Field 441-E6 (Result of Service Code): enter applicable value (**"1A"**, **"1B"**, **"1C"**, **"1D"**, **"1E"**, **"1F"**, **"1G"**, **"1H"**, **"1J"**, **"1K"**, **"2A"**, **"2B"**, **"3A"**, **"3B"**, **"3C"**, **"3D"**, **"3E"**, **"3F"**, **"3G"**, **"3H"**, **"3J"**, **"3K"**, **"3M"**, **"3N"**, **"4A"**)
- Field 420-DK (Submission Clarification Code): enter **"02"** *(Other Override)*

If the above override is attempted for a non-enrolled licensed practitioner, the claim will continue to be denied. Pharmacies may not use the above billing guidance for NY licensed practitioners. The only option available when a pharmacy is presented with a prescription or fiscal order written by a licensed, non-enrolled prescriber for a Medicaid member is to obtain a new prescription from an enrolled provider**.**

Documentation

With regard to any claims submitted for a prescription issued to a Medicaid enrollee by any unlicensed physician, records should be contemporaneously created and maintained supporting the issuance of such prescription. This requirement applies to all residents, interns and foreign physicians who participate in any medical training program. The documentation must include the National Provider Identifier (NPI) of the Medicaid provider who is responsible for supervising the prescribing unlicensed resident, intern or foreign physician in a training program.

All records related to the issuance of a prescription by non-enrolled physicians are subject to production upon request by NYS, including but not limited to, by NYS Department of Health (DOH), Office of the Medicaid Inspector General (OMIG), Office of the State Comptroller (OSC) and the NYS Office of the Attorney General.

Out-of-State (OOS) Licensed Prescribers

Under federal regulations, all ordering or referring physicians or other professionals (ORPs) must be enrolled in the Medicaid Program. However, the MPEC allows for payment of prescription claims prescribed by OOS licensed physicians or ORPs under limited circumstances as described below.

The following billing guidance applies to OOS licensed prescribers who are either enrolled in Medicare with an "approved" status or are enrolled in their own state's Medicaid plan. The prescription must be for:

- a ***single instance*** of emergency medical care or order for ***one*** Medicaid member within a 180-day period, or
- multiple instances of care provided to ***one*** Medicaid member when the services provided are more readily available in another state within a 180-day period.
- Pharmacy claims will initially reject for National Council for Prescription Drug Programs (NCPDP) Reject code **"56"** (Non-Matched Prescriber ID). This means the prescriber is ***not*** enrolled in NYS Medicaid.
- To override above rejection for the OOS prescription situations described above:
  - In Field 439-E4 (Reason for Service Code): enter **"PN"** *(Prescriber Consultation)*
  - In Field 441-E6 (Result of Service Code): enter applicable value (**"1A"**, **"1B"**, **"1C"**, **"1D"**, **"1E"**, **"1F"**, **"1G"**, **"1H"**, **"1J"**, **"1K"**, **"2A"**, **"2B"**, **"3A"**, **"3B"**, **"3C"**, **"3D"**, **"3E"**, **"3F"**, **"3G"**, **"3H"**, **"3J"**, **"3K"**, **"3M"**, **"3N"**, **"4A"**)
  - In Field 420-DK (Submission Clarification Code): enter **"02"** *(Other Override)*

Please note: The billing guidance above may not be used for claims or orders prescribed by an OOS licensed prescriber that is treating more than one Medicaid member for more than a single instance of emergency care within a 180-day period, or more than one Medicaid member for multiple instances of care when the services provided are more readily available in another state within a 180-day period. The only option available when a pharmacy is presented with a prescription or fiscal order outside of the MPEC exceptions is to obtain a new prescription from an enrolled provider because federal regulations require NYS Medicaid enrollment for these prescribers. Pharmacies may refer prescribers to the eMedNY Provider Enrollment Index for further information on how to enroll.

Free Choice

The choice of which pharmacy provider will fill the prescription or order for drugs rests with the Medicaid member. The prescribing practitioner should obtain the Medicaid member's pharmacy choice before prescribing any prescription or fiscal order in order to allow the Medicaid member to exercise his or her freedom of choice.

Record-Keeping Requirements

Pharmacies must keep on file the original prescription or fiscal order for which Medicaid payment is claimed. These original prescriptions and fiscal orders must be kept on file for six years from the date the service is provided or billed, whichever is later.

Pharmacies are not required to generate and keep a hard copy of electronic prescriptions and fiscal orders as long as they are securely stored and maintained. When stored electronically, the electronic imaging of prescriptions and fiscal orders that were e-prescribed must result in an exact reproduction of the original order and may be required to be authenticated.

Telephone Orders

Prescribers may telephone prescriptions and fiscal orders for drugs directly to a pharmacy unless otherwise prohibited by State or Federal law or regulations.

- Telephoned non-controlled prescription drug orders are considered original. Follow up hard copy is not required.
- Telephoned controlled prescriptions must follow all rules in 10 NYCRR Part 80 including the requirement of an original order (follow up hard copy) provided to the pharmacy from the prescriber within timeframe specified.
- Telephoned fiscal orders for OTC drugs or DME items or supplies are not considered original; the pharmacy must obtain the original signed fiscal order (follow up hard copy) from the ordering practitioner within 30 calendar days of the documented telephone order date.

The pharmacist is responsible to make a good faith effort to verify the prescriber's identity and validity of the prescription if the prescriber is unknown to the pharmacist.

- A telephone order must be reduced to writing, either through written communication or electronic record, indicating the time of the call and initials of the pharmacist.

- The format used to record the telephone order must conform to requirements of the NY State Education Law with regard to permitting substitution or dispensing as ordered.

- Prescriptions for multi-source brand drugs requiring “dispense as written” and "brand necessary" may be ordered over the telephone.

  - Prescriptions for multi-source brand drugs requiring “dispense as written” and "brand necessary" may be ordered over the telephone, the pharmacist must

notate such on the oral order. The prescriber or authorized individual prescribing by phone must verbally communicate both “dispense as written” and "brand necessary" and notate such in the Medicaid member’s medical record in his/her own handwriting that the drug is “brand medically necessary,” the reason that a brand name multi-source drug is required, and the prior authorization number for the drug if applicable. See Mandatory Generic Drug Program:

https://newyork.fhsc.com/providers/MGDP_about.asp.

Faxed Orders

Prescribers may fax prescriptions and fiscal orders for drugs directly to a pharmacy unless otherwise prohibited by State or federal law or regulations.

The pharmacist is responsible to make a good faith effort to verify the validity of the prescription and the prescriber’s identity if the prescriber is unknown to the pharmacist.

- A faxed order must originate from a secure and unblocked fax number from the prescriber. The source fax number must be clearly visible on the fax that is received.
- A faxed order must include the physician stamp **and** signature.
- Each faxed prescription or fiscal order may include only one (1) drug on a serialized Official New York State Prescription Form. Lists of drugs are not acceptable as faxed orders. Non-controlled drugs ordered from a nursing home are exempt from this requirement.
- Faxed orders for prescription drugs, OTCs, and DME not on the Official New York State Prescription form are not considered an original order and require a follow up hard copy.
-
- Faxed order forms from an intermediary may not be used as a prescription to submit a claim.
- Faxed forms, including enrollment into Patient Assistance Programs for specific medications, or Prior Authorization or Insurance information with prescription information and prescriber signature may not be used as a prescription to submit a claim.
- “Faxbacks” may not be used as a prescription to submit a claim.
- Fail-over electronically transmitted prescriptions that come to the pharmacy as a fax may not be used as a prescription to submit a claim.

Electronic Orders

Pharmacies are not required to generate and keep a hard copy of electronic prescriptions and electronic fiscal orders. Original orders received in electronic format may be securely stored electronically.

The pharmacist is responsible to make a good faith effort to verify the validity of the prescription and the prescriber's identity if the prescriber is unknown to the pharmacist.

- Electronic imaging of prescriptions and fiscal orders must result in an exact reproduction of the original order and may be required to be authenticated.

Section III - Scope of Pharmacy Benefits

List of Reimbursable Drugs

The List of Medicaid Reimbursable Drugs has been established by the New York State Commissioner of Health. Only those prescription and non-prescription drugs which appear on the List are reimbursable under the fee-for-service Medicaid Program. The List also contains those non-prescription therapeutic categories which the Commissioner of Health has specified as essential in meeting the medical needs of Medicaid members.

The entire List is available electronically at: https://www.emedny.org/info/formfile.aspx

The List includes the following information:

- Rx Type: identifies Prescription Type (value 01 indicates non-controlled legend drugs; values 02 through 06 indicate controlled substances; 07 indicates OTC drugs and supplies billed by NDC;
- National Drug Code (NDC);
- Maximum Reimbursable Amount (MRA Cost);
- Cost Alternate (ALT): identifies the NADAC price (when available) for drugs (other than blood products and diabetic supplies) when MRA Cost is less than the NADAC;
- Formulary Description (drug name and strength);
- PA CD (Prior Authorization/Approval Code): Value “0” indicates no PA required; Value “N” indicates PA required; Value “G” indicates PA required/may be required;
- Labeler (manufacturer);
- OTC IND (OTC Indicator): Indicates whether an over-the-counter medication meets the definition of a Covered Outpatient Drug (Y) or not (N).

Note: Reimbursable drugs are listed alphabetically in sections by Rx Type.

Drug Coverage Limitations

Medicaid only provides reimbursement for drugs included on the New York State List of Medicaid Reimbursable Drugs (unless provided by a facility which includes the cost of drugs in their all-inclusive rate). The following are examples of drugs/drug uses which are not reimbursable by Medicaid in accordance with Policy and/or State or Federal Legislation:

- Drugs used for the treatment of anorexia, weight loss or weight gain SSA §1927(d)(2);
- Drugs for the treatment of sexual dysfunction* pursuant to SSA §1927(d)(2), and Social Services Law §365-a(4)(f);
- Drugs without a federal rebate agreement pursuant to SSA§1927(a);
- Drugs indicated for cosmetic use or hair growth pursuant to SSA §1927(d)(2);
- Transgender drugs not used according to practice standards;
- Any item marked “sample” or “not for sale”;
- Any contrast agents, used for radiological testing (these are included in the radiologist’s fee);
- Any drug which does not have a National Drug Code;
- Drugs packaged in unit doses for which bulk product exists; and
- Any drug regularly supplied to the general public free of charge must also be provided free of charge to Medicaid members.

*Only drugs used for the treatment of sexual or erectile dysfunction require confirmation that the member is a registered sex offender.

Medical/Surgical Supplies

Prescribing practitioners may order medical/surgical supplies which are listed in the OTC and Supply Fee Schedule. If a medical/surgical supply does not appear in the OTC and Supply Fee Schedule, the practitioner may request the supply through the prior approval process.

Coverage for "Emergency Services Only" Category of Service

Medicaid FFS does **not** reimburse all covered drugs for patients with coverage for "Emergency Services only". Medicaid coverage may be available for services that are necessary for the treatment of a sudden and acute "emergency medical condition". Per federal regulation, the term emergency medical condition is defined as a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(a) Placing the patient's health in serious jeopardy;
(b) Serious impairment to bodily functions; or
(c) Serious dysfunction of any bodily organ or part.

Coverage will not be extended for medications when the federal definition of an "emergency medical condition" is not met regardless of where the prescription is being obtained (i.e., emergency department). Drugs not included in "emergency services coverage" will not change based on the type of facility at which a patient receives their prescription.

The policy and list of covered drugs for the Emergency Services category of eligibility can be found under article titled *Emergency Services Only Pharmacy Coverage* at: https://www.health.ny.gov/health_care/medicaid/program/pharmacy.htm. Pharmacies should not submit claims for ESO members for chronic, maintenance, prophylactic or suppressive use of the medications on this list.

Please note:

- Short acting narcotics should only be written for an emergency 5-day supply.
- HIV prophylaxis therapy following occupational exposure & non-occupational exposure (such as sexual assault) can be obtained via the exception/override process.
- Covered
  - Acute/short term: Drugs prescribed and dispensed for only the amount sufficient to treat the sudden and acute emergency medical condition. An acute condition is a medical condition that has a fast onset and short duration.
- Not Covered
  - Chronic/maintenance: Drugs prescribed or administered for a chronic medical condition or is taken as maintenance such as, on a regular consistent basis, are not allowable under this COE. A chronic medical condition is one that progresses slowly and generally long in duration.
  - Prophylactic & suppressive treatment: Drugs prescribed or administered for a prophylaxis or suppressive treatment are not covered under this COE.

Exception/Override Requests: Submission of such a request does not guarantee approval. Exception/override requests for chronic, maintenance, prophylactic or suppressive use or drugs systematically denied for this category of service must be

formally approved by the Department of Health (DOH). Prescribers seeking exception to this policy or for a drug not on the list linked above, may send a letter of necessity and supporting documentation via encryption to ppno@health.ny.gov.

If approved, NY Medicaid will send the dispensing pharmacy written authorization specific to the medication approved and duration of coverage. The override is only applicable to the **approved** prescription(s), pharmacy, and patient documented in the letter.

Note that obtaining a *clinical* PA from the Magellan Call Center does **not** supersede the requirement to obtain approval from NYS Medicaid for chronic use or a drug not included on the list linked above.

The NY Medicaid letter of authorization to dispense must be kept on file by the pharmacy in the event of an audit.

Dispensing Limitations for Items Provided by Residential Health Care Facilities

New York State residential health care facilities have included in their Medicaid rates non-prescription drugs and medical/surgical supplies. All prescription drugs are reimbursed on a fee-for-service basis. Residential health care facilities may:

- Operate an institutional pharmacy to provide these items; or
- Contract with Medicaid enrolled pharmacies to provide these items to Medicaid members. The pharmacy must be reimbursed by the facility for all non-prescription drugs and medical/surgical supplies. Prescription drugs may be billed directly to Medicaid by the dispensing pharmacy on a fee-for-service basis.

Drugs billed directly to Medicaid are limited to prescription drugs included on the New York State Medicaid List of Reimbursable Drugs and are subject to refill, frequency, quantity and duration, step therapy, and prior authorization/approval requirements as described in this Manual.

Medicaid members with both Medicare and Medicaid (dual eligible Medicaid members) who have met their residency requirements in a residential health care facility will receive their prescription drug coverage from their Medicare Part D Plan. Additional information regarding the Medicare Part D Prescription Drug Program and residential health care facilities may be accessed at:

https://www.health.ny.gov/health_care/medicaid/program/medicaid_transition/

Items Provided by Child (Foster) Care Agencies

Most New York State Child (Foster) Care Agencies have included in their Medicaid rates prescription drugs, non-prescription drugs and medical/surgical supplies. Child (Foster) Care Agencies may:

- operate an institutional pharmacy to provide these items; or
- contract with Medicaid enrolled pharmacies to provide these items to Medicaid residents. The pharmacy must be reimbursed by the facility for these items.

Child (Foster) Care Agencies with inclusive Medicaid rates for drugs and supplies may dispense these items to Medicaid residents regardless of the refill, frequency, quantity and duration, step therapy, and prior authorization/approval limitations described in this Manual.

Only drugs specifically carved out of the Medicaid all-inclusive rate may be billed directly to the Medicaid Program. Drugs carved out and billed directly to Medicaid are subject to refill, frequency, quantity and duration, step therapy and prior authorization/approval requirements as described in this Manual.

OMH Residential Treatment Facility Prescription Drug Carve-Out

Reimbursement of **prescription** drugs for children and youth between the ages of five and twenty-one who are residents of the Office of Mental Health (OMH) Residential Treatment Facilities (RTF) is a Medicaid fee-for-service (FFS) benefit and billed directly to Medicaid by the dispensing pharmacy.

Physician administered drugs, OTC drugs, medical supplies, immunization services (vaccines and their administration), nutritional supplies, sick room supplies, adult diapers, and durable medical equipment (DME) are not carved out of the RTF rate and remain the responsibility of the facility.

- The NY Medicaid FFS program provides reimbursement for prescription drugs included on the NY Medicaid Pharmacy List of Reimbursable Drugs, which can be found at: https://www.emedny.org/info/formfile.aspx.
- Prescriptions must be dispensed and billed by a Medicaid enrolled pharmacy, using the member's individual Medicaid Client Identification Number (CIN).

Smoking Cessation Policy

- Smoking cessation therapy consists of certain prescription and non-prescription agents.
- Some smoking cessation therapies may be used together. Professional judgment should be exercised when dispensing multiple smoking cessation products.
- For all smoking cessation products, the member must have a prescription or fiscal order.
- NY Medicaid reimburses for over-the-counter nicotine patches included on the Medicaid List of Reimbursable Drugs.

Emergency Contraception Drug Policy

Both prescription and OTC Emergency Contraception is a Covered Benefit for all Medicaid Fee-for-Service members without age restrictions. This includes individuals enrolled in the Family Planning Benefit Program.

Per NY State regulations, a fiscal order or prescription is not required for OTC emergency contraception for Medicaid-eligible females. Prescription-only contraceptive drugs continue to require a practitioner order. Both prescription-only and OTC emergency contraception is limited to six courses of therapy in a 12-month period.

For more information, please go to:
https://www.health.ny.gov/publications/2018/

Section IV - Basis of Payment

Covered Outpatient Drugs (COD) are defined in Federal statute. The following link provides information on the COD Policy & FAQ per CMS:
https://www.medicaid.gov/medicaid/prescription-drugs/covered-outpatient-drug-policy/index.html.

Prescription Drugs

Pharmacy reimbursement for prescription drugs under the New York State Medicaid Program is established in law.

The pricing methodology is systematically determined as follows:

Drug Type	If NADAC is available reimburse at:	If NADAC is unavailable, reimburse at:	Professional Dispensing Fee*
Generics	Lower of NADAC, FUL, SMAC or U&C	Lower of WAC – 17.5%, FUL, SMAC, or U&C	$10.08
Brands	Lower of NADAC or U&C	Lower of WAC – 3.3%, or U&C	$10.08
OTCs	Lower of NADAC, FUL, SMAC or U&C	Lower of WAC, FUL, SMAC, or U&C	$10.08

**** Professional Dispensing Fee** applies if the drug meets the definition of COD and is not paid at U&C.*

Note: Claims will pay at the pharmacy's U&C pricing if lower than drug ingredient cost plus dispensing fee.

Federal Upper Limit (FUL) is determined by the Secretary of Health and Human Services, a price ceiling used by Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies.

National Average Drug Acquisition Cost (NADAC) is determined by a federal survey and is an average of the drug acquisition costs submitted by retail community pharmacies.

State Maximum Acquisition Cost (SMAC) is developed by Magellan Medicaid Administration for NY Medicaid and is applied on multiple source generic drugs. It represents an upper limit that NY Medicaid will pay for these drugs.

Usual and Customary Cost (U&C) is the lowest net charge to the general public/cash customers on the date of provision of service, not to exceed the lower sale price, if any, in effect on that date.

Wholesaler Acquisition Cost (WAC) is an estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. The price is defined by federal law.

The NY Medicaid Pharmacy Benefit Manager will receive all requests from pharmacy providers concerning the validity of a SMAC price. The SMAC Research Request Form is posted on the Pharmacy Benefit Manager's web site at: https://newyork.fhsc.com/providers/smacinfo.asp

Questions from pharmacy providers concerning the validity of a SMAC price should be referred to the NY Medicaid Clinical Call Center at 877-309-9493.

Non-Prescription Drugs

NY Medicaid covers limited non-prescription (OTC) drugs. OTCs covered by the Medicaid FFS Program can be identified under Rx Type '07' in the List of Reimbursable Drugs found at the following website: https://www.emedny.org/info/formfile.aspx. Not all OTCs meet the definition of a COD. Those OTC drugs that meet the definition of a COD will have an OTC indicator value of "Y".

- When performing a search, select field "OTC Indicator" and then select a value of "Y"

Multiple Source Drugs

Reimbursement is only available for those multiple source drugs contained on the List of Medicaid Reimbursable Drugs.

For certain brand name prescriptions to be eligible for reimbursement, prescribers must certify that the brand name drug is required by writing directly on the face of the prescription "Brand Necessary" or "Brand Medically Necessary" in their own handwriting in addition to the "DAW", unless the brand drug is on the Brand Less Than Generic Program.

> *For handwritten orders, a rubber stamp or other mechanical signature device may not be used.*
>
> *In the case of electronic prescriptions, the prescriber MUST insert an electronic direction as stated above.*

Prior authorization must also be obtained for certain brand name drugs.

In order to dispense a brand name drug when the prescriber indicates "DAW" and, in the case of a prescription written on serialized official NY State prescription form, "Brand Necessary" or "Brand Medically Necessary" on the face of the prescription, the pharmacist must indicate a "yes" in the brand necessary field of the paper claim form or when billing electronically, refer to the NCPDP D.0 Companion Guide for one of the listed codes for submission in field 408-D8- (Dispense As Written (DAW)/Product Selection Code).

For more information, refer to:
https://www.emedny.org/ProviderManuals/Pharmacy/ProDURECCA_Provider_Manual/index.aspx

Compounded Prescriptions

A Compounded Prescription is one in which two or more ingredients are mixed by the dispensing pharmacist. All Medicaid pharmacy providers must comply with all federal and State requirements for compounding prescriptions. For more information, see also: U.S. Department of Health and Human Services, Food and Drug Administration: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm, and NY State Education Law, Pharmacy; Laws, Rules, and Regulations; http://www.op.nysed.gov/prof/pharm/pharmlaw.htm.

Topical compounded drug product ingredients must also be FDA approved or compendia supported for topical use. For more information on Federal and State regulations of topical compounded drugs visit: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm

In order to qualify for Medicaid payment, a compounded prescription must include:

- A combination of any two (2) or more legend drugs found on the list of Medicaid Reimbursable Prescription Drugs; or
- A combination of any legend drug(s) included on the list of Medicaid Reimbursable Prescription Drugs and any other item(s) not commercially available as an ethical or proprietary product(s); or
- A combination of two (2) or more products which are labeled "*Caution: For Manufacturing Purposes Only*."

The reconstitution of a commercially available drug is NOT regarded as a compounding procedure for NY Medicaid reimbursement.

For example:

- The combination of Aquaphor® and Hydrocortisone Cream 2.5% is **NOT** considered a compound, since it does not meet any of the above requirements.
- Intravenous prescription products that require reconstitution, further measurement, dilution and/or instillation into a suitable device (i.e., minibag, IV reservoir or syringe) for administration are not considered to have been compounded and should not be submitted for reimbursement as compounds.

For compound drug billing, pharmacy providers can submit up to 25 ingredients (NDCs) using the compound segment via the NCPDP D.0 format. All ingredients of a compounded prescription **MUST** be submitted to Medicaid regardless of reimbursement. Compound drugs will be returned on the 835 Remittance Advice using

the first ingredient's NDC Code of the Compound drug in SVC01-2 (Procedure Code) with an "N4" Qualifier in SVC01-1.

All compound claims must include Route of Administration code in NCPDP field 995-E2.

Some compounds may require a Topical Compounded Prior Authorization (PA). Prescribers may obtain this type of PA via the Magellan call center; then the prescriber will provide the PA number to the pharmacy.

The Department has made and will continually make formulary updates and system enhancements to support this compound policy.

NY Medicaid acknowledges the need for traditional extemporaneous compounding to customize a drug prescribed for a Medicaid covered medically accepted indication which the therapeutic amounts, combinations, and route of administration are FDA approved or compendia supported and there are no suitable commercially available products within the drug class. The NY Medicaid compound policy is further clarified below:

- Only the dispensing pharmacy may prepare the prescribed compounded prescription.
- Dispensing outsourced prepared compounds is not allowable.
- Compounds trademarked by pharmacies are not coverable.
- Refills of compounds must be specifically requested by the patient or patient's authorized agent before the item is prepared.
- Compounds may not be made to bypass the clinical criteria in the NY Medicaid Fee For Service Program.
- Active FDA approved ingredients submitted on compound claim must be otherwise available on the NY Medicaid List of Reimbursable Drugs.
- Compounds may not contain drugs or be made for Medicaid excluded indications as per the Social Security Act Section 1927(d)(2) including, but not limited to drugs to treat weight loss or sexual dysfunction or for cosmetic purposes.
- Compounds may not be made in therapeutic amounts or combinations not FDA approved, or compendia supported for use.
- Compounds may not be made to add coloring, flavoring, perfumes or other non-active ingredient additives to a commercially available product.
- Submitted compound claims may not include packaging materials or containers, syringes, or other items utilized or necessary in the preparation of final compounded product.
- Compounds must be adjudicated with the appropriate and matching final compounded product route code for the dosage form.
- Prepared compounds that mimic a commercial product must include on the prescription and in the members medical chart documentation of the reason for

compounding (i.e., sensitivity or contraindication to dyes, preservatives, or fillers or lack of availability of a commercial product).
- The FDA-approved or compendia supported use and dose of an ingredient must match the compound's intended therapeutic use.
- Reconstitution per product labeling is not considered a compound whether it comes as a kit or requires additional supplies.
- All Medicaid policies, NY and federal laws apply.

Topical

Examples of non-covered topical compounds are those made:
- with ingredients not FDA approved, compendia supported, or excluded from Medicaid coverage for topical use, or
- foot baths, other soaks, or irrigations.

Oral

Examples of non-covered oral compounds are those made:
- with ingredients not FDA approved, compendia supported for oral use, or excluded from Medicaid coverage, or
- by reconstituting commercially available products, or
- as an enteral nutrition product, see billing guidance here: https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Procedure_Codes.pdf or here https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Policy_Section.pdf.

Parenteral

Examples of non-covered parenteral compounds are those:
- inconsistent with sterile compound standards as required by State or federal law or regulation (8NYCRR Part 29.2 (13)), or
- made to simply dilute, reconstitute or otherwise prepare a medication for infusion per it's labeling, or
- products for nutrition or hydration. See billing guidance for these products here: https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Procedure_Codes.pdf

A Medicaid list of reimbursable drugs can be found at:
https://www.emedny.org/info/formfile.aspx

340B Pharmacy Drug Claims in Medicaid

Upon enrollment in the 340B program, 340B covered entities must determine whether they will use 340B drugs for their Medicaid patients.

Federal law prohibits duplicate discounts – manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. The federal Health Resources and Services Administration (HRSA) has rules and requirements for when a covered entity uses 340B drugs for Medicaid members, including listing the entity's Medicaid provider number/NPI on the HRSA Medicaid Exclusion File (MEF). Information on HRSA's requirements in this area can be found at the following site: http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html.

The NY Medicaid program does **not** use HRSA's Medicaid Exclusion File. NY Medicaid relies completely on the use of 340B claim level identifiers to avoid duplicate discounts. **These identifiers are required at the claim submission level for all 340B drug claims,** thereby avoiding duplicate discounts. Using these identifiers is the **only** way NY Medicaid will remove the claim from rebate invoicing. Note, applying claim level identifiers on non-340B purchased drug claims is considered fraudulent billing.

The following fields are required on Medicaid 340B drug claims submitted in the NCPDP format:

Field	Medicaid Primary Claim	Medicaid Secondary Claim (Medicare; Commercial)
420-DK, Submission Clarification Code (SCC)	20	20
423-DN, Basis of Cost Determination (BCD)	08	N/A
409-D9 Ingredient Cost Submitted	340B Acquisition Cost	N/A
426-DQ Usual and Customary Cost (U&C)	Lowest Net Charge to Cash Customers	Lowest Net Charge to Cash Customers

FAQs on the 340B program itself, as well as information on how to ask additional questions, can be found on the HRSA website at https://www.hrsa.gov/opa/faqs/index.html

Long Term Care Pharmacy Short Cycle Billing

Short cycle dispensing is used by long term care (LTC) facility pharmacies as required by federal law for certain Medicare
claims or by LTC contract to reduce wasteful dispensing of outpatient prescription drugs. The below guidance and chart
applies to any Medicaid claim dispensed to an LTC member who resides in a Private Skilled Nursing Facility,

Public Skilled Nursing facility, Private Health Related Facility, or Public Health Related Facility, (when **"NH"**
returns on eligibility response) where the member is stabilized on the drug and is taking it on a consistent
basis.

The Department requires the submission of the following appropriate code when dispensing an LTC
pharmacy claim for a maintenance drug in less than a 30-day supply. A maintenance drug is one where
the member is taking on a consistent basis.

Note: Use of the short cycle code allows for the full dispensing
of the prescription beyond five refills and removes the need for a new prescription after five refills (for example,
after seven-day supply dispensed each time) up until the end of the prescribed amount or six months.

LTC pharmacy providers should indicate, via an appropriate submission clarification code from the following table in field 420-DK,
when they are submitting claims for maintenance medications with short days' supply:

Valid Values	Short Name Description	Long Name Description
21	LTC14DAYLS	14 DAYS OR LESS [is not applicable due to Centers for Medicare and Medicaid Services (CMS) exclusion and/or manufacturer packaging may not be broken or special dispensing methodology (i.e. leave of absence, ebox, splitter dose); medication quantities are dispensed as billed]
22	LTC7DAY	7 DAY SUPPLY
23	LTC4DAY	4 DAY SUPPLY
24	LTC3DAY	3 DAY SUPPLY
25	LTC2DAY	2 DAY SUPPLY
26	LTC1DAY	1 DAY SUPPLY [pharmacy or remote

		(multiple shifts) dispenses medication in 1-day supplies]
27	LTC43DAY	4 THEN 3 DAY SUPPLY
28	LTC223DAY	2 THEN 2 THEN 3 DAY SUPPLY
29	LTCDAILY3D	DAILY AND 3 DAY WEEKEND (pharmacy or remote dispensed daily during the week and combines multiple days dispensing for weekends)
30	LTCSHIFT	PER SHIFT DISPENSING
31	LTCMED	PER MED PASS DISPENSING
32	LTCPRN	PRN ON DEMAND
33	LTC7ORLES	7 DAYS OR LESS (cycle not otherwise represented)
34	LTC14DAY	14 DAY DISPENSING
35	LTC814DAY	8-14 DAYS DISPENSING (cycle not otherwise represented)
36	LTCOUT	OUTSIDE SHORT CYCLE (claim was originally submitted to a payer other than Medicare Part D and was subsequently determined to be Part D)

Medical and Surgical Supplies

Reimbursement for each covered medical/surgical supply will be the lower of:

- The price as indicated on the New York State List of Medical/Surgical Supplies

-or-

- The usual and customary price charged to the general public.

"Covered supplies" are those on the OTC and Supply Fee Schedule section of this manual: https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx

For supplies not on that list, only those supplies for which the prescriber has obtained prior approval are covered.

Co-payments for Drugs and Medical Supplies

The New York State Medicaid Program charges co-payments for many drug and medical supply items.

Health care providers have an obligation to provide services and goods regardless of a Medicaid member's ability to pay co-payments.

- Pharmacy providers may not refuse services to otherwise eligible Medicaid members who cannot afford to pay the co-payment. ***To refuse to provide services is an unacceptable practice.***

- Pharmacy providers may:

  - Request the co-payment each time a Medicaid member is provided services or goods;

  - Ask a Medicaid member for outstanding co-payments the next time he/she comes in;

  - Send the Medicaid member bills; or

  - Use other legal means to collect the co-pay due.

- Pharmacy providers must not reduce the amount charged on a Medicaid claim by the copayment that is collected from a Medicaid member. Each claim that requires a co-payment will have the co-payment ***automatically deducted*** from the final payment when the claim is approved for payment.

Medicaid Co-payments:

- Some Medicaid members become eligible for Medicaid by spending part of their monthly income on medical care. Since co-payments paid or incurred can be used toward satisfying the spend-down (overage) in the following month, itemized bills or receipts for co-payments should be provided to members when requested.

- There is a maximum amount per Medicaid member for all co-payments incurred per year and is calculated on a quarterly basis. The co-payment year starts April 1 and ends March 31.
  When a member reaches the quarterly co-pay maximum, they will receive a letter confirming the date on which the co-pay maximum was met and exempting the member from a co-payment until the end of the current co-payment quarter.

- Co-payment amounts are as follows:

  - $3.00 for non-preferred Brand Name Drugs;
  - $1.00 for Generic Drugs, preferred Brand Name Drugs, and Brand Drugs included in the Brand Less Than Generic Drugs Program;
  - $0.50 for Non-Prescription (over the counter) Drugs;
  - $1.00 for Medical/Sickroom Supplies.

- Co-payment is not required for certain members and service categories which include:

  - Family planning (birth control) services including birth control pills, Plan B, and condoms;
  - FDA-approved drugs to treat tuberculosis;
  - FDA-approved drugs to treat mental illness (psychotropic drugs);
  - Medicaid members younger than 21 years old;
  - Medicaid members during pregnancy and for the two months after the month in which the pregnancy ends;
  - Residents of Adult Care Facilities licensed by the New York State Department of Health (DOH);
  - Residents of nursing homes;
  - Residents of Intermediate Care Facilities for the Developmentally Disabled (ICF/DD);
  - Residents of Office of Mental Health (OMH) or Office of Persons with Developmental Disabilities (OPWDD) certified residences;
  - Members in Comprehensive Medicaid Case Management (CMCM) or Service Coordination Programs;
  - Members in OMH or OPWDD Home and Community Based Services (HCBS) Waiver Programs; and

- Members in a DOH HCBS Waiver Program for Persons with Traumatic Brain Injury (TBI).
- Members with incomes below 100 percent of the federal poverty level.
- Members in Hospice
- American Indians and Alaska Natives who have ever received a service from the Indian Health Service, tribal health programs or under contract health services referral.

Section V - Utilization Management Programs

Eligibility

Pharmacy providers of Medicaid services are required to verify the eligibility of the Medicaid member. There are two methods available for utilization:

1) The Automated Response Unit (ARU or telephone);

2) The ePACES web-based application.

These systems enable pharmacy providers to quickly verify eligibility and facilitate electronic submission of claims.

Recipient Restriction Program (RRP)

Medicaid members who have been assigned to a designated pharmacy are required to receive all pharmacy services from the selected pharmacy provider. All claims from other pharmacies will be denied.

Medicaid members who are restricted to a primary Durable Medical Equipment (DME) dealer must receive all DME and prosthetic and orthotic appliances from the DME provider.

All primary pharmacy providers must maintain a patient profile for each restricted Medicaid member. The profile must contain, at a minimum, the member's name, and the date the drugs or supplies were dispensed. These profiles must be made readily available to the New York State Department of Health or its agents, upon request.

When a Medicaid member is restricted to an ordering practitioner (physician, clinic, inpatient hospital and/ or dentist), all pharmacy services must be ordered by the primary medical provider (clinic or MD) with the Medicaid member's restriction type.

A primary physician or primary clinic is responsible for providing all medical care to the restricted recipient, either directly or through referral of such recipient to another medical provider for appropriate services. If the primary provider refers the Medicaid restricted recipient to another provider for services, the primary provider's Medicaid identification number must be used in the referring field in order to bill for those services. **When dispensing medications prescribed by the 'referred' provider, the pharmacy must enter the primary provider's Medicaid identification number in the referring field in the pharmacy claim.**

Medicaid members may have durable medical equipment restrictions separate from pharmacy restrictions.

Utilization Threshold

The Utilization Threshold (UT) program places limits on the number of services a Medicaid member may receive in a benefit year. A benefit year is a 12-month period which begins the month the member became Medicaid eligible.

Medicaid members are assigned specific limits for the following services:

- Physician/Clinic Visits
- Laboratory Procedures
- Pharmacy
- Mental Health Clinic Visits
- Dental Clinic Visits

These service limits are established based on each member's clinical information. This information includes diagnoses, procedures, prescription drugs, age and gender. As a result, most Medicaid members have clinically appropriate service limit levels and will not need additional services authorized through the Threshold Override Application (TOA) process.

For details go to: https://www.emedny.org/info/index.aspx and click under Information tab for Utilization Threshold Program.

- Pharmacies encountering urgent or emergency situations should see the override instructions in the Provider Manual located at: https://www.emedny.org/ProviderManuals/Pharmacy/ProDURECCA_Provider_Manual/index.aspx

Pharmaceutical Management Programs

Overview

Drug Utilization Review (DUR) programs are intended to assure that prescriptions for outpatient drugs are appropriate, medically necessary and not likely to result in adverse medical consequences. DUR programs help to ensure that the patient receives the proper medicine at the right time in the correct dose and dosage form.

The benefits of DUR programs may include reduced Medicaid costs, reduced hospital admissions, improved health for Medicaid members, increased coordination of health care services, and reduced drug diversion. Information supplied to Medicaid pharmacy providers through the DUR programs may enhance their ability to prescribe and dispense medication more appropriately.

The federal legislation requiring states to implement DUR programs also requires states to establish DUR Boards whose function is to play a major role in each state's DUR program. The Department of Health contains a DUR Board comprised of health care professionals with recognized knowledge and expertise appointed by the Commissioner. More information regarding the DUR Board and Program may be found here: https://www.health.ny.gov/health_care/medicaid/program/dur/.

The two components of New York State's DUR program are Retrospective DUR (RetroDUR) and Prospective DUR (ProDUR). While the two programs work cooperatively, each seeks to achieve better patient care through different mechanisms.

Each of these programs is described in detail below.

RetroDUR

The Department of Health manages a RetroDUR program for Medicaid members. The RetroDUR program is designed to educate physicians by targeting prescribing patterns which need to be improved. Under RetroDUR, a review is performed subsequent to the dispensing of the medication.

The primary goal of RetroDUR is to educate prescribers and pharmacists through alert letters which are sent to providers detailing potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug allergy interactions and clinical abuse/misuse.

- It is expected that providers who receive alert letters identifying a potential problem relating to prescription drugs will take the appropriate corrective action to resolve the problem.

ProDUR

Medicaid enrolled pharmacies are required to perform in-house prospective drug utilization reviews. The Department of Health oversees a ProDUR program through the Medicaid Eligibility Verification System (MEVS).

The point-of-sale system allows pharmacists to perform on-line, real-time eligibility verifications, Electronic Claims Capture and Adjudication (ECCA) and offers protection to Medicaid members in the form of point-of-sale prevention against drug-induced illnesses.

The ProDUR/ECCA system maintains an on-line record of every Medicaid member's drug history for at least a 90-day period. The pharmacist enters information regarding each prescription and that information is automatically compared against previously dispensed drugs, checking for any duplicate prescriptions, drug to drug contraindications, over and under dosage and drug to disease alerts, among other checks.

In the event that this verification process detects a potential problem, the pharmacist will receive an on-line warning or rejection message. The pharmacist can then take the appropriate action; for example, contacting the prescribing physician to discuss the matter. The outcome might be not dispensing the drug, reducing the dosage, or changing to a different medication.

The ProDUR Program is administered by the Department's fiscal intermediary or its subcontractor. Use of the online DUR functions via MEVS by pharmacy providers, including those providers that are rate-based, is **mandatory**. Pharmacy providers are required to use personal computers or central processing units to access the online system either independently or through a switch company. Any data entered by the pharmacy provider is processed, including checking eligibility, third-party coverage, Utilization Threshold and Medicaid Recipient Restriction Program status before being passed to the DUR system.

The DUR system utilizes National Council on Prescription Drug Program (NCPDP) version D.O. NCPDP responses alert pharmacy providers to the type of drug interaction, drug/disease conflict, therapeutic duplication or over-utilization problems, and the most recent fill dates for the potentially hazardous drug.

A maximum of nine different codes/drug interactions per prescription per entry may be sequentially displayed for up to four prescriptions per entry.

All of the DUR messages are specified by the State DUR Board which is composed of doctors, pharmacists, and DUR experts in concert with the drug information contractors.

ProDUR Claims Submission

Pharmacy providers can submit most claims directly via the electronic claims adjudication system that was developed for the ProDUR system. If claim capture and adjudication is selected, the claim will be processed for eligibility verification, ProDUR, Utilization Threshold and, if requested, Dispensing Validation System (DVS). If approved, the claim will be fully adjudicated and paid.

For claims over 90 days from the date of service, a "non-captured" transaction may be submitted for eligibility verification but the claim must be submitted on a paper claim form or via electronic batch. See more about timely filing here: https://www.emedny.org/HIPAA/QuickRefDocs/FOD-7001_Sub_Claims_Over_90_days_Old.pdf.

Certification for ProDUR/ECCA

All Medicaid pharmacy providers are required to perform on-line prospective drug utilization review. Submitting claims via Electronic Claims Capture and Adjudication (ECCA) is optional. Under ProDUR, all pharmacies must enter their transaction using the NCPDP formats via one of the MEVS access methods. NCPDP format specifications can be found at:

https://www.emedny.org/ProviderManuals/Pharmacy/ProDURECCA_Provider_Manual/index.aspx

PLEASE CONSULT THE MEVS DUR USER MANUAL FOR SPECIFIC INFORMATION RELATING TO PRODUR, ELECTRONIC CLAIMS CAPTURE AND ADJUDICATION SUBMISSION AND MEVS ACCESS METHODS.

Section VI – Definitions

The following terms are defined for the purposes of the NY Medicaid program and are included to help clarify policies as provided in this Manual:

340B Ceiling Price

The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA). HRSA obtains the AMP and URA data from the Centers for Medicare and Medicaid Services (CMS) as part of quarterly reporting for the Medicaid Drug Rebate Program. This figure is then multiplied by the package size and case package size to produce a price that is used in the marketplace for purchasing covered outpatient drugs. For example, the AMP minus the URA indicates the cost of one pill.

Actual Acquisition Cost

Refers to the price paid by the Covered Agency for a 340B purchased drug with no added costs, delivery fees or dispensing fees, or, means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Bioavailability

The rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action.

For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

Bioequivalence

Bioequivalence is the pharmaceutical equivalent or pharmaceutical alternative products that display comparable bioavailability when studied under similar experimental conditions.

Covered Outpatient Drug

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Social Security Act, and are approved for safety and effectiveness as a prescription drug under the federal Food, Drug and Cosmetic Act, which is used for a medically accepted indication. (See 42 CFR Section 447.502)

Dose

The exact amount of medication to be taken at one time or at stated intervals according to the prescriber’s directions.

Electronic Prescription

As per New York State Education Law 6802 an electronic prescription is created, recorded or stored by electronic means; issued and validated with an electronic

signature; and transmitted by electronic means directly from the prescriber to a pharmacist.

Federal Upper Limit

CMS establishes and issues listings that identify and set upper limits for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis for which the FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent.

Payment for these drugs must not exceed, in the aggregate, a reasonable dispensing fee plus an amount that is no less than 175 percent of the weighted Average Manufacturer Price (AMP).

Fiscal Order

A fiscal order is a request written by a NY Medicaid Enrolled Provider to provide non-prescription drugs or medical/surgical supplies electronically prescribed or written on an Official NYS Prescription form.

General Public

The general public is defined as the group accounting for the largest number of non-Medicaid transactions from the individual pharmacy and does not include other third-party payers.

Generic Equivalent

A generic equivalent drug product is one which:

- Has been certified or approved by the FDA as being safe and effective for its labeled indications for use, and a new-drug application or an abbreviated new drug application is held; and
- The FDA has evaluated such drug product as pharmaceutically and therapeutically equivalent and has listed such drug product on the list of approved drug products with the therapeutic equivalence evaluations.

Labeler

Any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical

synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, re-labeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

Labeler is the entity holding legal title to or possession of the NDC number for the covered outpatient drug.

Medical and Surgical Supplies

Medical and surgical supplies include items for medical use other than drugs including prosthetic/orthotic appliances, durable medical equipment and orthopedic footwear.

These items are used to treat a specific medical condition and are usually consumable, non-reusable, disposable, for a specific purpose rather than incidental and generally have no salvageable value.

Medical and surgical supplies must be dispensed by a NY Medicaid enrolled provider who is licensed/registered by the appropriate authority, if existing, in the state in which the provider is located and in NY.

Medical/surgical supplies do not include items and supplies that are useful to persons in the absence of an illness or injury or that are primarily used to service needs other than health needs.

Multiple Source Drug

A multiple source drug is a drug product marketed or sold by two or more labelers or sold by the same labeler under two or more different brand names.

> Multiple source drugs are pharmaceutically equivalent and shown to meet an appropriate standard of bioequivalence.

NADAC

The National Average Drug Acquisition Cost for Medicaid covered outpatient drugs as calculated by the Centers for Medicare and Medicaid Services (CMS).

New York State List of Medicaid Reimbursable Drugs

A list consisting of the prescription and non-prescription drugs for which Medicaid will reimburse the enrolled pharmacy provider. This is available online at: https://www.emedny.org/info/fullform.pdf

Non-Prescription Drug

A non-prescription drug, also known as an OTC drug, is that for which no prescription is required by NY State Education law or regulation.

Non-prescription drugs may be obtained in the Medicaid Program only upon an original fiscal order (either e-prescribed or written on ONYSRx form) from a prescriber.

Original Order

A prescription or fiscal order, received in written or electronic format, that is executed in accordance with all applicable State and federal laws or regulation; can also be known as a hard copy or follow up if written in response to an oral or faxed order.

Pharmaceutical Equivalent

The pharmaceutical equivalent is a drug product which contains the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or dosage form, or concentration.

Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same compendial or other applicable standards (i.e.; strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time and within certain limits, labeling.

Prescribing Practitioner

A prescribing practitioner includes the following who are actively NY licensed and NY Medicaid enrolled:

- Physicians,
- Certified Nurse Practitioners,

- Midwives,
- Dentists,
- Podiatrists,
- Registered Physician Assistants, or
- New York State Education Department-certified optometrists licensed by law and currently registered to prescribe prescription drugs.

Unlicensed interns and residents may prescribe drugs (under the supervision of a licensed physician or dentist) as part of their official duties as members of a hospital staff. The Medicaid enrolled attending/supervising physician's name and NPI number must be provided on all prescriptions written by the unlicensed intern or resident.

Prescription Drug

A prescription drug includes any drug for which a prescription from a qualified licensed practitioner is required under New York State Education Law.

Prescription drugs are subject to the requirements of the Federal Food, Drug and Cosmetic Act and those stipulated by the State Commissioner of Health.

All controlled substances are prescription drugs.

Single Source Drug

A single source drug is a drug which is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross licensed producers or distributors operating under the new drug application.

This product is not generic, nor is it available as a generic.

State Maximum Acquisition Cost

This is a reimbursement amount established for any drug for which two or more A-rated therapeutically equivalent, multi-source, non-innovator drugs with a significant cost difference exist.

The State Maximum Acquisition Cost (SMAC) will be determined taking into account drug price status, marketplace status, equivalency rating, and relative comparable pricing.

Therapeutic Equivalent

A drug product which is expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

Usual and Customary Charge

This is the price a pharmacy charges to the general public.