



Policy: MA.5013
Title: **Pharmacy Audits and Reviews**
Department: Medical Management
Section: Pharmacy Management

CEO Approval: /s/ Michael Hunn 12/16/2024

Effective Date: 04/01/1999

Revised Date: 12/01/2024

Applicable to: ☐ Medi-Cal
☒ OneCare
☒ PACE
☐ Administrative

I. PURPOSE

This policy sets forth the processes to determine whether Participating Pharmacies adhere to CalOptima Health's Pharmacy program policies and procedures and conform to all regulatory and contractual requirements relating to Pharmacy.

II. POLICY

- A. CalOptima Health shall ensure that Pharmaceutical Services are provided to Members in accordance with applicable laws, contractual provisions, and CalOptima Health Pharmacy Program policies and procedures in order to protect the fiscal integrity of the Pharmacy Program and the best interest of Members.
- B. CalOptima Health may, at its discretion, delegate the authority to perform the Pharmacy Audit functions set forth in this Policy to a third party through a written agreement and subject to CalOptima Health's oversight and direction.
- C. Participating Pharmacies may appeal the findings of any Audit or file a grievance as set forth in this Policy.

III. PROCEDURE

A. Delegation

- 1. Except as otherwise indicated herein, the Pharmacy Audit process for Participating Pharmacies shall be delegated to a Pharmacy Auditor through a written agreement.
- 2. CalOptima Health shall oversee the delegated function and may reclaim the right to carry out the function, but shall not direct the daily operations of the function.

B. Performance Standards and Audit Selection Criteria

- 1. Performance Standards for Participating Pharmacies.

- a. The Pharmacy Auditor shall Audit the Participating Pharmacy's compliance with CalOptima Health's established performance standards, CalOptima Health's credentialing and access standards, as well as with any requirement set forth in the Participating Pharmacy Agreement (PPA) with respect to Pharmaceutical Services provided to Members.
 - b. Performance standards include, but are not limited to, the following:
 - i. Participating Pharmacy ensures that signature logs and delivery logs contain the required information listed in the CalOptima Health Pharmacy Manual;
 - ii. The Participating Pharmacy ensures that the California Board of Pharmacy required consumer notification of available services is posted in a place conspicuous to and readable by Members (community clinics are exempt from this requirement);
 - iii. The Participating Pharmacy ensures that the quantity and drug or medical supply product dispensed to the Member is the exact quantity and drug or medical supply product which is billed to the PBM;
 - iv. The Participating Pharmacy ensures that the quantity dispensed, and days supply of drugs or medical supplies are consistent with both the written Prescription and CalOptima Health requirements;
 - v. The Participating Pharmacy verifies that the service date submitted on all claims is the date that the Prescription was actually filled, whether or not the fill date is the same as the billing date;
 - vi. The Participating Pharmacy verifies that it meets all of the requirements contained in CalOptima Health Policy MA.5012: Pharmacy Network: Credentialing and Access, the PPA, and any other CalOptima Health policies and procedures.
 - c. Prescribing Provider compliance shall be audited in accordance with CalOptima Health Policy HH.1107: Fraud, Waste, and Abuse Investigation and Reporting.
2. Pharmacy Selection Criteria. Particular Pharmacies may be selected for Audits based upon criteria including but not limited to:
- a. High average ingredient cost of Prescriptions dispensed;
 - b. High proportion of over-the-counter (OTC) claims;
 - c. High proportion of drugs within a specific therapeutic/pharmacological category;
 - d. Dispensing of unusual numbers of Prescriptions to a given Member within a given period of time;
 - e. Dispensing of unusual quantities of controlled substances;
 - f. Intermittent or sporadic billings of maintenance medications, inconsistent with the dosage prescribed by the Prescribing Provider, dosages established in the official package insert for the drug product, or with dosages listed in the pharmaceutical compendia;

- g. Excessive number of Drug Utilization Review (DUR) system overrides;
- h. Member or physician complaints;
- i. Correlation of Pharmacy's utilization with Prescribing Providers under review for possible fraud or abuse;
- j. Unusually high proportion of Prescriptions from one (1) Prescribing Provider;
- k. Unusual fluctuations in a Pharmacy's utilization or costs;
- l. Any other criteria as required by CalOptima Health in the best interest of its Members; and
- m. Random sampling.

C. Types of Audits Performed

1. Onsite (In-Store) Pharmacy Audits

- a. An onsite Audit is a general examination of a Pharmacy's practices and procedures, its legal and regulatory compliance, its comprehension of and compliance with CalOptima Health policies and procedures, and its compliance with Participating Pharmacy Network access and credentialing standards as set forth in the CalOptima Health Policy MA.5012: Pharmacy Network: Credentialing and Access.
- b. An onsite Audit captures key facility, legal, and regulatory compliance characteristics (e.g., current licenses and permits, appropriate disability access, days and hours of service, etc.) of the Pharmacy, including all of its Records and its credentialing documents.
- c. Onsite Audits may include Prescription Records reviews unless otherwise determined by the Pharmacy Auditor or CalOptima Health.
- d. The Pharmacy Auditor shall conduct onsite Audits in accordance with the procedures set forth herein and as defined in the contract between CalOptima Health and the Pharmacy Auditor. The onsite Audit tool, as well as a written description of the Pharmacy Auditor's internal Audit process and procedures, shall be made available upon request.

2. Retrospective Audit (Desk-Top Audits)

- a. A retrospective Audit is a complete analysis of Pharmacy and Prescribing Provider Prescriptions and claims to ensure compliance with program policies and to identify potentially inappropriate claims submissions.
- b. The Pharmacy Auditor shall perform computerized review of one hundred percent (100%) of paid claims on a monthly basis in accordance with, but not limited to, CalOptima Health's performance standards and Audit criteria set forth in Section III.B of this Policy, to assist in identifying claims/Pharmacies for Audit each month.
- c. The Pharmacy Auditor shall perform retrospective Audits in accordance with the procedures set forth herein and as defined in the contract between CalOptima Health and the Pharmacy Auditor. A written description of the Pharmacy Auditor's internal Audit process and procedures shall be made available upon request.

3. Focused Investigation Audits (FIA)

- a. An FIA is an intensive review of particular drug and device prescribing and the Pharmacy's acquisition and disposition Records compared to claims billed, and is designed to detect potential or actual fraud and abuse and to measure and recoup overpayments made to the Pharmacy for Unsubstantiated Claims, as defined in the PPA.
- b. A FIA is performed as a result of one (1) or more factors including, but not limited to: poor performance in prior Audits, complaints from Members, observation of low customer traffic versus (vs.) relatively high average Prescription claim volume during an onsite Audit, variance from performance standards, or performance that is consistent with Audit selection criteria as established herein.
- c. The Pharmacy Auditor shall perform a FIA in accordance with the process set forth herein and as defined in the contract between CalOptima Health and the Pharmacy Auditor. A written description of the Pharmacy Auditor's internal Audit process and procedures shall be made available upon request.
- d. The Auditor's written reports of the initial findings and post-appeal findings, if any, shall be forwarded to regulatory and law enforcement agencies as required by CalOptima Health.

D. Audit Process

1. Audits shall be performed by a licensed Pharmacist or Pharmacy Technician, with the exception of retrospective Audits, which may be performed by appropriate non-licensed persons and entities, as selected and assigned by CalOptima Health.
2. The Pharmacy Auditor shall notify an Audited Pharmacy no less than three (3) calendar days in advance of an onsite Audit and fourteen (14) calendar days in advance of a focused investigation Audit. The Pharmacy Auditor shall notify an Audited Pharmacy of a retrospective Audit by providing a written request for documentation to be provided within twenty (20) business days.
3. The Audited Pharmacy shall cooperate with the Pharmacy Auditor so that the Pharmacy Auditor can make timely assessment of the Audited Pharmacy's adherence to CalOptima Health Pharmacy program policies and procedures, to the terms of the PPA, and to applicable federal, state and local laws and regulations. The Audited Pharmacy shall comply with the deadlines established in writing by the Pharmacy Auditor for the Pharmacy to submit requested documentation and for submission of an appeal.
4. If an Audited Pharmacy fails to present to the Pharmacy Auditor the Records required to be maintained in accordance with the PPA, CalOptima Health may take action as set forth in Section III.G of this Policy.
5. In conjunction with an Audit, the Pharmacy Auditor may review the claims database and the Pharmacy's Records to determine whether the Audited Pharmacy has met the performance standards and Audit selection criteria set forth in Section III.B of this Policy and to detect unusual variances from mean, required, or expected performance in, but not limited to, the following factors:
 - a. Prescription utilization or cost;

- b. Volume of OTC Prescriptions;
 - c. Total dollar volume vs. volume of prior authorization activity;
 - d. Medical incident-associated Prescriptions (e.g., cough and cold liquids and analgesics prescribed with every antibiotic Prescription);
 - e. Prescription claim volume vs. observed customer traffic;
 - f. Prescription claim volume vs. observed inventory and Records.
6. For onsite Audits and focused investigative Audits, the Pharmacy Auditor shall present its initial findings to the Audited Pharmacy at an exit interview at the end of the onsite portion of such Audit. For retrospective Audits, the Pharmacy Auditor shall present its initial findings to the Audited Pharmacy by sending a written report of the findings to the Audited Pharmacy within forty-five (45) calendar days after receipt of the requested documentation from the Pharmacy. In the event an overpayment amount is determined, the written report of initial findings shall include notice of the amount of funds that may be subject to recoupment.
 7. For onsite Audits, the Pharmacy Auditor shall provide in writing with the initial findings any corrective actions that may be required in order to be considered in compliance with standards. The Audited Pharmacy shall perform the corrective actions and respond in writing as instructed by the Pharmacy Auditor.
 8. If the Audited Pharmacy disagrees with the Pharmacy Auditor's initial findings or corrective action(s), the Audited Pharmacy may appeal within ten (10) days after receiving the Pharmacy Auditor's written report by sending a written appeal to the Pharmacy Auditor explaining the reasons for the appeal. The Pharmacy Auditor shall evaluate the appeal based on the Records originally presented by the Audited Pharmacy. The Pharmacy Auditor shall respond to the appeal in writing within ten (10) calendar days after receipt of the appeal request by either rejecting the appeal or revising the initial findings or corrective actions. In any event, all Audit findings shall be deemed final thirty (30) calendar days after the receipt of the Pharmacy Auditor's written report of initial findings.

E. Audit Results

1. Within forty-five (45) calendar days after the findings become final, the Pharmacy Auditor shall provide in writing to CalOptima Health the final Audit findings, any corrective actions taken, and a summary of appeals, if any.
2. CalOptima Health shall be responsible for reviewing the Pharmacy Auditor's final findings and may modify or take additional actions authorized by this Policy or the PPA within forty-five (45) calendar days after receipt of the Pharmacy Auditor's final findings.
3. If CalOptima Health modifies or takes additional actions, CalOptima Health shall notify the Audited Pharmacy in writing, including an explanation of the Pharmacy's right to file a grievance with respect to the decision. Decision(s) shall be effective within fifteen (15) calendar days after the date of notification unless the Pharmacy makes a timely request to file a grievance.

4. Copies of Audit findings, any action taken by CalOptima Health, and any supportive documentation, may be sent to the appropriate regulatory and law enforcement agencies including, but not limited to, the following:
 - a. California Board of Pharmacy;
 - b. California Department of Justice, Bureau of Medi-Cal Fraud; and
 - c. Department of Health Services, Southern California Investigations Section.

F. Corrective Actions

1. CalOptima Health, its PBM, or the Pharmacy Auditor may require the Audited Pharmacy to take corrective actions materially related to the requirements of the PPA or CalOptima Health's policies and procedures as published in the Pharmacy Manual.

G. Recoupment of Overpayments, Sanctions, and Termination. In addition to any other remedy available under applicable law, CalOptima Health may impose any of the following sanctions, in any combination, based upon final Audit findings:

1. Recoupment of Overpayment: CalOptima Health may direct its PBM to make recoupments for overpayments made to a Pharmacy by deducting the recoupment from the next payment due to the Participating Pharmacy, by reversing the affected paid claims in full, or by reversing and resubmitting the affected paid claims in the correct amount due.
 - a. For overpayments documented on a retrospective Audit, the recoupment amount shall be one hundred percent (100%) of the overpayment amount.
 - b. For overpayments documented on a focused investigation Audit, CalOptima Health may recoup an amount using probability sampling to extrapolate the recouped amount when the extrapolated recoupment amount exceeds the cost to CalOptima Health of doing the Audit.
 - c. The PBM shall notify the Audited Pharmacy in writing of recoupments related to a focused investigation Audit. In the event the total amount of recoupment is greater than the total of the next payment due to the Pharmacy, CalOptima Health or the PBM shall notify the Pharmacy in writing to remit the balance of the amount due directly to CalOptima Health within fifteen (15) calendar days after the date of the initial portion of the recoupment.
 - d. The PBM shall forward a confirmation of recoupments made to CalOptima Health including the date of the billing cycle from which the recoupment was deducted.
2. Sanction by Stipulations: CalOptima Health may place specific conditions or requirements on a Pharmacy's participation in the program. Such stipulations shall be in writing and may remain in effect for a predetermined period of time or until the Pharmacy complies with the stipulation as determined by CalOptima Health. In the event the Pharmacy does not comply with the stipulation or does not comply within the specified time, CalOptima Health may take any other actions set forth in this section.
3. Termination from Pharmacy Program: CalOptima Health may recommend a Participating Pharmacy's termination in accordance with the terms of the PPA.

H. Appeals and Grievances

1. An Audited Pharmacy may appeal the initial findings of an Audit in accordance with Section III.D.8 of this Policy.
2. If an Audited Pharmacy is not satisfied with the final findings of an Audit or with CalOptima Health's decision related to those findings, the Audited Pharmacy may file a grievance with the PBM in accordance with CalOptima Health Policy HH.1101: CalOptima Health Provider Complaint and MA.9006: Contracted Provider Complaint Process within fifteen (15) calendar days after the date of notification of such final findings or of CalOptima Health's decision.
3. If a timely request for a grievance is filed, any actions specified in association with the Audit or decision made by CalOptima Health shall be stayed during the grievance process, unless CalOptima Health determines that to stay such actions or decision is not in the best interests of its Members. If a timely grievance is not requested, the actions or decision shall be effective upon the expiration of the period during which a grievance may be requested.
4. The decisions of any provider grievance shall be final and binding upon all parties.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

- A. CalOptima Health Contract Between Orange County Health Authority d.b.a. CalOptima Health and MedImpact
- B. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
- C. CalOptima Health Contract for Health Care Services
- D. CalOptima Health Pharmacy Benefit Manager Agreement
- E. CalOptima Health Pharmacy Services Program Manual
- F. CalOptima Health Policy MA.5012: Pharmacy Network: Credentialing and Access
- G. CalOptima Health Policy GG.1619: Delegation Oversight
- H. CalOptima Health Policy HH.1101: CalOptima Health Provider Complaint
- I. CalOptima Health Policy HH.1107: Fraud, Waste, and Abuse Investigation and Reporting
- J. CalOptima Health Policy MA.9006: Contracted Provider Complaint Process
- K. Participating Pharmacy Agreement
- L. California Business and Professions Code, §4040

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

Date	Meeting
01/11/2000	Regular Meeting of the CalOptima Board of Directors
08/10/2004	Regular Meeting of the CalOptima Board of Directors
02/01/2005	Regular Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	04/01/1999	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	11/01/1999	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	08/01/2000	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	02/01/2005	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	09/01/2016	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	10/01/2017	GG.1408	Pharmacy Audits and Reviews	Medi-Cal
Revised	10/01/2018	GG.1408	Pharmacy Audits and Reviews	Medi-Cal OneCare OneCare Connect
Revised	08/01/2019	GG.1408	Pharmacy Audits and Reviews	Medi-Cal OneCare OneCare Connect
Revised	08/01/2020	GG.1408	Pharmacy Audits and Reviews	Medi-Cal OneCare OneCare Connect
Revised	09/01/2021	GG.1408	Pharmacy Audits and Reviews	Medi-Cal OneCare OneCare Connect
Number retirement	01/01/2023	GG.1408	Pharmacy Audits and Reviews	Medi-Cal OneCare Connect
Revised	01/01/2023	MA.5013	Pharmacy Audits and Reviews	OneCare PACE
Revised	12/01/2024	MA.5013	Pharmacy Audits and Reviews	OneCare PACE

IX. GLOSSARY

Term	Definition
Audit	Any review or audit of a Pharmacy performed by CalOptima Health, CalOptima Health's authorized representative, or by any regulatory or law enforcement agency, except, however, a review or audit of a Pharmacy conducted by the PBM or its designee.
Audited Pharmacy	The Pharmacy identified by CalOptima Health or the Pharmacy Auditor to be the subject of an Audit.
Chain Pharmacy	Multiple licensed retail Pharmacies operated under a single business name and logo in a standardized manner, which follow a uniform set of policies and procedures covering all aspects of their operation, and which are organized under a single ownership and management structure (definition excludes franchises).
Member	A beneficiary enrolled in a CalOptima Health program.
Participating Pharmacy	Any Pharmacy that is credentialed by and contracted with the PBM to provide Pharmaceutical Services to Members.
Participating Pharmacy Agreement (PPA)	The contract between the PBM and each Participating Pharmacy that provides Pharmaceutical Services to Members.
Participating Pharmacy Network	The Pharmacies that are authorized by the PBM to provide Pharmaceutical Services to Members, as set forth in CalOptima Health's list of Participating Pharmacies.
Pharmaceutical Services	Covered drugs and related professional services provided to a Member pursuant to applicable state and federal laws, CalOptima Health's Pharmacy Services Program Manual, and the standard of practice of the Pharmacy profession of the state in which the Pharmacy is located.
Pharmacist	A person to whom the State Board of Pharmacy has issued a license, authorizing the person to practice Pharmacy.
Pharmacy	An area, place, or premises licensed by the State Board of Pharmacy in which the profession of Pharmacy is practiced and where Prescriptions are compounded and dispensed, and for the purpose of this policy, the licensed dispensing area of a community clinic.
Pharmacy Auditor	The entity contracted by CalOptima Health to perform audits of its participating pharmacies, including review of the prescribing records of Prescribing Providers.
Pharmacy Benefit Manager (PBM)	The entity that performs certain functions and tasks including, but not limited to, Pharmacy credentialing, contracting, and claims processing in accordance with the terms and conditions of the PBM Services Agreement.
Pharmacy Benefit Manager (PBM) <u>Services Agreement</u>	The written agreement between a PBM and CalOptima Health regarding the delivery and maintenance of the Participating Pharmacy Network.
Pharmacy Manual	The CalOptima Health Pharmacy Program Services Manual, which contains program information, policies and procedures, and various forms.
Pharmacy Technician	A person who assists a Pharmacist in the performance of Pharmacy-related duties, to whom the State Board of Pharmacy has issued a certificate of registration to act as a Pharmacy Technician.

Term	Definition
Prescribing Provider	The physician, osteopath, podiatrist, dentist, optometrist, or authorized mid-level practitioner who prescribes medications or medical supplies for a Member.
Prescription	An oral, written, or electronic transmission order that meets the requirements of the California Business and Professions Code, Chapter 9, Division 2, Article 2, Section 4040.
Purchase Records	All of the Participating Pharmacy's purchase invoices, periodic statements, and credit or return memos from all sources, and documentation of the Participating Pharmacy's payments for all drug or medical supply acquisitions, including business bank statements, copies of checks, and any other documents required by the PBM or CalOptima Health.
Records	All physical and electronic Records of drug and medical device acquisition from and disposition to all persons and entities including, but not limited to: drug wholesalers, drug manufacturers and distributors, other pharmacies and Members, and any other documentation related to the terms of the PPA. Such Records include, but are not limited to: license and credentialing Records, claims transaction Records, Purchase Records, Prescriptions (including all Prescription-related physical and electronic notations), all Member signature logs, Records of payments for drug and device acquisitions, and remittance advice Records from PBM.
Unsubstantiated Claims	Claims for medications, pharmaceutical or nutritional products or medical supplies that are not supported by the Participating Pharmacy's Records, supplier's Records, or a Member's medical Records.