

THE PACE PROGRAM

PROVIDER AUDIT PRINCIPLES AND PRACTICES

March 25, 2016

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Principles Statement

The PACE Program (Program) conducts provider audits in a professional and transparent manner in order to preserve the valued relationships among the Program cardholders, the community of pharmacy providers (providers) and Program administrators. The audit procedures are fair and equitable to all contracted pharmacies without being a severe burden to the pharmacies while they conduct business. Claim selection results from the use of an unbiased, algorithm-based analysis. The Program does not use the practice of extrapolation for the calculation of audit discrepancy recoupments. Audit recoveries are not intended to underwrite the cost of the Program.

Best Practices Statement

The Program provides a safe and effective prescription drug benefit for qualified older Pennsylvanians. Audits of providers ensure compliance with Program policies, Program contract requirements, and pharmacy standards of practice.

The Program establishes provider compliance by conducting thorough audits of pharmacies by reviewing data entry, prescription documentation, and provider record keeping in conjunction with prescription claims adjudicated through the Program online point-of-sale system. The auditor looks for consistency between the paid claim submission and the prescription that generated the claim.

Providers broadly share their audit experience with colleagues in the pharmacy practice community and frequently offer feedback to the Program. An onsite compliance audit serves as an educational opportunity for the provider staff and for the auditors, who represent the Program, to exchange information for purposes of Program improvement.

The Program conducts audits by following commonly recognized principles. Compliance audits validate data entry and the documentation of claims to ensure that they meet regulatory and Program contract requirements. The Program expects providers to evaluate their record-keeping and implement the necessary procedures and controls to ensure full compliance with all applicable authority pertaining to the Program and the Pennsylvania State Board of Pharmacy. By contracting with the Program, a provider agrees to be knowledgeable of, and to comply with, the applicable rules, regulations, rates and fee schedules promulgated under applicable laws. Any detection of fraud, waste, or abuse may lead to further investigation by the Program and other federal and state agencies.

A. **Conducting Compliance Audits**

At least two weeks prior to the onsite audit, the Program sends to the provider an audit announcement letter with essential information regarding the records required to conduct and complete the audit. There are three basic parts to the audit: **the prescription audit, the patient certification audit, and the acquisition audit.**

- **For the prescription audit portion**, the letter identifies a date range and a prescription number range for the prescriptions. A list of prescriptions will not be provided for this part of the audit prior to the onsite visit.
- **For the audit of patient certifications**, the provider verifies the dispensing date of the prescription by showing the auditor a clear, accurate signature log for selected claims.
- **For the product acquisition part of the audit**, the letter includes a list of claims so that the provider can prepare for the audit by retrieving the invoice or product acquisition records (not prescriptions) from the wholesaler or warehouse.
- During the audit, auditors will need to access the following records:
 - Prescriptions within the audit range listed in the announcement letter
 - Computerized patient profiles, if needed
 - Patient certification and the prescription receipt log
 - Wholesaler invoices or other warehouse product documentation that confirm the list of acquisition claims that are provided with the announcement letter; the date of purchase may be up to 12 months prior to the date of service and only the first 9 digits of the NDC will be reviewed.

The Program--

- Identifies the claims adjudication period, usually within two years of the audit date. The original prescription could be dated prior to the date range identified in the announcement letter.
- Identifies prescriptions by using reasonable algorithms and experienced desk review
- Confirms audit date, time of day and the required audit records list with the provider one week prior to audit
- Employs experienced pharmacists for prescription review and auditing
- Conducts audits during regular business hours
- Minimizes disruptions while onsite
- Grants an audit exit interview conducted by the auditor to review discrepancies recorded on the PACE Audit Exit Summary and Corrective Action Plan (Attachment A) with the provider, prior to leaving the pharmacy after onsite audit
- Answers questions and discusses comments about the audit
- Sends an audit results letter and final audit report to the provider within six months after the completion of the audit
- Promotes the use of the appeal process by allowing the provider an opportunity to produce documentation to address discrepancies found in the final audit report. After the fact documentation is generally not accepted. However, valid invoices and documents for the product acquisition part of the audit are accepted within two weeks of the audit date.
- Does not use extrapolation for calculation of audit discrepancy recoupments
- Recoups claims payment from a provider based on actual value of claims with discrepancies
- Reviews the days supply amount for insulin, ophthalmics, creams, ointments and otic products and takes into consideration the patient's over or under use of the product

B. Program Expectations of the Provider and Provider Employees

The provider--

- Follows dispensing requirements relating to the Pennsylvania State Board of Pharmacy standards of practice
- Is knowledgeable of the Program provider agreement, rules, regulations, policies and bulletins of the Program
- Prepares for the audit by ensuring that the required records are accessible and readily retrievable for the auditor
- Receives the auditors and cooperates during the audit in a professional manner
- Provides the auditors with adequate workspace
- Remains available to respond to questions raised by the auditor during the audit
- Recognizes the implications of non-compliance, but takes into consideration the patient's over or under use of insulin, ophthalmic, creams, ointments and otic products
- Maintains appropriate records necessary to disclose the full nature and extent of prescription drugs, both covered and not covered by the Program, which were dispensed by the provider
 - Retains these records for a minimum of four years
 - Makes these records available for review, copying, photographing, or scanning by authorized Commonwealth officials or their authorized agents within seven business days of the audit announcement letter
 - Complies with requests to review records for prescription drugs not covered by the Program to determine compliance with Program laws, regulations or contract requirements or for the purpose of providing information to other state or federal agencies regarding the provider's compliance with other laws, regulations or contract requirements
- Signs the PACE Audit Exit Summary and Corrective Action Plan (Attachment A) to acknowledge notification of discrepancies reviewed during the onsite audit
- Informs the Program office of any concerns or issues regarding the onsite audit

C. Unacceptable Documentation

The Program expects all prescriptions to have the minimum required information per the Pennsylvania State Board of Pharmacy, Pennsylvania Code, § 27.18 and all required information for a controlled substance prescription per Federal Law (21 CFR 1306.05(a)).

Examples of the most frequent uses of unacceptable documentation—

- After the fact documentation; for example, corrections to prescriptions and rewritten prescriptions obtained from prescriber are not acceptable
- Telephone prescriptions without required prescription fields
- Transfer prescriptions without full documentation and original date of fill
- Claims with pharmacy National Provider Identification (NPI) instead of prescriber NPI
- Written prescriptions without DEA registration number written on hard copy prescription
- Prescriptions without directions to the patient; for example, "as directed" is not acceptable except in sliding scale insulin orders
- Claims with incorrect prescriber identification; for example, incorrect NPI
- Claims with incorrect use of the dispense as written (DAW) codes
- Prescription cannot be located in records
- Claims with a date of dispensing that cannot be verified by a clear, accurate signature log

D. Responses to an Audit

Upon receiving the audit results letter and final audit report, the provider has three options for response.

Option #1 - Provider agrees with audit findings

Providers have thirty calendar days from the date of the audit results letter to send a written response:

- To agree with the audit findings
- To provide a statement for corrective actions

Send written response to:

PACE Operations Unit
Forum Place Building
555 Walnut Street, 5th Floor
Harrisburg, PA 17101

Option #2 - Provider disagrees with audit findings and seeks administrative appeal

Providers have thirty days from the date of the audit results letter to submit an administrative appeal consisting of a written response that includes:

- Reasons why the provider disagrees
- Dated documentation to support the National Drug Code (NDC) and other details for the product acquisition portion of the audit

The Program will review the written response to determine if revisions should be made to the final audit report. For more information about the Administrative Appeal Process, refer to Section E, below.

Send written response to:

PACE Operations Unit
Forum Place Building
555 Walnut Street, 5th Floor
Harrisburg, PA 17101

Option #3 - No response from provider

If the provider chooses not to respond to the audit report, audit recoveries will be made through an adjustment in the provider's Weekly Remittance Advice.

E. Administrative Appeal Request

A provider may file an administrative appeal within thirty days of the date of the audit results letter in accordance with 6 Pa. Code Subsection 22.101. An administrative appeal is considered to be submitted in a timely manner if it is postmarked on or before the required date. A provider may obtain a certificate of mailing from the postal service to document the date an item is sent to the Program. The deadline date for filing an appeal will be strictly enforced. Any extension must be approved in writing by the Program prior to the required response date.

- If a timely appeal to the audit results letter is not filed, the report is deemed final and the Program may recoup the disallowed costs as a claim against the provider. The Program may either recoup the disallowed costs from a future Remittance Advice or take other action as authorized by law for the collection of amounts due to the Commonwealth.
- The form and content of the provider’s appeal shall conform to 1 Pa. Code Subsection 35.10, relating to form and content of formal complaints. The provider must submit a written response stating why they disagree with each of the preliminary findings in the report. A provider must attach either copies or a summary of all documents or other evidence upon which the appeal is based.
- The Program will review the written response to determine if revisions should be made to the final audit report. The process of reviewing the audit report and the provider’s response is known as “audit resolution.” In the audit resolution process, the Program will evaluate all of the facts and circumstances relevant to any disallowance of reimbursement, and will interpret the relevant laws, regulations and contractual requirements.
- The administrative appeal decision will be issued in the form of a written response by the Program, generally within sixty days of receipt. However, there is no time limit for the Program response. The decision will be binding between the Department of Aging and the provider.

F. Formal Hearing Request

A provider may request a formal hearing within thirty days of the date of the Program’s issuance of the administrative appeal decision.

- A formal hearing, if requested, will be conducted by a hearing examiner appointed by the Director of the Department of Human Service’s Office of Hearings and Appeals. Hearings shall be conducted in accordance with the Rules and Administrative Practice and Procedure as set forth in 1 Pa. Code Title I, Part 2.
- At the hearing, the provider has a right to representation by counsel, a right to present relevant and material evidence to the hearing examiner, and a right to cross examine Program witnesses.

Information about the formal hearing process can be obtained from:

Pennsylvania Department of Aging
 Office of Chief Counsel
 Forum Place Building
 555 Walnut Street, 5th Floor
 Harrisburg, PA 17101

- The formal hearing decision will be issued in the form of a written opinion by the Department of Human Service’s Office of Hearings and Appeals which will set forth findings of fact, conclusions of law, and a final order of the Department. A final decision will be binding between the Department of Aging and the provider.

G. Audit Recoupment

Audit recoveries will be made through an adjustment in the provider’s Weekly Remittance Advice after administrative appeals are fully addressed. Alternate payment methods must be authorized by the Program.

H. Summary

The audit is an important opportunity for the Program to present itself to the pharmacy community by sharing the goals of the benefit design, discussing the importance of adherence to the provider agreement, and gathering important service information from the provider. The goal of a thorough auditing protocol is an improved relationship between the provider and the Program. Audits that result in improved understanding of, and adherence to, the Program requirements strengthen the Program pharmacy benefit for older Pennsylvanians.

PACE PROVIDER AUDITS

I. Desk Audit

A. Provider Selection

1. Auditors review computer generated profiles that analyze multiple billing measures
2. Auditors examine characteristics of providers with unusual measures of claim billing, types of services, and service areas
3. Auditors may refer providers to discovery audit for prescription claims review

B. Claim Selection

All claims are included in the analysis that may be specific to provider type and location.

II. Discovery Audit

A. Provider Selection

1. A multiple county focus accounts for a large percent of the Program claims activity and enforcement actions
2. Analysis starts with high volume retail providers by county

B. Claim Selection—Two hundred claims per audit

Parameters for selection include but are not limited to:

1. File request

- a. The Program pharmacy benefits administrator creates a file of all providers by county by time period (Eighteen to twenty-four month time period)
- b. File includes all providers enrolled on the day of the file creation
- c. Duplicate claims and voided claims occurring outside of time frame are excluded

2. Inclusion Criteria

- a. All claims within time period, excluding claim reversals
- b. Paid, original claims

3. Pool of claims goes to desk review for final claim selection

- a. Claims included are for PACE, Chronic Renal Disease Program, and Aids Drug Assistance Program (ADAP) in the Special Pharmaceutical Benefits Program
- b. Claims selected for level of agreement among several measures: dosage, form, strength, day supply, quantity (creams, ointments, liquids, eye drops, inhalers)
- c. Claims selected with combination of circumstances based upon practice standards and program policy criteria (price, NDC, origin code, quantity, day supply, frequency, prescriber NPI, and DEA registration number, if DEA number is required by law)

III. Recovery Audit

- A. Occurs after discovery audit and after review of discovery audit findings at the quarterly Screening Meeting between the auditors and the Program
- B. Time period of audit determined by Program (up to four years)
- C. Collective determination (auditors and Program) of the need for a recovery audit
- D. Claims selection—new claim sample and new review period which excludes previously sampled claims
- E. Time period of audit collectively determined by auditors and Program
- F. Audit review criteria same as for discovery audit

IV. Investigational Audit

- A. Provider selected as a result of findings from previous audits or by recommendation from another creditable source or agency
- B. Time period of audit determined by Program (up to ten years)
- C. Audit review criteria same as for discovery audit or selected criteria from recommendation
- D. Four hundred claim sample; forty cardholder patient certifications; and fifty product acquisition invoices

V. Nursing Home Audit

- A. Audit review criteria same as for discovery audit
- B. Provider selected by recommendation of the Program
- C. Two hundred claim sample; selecting cardholders with the highest claim counts

VI. Mail Order/Specialty Pharmacy Audit

- A. Audit Review Criteria same as for discovery audit
- B. Provider selected by recommendation of the Program
- C. Two hundred claim sample; selecting cardholders with the highest claim counts

ONSITE AUDIT REVIEW CRITERIA

Criteria include but are not limited to:

I. Standards of Practice and Program Policy Criteria

- A. Prescription retention for claims submitted (four years)
- B. Signature log
- C. Dispensed brand name drug has correct DAW (dispense as written/product selection) code
- D. Day supply amount is accurate and within policy limit
- E. Prescription matches prescription origin code on the claim
- F. Metric quantity matches quantity of prescription
- G. Correct NDC for prescription and product dispensed
- H. Prescription with correct prescriber NPI
- I. Date handwritten on prescription
- J. Authorization for refills on original prescription
- K. Refills are within six months of original date written

II. Other Items

- A. Drug Enforcement Administration (DEA) number on prescriptions for Schedule II through V drugs
- B. Physician signature on prescriptions
- C. Invoices
- D. Voided/negated prescriptions
- E. Additional prescription errors not in the claim sample but fall within the audit period
- F. Acquisition errors
- G. Proper documentation on prescription, including dosing

III. Pennsylvania State Board of Pharmacy, Pennsylvania Code, § 27.18. Standards of Practice

DEFINITIONS

Abuse—provider actions resulting in improper payment for prescriptions that fail to meet standards of care or the provision of medically unnecessary services or prescriptions.

Adjudication—the processing of a prescription claim for payment through the claims processing system.

Audit—review of provider procedures and claim submission in order to assess compliance with Commonwealth regulations, Commonwealth program policies, and pharmacy practice standards.

Controlled Substances—prescription drug products and chemical entities listed as Schedule I through V in the Controlled Substances Act.

Days—refer to calendar days unless indicated as business days.

DEA—federal Drug Enforcement Administration

Desk Audit—an in-house review of claims adjudicated through the claims processing system; also called a documentation and verification audit.

Discovery Audit—an onsite audit conducted to evaluate compliance with Program rules, regulations and bulletins and which may result in the disallowance reimbursement for pharmaceutical services paid by the Program. (See onsite audit)

Documentation and Verification Audit—an in-house review of adjudicated claims processed through the claims processing system; also called a desk audit.

Fraud—by using false representations, an intentional attempt or an action to defraud a Commonwealth benefit program of money or products controlled by the Commonwealth benefit.

Investigational Audit—a more extensive review of provider performance, usually done after a recovery audit when:

- findings indicate a pattern of abuse or misconduct by a provider;
- an internal review of data indicate potential billing discrepancies by a provider;
- information of alleged abuse is provided by other third party payers or law enforcement officials.

NDC—National Drug Code

NPI—National Provider Identifier

Onsite Audit—when an auditor goes to the provider's location to review adjudicated claims against original prescriptions, to examine compliance with contract requirements, to discuss the discrepancies found with the pharmacist, and to provide recommendations for improvement. A final audit report is sent to the provider following an onsite audit.

PACE—The Pharmaceutical Assistance Contract for the Elderly Program

Recovery Audit—an audit that is conducted when the findings from a discovery audit disclose substantial noncompliance with the Program requirements. A recovery audit may result in additional claim disallowances or may be referred to the Program for further investigation.

Waste—is the over-utilization or misuse of product and services resulting in unnecessary expenditures for the Commonwealth benefit program or for beneficiaries of the program.



Attachment A

**PACE AUDIT EXIT SUMMARY
AND
CORRECTIVE ACTION PLAN**

Pharmacy Name: _____

Audit Date: _____

Address: _____

Provider No.: _____

RPh In Charge: _____

No. of claims in sample: _____

RPh On Duty: _____

Sample Period: _____

Audit Letter Notification Date: _____

DISCREPANCY	Primary	Secondary		
Document Not on File	_____	_____		
Patient Certification	_____	_____		
DAW Violation	_____	_____	Additional errors not in sample	_____
No Authorization	_____	_____	Negated Prescriptions	_____
Day Supply	_____	_____	Acquisition Errors	_____
Rx Org. Code	_____	_____	% of Telephone Rx in Sample	_____
Metric Qty Hype	_____	_____	Total Errors (Primary & Secondary)	_____
Metric Qty Cut	_____	_____	%	_____
NDC-/Drug Description	_____	_____		
Prescriber ID	_____	_____		
Rx not Dated	_____	_____		
Other	_____	_____		
No. of Errors in Sample	_____	_____		
% of Errors in Sample	_____	_____		

Auditor's comments and corrective action steps, if applicable: _____

Provider's comments: () YES () NO _____

By signing this document, provider acknowledges above discrepancies and agrees to take corrective action, if necessary:

Signatures: _____

Title: _____

RPh (Auditor)