



OMIG AUDIT PROTOCOL

FFS Pharmacy Services

Revised 05/24/2022

(For Services 01/01/2015 through 12/31/2019)

Audit protocols assist the Medicaid provider community in developing programs to evaluate compliance with Medicaid requirements under federal and state statutory and regulatory law. Audit protocols are intended solely as guidance in this effort. This guidance does not constitute rulemaking by the New York State Office of the Medicaid Inspector General (OMIG) and may not be relied on to create a substantive or procedural right or benefit enforceable, at law or in equity, by any person. Furthermore, nothing in the audit protocols alters any statutory or regulatory requirement and the absence of any statutory or regulatory requirement from a protocol does not preclude OMIG from enforcing the requirement. In the event of a conflict between statements in the protocols and either statutory or regulatory requirements, the requirements of the statutes and regulations govern.

A Medicaid provider's legal obligations are determined by the applicable federal and state statutory and regulatory law. Audit protocols do not encompass all the current requirements for payment of Medicaid claims for a particular category of service or provider type and, therefore, are not a substitute for a review of the statutory and regulatory law. OMIG cannot provide individual advice or counseling, whether medical, legal, or otherwise. If you are seeking specific advice or counseling, you should contact an attorney, a licensed practitioner or professional, a social services agency representative, or an organization in your local community.

Audit protocols are applied to a specific provider type or category of service in the course of an audit and involve OMIG's application of articulated Medicaid agency policy and the exercise of agency discretion. Audit protocols are used as a guide in the course of an audit to evaluate a provider's compliance with Medicaid requirements and to determine the propriety of Medicaid expended funds. In this effort, OMIG will review and consider any relevant contemporaneous documentation maintained and available in the provider's records to substantiate a claim.

OMIG, consistent with state and federal law, can pursue civil and administrative enforcement actions against any individual or entity that engages in fraud, abuse, or illegal or improper acts or unacceptable practices perpetrated within the medical assistance program. Furthermore, audit protocols do not limit or diminish OMIG's authority to recover improperly expended Medicaid funds and OMIG may amend audit protocols as necessary to address identified issues of non-compliance. Additional reasons for amending protocols include, but are not limited to, responding to a hearing decision, litigation decision, or statutory or regulatory change.

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1.	Missing Original Order
OMIG Audit Criteria	If the original order is missing, the paid claim will be disallowed.
Regulatory References	18 NYCRR § 505.3(a)(7) 18 NYCRR § 505.3(b)(1) 18 NYCRR § 505.3(b)(3) 18 NYCRR § 505.3(c) 18 NYCRR § 517.3(b)(1) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section II
2.	Missing Follow-Up Prescription for Controlled Drugs
OMIG Audit Criteria	If a written or electronic prescription is not received within 72 hours of the emergency dispensing, the paid claim will be disallowed. If the written or electronic prescription does not read “Authorization for emergency dispensing”, the paid claim will be disallowed.
Regulatory References	10 NYCRR § 80.68(a) and (c) 10 NYCRR § 80.70(a) and (c) 10 NYCRR § 80.73(g)(5) and (h) 10 NYCRR § 80.74(d)
3.	Missing Follow-Up Order for Medical Supplies and/or Enteral Nutrition
OMIG Audit Criteria	A fiscal order written for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) on an Official NYS Serialized Prescription Form and faxed to the Pharmacy provider will be considered an original order. When an order for DMEPOS not written on the serialized official prescription form has been telephoned or faxed to the provider, it is the Pharmacy provider’s responsibility to obtain the original signed fiscal order from the ordering practitioner within 30 calendar days. If the original signed fiscal order is not received within 30 days, the claim will be disallowed.
Regulatory References	18 NYCRR § 505.5(a)(2) 18 NYCRR § 505.5(a)(8) 18 NYCRR § 505.5(b)(1) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I

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4.	Missing Documentation Confirming Receipt / Delivery of Billed Service
OMIG Audit Criteria	<p>If there is no signature from the beneficiary or their designee confirming receipt/delivery, the claim will be disallowed.</p> <p>If the signature documentation does not include the prescription number along with the date the prescription or fiscal order was picked up, the claim will be disallowed.</p>
Regulatory References	<p>18 NYCRR § 504.3(a) 18 NYCRR § 504.3(e) 18 NYCRR § 504.3(i) NYS DOH Medicaid Update, January 2013, Vol. 29, No. 2 NYS DOH Medicaid Update, September 2011, Vol. 27, No. 13 NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I</p>
5.	Order Date Conflicts with Claimed Order Date
OMIG Audit Criteria	When the order date of the prescription/fiscal order conflicts with the claimed order date of the prescription or fiscal order, the paid claim will be disallowed.
Regulatory References	<p>8 NYCRR § 29.7(a)(1) 18 NYCRR § 504.3(h) 18 NYCRR § 505.3(b)(3) 18 NYCRR § 518.1(c) NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2013-1 through 2019-1, Section I NYS eMedNY Billing Guidelines, Pharmacy, Version 2013-01, Section 2.4.1</p>
6.	Original Order Filled Beyond Allowed Timeframe
OMIG Audit Criteria	If the prescription or fiscal order is filled more than sixty days after it has been initiated by the prescriber, the claim will be disallowed.
Regulatory References	<p>NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I</p>
7.	Original Prescription for a Controlled Substance Filled Beyond Allowed Timeframe
OMIG Audit Criteria	If the prescription for a controlled substance is filled more than 30 days after it has been initiated by the prescriber, the claim will be disallowed.
Regulatory References	<p>10 NYCRR § 80.73(a) 10 NYCRR § 80.74(a) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I</p>

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8.	Order Refilled More Than 180 Days from the Original Date Ordered
OMIG Audit Criteria	If an order is refilled more than 180 days after it has been initiated by the prescriber, the paid claim will be disallowed.
Regulatory References	18 NYCRR § 505.3(d)(2) 18 NYCRR § 505.5(b)(1) and (b)(4)(iii) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I

9.	Information Missing from Order
OMIG Audit Criteria	If the prescription or fiscal order is missing information, the paid claim will be disallowed. Required information includes, but is not limited to the following: <ul style="list-style-type: none"> • date written / order date • patient name • name of drug/item • strength (if applicable) • directions for use • quantity
Regulatory References	8 NYCRR § 29.7(a)(1) 10 NYCRR § 80.67(b) 10 NYCRR § 80.67(g) 10 NYCRR § 80.67(h) 10 NYCRR § 80.67(i) 10 NYCRR § 80.69(b) 10 NYCRR § 80.69(l) 10 NYCRR § 80.69(m) 10 NYCRR § 80.69(n) 10 NYCRR § 80.70(a)(1) 10 NYCRR § 80.73(g)(1) and (i) 10 NYCRR § 80.73(k) 10 NYCRR § 80.73(l) 10 NYCRR § 80.73(m) 10 NYCRR § 80.74(g) 10 NYCRR § 80.74(h) 10 NYCRR § 80.74(i) 10 NYCRR § 80.131(b)(1) and (c) 18 NYCRR § 505.3(b)(2) 18 NYCRR § 505.3(b)(3) 18 NYCRR § 505.3(b)(5) 18 NYCRR § 505.5(b)(3) NY Public Health Law § 3332(2)(b) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I

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10.	Billed for Different Drug Than Ordered
OMIG Audit Criteria	If the pharmacy bills for a drug different than the drug ordered, the claim will be disallowed.
Regulatory References	8 NYCRR § 29.7(a)(1) 8 NYCRR § 29.7(a)(5) 18 NYCRR § 504.3(f) and (h)
11.	Billed NDC/HCPCS Differs from Dispensed NDC/HCPCS
OMIG Audit Criteria	Regardless of cost difference, if the National Drug Code (NDC) claimed does not correspond to the actual prescription dispensed, the claim will be disallowed. Regardless of cost difference, if the HCPCS claimed does not correspond with the product dispensed, the claim will be disallowed.
Regulatory References	18 NYCRR § 504.3(f) and (h) NYS DOH Medicaid Update, March 2010, Vol. 26, No. 4
12.	Procedure Code Billed Conflicts with Item Ordered
OMIG Audit Criteria	If the procedure code billed conflicts with the procedure code of the item ordered, the claim will be disallowed.
Regulatory References	18 NYCRR § 504.3(f) and (h) 18 NYCRR § 505.5(b)(1) 18 NYCRR § 505.5(d)(3)(ii) 18 NYCRR § 518.1(c) NYS eMedNY Billing Guidelines, Pharmacy, Version 2013-01 Section 2.4.1
13.	Billed for Different Strength than Ordered
OMIG Audit Criteria	If the pharmacy claims a different dosage or strength than ordered, the claim will be disallowed.
Regulatory References	8 NYCRR § 29.7(a)(1) 10 NYCRR § 80.67(h) and (i) 10 NYCRR § 80.69(m) and (n) 18 NYCRR § 504.3(f) and (h) NY Education Law § 6816.1.a

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14.	Billed in Excess of Prescribed Quantity
OMIG Audit Criteria	If the pharmacy is paid for a claim where the quantity of the item exceeds the amount prescribed, the difference between the cost of the quantity dispensed and the cost of the quantity ordered will be disallowed.
Regulatory References	18 NYCRR § 504.3(f) and (h) NY Education Law § 6816.1.a NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I
15.	Refilled in Excess of the Number of Refills Indicated on the Order
OMIG Audit Criteria	If a paid claim exceeds the prescribed number of refills, the claim will be disallowed.
Regulatory References	10 NYCRR § 80.69(g), (j), and (k) 18 NYCRR § 505.3(d)(1) 18 NYCRR § 505.5(b)(4)(i) NY Education Law § 6810.2(a) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I
16.	Order Refilled in Excess of Regulatory Limits
OMIG Audit Criteria	No more than five (5) refills are permitted for Medicaid orders. If a paid claim exceeds the allowed number of refills on the prescription / fiscal order, the claim will be disallowed.
Regulatory References	10 NYCRR § 80.69(g), (j), and (k) 18 NYCRR § 505.3(d)(2) and (3) 18 NYCRR § 505.5(b)(4)(i) and (ii) NY Education Law § 6810.2(a) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section 1
17.	Automatic Refill Invalid for Payment
OMIG Audit Criteria	Automatic refilling is not allowed under the Medicaid program. Automatic-refill programs offered by pharmacies are not an option for beneficiaries. If a pharmacy refills a prescription that was not requested by the Medicaid patient, caregiver, or patient representative, the paid claim will be disallowed.
Regulatory References	NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I

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18.	Changed/Altered Order Missing Pharmacist Annotation
OMIG Audit Criteria	If a change/alteration to the original prescription or fiscal order is not annotated and initialed by the pharmacist, the claim will be disallowed. When filling an electronic prescription, the pharmacist shall make the same notation electronically and retain the annotation electronically in the prescription record.
Regulatory References	10 NYCRR § 80.73(l) 10 NYCRR § 80.73(m) 10 NYCRR § 80.74(h) 10 NYCRR § 80.74(i) 18 NYCRR § 515.2(b)(2)(i)
19.	Invalid Order
OMIG Audit Criteria	An invalid prescription/fiscal order includes, but is not limited to, the following: <ul style="list-style-type: none"> • Electronic orders not transmitted by electronic means • Postdated orders (ordered after the original date of service) • Orders that are billed for a different patient than ordered When a prescription/fiscal order is invalid, the claim will be disallowed.
Regulatory References	18 NYCRR § 504.3(f) and (h) 18 NYCRR § 505.3(a)(7) 18 NYCRR § 505.3(b)(6) 18 NYCRR § 518.1(c) NY Public Health Law § 281(1) NY Public Health Law § 281(3)

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20.	Invalid Fax Order
OMIG Audit Criteria	<p>In order to be valid a faxed prescription/fiscal order must:</p> <ul style="list-style-type: none"> • originate from prescriber • be a fax of an original hard copy prescription • be manually signed by the prescriber • be on an Official New York State Prescription form (if issued in NY) • contain the fax source number <p>In most instances, faxed prescriptions for controlled substances must comply with requirements for oral prescriptions for controlled substances, including issuance of the follow-up prescription. When a fax prescription / fiscal order is invalid, the claim will be disallowed.</p>
Regulatory References	<p>18 NYCRR § 504.3(i) 18 NYCRR § 505.3(a)(7) 18 NYCRR § 505.3(b)(1) NY Public Health Law § 281(1) NY Public Health Law § 3302(37) NY Education Law § 6810.9 NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2013-1 through 2019-1, Section II</p>
21.	Compound Prescription Invalid for Payment
OMIG Audit Criteria	<p>The paid claim will be disallowed if the compounded prescription does not include:</p> <ul style="list-style-type: none"> • 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.” <p>The reconstitution of a commercially available drug is NOT regarded as a compounding procedure for NYS Medicaid reimbursement.</p>
Regulatory References	<p>18 NYCRR § 505.3(a)(1) NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section IV</p>

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22.	Missing DEA Number on Controlled Substance Prescription
OMIG Audit Criteria	If an official prescription or electronic prescription issued by a practitioner for a controlled substance does not contain the prescriber's DEA #, the paid claim is disallowed.
Regulatory References	10 NYCRR § 80.67(b)(2) 10 NYCRR § 80.67(b)(6) 10 NYCRR § 80.69(b)(2) 10 NYCRR § 80.69(b)(6) 10 NYCRR § 80.70(a)(1)
23.	Billed in Excess of Supply Limit for Emergency Controlled Substance Prescription
OMIG Audit Criteria	If the pharmacy is paid for a claim which quantity exceeds the days supply limit allowed for an emergency controlled substance prescription, the claim will be disallowed.
Regulatory References	10 NYCRR § 80.68(b) 10 NYCRR § 80.70(b)
24.	Controlled Prescription Missing Pharmacist Endorsement
OMIG Audit Criteria	If the prescription for a controlled substance is missing the pharmacist endorsement, the claim will be disallowed.
Regulatory References	10 NYCRR § 80.68(d)(1) 10 NYCRR § 80.70(a)(1) 10 NYCRR § 80.70(e) 10 NYRCC § 80.73(d) 10 NYCRR § 80.74(e) NY Public Health Law § 3333(3)
25.	Prescription Missing Condition or Exception Code Allowing for Greater Than a 30-Day Supply of Controlled Substance
OMIG Audit Criteria	If a controlled substance prescription is filled for greater than 30 day supply but does not include a valid condition or exception code, the claim will be disallowed.
Regulatory References	10 NYCRR § 80.67(d)(3) 10 NYCRR § 80.69(b) and (d)(3) NY Public Health Law § 3333(1)
26.	Multiple Drug Orders on a Non-Nursing Home Prescription
OMIG Audit Criteria	If a written, fax, or electronic prescription/fiscal order contains multiple drug orders the paid claim is disallowed.
Regulatory References	NY Education Law § 6810.7(a) and (b) NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2013-1 through 2019-1, Section II

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27.	Prescriber's Signature Missing from Order
OMIG Audit Criteria	<p>If the prescriber's signature is missing on a prescription or fiscal order, the paid claim will be disallowed.</p> <p>If an imprinted or stamped name is utilized in place of a signature on a written/faxed prescription or fiscal order, the paid claim will be disallowed.</p> <p>Electronically transmitted orders must contain the prescriber's signature or electronic equivalent; this can include a digitized signature, a verification/authentication number, or a printed name (which also meets the requirement for the imprinted name of the prescriber).</p>
Regulatory References	<p>8 NYCRR § 29.7(a)(1) 10 NYCRR § 80.67(b) 10 NYCRR § 80.69(b) 18 NYCRR § 505.3(a)(7) NY Public Health Law § 3332(2)(b) NY Education Law § 6810.6(a) NY Education Law § 6810.8 NY Education Law § 6811.15 NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section I For Services After 03/26/2016: NYSED Electronic Transmittal of Prescriptions in NYS Frequently Asked Questions No. 2 NYSED Electronic Transmittal of Prescriptions in NYS Frequently Asked Questions No. 4</p>
28.	Ordering Prescriber Conflicts with Claim Prescriber
OMIG Audit Criteria	<p>If the NPI number in the prescriber ID claim field identifies a different prescriber than the ordering prescriber, the paid claim will be disallowed.</p> <p>If the prescriber name contained on a telephone order conflicts with the prescriber identified on the claim, the paid claim will be disallowed.</p>
Regulatory References	<p>8 NYCRR § 29.7(a)(1) 18 NYCRR § 504.3(f) and (h) 18 NYCRR § 505.5(c)(1) NYS eMedNY Billing Guidelines, Pharmacy, Version 2013-01 Section 2.4.1 NYS DOH Medicaid Update, June 2016, Vol. 32, No. 6 NYS DOH Medicaid Update, November 2010, Vol. 26, No. 13</p>

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29.	Order Ordered by Excluded Prescriber
OMIG Audit Criteria	If the prescription / fiscal order was prescribed by a provider excluded from the Medicaid program, the paid claim will be disallowed.
Regulatory References	18 NYCRR § 505.5(b)(1)(ii) 18 NYCRR § 515.2(b)(7) NYS DOH Medicaid Update, December 2013, Vol. 29, No. 13
30.	Unqualified Ordering Practitioner
OMIG Audit Criteria	Prescribers must be actively NY licensed and have a current registration to be considered qualified to prescribe prescription drugs. Prescribers must be enrolled in the NYS Medicaid Program in order to be considered qualified to prescribe drugs and medical / surgical supplies to Medicaid Recipients. If the prescription / fiscal order was prescribed by a practitioner who was unqualified to prescribe the order, the paid claim will be disallowed.
Regulatory References	18 NYCRR § 505.5(a)(6) NY Education Law § 6810.1 NYS DOH Medicaid Update, July 2013, Vol. 29, No. 8 NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2013-1 through 2019-1, Section VI For Services After 12/31/2018: NYS DOH Medicaid Update, December 2018, Vol 34, No 12
31.	Unqualified Dispenser
OMIG Audit Criteria	Pharmacists must be licensed and have a current registration by the NYS Board of Pharmacy to be considered qualified to dispense drugs and medical/surgical supplies. Pharmacies must be enrolled in the NYS Medicaid Program in order to be considered qualified to dispense drugs and medical/surgical supplies to Medicaid Recipients. If the prescription/fiscal order was dispensed by a pharmacist who was unqualified to dispense the order, the paid claim will be disallowed.
Regulatory References	18 NYCRR § 505.3(c) 18 NYCRR § 505.5(b)(1)(ii) 18 NYCRR § 505.5(d)(5)(ii) NY Education Law § 6810.1 NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2019-1, Section II

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32.	Billed in Excess of the Maximum Payment Allowance
OMIG Audit Criteria	<p>If the paid claim exceeds the maximum payment allowance for the item, the amount exceeding the maximum is disallowed.</p> <p>Reimbursement amounts for unlisted items cannot exceed the lower of: (1) the acquisition cost to the provider plus 50% or (2) the usual and customary price charged to the general public. Amounts paid in excess of this amount will be disallowed.</p>
Regulatory References	<p>18 NYCRR § 505.5(d)(1)(vi) 18 NYCRR § 518.1(c) For Services 04/01/16 through 12/31/19: 42 C.F.R. § 447.512 For Services 12/02/13 through 10/23/19: NYS Medicaid Program Pharmacy Manual Policy Guidelines Versions 2013-1 through 2015-1, Section IV</p>
33.	No Explanation of Benefits (EOB) Documentation for Other Insurance Covered Items
OMIG Audit Criteria	<p>If no EOB documentation for a Medicare eligible recipient is present, the paid claim will be disallowed.</p> <p>If no EOB documentation for a recipient with TPHI coverage is present, the paid claim will be disallowed.</p>
Regulatory References	18 NYCRR § 540.6(e)(1) and (2)
34.	Other Insurance Payments Not Applied
OMIG Audit Criteria	<p>If services were not billed to Medicare for payment prior to submission to Medicaid for a Medicare eligible recipient, the paid claim will be disallowed.</p> <p>If services were not billed to a commercial carrier for payment prior to submission to Medicaid for a recipient with TPHI coverage, the paid claim will be disallowed.</p>
Regulatory References	<p>18 NYCRR § 360-7.2 18 NYCRR § 505.5(d)(1)(v) NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2013-1 through 2019-1, Section I NYS Medicaid Program Durable Medical Equipment Manual Policy Guidelines, Versions 2013-1 through 2019-1, Section III</p>

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