NYRx
Medicaid Pharmacy Program

Pharmacy Manual Policy Guidelines

New York State Medicaid
Office of Health Insurance Programs
Department of Health

CONTACTS:

eMedNY URL
https://www.emedny.org/

ePACES Reference Guide

https://www.emedny.org/selfhelp/ePACES/PDFS/5010_ePACES_Professional_Real_Time_Claim_Reference_Guide.pdf

(800)343-9000
eMedNY: Billing Questions, Remittance Clarification, Request for Claim Forms, ePACES Enrollment, Electronic Claim Submission Support (eXchange, FTP), Provider Enrollment

(877)309-9493
Prior Approval, Prime Therapeutics State Government Solutions Clinical Call Center also known Clinical Call Center

All eMedNY Contact Information
eMedNY Contacts PDF

NYRx Medicaid Helpline
(800)541-2831, TTY (800)662-1220

Pharmacy Benefits and Coverage website
https://member.emedny.org/pharmacy/benefits

Pharmacy Policy Questions
NYRx@health.ny.gov

Policy Guidelines

NYRx

NEW YORK STATE OF OPPORTUNITY. Department of Health

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This Policy Manual applies to NYRx, the Medicaid Pharmacy Program, formerly known as Medicaid Fee-for-Service. 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. This manual applies to the Medicaid Pharmacy Program for pharmacy claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format.

Providers who service NY Medicaid members must comply with all federal, and State laws, rules, or regulations and must comply with Medicaid rules and policies.

Enrolled providers may not exclude Medicaid covered services based on a member's coverage type such as Fee-For-Service, Managed Care, or Dual Eligible Medicaid covered members. Enrolled providers agree to accept payment as payment in full.

For initial and continued enrollment in the Medicaid program, providers may not have any excluded individual or entity involved in any activity relating to furnishing medical care, services or supplies to recipients of medical assistance for which claims are submitted to the program or relating to claiming or receiving payment for medical care, services or supplies during the period of exclusion. Information regarding Medicaid exclusions is found here: https://omig.ny.gov/medicaid-fraud/medicaid-exclusions.

1.0 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.
- Refills must be notated if any are prescribed using a number, ("prn" or time frames are not permitted)
- 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.

Non-Patient Specific Drug Orders

New York State (NYS) law and regulation allow some drugs (i.e., certain vaccinations) to be dispensed to a patient without a patient-specific prescription or fiscal order from their practitioner. This is known as a non-patient specific order or standing order. A pharmacy, in compliance with NYS law and regulations, may dispense and submit a claim according to the protocol and terms of the standing order when the following all apply:

- A NYRx or Medicaid Managed Care (MMC) member/enrollee specifically requests the item on the date of service.
- A pharmacy submits one course of therapy with no refills or up to the terms of the standing order, and
- The drug item(s) are dispensed according to Food and Drug Administration (FDA) guidelines, NYS laws, rules, and regulations, as well as Medicaid Policy and NYRx billing Instructions.

Providers should:

- Enter a value of "5" in the Prescription Origin Code field 419-DJ to indicate pharmacy dispensing.
- Enter a value of "99999999" in the Serial Number field 454-EK, and
- Enter in the prescriber identification field 411-DB either the pharmacy NPI for services that do not require a prescription or fiscal order (i.e., OTC emergency contraception) or the authorizing practitioner's NPI for standing orders (i.e., influenza vaccinations).
- Maintain documentation that includes:
    - Member consent, and
    - Modality of request (in pharmacy or by phone), and
    - Date and time of the request.

Medical/Surgical Supply Orders

See the DME Policy Guidelines for information regarding fiscal order requirements for supply (non-drug) orders.
NOTE: If the prescriber sends multiple supplies on same order the pharmacy should validate the order and treat the additional supplies as a phone order. Each supply must have its own quantity and refill and direction annotated.

Diabetic Supply

Select pen needles, syringes, and lancets may be billed to NYRx, the Medicaid Pharmacy Program, by pharmacy providers on a pharmacy claim using the product's 11-digit National Drug Code (NDC) or the Healthcare Common Procedure Coding System (HCPCS) code. Pen needles, syringes, and lancets reimbursable through NYRx are subject to the products listed on the Pharmacy List of Reimbursable Drugs found at: https://www.emedny.org/info/formfile.aspx.

The 11-digit NDC on the package dispensed must match the NDC billing code on the Pharmacy List of Reimbursable Drugs and the NDC submitted on the claim. In the event an NDC is not found on the list of reimbursable drugs, providers should continue to submit claims using the Healthcare Common Procedure Coding System (HCPCS) code found in the NYRx, Medical Supply Codes Billable by a Pharmacy document at:
https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Procedure_Codes.pdf.

A pharmacist in receipt of a fiscal order for an OTC diabetic supply should consult the Diabetic Supply list. If in receipt of a fiscal order for a diabetic supply that is not on the list, pharmacists should use their professional discretion and substitute with a covered supply on the list (e.g., OTC glucose meters and corresponding test strips). For OTC diabetic supplies ordered for a visual or audio impairment, consultation with the prescriber may be necessary. Prescriptions written for a non-covered Rx Only diabetic supply continue to require a new prescription for a covered Rx Only diabetic supply (e.g., continuous glucose monitors and corresponding supplies, and insulin pumps).

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 on an Official New York State Prescription form. The table below describes other situations in which a Medicaid covered service 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* – non-controlled ONYSRx Prescriptions and fiscal orders obtained via fax machine transmission.
4	SSSSSSSS	Facsimile*– Fiscal orders for OTC drugs or supplies not on a ONYSRx obtained via fax machine transmission.
4	NNNNNNNN	Facsimile – non-controlled prescriptions obtained via fax machine transmission for **nursing home** patients*** (e.g., roster billing") 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 lawful reason necessary to give it a new number. ****

** See the DME Policy Guidelines for information regarding fiscal order requirements for facsimile and oral orders. Fail-over electronically transmitted **fiscal drug orders** (OTC drugs) that come to the pharmacy as a facsimile are considered an original order. OTC drug orders may be obtained via a facsimile on a ONYSRx or a failed electronic prescription.*
***Facsimile prescriptions are not valid without a unique ONYSRx#.*

Fail-over electronically transmitted prescription drug orders that come to the pharmacy as a facsimile are invalid. Reference: https://op.nysed.gov/professions/pharmacist/frequently-asked-questions/electronic-transmittal-of-prescriptions.
****As per NYS Education Department Law (SED) Article 137 §6810(7)(b) and Regents Rules Section 29.7(a)(1).*
*****Remember to use original date prescribed as "written date" when processing prescription transfers. Transfers are not allowed for controlled substances in New York State.*

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.

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 to be dispensed by a pharmacy. Multiple drug orders are not allowed on prescriptions for controlled substances.

Refills

Per the State regulation, a prescription or fiscal order may not be refilled unless the prescriber has indicated the number of allowable refills on the order. Prescription drug, OTC drugs, and pharmacy dispensed supplies authorized by the prescriber with "PRN" refill equates to one refill.

All refills of prescription drugs must be in accordance with federal and state laws and bear the same prescription number and written date 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.

A NYS Medicaid Member may obtain a refill in one of the following two ways:

- The Medicaid member or their designee may contact their pharmacy requesting a refill.
- The pharmacy may contact the Medicaid member to inquire if a refill is necessary, obtain consent if necessary, and then submit a claim for dispensing on their behalf.

Early Refill
Members are allowed to refill a prescription before the total amount of previous supply was used. A pharmacy claim will pay when more than 75 percent of the previously dispensed amount has been used, or up to a 10-day supply of medication is remaining of the cumulative amount that has been dispensed over the previous 90 days (the more stringent rule will apply). Therefore, members may refill their prescription(s) early, allowing for an ample supply of their medication(s) on hand.

Early filling of more than the allowed amount for vacation or a temporary absence, as stated above, is not permissible.

Long Term Care Pharmacy Billing for Residents-Special Considerations
The following two sections, New Patient and Leave of Absence, apply to Long Term Care Pharmacies servicing Medicaid members in a Private Skilled Nursing Facility, Public Skilled Nursing Facility, Private Health Related Facility, or

Public Health Related Facility, when "NH" or, "N1", "N2", "N3", "N4", "N5", "N6", "N7", "N8", or "N9" returns on eligibility response. The following guidance is not intended for community pharmacies, or those servicing facility types not as described above. Community pharmacies, or those servicing facility types not as described above should contact the Department for assistance with 'Early Fill Overuse' denials for members recently discharged from a LTC facility without their medication.

New Patient

LTC pharmacies dispensing to Medicaid members who were newly admitted without their medications may use the New Patient Processing (NP) override when medically necessary when all the following conditions are met:

- The dispensing pharmacy is a LTC servicing pharmacy, and
- The member was recently admitted to a Private Skilled Nursing Facility, Public Skilled Nursing Facility, Private Health Related Facility, or Public Health Related Facility, when "NH" returns on eligibility response, and
- The claim denied for "Early Fill Overuse" edits "01642" or "02242" represents the first dispensing of a medication after the member's recent admittance to the LTC facility (as described above).

If all conditions above are met, LTC pharmacists may override the "Early Fill Overuse" "01642" or "02242" denials by using a combination of Reason for Service Code "NP" (New Patient Processing) in the National Council for Prescription Drug Programs (NCPDP) field (439-E4), and Submission Clarification Code "18" (LTC Patient Admit/Readmit Indicator). Note: Day supply is limited to 30-days unless the medication is subject to short-cycle billing (see section Long Term Care Pharmacy Short Cycle Billing).

If all three conditions are not met, the billing provider may call the Department for assistance.

This override may not be used when the:

- Pharmacy is not an LTC-servicing pharmacy, or
- Member is not a resident of a Private Skilled Nursing Facility, Public Skilled Nursing facility, Private Health Related Facility, or Public Health Related Facility, when "NH" does not return on eligibility response, or
- Member is not a new resident to the facility, or
- The claim is not the first fill of the prescription for the same drug, strength, and directions by the LTC pharmacy.

Leave of Absence

LTC pharmacies may accommodate a LTC facility request for medication supply for a member leaving for a short absence using one of these options:

- LTC pharmacy relabeling and repackaging dispensed medications for member use during their leave, or
- LTC facility covers the cost for the additional supply of medication needed for the leave of absence, or
- LTC facility prepares for the absence by ensuring the medication supply is filled for a shorter supply before the expected absence.

If the above or other options are not available, the LTC pharmacy may override the 'Early Fill Overuse' denial when these four conditions are met:

- Dispensing pharmacy is a LTC servicing pharmacy, and
- Member is a current resident of a Private Skilled Nursing Facility, Public Skilled Nursing Facility, Private Health Related Facility, or Public Health Related Facility, when "NH" returns on eligibility response, and
- The claim denied for "Early Fill Overuse" edits "01642" or "02242", and
- The claim is limited to a 7-day maximum dispensed supply.

If all four conditions above are met, the LTC pharmacy may use a combination of Reason for Service Code (439-E4) "AD" (Additional Drug Needed), and a Submission Clarification Code (420-DK) of "14" (LTC Leave of Absence) to override the Early Fill Overuse edit. When using the Leave of Absence override, it is expected that the next regular fill date for the member will be later to account for the extra supply the member received for the leave. The pharmacy must maintain documentation, retrievable upon audit, of the use of the override, including but not limited to the facility's request for leave of absence supply for their resident member.

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.

New Prescriptions/Renewals

Providers may not use software to submit claims without a pharmacist on duty.

Reminders regarding original prescriptions:

- A prescription/fiscal order must originate from the office of the prescriber.
- A prescription/fiscal order must maintain the same original prescription number and date written throughout the life of the order; it may not receive a new number for same original date.
- A faxback may not be used to bill a prescription/fiscal order to Medicaid.
- A fax received as a failed electronic prescription order may not be used to bill a prescription drug to Medicaid.
- A fax received as a failed electronic fiscal drug order is an original order and may be used to bill Medicaid.
- A fax received at the pharmacy, that is not on an Official NYS Prescription (ONYSRX) form with its unique serial number, is not an original prescription.
- Prescribers may choose by their professional judgement to prescribe:
    - Up to a 90-day supply on most maintenance medications when the member has been stabilized and has been taking their medication on a consistent basis, and there are no concerns about storage of the extended supply.
    - Most non controlled prescriptions up to 12 fills (original and 11 refills).
- Non-controlled prescriptions remain active and refillable up to one year after date written.

A NYS Medicaid member who has exhausted prescription refills, may obtain a renewal in one of the following three ways:

- The Medicaid member/enrollee may contact their prescriber for a renewal.
- The Medicaid member/enrollee may contact their pharmacy for a renewal and give the pharmacy consent to contact the prescriber on their behalf.
- The pharmacy may contact the Medicaid member/enrollee to inquire if a renewal is necessary, obtain consent if necessary, and then contact the prescriber on their behalf.

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

Transfers

Transfers are allowed when all other state laws and Medicaid policies are adhered to. This includes using the original written date of the original order and the appropriate serial number and origin code requirements, as stated in the above section *Serial Number and Origin Code Requirement*. Changing a written date or other details on a transferred prescription submitted for payment is considered fraudulent billing and is subject to audit.

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.
NYRx is not responsible for replacement of drugs or supplies that were lost in delivery regardless of sender.

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. Medicaid does not provide additional medication supply for a vacation or a temporary absence.

Members should prepare in advance of travel by speaking to their pharmacist and physician to ensure they have the supply needed for a temporary absence. Pharmacies may also assist Medicaid members by:

- Recommending a larger day supply (some maintenance medications allow up to 90-day supply). Members may ask their prescriber to increase the day supply dispensed when the member has been stabilized on the medication and has been taking their medication on a consistent basis. This option may require a new prescription) or,
- Mailing the medication per Medicaid Policy to the member's temporary location, and/or,
- Refilling early (see Early Refill section above).

Note: Members should be advised that NY Medicaid provides services in the geographic area of the state by NY Medicaid enrolled providers. Members who travel out of state may incur out of pocket costs that are not reimbursable. There are very few if any out-of-state pharmacy providers that are enrolled. Members can use the search tool for enrolled providers here: https://member.emedny.org/ for the area intended for travel and should call ahead. Not all enrolled pharmacies are retail/community pharmacies, and the pharmacies found as enrolled may not be able to service them.

Pick Up / Receipt

- Pharmacies/DME providers must obtain a legible 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.
- Providers must ensure that a pharmacist counsel the patient consistent with federal (including but not limited to 42 CFR § 456.705(c) and SSA § 1927 (g)(2)(A)(ii)) and State law, rule, or regulation (8 NYCRR § 63.6(8)), and retain records for six years of provision of counseling in compliance with federal and State law, rule, or regulation. Reminder, counseling must include proper storage and use of the drug or item dispensed.
- The pharmacy is accountable to provide intact, usable product. Replacement for any recalled, defective, or otherwise unusable product is the responsibility of the provider.
- All Medicaid claims for drugs, over-the-counter products, or medical/surgical supplies that were not furnished (i.e., no proof of receipt) to the Medicaid member must be reversed within 14 days.

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:

- If the provider uses a shipping service (e.g., FedEx, USPS, or courier), or any other delivery method, proof of delivery documentation must include a complete record of tracking the item(s) from the pharmacy to the member. This would include both the provider's own detailed description of the prescriptions including prescription numbers, and fiscal orders being delivered and the delivery service's tracking information, including date and time of delivery.
- A legible handwritten or electronic signature of the recipient or authorized agent or designee at time of delivery is required for any out of state, any instate controlled substance, or any instate facility (site of administration) deliveries. When a person other than the member is confirming receipt, the relationship of the designee to the member should be noted in addition to the signature.
- Delivery industry tracking receipts (e.g., FedEx or USPS tracking receipts) qualify as a signature for receipt of delivery for in state non-controlled substance deliveries only.
- A single legible signature (or tracking receipt as noted above) of the recipient or authorized agent or designee verifying receipt will be sufficient for all the medications in the delivery.
- 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.
- Electronic signatures of the recipient or authorized agent or designee for receipt or electronic tracking slips for delivery are permitted only if retrievable on audit.
- Providers must ensure that a pharmacist counsel the patient consistent with federal (including but not limited to 42 CFR § 456.705(c) and SSA § 1927 (g)(2)(A)(ii)) and State law, rule, or regulation (8 NYCRR § 63.6(8)), and retain records for six years of provision of counseling in compliance with federal and State law, rule, or regulation.
- Delivery confirmation must be maintained by the pharmacy for six years from the date of payment and must be retrievable upon audit.
- All shipping and delivery costs are the responsibility of the pharmacy.
- Medicaid members cannot be charged for delivery if Medicaid reimburses for all, or any portion of the item being delivered.
- The pharmacy is accountable for proper delivery of intact, usable product. Replacement for any recalled, defective, or otherwise unusable product is the responsibility of the provider.
- 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 or when confirmation of delivery was made with delivery industry tracking receipts (where there is no handwritten or electronic signature of receipt by recipient or authorized agent or designee).
- Once delivered and signed for by a facility or agent of a facility, the site of receipt/handling/administration is responsible for replacement of improperly stored, handled, lost, or stolen drugs.
- The pharmacy must ensure proper storage is available and authorized agent or recipient is aware of requirements before delivery.

- All Medicaid claims for drugs, over-the-counter products, or medical/surgical supplies that were not furnished (i.e., no proof of receipt) to the Medicaid member must be reversed within 14 days.
- The Department reserves the right to require member or caregiver signatures in situations where there is high probability of lost or stolen items, or an increase in complaints from members concerning lost or stolen items.

For Home Deliveries:

- 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.
- The number of times a pharmacy attempts to deliver is left to the discretion of the pharmacy.
- 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.
- 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:

- The drug must be able to be billed in the NCPDP format.
- The drug must be able to be delivered directly to the place of administration. (See Delivery section)
- The drug must be available from a dispensing pharmacy that is enrolled in Medicaid.
- 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.
- Providers must ensure that a pharmacist counsel the patient consistent with federal (including but not limited to 42 CFR § 456.705(c) and SSA § 1927 (g)(2)(A)(ii)) and state law, rule, or regulation (8 NYCRR § 63.6(8)), and retain records for six years of provision of counseling in compliance with federal and state law, rule, or regulation.
- 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 NYRx 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:

- 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.
- 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.

- Delivery charges may not be billed to the member or Medicaid.
- 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.
- The pharmacy must confirm an appropriate administration plan is in place for home deliveries.
- 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.
- All Medicaid claims for drugs that were not deliverable must be reversed within 14 days.
- Once delivered and signed for, the site of administration is responsible for replacement of improperly stored, handled, lost, or stolen practitioner-administered drugs.

"Brown bagging" is when drugs designated for self-administration or practitioner administration are dispensed directly to a patient by the pharmacy. Brown bagging practitioner administered drugs causes concern regarding proper storage or handling, which can affect the drug's efficacy. Brown bagging is acceptable only when the drug is intended, prescribed, or labeled for *self-administration*.

Prescribers should use their professional judgement to determine the best method for members to obtain practitioner administration drugs. It is the responsibility of the pharmacist to ensure white or brown bagged drugs are appropriately dispensed.

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

Unused Medication

Whenever possible Medicaid members should be discharged or admitted to a Long-Term Care (LTC) facility with their ongoing medication supplies on hand. It is expected that medications provided by the Medicaid benefit that go unused by the Medicaid member are returned to the LTC pharmacy in a timely basis for immediate credit as allowed by Medicaid policy and other state law and regulation (PHL 2803-e, Title 10 NYCRR 415.18). LTC facilities and their pharmacies are encouraged to review their protocols to ensure any waste is at a minimum and that the regulations and law requirements are met.

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 Durable Medical Equipment 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, because 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. Only prescribers or their authorized agent may submit a request for a prior authorization. Third party requests are prohibited: prescribers may not contract with or assign authority to dispensing pharmacists, manufacturers, or other persons or companies to initiate their PA requests. 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 for any drug that requires prior authorization, subject to state laws and Medicaid restrictions. 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.

Electronic Prior Authorization (ePA)

The Medicaid program accepts electronic prior authorization (ePA) requests via CoverMyMeds. Medicaid enrolled pharmacy providers who utilize CoverMyMeds can initiate medication ePA requests on behalf of the member for completion by the prescriber. CoverMyMeds will direct the case to the prescriber's queue and prompt them to complete and submit the ePA to NYRx. CoverMyMeds prompts prescribers to answer required clinical questions that can offer real-time approvals if clinical criteria are met. Medicaid enrolled prescribers can electronically submit prior authorization requests, upload supporting documents, and track request status in real time. Only prescribers or their authorized agent may submit a request for a prior authorization. Pharmacists who are not employed by the prescriber's office are not authorized agents.

The CoverMyMeds website is available here: Prior Authorization Forms | CoverMyMeds.

For additional information visit the NYRx Education and Outreach (E&O) website or contact the E&O call center. The E&O Call Center is available by phone at 1-833-967-7310 or by email at NYRxEO@primetherapeutics.com from 8:00 AM to 5:00 PM ET, Monday through Friday, excluding holidays.

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 a certified pharmacist or a certified pharmacy intern under the supervision of a certified pharmacist 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/phar_immun_fact.htm.

Pharmacists Administering Mental Health or Substance Abuse Treatment Injections at the Pharmacy

Registered pharmacists, certified by the NYS Education Department, may administer a long-acting injectable (LAI) approved by the Food and Drug Administration for the treatment of mental health or substance abuse based on a patient specific prescription or order after the initial injection was provided in the practitioner's office.

Policy

- The certified pharmacist must confirm the initial injection has been given by the practitioner and the member is ready for maintenance therapy.
- The member or member's representative must consent to the administration by a certified pharmacist.
- The pharmacy must provide a private area for the administration.
- The certified pharmacist must notify the member's prescriber of the drug administration, and if there were adverse reactions or any side effects.

Billing Guidelines

Pharmacies will be reimbursed for the medication and an administration fee when billed to NYRx. The member will not have a copayment for drug administration.

- NYS legislation requires a patient specific prescription or order for administration. These orders must be kept on file at the pharmacy.
- If billing for both the drug and administration, these claims must be submitted separately.
- For the drug, the claim must be submitted using the ordering prescriber's NPI in the Prescriber ID field. The pharmacy will be reimbursed for the medication when billed via National Drug Code (NDC) using reimbursement methodology.

- For the administration, the claim must be submitted using procedure code 96372, and the pharmacy's NPI in the Prescriber ID field. A pharmacy will be reimbursed the current administration fee.

Service Limits

90-day Supplies
NYRx allows up to a 90-day supply of most maintenance medications and over the counter drugs. A maintenance medication is a medication taken on a regular basis, often daily, to treat an ongoing or chronic condition or illness such as, but not limited to, high blood pressure, high cholesterol, diabetes, asthma, depression, mild pain. Prescribers should consider prescribing a 90-day supply once a patient is on a stable dose of a maintenance medication. Note: State and federal laws regarding controlled substances and day supply will apply.

Medical/Surgical Supplies
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.

Third Party Liability

Federal regulations require that all available resources be used before Medicaid considers payment. Medicaid regulations at 18NYCRR §540.6(e) require a provider to pursue any available other coverage prior to submitting a claim to Medicaid. If there is a responsible third party who should be paying for the Medicaid member's health benefits as primary payor, that responsible third party must pay first. Failure to obtain prior authorization does not overcome the responsibility of the primary payor.

Claims for members with other coverage will be denied at point of service with National Council for Prescription Drug Programs (NCPDP) response code/message "717- Client Has Other Insurance". Through coordination of benefits, Medicaid will pay the patient responsibility for a correctly submitted Medicaid coverable claim or will pay up to the Medicaid allowed amount for a drug in a class specifically excluded from being covered under the Third-Party Liability Plan (TPL) including Medicare.

Claims submitted to NYS Medicaid with a "no reimbursement" from any TPL must correctly be submitted. Pharmacy providers who receive a "no TPL reimbursement" must ensure that the claim was adjudicated within the TPL's claim process requirements. This includes submitting the claim under the appropriate coverage benefit, medical or pharmacy, such as with the Healthcare Common Procedure Coding System (HCPCS) or by the National Drug Code (NDC). Additionally, pharmacies not contracted with the member's TPL Plan may need to attempt an override with the plan, or enroll with the plan, or advise the member and prescriber of the need to change dispensing to a network pharmacy.

It is the responsibility of the prescriber to prescribe, per the plan's formulary, and to pursue any claim issues such as, but not limited to:

- Necessary prior authorizations or appeals, or
- Prescription alternatives (for a non-formulary or non-preferred drug) or
- Necessary changes (quantity or day supply, etc.) or
- Selecting an in-network pharmacy that is agreeable to the member, or
- Billing the appropriate benefit (medical vs. pharmacy or HCPCS vs NDC).

Pharmacies have a corresponding responsibility to submit claims to a Medicaid member's other coverage per the plan's requirements before submitting the claim to Medicaid. Pharmacies that have difficulty in billing a plan should advise the prescriber and member of potential delays and options for resolution. If the claim issues are resolved, the pharmacy may then resubmit the claim to Medicaid after the claim is properly adjudicated with the TPL.

Submitting a TPL covered claim that bypasses the TPL's responsibility of payment is considered fraudulent billing and is subject to audit. Reminder: Providers must retain evidence that the responsible TPL denied the claim, other TPL responses where applicable, and payment information was retained, for a minimum of six years following the date of Medicaid payment.

NOTE:

- The Medicaid payment must be accepted as payment in full.
- Obtaining a clinical PA from the Prime Therapeutics State Government Solutions Call Center does not negate the requirement to obtain payment from responsible third-party payor.

Workers' Compensation and Coordination of Benefits

If a member has a work-related injury, for which they have an open Workers' Compensation case, Workers' compensation coverage must be utilized prior to billing the NYRx Medicaid Pharmacy Program.

If the drug claim is NOT related to a member's Workers' Compensation case, such as a maintenance medication for an unrelated chronic condition, NYRx may be billed as the primary payer with an Eligibility Clarification Code of "2" in field 309-C9. Medicaid is the payer of last resort, and providers must ensure all other responsible payers are included on the claim, if applicable.

The Workers' Compensation Board can be accessed here: https://www.wcb.ny.gov/content/main/hcpp/hcpp.jsp.

Medicare/Medicaid 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.

Analogous to TPL in the section above, Medicare benefits must also be maximized prior to billing Medicaid. Services covered by both Medicare and Medicaid must first be billed to Medicare (See below for Parts A, B, D).

It is the pharmacy's responsibility:

- To bill the appropriate Medicare benefit.
- To notify both the member and the prescriber of any needed authorizations or changes the Medicare Plan requires.

Pharmacy providers can bill Medicaid only after payment information is received from Medicare. Pharmacy providers may not circumvent Medicare billing procedures for a Medicare covered member and must bill by the Healthcare Common Procedure Coding System (HCPCS) or by the National Drug Code (NDC) as the Medicare Plan requires. For audit purposes, payment information must be retained for a minimum of six years following the date of payment.

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 if 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 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. It is not appropriate to bill Medicaid for any prescription drug for a Medicare Part D member unless as stated below.

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-eligible members 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 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.

2.0 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 operate independently of any other entity, that meet one of the descriptions below are classified as a COS 0441:

- Outpatient dispensing, community-based, immunizing pharmacies that include:
  - Independently owned,
  - Chain, and
  - Those owned by a non-profit entity, and

    - Pharmacies with a primary taxonomy classification as 'Community/Retail Pharmacy.'
- Pharmacies that are contracted with NY Medicaid enrolled healthcare facilities or assisted living facilities (ALF) in the pharmacy's location state where a NY Medicaid member resides.
- Pharmacies that provide drugs to NY Medicaid members to the site where they are being administered or infused by a practitioner, in the pharmacy's location state.
- Pharmacies that contract with a NYS Licensed Home Care Services Agency (LHCSA) to provide practitioner administered drugs to NY Medicaid members at home where the drugs are being administered.

Note:

- Outpatient dispensing, community-based, open-door pharmacies applying for enrollment in COS 0441 must be full-service. This is defined as dispensing and maintaining an inventory of commonly dispensed outpatient prescription medications, as well as providing diabetic supplies and immunizations. Community pharmacies that service a particular diagnosis, situation, or niche or that do not immunize do not meet COS 0441 enrollment criteria.
- 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 or enrollable under COS 0441 (see clinic and hospital pharmacy COS below), this includes pharmacies with pass through windows or doors, or situated where patients have to walk through a healthcare facility, office area, or otherwise to reach the pharmacy or those that share a waiting area.
- Pharmacies whose physical space is not separate and distinct from other unaffiliated or separately operated retail or medical entities do not qualify for pharmacy enrollment.
- A pharmacy with a layout where there is not a clear line of sight, or inadequate pharmacist supervision and oversight do not qualify for 0441 enrollment. Supervision is defined as the pharmacist remaining in the immediate area at all times of preparation, dispensing/pick up, and storage of medications. Layouts that do not allow the pharmacist to remain in the immediate area as all these procedures are performed does not meet criteria for enrollment.
- Pharmacies without a designated area for pickup/dispensing do not qualify for 0441 enrollment.
- Not all NY registered pharmacies will meet criteria for NY Medicaid enrollment.
- Contracts between a pharmacy and ALF must ensure member choice of pharmacy.

Clinic Pharmacy (COS 0161)

- Owned and operated by an Article 28 facility or Public Health Law authorized entity.
- 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.
- Pharmacies with a primary taxonomy classified as 'Clinic Pharmacy.'

Hospital Pharmacy (COS 0288)

- Owned and operated by an Article 28 facility or Public Health Law authorized entity.
- 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.
- Pharmacies with a primary taxonomy classified as 'Institutional Pharmacy.'

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 in the pharmacy's service location state that is outside of NY state or outside of the bordering states (e.g., a NY Medicaid enrolled foster care child, or a NY Medicaid member residing in a NY Medicaid enrolled residential healthcare facility as defined by Article 28) or
- The pharmacy has an exclusive arrangement to dispense a drug on the Medicaid Pharmacy List of Reimbursable Drugs found here: https://www.emedny.org/info/formfile.aspx.

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.
- Accept Medicare claims assignment and submit Medicare claims for all Medicare covered services on behalf of a Medicaid member.
- Accept payment from the Medicaid program as payment in full for all care, services and supplies billed under the program, except where specifically provided in law to the contrary.
- 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.
- Maintain active DEA registration.
- Maintain applicable State registration.
- Out of state pharmacies:
    - must maintain NY non-resident registration.
    - must maintain state registration in service location.
    - must maintain Pharmacy / Wholesale Distributor / Manufacturer License Verification with the NYS Education Department.
    - must maintain Medicaid enrollment in service location state.
- Submits any subsequent forms and information as required by the Department.
- Update the Department promptly as needed for pharmacy enrollment changes. Failure to notify the Department may result in termination of existing pharmacy enrollment which includes payment rejection in accordance with 18 NYCRR Sections 502.5(b), 504.7(d)(1), (f), 42 CFR Section 455.416. Updates include but not limited to the following:
    - changes to service location, which must be submitted within 15 days of location change.
    - ownership changes and transfers of ownership must be submitted within 15 days of a change or transfer in ownership, and
    - managing employee changes, including supervising pharmacist, which must be submitted within 7 days.
- Maintain all required accreditations from a CMS-approved organization in compliance with CMS regulations. A complete list of CMS-Approved Accrediting Organizations may be found here: www.cms.gov/files/document/accrediting-organization-contacts-prospective-clients.pdf
- Follow all federal and NYS laws, regulations, and Medicaid policies.

*The New York State (NYS) Medicaid program requires Medicare enrollment for pharmacies enrolling in Medicaid to ensure that Medicaid dual eligible members receive drugs and supplies from Medicaid providers enrolled in accordance with federal and State laws, and regulations. The three types of Medicare enrollment include CMS-460 Medicare Participating Physician or Supplier Agreement, CMS-855B Medicare enrollment for clinics/group practices

and other suppliers, and CMS-855S Medicare enrollment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. Pharmacies that choose to enroll in the CMS-460 Medicare Participating Physician or Supplier Agreement, agree to accept assignment for all their Medicare claims, including those not subject to Medicaid payment. This Medicare enrollment is optional. However, all Medicaid enrolled pharmacy providers are still required by federal law to submit claims and accept assignments for Medicare covered services provided to Medicaid dual eligible members, regardless of CMS-460 enrollment status.

Pharmacies missing one or more Medicare enrollments, must determine if their business situation or business model requires CMS-855B or CMS-855S Medicare enrollment or both before applying for NY Medicaid Pharmacy enrollment. The Attestation of Need for/Exemption from Medicare Enrollment form #409602 located here: https://www.emedny.org/info/ProviderEnrollment/ProviderMaintForms/409602_Attestation_Need_Exemption_from_Medicare_Enrollment.pdf enables pharmacy applicants the opportunity to clarify and attest to the need for an exemption from each type of Medicare enrollment. Note, all community pharmacy applicants would not qualify for exemption, see table below.

See **Table below**, which describes pharmacy type with corresponding expected services and Medicare-type enrollment expected at the time of pharmacy application submission. *The more stringent Medicare requirement applies to mixed pharmacy types.* For example, a pharmacy would be a mixed pharmacy type if the pharmacy stocked and dispensed specialty medications and select supplies, or dispensed specialty medications and common outpatient drugs. More information about the Pharmacy provider enrollment application process can be found here: https://www.emedny.org/info/ProviderEnrollment/pharm/index.aspx.

A short description of the three types of Medicare enrollment:

- CMS-460, Medicare Participating Physician or Supplier Agreement is completed at time of or within 90 days of Medicare enrollment or during certain enrollment time frames. Providers will accept assignment for Medicare covered services and ensure Medicaid members will not be charged for services.
- CMS-855B, Medicare Enrollment for Clinics/Group Practices and Other Suppliers. Pharmacy dispenses drugs administered by a practitioner in a long-term care facility, practitioner's office, infusion center, or home setting, or is dispensing and administering vaccines covered by Medicare Part B.
- CMS-855S, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers. Pharmacy dispenses diabetic supplies, nebulizer drugs, oral anticancer or antiemetic drugs, etc. covered by Medicare Part B.

Pharmacies are subject to audit, recovery, and Medicaid provider termination for non-compliance with the requirement of Medicare enrollment. **Pharmacies that do not have or maintain CMS-855B (Supplier Type – Pharmacy) and CMS-855S (Supplier Type - Pharmacy) enrollment where required do not meet enrollment criteria,** pharmacies that do not have or maintain Medicare enrollment may not be enrolled or may be disenrolled. Please note, that the CMS-855B and CMS-855S are required for all new pharmacy applicants for categories of service (COS) 0441 and 0442.

COS 0441 Pharmacy Type Description*	**Stocks and Dispenses**	**Medicare 855B****	**Medicare 855S****
Closed-door infusion pharmacy	Practitioner administered drugs	Required	Situational***
Closed-door specialty pharmacy (mail order, limited distribution	Only select medications	Situational***	Situational***

drug, high-cost drugs, special handling drugs)			
Closed-door long-term care pharmacy	Full-service; outpatient type drugs, supplies, and select practitioner administered drugs provided with a contract to a NY Medicaid enrolled residential healthcare facility	Required	Required
Open-door community pharmacy with immunization services	Full-service; outpatient-type drugs, supplies, and vaccines	Required	Required
Open-door community pharmacy with practitioner administered drugs	Full-service; outpatient-type drugs, supplies, vaccines, and practitioner administered drugs	Required	Required

**Closed door is defined as a pharmacy provider that does not serve the general public using walk-in service; they service directly to the member at the place of administration or facility or home to which the member resides.*

Open-door pharmacies are defined as those that serve the general public using walk-in service; they generally provide all commonly prescribed or ordered drugs and supplies.

***Supplier Type – as a "Pharmacy" for both 855B and 855S as required by the drugs and supplies dispensed. May additionally be Supplier Type "Mass Immunization" for 855B for "Roster Billing Only".*

****Enrollment in this Medicare type is required when the pharmacy carries one or more items that would be required to be billed to Medicare on behalf of a dual-eligible member.*

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. Practitioners that choose to dispense may provide the drug free of charge, through medical billing or alternatively, 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 NYRx 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 practitioner).
- Ensure that the dispensing practitioner counsel the patient consistent with federal (including but not limited to 42 CFR § 456.705(c) and SSA § 1927 (g)(2)(A)(ii)) and State law, rule, or regulation (8 NYCRR § 63.6(8)), and retain records for six years of provision of counseling in compliance with federal and State law, rule, or regulation.
- 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 relieve side effects of these therapies or distressing symptoms (such as nausea or pain). [Education Law §6807]

Note:
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 NYRx@health.ny.gov.

Who May Prescribe

Practitioners authorized to prescribe by New York State must be enrolled in the Medicaid Program 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) https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf 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 be rejected for National Council for Prescription Drug Programs (NCPDP) Reject code "889" (Non-Matched Prescriber ID). This means the prescriber is not enrolled in Medicaid. To allow claims by unlicensed physicians who are authorized to prescribe pharmacies may use the following billing guidance.

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

For 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 be rejected for National Council for Prescription Drug Programs (NCPDP) Reject code "889" (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 New York State 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.

Note: Steering is prohibited in the NYS Medicaid Program.

The following are examples of steering:

- Dispensing pharmacists obtaining PA when not employed by the practitioner, and
- Prescribers contracting or assigning authority to dispensing pharmacists to facilitate PA, and
- Where the provider has agreement, relationship, contract or otherwise receives incentive, where the
    - Pharmacists are directing members to seek medical care to a specific practitioner, and
    - Practitioners are limiting members to use a specific pharmacy*

*A pharmacy with an exclusive arrangement from the Manufacturer to dispense a drug on the Medicaid Pharmacy List of Reimbursable Drugs is not considered steering.

Complaints from providers and enrollees involving steering should be sent to the Office of Medicaid Inspector General. Their website (http://www.omig.ny.gov/fraud/file-an-allegation) contains online forms for complaints.

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

- 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.

See the DME Policy Guidelines for information regarding fiscal order requirements for oral supply (non-drug) orders.

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 for making a good faith effort to verify the validity of the prescription and the prescriber's identity if the prescriber is unknown to the pharmacist. Please note:

- 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. See here for more information regarding the NY Official Prescription Program: https://www.health.ny.gov/professionals/narcotic/official_prescription_program/.
- 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 to be dispensed at a community pharmacy not on the Official New York State Prescription form are not valid.
- 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 (including but not limited to patient support enrollment forms, copay assistance programs, education support programs, specialty drug order forms) 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.

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 for making 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.

Storage Requirements – Vaccine and Medication

Medicaid Pharmacy providers are required to follow Regulations set forth by the Commissioner of Education, section 63.6(b)(3) and the CDC guidelines in the CDC Storage and Handling Toolkit for vaccines and medication requiring cold storage. Pharmacies must have a purpose-built or pharmaceutical grade refrigerator with adequate storage space with fan-forced air circulation; a dorm-style or bar-style unit with an evaporator plate/cooling coil does not qualify.

Additionally, Medicaid providers who are part of the Vaccine for Children (VFC) program must meet criteria for refrigeration and vaccine storage set forth in the guidelines outlined in the *Stand-Alone Storage Unit Purchasing Guidance* and *Temperature Monitoring Requirements* documents.

3.0 Scope of Pharmacy Benefits

NYRx, the Medicaid pharmacy program, covers most medically necessary FDA-approved drugs when used for Medicaid-covered FDA approved or compendia supported indications.

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 NYRx. 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 pursuant to 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).
- Drugs that are not approved as safe and effective by the FDA pursuant to SSA §1927(d)(4)(C).
- Any contrast agents, used for radiological testing (these are included in the radiologist's fee).
- Drugs packaged in unit doses for which bulk product exists.

*Some exceptions apply, see Unapproved Drugs

Unapproved Drugs

NYRx, the Medicaid Pharmacy Program, covers medically necessary FDA-approved drugs when used for Medicaid-covered indications. Some unapproved drugs are in the marketplace due to certain Food and Drug Administration (FDA) exceptions; however, these drugs have not been evaluated for safety and efficacy. NYRx covers certain unapproved drugs as permitted by federal law, in circumstances such as a drug shortage of an approved drug, or when the Program has determined the drug to be medically necessary, such that without the drug it would cause a significant impact in the health of a Medicaid member, and when there is no FDA approved alternative to treat the medical condition. NYRx has ensured that the formulary coverage of non-approved drugs is limited to those that are identified by the FDA as on shortage, or those that are considered to be medically necessary when there is not an FDA approved suitable alternative.

☑ Drugs that are not FDA approved, are covered when:

- There is a shortage identified by the FDA of an approved product
- The drug is from a manufacturer that has an agreement with the Medicaid Drug Rebate Program and
  - Is a narrow therapeutic index drug, or
  - There is no other alternative and clinical value to patients is documented

☒ Drugs that are not FDA approved are not coverable when:

- There is an approved drug alternative that is on the NY Medicaid Pharmacy List of Reimbursable Drugs, or
- There is no efficacy documented, or
- The drug may cause harm

If a prescriber has determined that an unapproved drug, not on the NY Medicaid List of Reimbursable Drugs is the only treatment appropriate for a member, the prescriber may submit a letter of medical necessity and supporting documentation to NYRx by fax at 518-473-5508 for a review of available coverage.

Medical/Surgical Supplies

Prescribing practitioners may order medical/surgical supplies which are listed in the OTC and Supply Fee Schedule https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx. 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

NYRx does not reimburse all covered drugs for patients with coverage for "Emergency Services only" (ESO). 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:

- Placing the patient's health in serious jeopardy.
- Serious impairment to bodily functions or
- 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 (COE) can be found under article titled "Emergency Services Only Pharmacy Coverage" at: https://www.health.ny.gov/health_care/medicaid/program/pharmacy/provider_info.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.

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: https://www.emedny.org/info/formfile.aspx 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/.

See Section 4.0 for Long Term Care Pharmacy Short Cycle Billing information.

Items Provided by Child (Foster) Care Agencies

Please see this link for items provided by Childcare Agencies:
https://www.health.ny.gov/health_care/medicaid/program/carveout.htm.

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 NYRx 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 NYRx 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 Pharmacy List of Reimbursable Drugs: https://www.emedny.org/info/formfile.aspx.

Emergency Contraception Drug Policy

Both prescription and OTC Emergency Contraception are a covered benefit for all Medicaid members without age restriction. 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 patient specific practitioner order.

A pharmacy, in compliance with NYS law and regulations, may dispense and submit a claim for emergency contraceptives when the following apply:

- A prescriber submits a prescription order for either the OTC or prescription-only emergency contraceptive or
- A NYRx member or MMC enrollee specifically requests the OTC emergency contraceptive item on the date of service and
- A pharmacy submits one course of therapy with no refills and
- The drug item(s) are dispensed according to:

- Food and Drug Administration (FDA) guidelines,
- NYS laws, rules, and regulations, and
- NYS Medicaid policy.

Both prescription-only and OTC emergency contraception are limited to six courses of therapy in a 12-month period. For more information, please see: https://www.health.ny.gov/publications/2018/.

4.0 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	$10.18
Brands	Lower of NADAC or U&C	Lower of WAC or U&C	$10.18
OTCs	Lower of NADAC, FUL, SMAC or U&C	Lower of WAC, FUL, SMAC, or U&C	$10.18
340B**Purchased Drug	340B Acquisition Cost	340B Acquisition Cost	$10.18

Note: Claims will pay at the pharmacy's Usual and Customary (U&C) pricing if lower than drug ingredient cost plus dispensing fee.
* Professional Dispensing Fee applies if the drug meets the definition of Covered Outpatient Drug and is not paid at U&C.
** See subsection 340B Pharmacy Drug Claims below for more information.

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 Prime Therapeutics State Government Solutions 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.

Note: the Medicaid payment must be accepted as payment in full.

Non-Prescription Drugs

NY Medicaid covers limited non-prescription (OTC) drugs. OTCs covered by NYRx 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 not in the Brand Less Than Generic Program, 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", or
- in the case of electronic prescriptions, the prescriber must insert an electronic direction to clarify "Brand Medically Necessary" or "Brand Necessary".

For handwritten orders, a rubber stamp or other mechanical signature device may not be used.

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

Additionally, in order to dispense a brand name drug when the prescriber indicates "DAW" and, indicates "Brand Necessary" or "Brand Medically Necessary" on 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/ProDUR-ECCA_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.

The Department will only reimburse for ingredients with compendia support and where the final compounded product is produced to meet the specific clinical needs of an individual patient that cannot be met by a commercially available FDA-approved drug. For more information on Federal and State regulations of compounded drugs visit: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376733.htm.

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".

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., mini-bag, IV reservoir or syringe) for administration are not considered to have been compounded and should not be submitted for reimbursement as compounds.

NYS Medicaid compound policy:

- 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 designee before the item is prepared and submitted for payment.
- Ingredients in a compound claim will only be reimbursed if available on the NYS Medicaid List of Reimbursable Drugs.
- Ingredients will only be reimbursed if they are compendia-supported for the intended route of administration and indication.
- Compounds may not contain excluded drugs or be made for NYS Medicaid excluded indications as per the Social Security Act §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 to bypass the criteria within the NYS Medicaid Fee-for-Service Programs.
- Compounds may not be made with or to replace drug products removed from the marketplace due to safety reasons.
- 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 or use 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.
- Compounding kits packaged for convenience with premeasured ingredients are not covered as an outpatient drug per Social Security Acts §1927(k)(2)(A)(i) and §1902(a)(54). See billing section below for claim submission of individual ingredients.
- Reconstitution per product labeling is not considered a compound whether it comes as a kit or requires additional supplies, including those prepared for topical, oral, or parenteral use.
- All NYS Medicaid policies, NYS and federal laws apply.

The Department of Health (DOH) has made and will continually make formulary updates and system enhancements to support this policy. The Office of the Medicaid Inspector General (OMIG) will continue to review claims for Policy adherence.

Topical

Examples of non-covered topical compound claim submissions are those made with ingredients which are not FDA approved, compendia supported, or excluded from NYS Medicaid coverage for topical use, including but not limited to:

- anticonvulsants,
- non-steroidal anti-inflammatory drugs (NSAIDS),
- skeletal muscle relaxants,
- tricyclic antidepressants,
- combinations of two or more antifungals,
- foot baths or soaks,
- other soaks, or
- irrigations

Oral

Examples of non-covered oral compound claim submissions 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. Providers can refer to the correct billing guidance for these products in the Medical Supplies Procedure Codes & Coverage Guidelines found here: https://www.emedny.org/ProviderManuals/DME/PDFS/MedicalSupply_Procedure_Codes.pdf

Parenteral

Examples of non-acceptable parenteral compound claim submissions are those:

- inconsistent with sterile compound criteria 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 made for nutrition or hydration. Providers can refer to the correct billing guidance for these products in the *Medical Supplies Procedure Codes & Coverage Guidelines* found here: https://www.emedny.org/ProviderManuals/DME/PDFS/MedicalSupply_Procedure_Codes.pdf

Pharmacy Billing

Per Medicaid policy, when billing a compound via National Council for Prescription Drug Programs (NCPDP) D.0 transaction, providers must submit a minimum of two ingredients, or National Drug Codes (NDCs), in the Compound Segment, field 489-TE (Compound Product ID). Providers can submit up to 25 NDCs using this field. Providers must also submit a compound code of **"02–Compound"** in field 406-D6 (Compound Code) in the Claim Segment. Claims with NDCs listed in the Compound Segment submitted as a compound code **"01-Not a compound"** will not be accepted. All compound claims must include a valid Route of Administration code using terminology from the Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT) in NCPDP field 995-E2. All ingredients of a compounded prescription MUST be submitted to Medicaid regardless of reimbursement.

eMedNY Edit Number/Message	NCPDP Response Code/Description
"70420" – Compound Segment found when compound drug code is not compound	**"8D"** – Compound Segment present on a non-compound claim

Compound-Only Ingredients

Items intended for compound use only such as suspending agents or bulk powders, may only be reimbursed as part of a compound claim. These items will not be reimbursed when submitted as a single ingredient claim and will deny when compound code **"01–Not a compound"** is submitted in field 406-D6 (Compound Code) in the claim segment.

eMedNY Edit Number/Message	NCPDP Response Code/Description
"02326" – Drug only covered in compound	**"8H"** – Product/service only covered on compound claim

Non-Reimbursable Ingredients

Payment will only be issued for drugs found on the eMedNY "Medicaid Pharmacy List of Reimbursable Drugs" found here: https://www.emedny.org/info/formfile.aspx. If an ineligible drug or drug product is included in the compound, the claim will deny. The pharmacy provider may then elect to receive payment only for those reimbursable drugs by resubmitting the claim with of **"08–Process Compound for Approved Ingredients"** in field 420-DK (Submission Clarification Code) when all other coverage criteria is met.

Please note: Submission Clarification Code of **"08"** should only be utilized in accordance with NYS Medicaid policy. The NYS Department of Health (DOH) will monitor the use of these codes.

Prior Authorization

- Per the September 2015 NYS Medicaid Drug Utilization Review (DUR) Board recommendation and the November 2018 Medicaid Update article titled, *Update on Medicaid Fee-for-Service Prior Authorization of Topical Compounded Drug Products*, Prior Authorization (PA) and editing on prescriptions for all topical compounded drug products is required and will be implemented on certain NYRX Medicaid Fee-for-Service (FFS) claims. This process will ensure that compounded topical drug products meet State and Federal regulations and that the compound ingredients are Food and Drug Administration (FDA)-approved or compendia-supported for topical use when submitted to NYRx.

Pharmacies that submit compounds may receive the following edits:

Edit#	Edit Description	NCPDP Reject Code	Reject Message	Notes/Resolutions
00551	Item Not Eligible For Payment On Fill Date	MR	Product not on formulary	
02282	Compound Claim Requires PRIME PA	75	Prior Authorization Required	PA Required Call Prime Therapeutics State Government Solutions. This is specific to topical compounds. To obtain a PA, the prescriber must call the prior authorization clinical call center at 1-877-309-9493. The clinical call center is available 24 hours per day, 7 days per week staffed by pharmacy technicians and pharmacists who will work with the prescriber or their authorized agent, to obtain a PA.
02283	Route of Administration Missing	E2	M/I Route of Administration	(Route of Administration) will be required for any compound claim.
02337	Invalid SNOMED To Route Code Mapping	E2	M/I Route of Administration	
01613	Missing Or Invalid Compound Code	20	M/I Compound Code	
02145	Must Have More Than One NDC For A Compound Claim	7Z	Compound Requires Two or More Ingredients	
02147	All Ingredients Of Compound Are Not Payable	8A	Compound Requires At Least One Covered Ingredient	

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

340B Pharmacy Drug Claims

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 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 guidance and chart below apply to any Medicaid claim dispensed to an member who resides in a Private Skilled Nursing Facility, Public Skilled Nursing facility, Private Health Related Facility, or Public Health Related Facility, (when "NH" or, "N1", "N2", "N3", "N4", "N5", "N6", "N7", "N8", or "N9" 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 drugs in 14-day supply or less.

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. A maintenance drug is one where the member is taking on a consistent basis.

Valid Values	Short Name Description	Long Name Description
"06"	START DOSE	STARTER DOSE

"10"	MT PLN LMT	MEETS PLAN LIMITATIONS (The pharmacy certifies that the transaction is compliant with program policies and rules that are specific to the product being billed)
"14"	SHRTLOALTC	SHORT-FILL (Leave of absence from LTC)
"17"	REMANAFTEK	REMAINDER AFT EMERGENCY KIT
"21"	LTC14DAYLS	FOURTEEN DAYS OR LESS NOT APPLICABLE (Fourteen days or less dispensing is not applicable due to CMS exclusion and/or manufacturer packaging may not be broken or special dispensing methodology)
"22"	LTC7DAY	SEVEN DAY SUPPLY
"23"	LTC4DAY	FOUR DAY SUPPLY
"24"	LTC3DAY	THREE DAY SUPPLY
"25"	LTC2DAY	TWO DAY SUPPLY
"26"	LTC1DAY	ONE DAY SUPPLY
"27"	LTC43DAY	FOUR THEN THREE-DAY SUPPLY
"28"	LTC223DAY	TWO THEN TWO THEN THREE-DAY SUPPLY
"29"	LTCDAILY3D	DAILY AND THREE-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	SEVEN DAYS OR LESS (cycle not otherwise represented)
"34"	LTC14DAY	FOURTEEN DAY DISPENSING
"35"	LTC814DAY	EIGHT TO FOURTEEN DAYS DISPENSING (cycle not otherwise represented)

Abbreviations: "MT PLN LMT" - Meets Plan Limitations. "SHRTLOALTC" - Short-Fill Leave of Absence from LTC. "REMANAFTEK" - Remainder AFT Emergency Kit. "AFT" - After hours or indicates that the transaction is a replacement supply for doses previously dispensed to the patient after hours. "CMS" - Centers for Medicare and Medicaid Services
Please note: Values **"06"**, **"14"**, **"17"** and **"22"** through **"35"** will have a prorated dispensing fee applied.

Pharmacists may use SCC **"10"** and **"21"** for scenarios where drugs are dispensed in their original container, as indicated in the Food and Drug Administration (FDA) prescribing information, or those that are customarily dispensed in their original packaging to assist patients with compliance. Reminder: Medicine cabinet drugs and emergency kit replenishment is included in the LTC rate and may not be separately billed to Medicaid.

The NYS DOH will continue to monitor the use of these codes to ensure compliance.

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 manual located here: https://www.emedny.org/ProviderManuals/Pharmacy/index.aspx. For supplies not on this 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, per Social Security Act (SSA) § 1916 and Title 18 NYCRR § 360-7.12. **To refuse to provide services is an unacceptable practice.**
    - Providers may attempt to collect outstanding copayments through methods such as requesting the copayment each time the member is provided services or goods, sending bills or any other legal means.
- 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.
- Providers cannot offer gifts or cash per SSA § 1128A (a)(5), Title 18 NYCRR § 515.2, and Rules of the Board of Regents §29.1. It is not permissible for providers to:
    - Providers cannot make offers where it is likely to influence the enrollee's selection of a provider of Medicaid items or services. Note: NYRx allows for the provision of an item or device to a NYRx member or enrollee which is directly related to the administration of medication for that person (e.g., medicine cup, dosing spoons, or pill organizer).
    - Providers cannot proactively waive copays. Copays may be waived only as provided on a case-by-case basis per the financial need by request of the individual member or enrollee.

<u>Medicaid Co-payments:</u>

- 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, emergency contraception, 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.

5.0 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:

- The Automated Response Unit (ARU or telephone).
- The ePACES web-based application.

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

Recipient Restriction Program

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 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 Program (UT) is a post payment review of services and procedures provided to members that evaluates medical necessity while maintaining fiscal responsibility to the Medicaid Program. For additional information please see the General Providers Policy Manual at:
https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_All_Providers-General_Policy.pdf.

Pharmaceutical Management

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 after 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.

If 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.

6.0 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 for a drug or supply by the provider or in the case of a Covered Agency for a 340B purchased drug, from a supplier 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.

Authorized Agent

An authorized agent is someone who is employed by the same professional practice as the prescribing practitioner and has access to the patient's medical records. For example, a nurse, medical assistant, etc., employed by the prescribing practitioner or medical group. The practitioner is responsible for the activities of the authorized agent.
NOTE: Third party request are prohibited: prescribers may not contract with or assign authority to dispensing pharmacists, manufacturers, or other persons or companies to initiate their PA requests.

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)

Designee

A designee is a person specifically selected or appointed by a member to act on or to perform the obligations required by the member, in other words, a representative of the member. For the purpose of pickup or delivery a designee is a person specifically selected or appointed by a member to sign and accept Medicaid services on behalf of the member.

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. This 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

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.

Unless otherwise exempt by law or regulation, non-prescription drugs may be obtained in the Medicaid Program only upon an original fiscal order (either handwritten on an Official NY Serialized Prescription Form, electronic, or verbal) from an enrolled prescriber dispensed by an enrolled pharmacy.

Original Order- Prescription and OTC Drugs

A prescription or fiscal order for drugs, received either handwritten on an Official NY Serialized Prescription Form, electronic, or verbal, 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 a controlled 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.

Professional Dispensing Fee

A professional dispensing fee is an additional payment to enrolled Medicaid pharmacy providers when dispensing a covered outpatient drug. The fee includes any professional services such as but not limited to reconstitution, preparation, compounding, and other non-professional services such as packaging, or handling. Any eligible service will not receive more than one dispensing fee per claim per date of service.

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.

Short Cycle

Short Cycle refers to the day supply for a pharmacy claim that is dispensed in a shorter day supply than usual due to the policies or requirements of the residential healthcare facility or third-party coverage.

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 considering 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.

Unapproved Drug

A drug that has not been evaluated by the FDA for efficacy and safety.

Unmet Need

In context of pharmacy enrollment, when the service is generally unavailable to NY Medicaid members by other enrolled providers.

Usual and Customary Charge

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