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OMIG AUDIT PROTOCOL – PHARMACY

For service dates prior to May 5, 2012

Effective 05/02/13

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. 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. The 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 or category of service in the course of an audit and involve the OMIG's application of articulated Medicaid agency policy and the exercise of agency discretion. 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.

Audit protocols are amended as necessary. Reasons for amending protocols include, but are not limited to, responding to a hearing decision, litigation decision, or statutory or regulatory change.

OMIG AUDIT PROTOCOL – PHARMACY

Effective 05/02/13

1.	Missing Fiscal Order
OMIG Audit Criteria	If the original fiscal order is missing, the paid claim will be disallowed. Exception is made for an exact reproduction (color not necessary) of the original fiscal order that is stored in the pharmacy’s electronic record storage system.
Regulatory References	For Services 1/24/12 Forward , 18 NYCRR Section 505.3(a)(7) For Services Prior to 1/24/12 , 18 NYCRR Section 505.3(a)(6) 18 NYCRR Section 505.3(b)(1) 18 NYCRR Section 505.3(c) 18 NYCRR Section 505.5(a)(8) 18 NYCRR Section 505.5(b)(1) 18 NYCRR Section 517.3(b)(1) For Services 8/7/06 forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines, Version 2006-1, Section I For Services Prior to 8/7/06 , MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4

2.	Missing Follow-Up Hard Copy Prescription for Controlled Drugs
OMIG Audit Criteria	A written prescription, or effective 4/19/06 an official New York State prescription, must be issued to follow-up a telephoned or faxed order for controlled substances. If such follow-up prescription is missing, the paid claim will be disallowed. <ul style="list-style-type: none"> • OMIG will not take disallowance if the pharmacist has recorded on the telephone or fax order all of the following: 1) a statement that the follow-up prescription was not received, 2) the name/initials of the pharmacist making the statement, and 3) the date of the statement.
Regulatory References	10 NYCRR Section 80.68(c) For Services 4/19/06 Forward , 10 NYCRR Section 80.73(i) and (j) 10 NYCRR Section 80.70(c) 10 NYCRR Section 80.74(d) For Services Prior to 4/19/06 , 10 NYCRR 80.73(f) 10 NYCRR Section 80.70(c)

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OMIG AUDIT PROTOCOL – PHARMACY

Effective 05/02/13

3.	Missing Prescription
OMIG Audit Criteria	If the original prescription is missing, the paid claim will be disallowed. Exception is made for an exact reproduction (color not necessary) of the original prescription that is stored in the pharmacy’s electronic record storage system.
Regulatory References	For Services 1/24/12 Forward , 18 NYCRR Section 505.3(a)(7) For Services Prior to 1/24/12 , 18 NYCRR Section 505.3(a)(6) 18 NYCRR Section 505.3(b)(1) 18 NYCRR Section 505.3(b)(3) 18 NYCRR Section 505.3(c) 18 NYCRR Section 517.3(b)(1) For Services 8/7/06 Forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I
4.	Non-Controlled Prescription/Fiscal Order Filled More Than 60 Days After It Has Been Initiated by the Prescriber or Controlled Prescription Filled More Than 30 Days After the Date Such Prescription Was Signed by the Authorized Practitioner
OMIG Audit Criteria	Paid claim will be disallowed if a non-controlled prescription or fiscal order is filled more than 60 days after it has been initiated by the prescriber (order date). Paid claim will be disallowed if a controlled prescription is filled more than 30 days after the date such prescription was signed by the authorized practitioner (order date).
Regulatory References	For Services 4/19/06 Forward , 10 NYCRR Section 80.74(a) 10 NYCRR Section 80.73(a) For Services Prior to 4/19/06 , 10 NYCRR Section 80.74(a) 10 NYCRR Section 80.73(a) For Services 8/7/06 Forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines, Version 2006-1, Section I For Services Prior to 8/7/06 , MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4

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5.	Prescription/Fiscal Order Refilled More Than 180 Days After It Has Been Initiated By the Prescriber
OMIG Audit Criteria	Paid claim will be disallowed if a prescription or fiscal order is refilled more than 180 days after it has been initiated by the prescriber (order date).
Regulatory References	18 NYCRR Section 505.3(d)(2) Remove the following citation if finding does not include DME items: 18 NYCRR Section 505.5(b)(1) and (4)(iii) For Services 8/7/06 Forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines, Version 2006-1, Section I For Services Prior to 8/7/06 , MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4
6.	Missing Information from Prescription/Fiscal Order
OMIG Audit Criteria	This finding applies to prescriptions and fiscal orders. Paid claim will be disallowed if the prescription or fiscal order is missing information. OMIG will disallow for any of the following: <ul style="list-style-type: none"> • Missing patient name • Missing name of drug/item • Missing strength (if applicable) • Missing quantity. • For telephone orders, the disallowance is taken when the prescriber name, or any of the above items, is not present on either the prescription document or the attached label/sticker.
Regulatory References	8 NYCRR Section 29.7(a)(1) For Services 4/19/06 Forward , 10 NYCRR Section 80.67(b)(1) & (5) 10 NYCRR Section 80.73(g)(1) & (i) 10 NYCRR Section 80.69(b)(1) & (5) 10 NYCRR Section 80.70(a)(1) & (c) 10 NYCRR Section 80.67(g) 10 NYCRR Section 80.69(l) 10 NYCRR Section 80.73(m) 10 NYCRR Section 80.74(g) 10 NYCRR Section 80.67(h) 10 NYCRR Section 80.69(m) 10 NYCRR Section 80.73(n) 10 NYCRR Section 80.74(h) For Services Prior to 4/19/06 , 10 NYCRR Section 80.67(b)(1) 10 NYCRR Section 80.73(d)(1) & (f)

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	<p>10 NYCRR Section 80.69(b)(1) 10 NYCRR Section 80.70(a)(1) & (c) 10 NYCRR Section 80.67(i) 10 NYCRR Section 80.69(j) 10 NYCRR Section 80.73(i) 10 NYCRR Section 80.74(d) 10 NYCRR Section 80.67(j) 10 NYCRR Section 80.69(k) 10 NYCRR Section 80.73(j) 10 NYCRR Section 80.74(e) 10 NYCRR Section 80.131(b)(1)(i) and (b)(4) 18 NYCRR Section 505.3(b)(2) 18 NYCRR Section 505.3(b)(3)</p> <p>(Remove this citation if finding does not include DME items):18 NYCRR Section 505.5(b)(3)</p> <p>For Services 8/7/06 Forward, NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I</p> <p>NYS Medicaid Program Pharmacy Manual Policy Guidelines, Version 2006-1, Section III</p>
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7.	Prescriber’s Signature Missing on Prescription/ Fiscal 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> <ul style="list-style-type: none"> • An imprinted or stamped name in place of a signature on written or fax prescriptions/fiscal orders is disallowed. • 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).
Regulatory References	<p>Education Law Article 137 Section 6810.6(a) Education Law Article 137 Section 6810.8 Education Law Article 137 Section 6811.15 8 NYCRR Section 29.7(a)(1) For Services 1/24/12 Forward, 18 NYCRR Section 505.3(a)(7) For Services Prior to 1/24/12, 18 NYCRR Section 505.3(a)(6) 18 NYCRR Section 505.5 (a)(8) For Services 8/7/06 Forward, NYS Medicaid Program Pharmacy Manual Policy</p>

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	Guidelines, Version 2006-1, Section I For Services Prior to 8/7/06 , MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.6
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8.	Imprint/Stamp of Printed Name of Prescriber Missing on Prescription
OMIG Audit Criteria	If the imprint/stamp of the printed name of the prescriber is missing on the prescription, the paid claim is disallowed. <ul style="list-style-type: none"> • OMIG will not disallow a hand printed prescriber name for the imprint/stamp. • On electronic orders, a printed name which meets the requirement for the signature of the prescriber (Protocol # 7), will also meet the imprint requirement.
Regulatory References	Education Law Article 137 Section 6810.8 18 NYCRR Section 505.3(b)(3) 10 NYCRR Section 80.67 (b)(2) For Services 4/19/06 Forward , 10 NYCRR Section 80.69 (b)(2) For Services Prior to 4/19/06 , 10 NYCRR Section 80.69(b)(2)

9.	Prescription/Fiscal Order Refilled in Excess of Prescriber’s Authorization and/or Refilled in Violation of Medicaid Regulations
OMIG Audit Criteria	Any paid claim which exceeds the ordered and/or allowed number of refills on the prescription/fiscal order is disallowed. <ul style="list-style-type: none"> • A prescription/fiscal order cannot be refilled more times than allowed on the prescription/fiscal order. • No more than five (5) refills are permitted for Medicaid prescriptions or fiscal orders.
Regulatory References	Education Law Article 137 Section 6810.2 For Services 1/24/12 Forward , 18 NYCRR Section 505.3 (a)(7) For Services Prior to 1/24/12 , 18 NYCRR Section 505.3(a)(6) 18 NYCRR Section 505.3(d)(1),(2),(3) 18 NYCRR Section 505.5 (b)(4)(i) For Services 8/7/06 Forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I For Services Prior to 8/7/06 , MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4

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10.	Pharmacy Billed in Excess of Prescribed Quantity
OMIG Audit Criteria	<p>If the pharmacy is paid for a claim where the quantity of the item exceeds the amount ordered on the prescription, the difference between the cost of the quantity dispensed and the cost of the quantity ordered will be disallowed.</p> <ul style="list-style-type: none"> • The quantity ordered is either specified on the prescription/fiscal order, or results from a calculation of ordered directions/ordered days supply/patient weight. • For non-prescription drug orders, if the ordering prescriber does not request a quantity that corresponds to the pre-packaged unit, the OMIG will not disallow when the pharmacist supplies the non-prescription drug in the pre-packaged quantity that most closely approximates the amount ordered.
Regulatory References	<p>Education Law Article 137 Section 6816.1.a 18 NYCRR Sections 504.3(f) and (h) For Services 8/7/06 Forward, NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I For Services Prior to 8/7/06, MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4</p>

11.	Pharmacy Billed for Different Strength than Ordered
OMIG Audit Criteria	<p>If the pharmacy is paid for a claim where the strength of item is different than the strength ordered on the prescription/fiscal order, the paid claim is disallowed.</p> <ul style="list-style-type: none"> • For controlled drugs, the pharmacist may adjust the strength only with prescriber authorization. The pharmacist shall write on the prescription the date the authorization was received, the reason for the change, and his/her signature. The pharmacist shall also indicate the change on the prescription and initial the change. • For non-controlled drugs, the pharmacist may (without authorization) have reason to adjust the strength due to product availability, or appropriate patient request (such as inability to swallow strength/form prescribed). The reason for change, and substitution made, should be documented by the pharmacist.
Regulatory References	<p>Education Law Article 137 Section 6816.1.a 8 NYCRR Section 29.7(a)(1) 8 NYCRR Section 29.7(a)(5) 18 NYCRR Sections 504.3(f) and (h) For Services 4/19/06 Forward, 10 NYCRR Section 80.67(h) 10 NYCRR Section 80.69(m) For Services Prior to 4/19/06, 10 NYCRR Section 80.67(j) 10 NYCRR Section 80.69(k)</p>

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12.	Missing Documentation Confirming Receipt/Delivery of Prescription/Fiscal Order
OMIG Audit Criteria	<p>For services 10/1/11 forward, if the pharmacy does not have all of the following documented to confirm receipt/delivery of claim, the paid claim is disallowed:</p> <ul style="list-style-type: none"> Signature(s) of beneficiary or designee Prescription number(s) being picked up/delivered Date(s) of pick-up/delivery <p>If multiple prescriptions are being picked up/delivered at one time, a single signature verifying receipt will be sufficient for all of the prescriptions/fiscal orders in the receipt or delivery.</p>
Regulatory References	<p>For Services 10/1/11 Forward, 18 NYCRR Section 504.3(a) 18 NYCRR Section 504.3(e) 18 NYCRR Section 504.3(i) DOH Medicaid Update September 2011 Vol. 27, No. 13, Office of Medicaid Management</p>
13.	Ordering Prescriber Conflicts with Claim Prescriber
OMIG Audit Criteria	<p>A claim identifies the prescriber by either: a Medicaid Provider ID number, a license number with profession code, or an NPI number. A disallowance is taken when:</p> <ul style="list-style-type: none"> • A prescription/fiscal order containing both a prescriber name and ID conflicts with the claim. (If the prescription/fiscal order does not contain an ID there is no disallowance). • The prescriber name contained on a telephone order conflicts with the prescriber name on the claim. <p>If it is demonstrated through documentation that the prescriber was working under the supervision of a physician for a specified purpose, a disallowance will not be taken.</p> <p>When the claim is for a restricted recipient, the actual prescriber’s and/or the referring provider’s provider ID/license/NPI number will be accepted by OMIG on the claim.</p> <p>OMIG will NOT take a disallowance for a truncated out-of-state prescriber license number due to leading zeros on the claim (i.e. MA001234 vs. MA123456).</p> <p>OMIG will NOT take a disallowance when the prescriber ID number listed on the prescription is incorrect for the actual prescriber due to print-shop mistake.</p>
Regulatory References	<p>18 NYCRR Sections 504.3(f) and (h) (Remove this citation if finding does not include DME items):18 NYCRR Section 505.5(c)(1) For Services Prior to 4/1/05, MMIS Provider Manual for Pharmacy</p>

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	<p>Version 2004-1, Section 3 For Services 4/1/05-7/6/08, NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2005-1, Section II NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2007-1, Section II NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2008-1, Section II For Services 7/7/08-9/30/09, NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2008-2, Section II NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2008-3, Section II For Services 10/1/09-5/31/11, NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2009-1, Section II NYS Electronic Medicaid System eMedNY 000301 Billing Guidelines, Pharmacy Version 2010-01, Section 2.4.1 For Services 6/1/11 Forward, NYS eMedNY Billing Guidelines, Pharmacy Version 2011-01, Section 2.4.1 For Services 3/1/04 Forward, DOH Medicaid Update March 2004 DOH Medicaid Update October 2004 DOH Medicaid Update September 2005 For Services 3/1/00 Forward, DOH Medicaid Update March 2000 For Services 1/1/08 Forward, DOH Medicaid Update January 2008 For Services 12/2/10 Forward, DOH Medicaid Update October 2010 DOH Medicaid Update November 2010</p>
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14.	Pharmacy Billed for Different Drug Than Ordered
OMIG Audit Criteria	<p>If the pharmacy bills for a different drug than was ordered on the prescription or fiscal order, the paid claim is disallowed.</p> <ul style="list-style-type: none"> • Pharmacist notation on a non-controlled prescription or fiscal order regarding authorization of change by prescriber is acceptable to OMIG. This notation should reasonably include the prescriber’s message, date of message, and pharmacist initials.
Regulatory References	<p>Education Law Article 137 Section 6816.1.a 8 NYCRR Section 29.7(a)(1) 8 NYCRR Section 29.7(a)(5) 18 NYCRR Sections 504.3(f) and (h) For Services 4/19/06 Forward, 10 NYCRR Section 80.67(h), 10 NYCRR Section 80.69(m) For Services Prior to 4/19/06, 10 NYCRR Section 80.67(j) 10 NYCRR Section 80.69(k)</p>

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Effective 05/02/13

15.	Missing Follow-Up Hard Copy Order for Medical Supplies and/or Enteral Nutrition
OMIG Audit Criteria	<p>If a written prescription to follow-up a telephoned or faxed order for medical supply items and/or enteral nutrition is not available, the paid claim will be disallowed.</p> <p>For dates of service on and after July 1, 2008, 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.</p> <p>Effective October 1, 2009, an electronically transmitted fiscal order for DMEPOS will be considered an original fiscal order when the following requirements are met:</p> <ul style="list-style-type: none"> • The order must originate from the practitioner’s computer and must be directly transmitted to the Pharmacy provider’s computer or fax. <p>OMIG will not take disallowance if, on a telephone fiscal order or fax fiscal order not on an Official NYS Prescription Form, a contemporaneous notation is recorded stating that the original signed hard copy fiscal order was never received, along with the name/initials of the pharmacist and the date of the notation.</p>
Regulatory References	<p>18 NYCRR Section 505.5(a)(2) 18 NYCRR Section 505.5(a)(8) 18 NYCRR Section 505.5(b)(1) For Services 8/7/06 Forward, NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section I For Services Prior to 8/7/06, MMIS Provider Manual for Pharmacy Version 2004-1, Section 2.2.4</p>

16.	Procedure Code Billed Conflicts with Item Ordered
OMIG Audit Criteria	If the pharmacy bills Medicaid for a procedure code item that is different than the ordered item, the paid claim is disallowed.
Regulatory References	<p>18 NYCRR Sections 504.3(f) and (h) 18 NYCRR Section 505.5(b)(1) 18 NYCRR 505.5(d)(3)(ii) 18 NYCRR Section 518.1(c) For Services Prior to 4/1/05, MMIS Provider Manual for Pharmacy Version 2004-1, Section 3.0 For Services 4/1/05 Forward, NYS Medicaid Program Pharmacy Manual Billing Guidelines, Version 2005-1, Section II</p>

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17.	Invalid Prescription/Fiscal Order
OMIG Audit Criteria	<p>The paid claim is disallowed when a prescription/fiscal order is invalid. An invalid prescription/fiscal order shall include, but is not limited to, the following:</p> <ul style="list-style-type: none"> • Postdated prescriptions/fiscal orders (ordered after the original date of service) • Prescriptions/fiscal orders that are billed for a different patient than ordered
Regulatory References	<p>NYS Public Health Law Article 1 Title 2 Section 21 18 NYCRR Sections 504.3(f) and (h) For Services 1/24/12 Forward, 18 NYCRR Section 505.3(a)(7) For Services Prior to 1/24/12, 18 NYCRR Section 505.3(a)(6) 18 NYCRR Section 505.3(b)(1) 18 NYCRR Section 505.3(b)(5) 18 NYCRR Section 518.1(c)</p>

18.	Missing DEA# on Controlled Substance Prescription
OMIG Audit Criteria	<p>If an official prescription prepared by a practitioner for a controlled substance is incomplete of the prescriber's DEA #, the paid claim is disallowed.</p> <ul style="list-style-type: none"> • The pharmacist may add the DEA# to the prescription upon oral authorization by the practitioner. This authorization must be noted by the pharmacist on the prescription and indicate the date the authorization was received and the pharmacist's signature.
Regulatory References	<p>10 NYCRR Section 80.67(b)(2) For Services 4/19/06 Forward, 10 NYCRR Section 80.67 (g) 10 NYCRR Section 80.69(b)(2) 10 NYCRR Section 80.69 (l) For Services Prior to 4/19/06, 10 NYCRR Section 80.67(i) 10 NYCRR Section 80.69(b)(2) 10 NYCRR Section 80.69(j)</p>

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19.	Invalid Fax Prescription/Fiscal Order
OMIG Audit Criteria	If the faxed prescription or fiscal order does not contain the source fax number, the paid claim is disallowed.
Regulatory References	NYS Public Health Law Article 1 Title 2 Section 21 18 NYCRR Section 504.3(i) For Services 1/24/12 Forward , 18 NYCRR Section 505.3(a)(7) For Services Prior to 1/24/12 , 18 NYCRR 505.3(a)(6) 18 NYCRR Section 505.3(b)(1) For Services 8/7/06 Forward , NYS Medicaid Program Pharmacy Manual Policy Guidelines Version 2006-1, Section II
20.	Multiple Drug Orders on a Non-Nursing Home Prescription
OMIG Audit Criteria	If a written prescription contains multiple prescription drug orders the paid claim is disallowed. The exception: non-controlled drugs administered in a nursing home, which can be ordered on a single patient specific prescription document.
Regulatory References	Education Law Article 137 Section 6810.7(a) & (b)
21.	Electronic Prescription Invalid for Controlled Substance
OMIG Audit Criteria	The paid claim is disallowed when an electronic prescription/fiscal order is transmitted for a controlled substance prescription.
Regulatory References	18 NYCRR Section 505.3(b)(6) For Services 4/19/06 Forward , 10 NYCRR Section 80.73(a) 10 NYCRR Section 80.74(a) For Services Prior to 4/19/06 , 10 NYCRR Section 80.73(a) 10 NYCRR Section 80.74(a)

Protocol Regarding Pharmacy Sampled Claims with the Same Prescription Number:

- It has come to our attention that within the sample, the same prescription number can occur more than once (i.e., first fill and subsequent refills); this could result in projected disallowances taken more than once for the same prescription number. This is most often seen in those pharmacies with a small universe/small distinct recipient population.
- To address this issue of disallowances for the same prescription within pharmacy audit samples, **audits beginning on or after 2/1/09** will take a projectable disallowance **ONLY** once on the first occurrence of the prescription, and then an actual disallowance on each subsequent sampled occurrence of the same prescription number.

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