

Audit assistance ... you're not alone anymore

Leader® Total Pharmacy Manager



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benefits
Pharmacy benefits
and features
features

General information

Audit assistance is a value-added service, providing comprehensive professional, educational and informational services and support to participating member pharmacies.

It is designed to help pharmacies:

- Understand what triggers an audit
- How to improve performance and compliance
- How to identify and prevent prescription fraud and abuse

Audit assistance services and support include:

- Coordination and assistance from the point of audit notification to review of final discrepancy reports and appeals
- Education and information on applicable state and federal laws, rules and pharmacy regulations
- Audit preparedness and procedures
- Common and potential audit “triggers”
- Rights and responsibilities
- Auditable records

- HIPAA compliance
- PBM guidelines and exceptions
- Website resources

With audit assistance you will:

- Gain knowledge and education to prepare for audits
- Gain insight on increased third-party accuracy and submit “clean” prescription claims
- Receive tips for audit compliance
- Minimize unforeseen expenses
- Obtain a better understanding of HIPAA regulations
- Experience fair pharmacy audit charge-backs

For more information, contact your Cardinal Health Pharmacy Business Consultant or Amy Myers, CPhT, Audit Specialist, Leader® Member Services at amy.myers@cardinal.com.



Rights and responsibilities

Tips to remember

- If applicable, all additional information supplied to the auditor should be a copy; do not give an auditor original information or documentation from your pharmacy records
- Know what information you should supply.
- Know which questions you should answer.
- Information and questions requested by the auditor should only pertain to those claims that were previously selected for the audit by that particular PBM or plan.
 - Answering questions not related to selected claims is a HIPAA violation, and could provide grounds for fines to your pharmacy or the PBM.
- You have the responsibility to maintain patient confidentiality.
 - Never grant an auditor unsupervised access to pharmacy records or volunteer additional claim information.

Know your rights and responsibilities before the audit. As part of the preparation process, start by reading over the PBM/Plan Pharmacy Manual. Most major third-party manuals are posted on myleader.com. This will give you a better understanding of the contractual and procedural guidelines as well as obligations to help prepare for the audit.

Both the pharmacy and the auditor have the right and responsibility to be professional and conduct the audit in a businesslike manner. The pharmacy has the responsibility to supply certain information and documentation requested by the auditor.

Preparing for an audit

What should I expect when an audit is scheduled in my pharmacy?

The best way to prepare for any audit is to be well organized. This will save time and cause less disruption to the pharmacy, your staff and your patients. Completing the pharmacy audit checklist (a copy of the checklist is included on page 7) and having all information available prior to the scheduled audit will make the process more efficient for all.

Key preparation tips include:

- Create and document all pertinent audit information and details for all prescriptions identified by the PBM.
- Inform pharmacy staff of the upcoming audit and direct all questions from the auditor to the scheduled pharmacy staff member designated to assist.
- Prepare a clean, quiet, detached workspace near an electrical outlet for the auditor.
- Read and review the audit sections of the PBM or plan manual prior to the arrival of the auditor.

On the day of the audit you should expect the auditor to arrive at the designated time, be polite and maintain professional behavior. The auditor should show identification and sign into the pharmacy visitor log. Once they have set up, the auditor should go over basic audit procedures,

expectations, review the agenda for the day of the audit and future communications, and any other information pertaining to or required for the audit. The auditor will be in the pharmacy for at least two hours, depending on how many scripts he/she is looking at and how much additional information or documentation will be requested during the audit.

Note: State, Federal and Fraud audits can take several hours or even days.

Once the audit is completed, the auditor should inform you of the findings. This is a great time to ask questions such as:

- What to expect next?
- How or why was I selected for an audit?
- Which prescriptions were selected and why?
- How can I avoid audits in the future?

Some PBMs or plans will have pre-printed educational materials and documentation policies that the auditor will explain and leave at the pharmacy (share these with your pharmacy staff). The auditor should also:

- Outline the post-audit and appeal procedures.
- Tell you approximately when you should receive the discrepancy evaluation report or congratulatory letter (if applicable).
- Leave contact information with you for future questions or concerns.

Pharmacy Pharmacy documentation documentation

The following pharmacy documentation needs to be readily available for the scheduled auditor and attending auditor to view in the pharmacy or upon request.

Mandatory documents are:

- State pharmacy license
- Pharmacy DEA license
- All pharmacist license and DEA license
- All pharmacy technician license nos. (in state where applicable) or certificate
- Insurance certificate/affirmation of coverage
- Patient signature logs

Documents that may be required or requested could include:

- Delivery logs (if applicable)
- Shipped/mailed logs (if applicable)
- Controlled substance logs
- U & C price chart (if printed)
- Desktop or Internet references
- Policy and procedures or pharmacy manuals
- HIPAA guidelines and procedures

Auditable records *(in accordance with industry standards, applicable laws, rules and regulations)*

1. All prescriptions, including paper, verbal, telephone and computer generated
2. Signature logs
3. Quality assurance plans and/or dispensing procedures
4. Daily prescription logs
5. Wholesaler, manufacturer and distributor invoices
6. Refill information
7. Prescriber information
8. Patient information
9. Transfer of prescription stock/records
10. Pharmacy records stored electronically
11. Compounded prescriptions dispensed by pharmacy
12. Medication pricing brochures for cash customers

HIPAA HIPAA privacy and how it may affect your audit privacy

As you are aware, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA") require pharmacies to enter into business associate agreements with their "business associates." In the course of providing services to you. We may receive Protected Health Information (PHI) as defined by HIPAA, and you would be considered a "business associate" within the meaning of 45 CFR Parts 160 and 103. Now, as a result of the implementation of the HIPAA security standards the business associate agreements (BAA) must be completed, signed and received by Leader®/LeaderNET® then placed in the pharmacy's file for reference and compliance.

What does this mean for you?

When a pharmacy contacts the Leader®/LeaderNET®/Managed Care Connection Help Desks or other staff members directly to resolve issues relating to audit, enrollment, claims, member eligibility, reimbursement and other related support activities, we will not be able to obtain patient or claim information from you to resolve your issues in a timely manner, without this form on file. In order to provide you with a prompt response, we ask that you fax a BAA back at your earliest convenience when requested.

We may have enclosed a copy of the BAA in this packet, if records do not indicate a current copy on file. This will be used to facilitate your compliance with the applicable provisions of both the Privacy and Security Rules regarding the business associate relationship.

How may it affect your audit?

Leader®/LeaderNET®/Managed Care Connection support staff will not be able to assist in the review of claim information, receive/request copies of audit discrepancy reports or speak with the PBM's, auditors or audit entity on your behalf to resolve audit issues.

What PHI to protect:

- Patient name
- Address and phone
- Social Security number or identification number
- Name of medication or NDC number dispensed
- Prescription number
- Procedures or test Information

During an audit by phone, desk, or on-site, it is imperative to secure patient information and claims data. The auditor may only request and review information that is proprietary to their PBM/Plan. Inappropriately allowing the auditor access or releasing the above information may result in a HIPAA violation, and/or violate a patient's privacy. Misuse or violation could result in a Federal penalty punishable by fine up to \$50,000 or imprisonment for a term of up to one year.

Pharmacy
Pharmacy records
records

Pharmacy audit checklist



Pre-audit

- Audit notification letter received from PBM
- Acknowledgment of Leader® notification
- Audit scheduled
- Re-scheduled
- Arrival times
- Audit masked list received (if applicable)
- Prescription books pulled and arranged in order of masked list
- Scheduled staff to assist

Day of audit

- Prepared clean, quiet, well lit and detached workspace near electrical outlet for auditor and away from the pharmacy counter
- Auditor identification verified or business card presented
- Auditor name _____
- Auditor signed visitor log in accordance with HIPAA security regulations
- Pharmacy documentation made available
- Staff list printed and provided to auditor or auditing entity
- Completed audit log sheet
- Question and answer list for auditor
- Overview of audit findings reviewed with auditor or auditing entity

Post-audit

- Received copy of discrepancy evaluation report or congratulatory letter
- Received educational or informational materials from auditor
- Obtain auditor business card or contact information
- Provided copies of additional information requested by auditor
- Completed appeal process and letter (if applicable)
- Established repayment schedule (if applicable)

Date _____

Date _____

Date _____ Time _____

Date _____ Time _____

Time _____

Date _____

Name _____

Name _____

Auditing agency _____

Date _____

Date _____

References

References

Audit assistance tips *tips*

Each Pharmacy Benefit Manager (PBM), state or federal entity employs similar audit procedures. The types of audits and procedures for each entity are outlined in their respective pharmacy services manual or in state or federal pharmacy audit guidelines. Audits may be random, or a result of “triggers” indicating pharmacy trends outside the normal processing. Every community pharmacy should anticipate participating in an audit; anticipating this will reduce the potential “triggers” and make for a more successful outcome.

Types of audits

Desk Desk audits are when an auditor identifies paid claims with possible discrepancies. Most PBMs review claims on a daily basis. The pharmacy can be contacted by fax, phone or e-mail.

Mail A mail audit is similar to a desk audit of several claims for a particular pharmacy. The pharmacy will be contacted via letter requesting specific prescription information.

On-site On-site audits are random or can be triggered. Triggers can include specific claim trends, preview audit findings, news articles, information from pharmacists, staff, physicians, law enforcement, plan members or clients.

When a pharmacy receives notification of an on-site audit, confirm the schedule and records required for the audit. Though an audit typically covers the previous year, it may cover several years, as allowed by the contract (confirm all contract specifications with your Leader® audit specialist). A pharmacy employee should be the individual that pulls all prescriptions for an audit to ensure compliance with HIPAA.

At the conclusion of the audit, the pharmacy should review all findings prior to the auditor or auditing entity leaving. Any clarification of additional documentation that may be required to support claims should also be covered at this time. An appropriate time table should be provided for the pharmacy to respond to the results of an audit. Additional time may be requested by your pharmacy to follow up.

For assistance, contact your Leader® audit specialist at 800.200.6313.



Common audit "triggers"

1. High average ingredient cost
2. High claim volume
3. High refill rate
4. High compound submission rate
5. High DAW-1 submission on multisource brands
6. High claim reversal rate
7. Low claim reversal rate
8. Quantity vs. day supply
9. Nonbreakable packaged medications
10. Low rate of claims paid at U & C
11. Incorrect DEA or license numbers
12. Generic substitution rate



Tips for the pharmacy

1. Know and follow all applicable state laws, rules and pharmacy regulations.
2. Review contract and related pharmacy services manual(s).
3. Perform self-audits.
4. Submit correct information including: DAW, quantity, day supply, DEA or license number.
5. Review all online messages during the adjudication process to ensure plan compliance.
6. Do not reduce a days supply submitted to adjudicate a claim after receiving a rejection for exceeding plan limits. Appropriately reduce the quantity dispensed to accommodate plan limitations or contact the plan for further clarification.
7. Review payment remittances or reconciliation reports to find errors resulting in an underpaid or overpaid claim by the PBM.
8. Document quantity of medication used on an “as directed” prescription and use to calculate day supply.
9. Verify the number of drops per milliliter a PBM uses to calculate day supply to reduce overbilling liquid nonbreakable packages.

Dispense as written

DAW Code definitions

The following are NCPDP Standard DAW codes. These codes should be part of the claim record whenever a multi-source brand drug product is dispensed. Proper use of the correct DAW code is important for reimbursement and copay processing.

DAW – 0

Generic or single-source brand. No product selection indicated

This is a field default value that is appropriately used for prescriptions where selection is not an issue. Examples include prescriptions written for single source brand products and prescriptions written using the generic name and a generic product is dispensed. Plans mandate that generic pricing be applied when DAW – 0 is submitted.

DAW – 1

Physician DAW. Substitution not allowed by prescriber

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws that the product is to be “Dispensed As Written”. This may be subject to verification.

DAW – 2

Pharmacist selected brand. Substitution allowed – patient requested product dispensed

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws, that generic substitution is permitted and the patient requests the brand product. This situation can occur

when the prescriber writes the prescriptions using either the brand or generic name and the product is available from multiple sources. “Patient requested brand” should be documented on the prescription and may affect patient copay.

DAW – 3

Pharmacist selected brand. Substitution allowed – pharmacist selected product dispensed

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws, that generic substitution is permitted and the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources. Plans mandate that generic pricing be applied when DAW – 3 is submitted.

DAW - 4

Substitution allowed – generic not in stock

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws that the generic substitution is permitted and the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation

exists due to the buying habits of the pharmacist, not because of the availability of the generic product in the marketplace. Plans mandate that generic pricing be applied when DAW – 4 is submitted.

DAW – 5

Substitution allowed – brand drug dispensed as generic

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws, that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity. Plans mandate that generic pricing be applied when DAW – 5 is submitted.

DAW – 6

Override

NCPDP Override code with no meaningful application. Plans mandate that generic pricing be applied when DAW – 6 is submitted.

DAW – 7

Substitution not allowed – brand drug mandated by law

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws, that

generic substitution is permitted, but prevailing law or regulation prohibits the substitution of a brand product, even though generic versions of the product may be available in the marketplace.

DAW – 8

Substitution allowed – generic drug not available in marketplace

This value is used when the prescriber has indicated, in a manner specified by prevailing state laws, that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed or is temporarily unavailable. Plans usually mandate that generic pricing be applied when DAW – 8 is submitted.

DAW – 9

Other

NCPDP code with no meaningful application by PAID. Plans mandate that generic pricing be applied when DAW – 9 is submitted

Inhalers

Inhalers

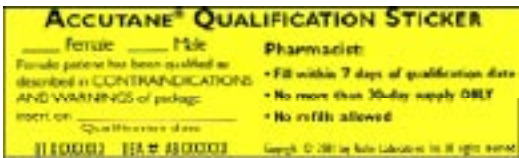
Information compiled by Leader® based on manufacturer and First Data Bank information.

Inhaler	Size	Dose/unit	MAX dosage	Sprays/ inhalations per day	Days supply
Advair Diskus	1	60 Blisters	1 inh twice a day - max 2 inh a day	2	30
Albuterol Inhaler	17GM	200	2 inh every four hours	12	17
Albuterol HFA Inhaler	9GM	200	2 inh every four hours	12	17
Aerobid Inhaler	7GM	100	2 inh every four hours	12	17
Aerobid M Inhaler	7GM	100	2 inh four times a day	8	13
Alupent Inhaler	7GM	100	2 to 3 inh every three to four hours - max 12 inh a day	12	8
Alupent Inhaler	14GM	200	2 to 3 inh every three to four hours - max 12 inh a day	12	17
Astelinal Nasal Spray	30ML	200	2 sprays in each nostril twice a day	8	25
Atrovent HFA Inhaler	13GM	200	2 inh four times a day - max 12 inh a day	12	17
Atrovent 0.03% Spray	30ML	345	2 sprays in each nostril three times a day	12	29
Atrovent 0.06% Spray	15ML	165	2 sprays in each nostril four times a day	16	10
Azmacort Inhaler	20GM	240	2 inh every three hours	16	15
Beclovent Inhaler	7GM	80	2 inh every three to four hours	10	8
Beclovent Inhaler	17GM	200	2 inh every three to four hours	10	20
Beconase Nasal Inhaler	7ML	80	1 spray in each nostril four times a day	8	10
Beconase Nasal Inhaler	17ML	200	1 spray in each nostril four times a day	8	25
Beconase AQ Nasal Inhaler	25GM	180	2 sprays in each nostril twice a day	8	22
Brethair Inhaler	11GM	300	2 inh every four hours	12	25
Bronkometer Inhaler	10ML	200	2 inh every four hours	12	17
Bronkometer Inhaler	15ML	300	2 inh every four hours	12	25
Combivent Inhaler	15GM	200	2 inh every four hours	12	17
DDAVP Nasal Spray	5ML	50	0.1ml to 0.4 ml daily in two to three divided doses	4	13
Dexacort Turbinaire Nasal Spary	13GM	170	2 sprays in each nostril three times a day	12	14
Duo-Medihaler	15ML	300	2 inh every four hours	12	25
Duo-Medihaler	23ML	450	2 inh every four hours	12	38
Flonase Nasal Spray	16GM	120	2 sprays in each nostril once daily	4	30
Flovent HFA 44 MCG Inhaler	11GM	120	2 inh twice a day - max 440 mcg twice daily	10	12
Flovent HFA 110 MCG Inhaler	12GM	120	2 inh twice a day - max 440 mcg twice daily	4	20
Flovent HFA 220 MCG Inhaler	12GM	120	2 inh twice a day - max 880 mcg twice daily	4	30
Intal Inhaler	9GM	112	2 inh four times a day	8	14
Intal Inhaler	15GM	200	2 inh four times a day	8	25
Suprel Inhaler	12GM	200	2 inh every three hours	16	13

Inhaler	Size	Dose/unit	MAX dosage	Sprays/ inhalations per day	Days supply
Suprel Inhaler	15ML	300	2 inh every three hours	16	19
Maxair Inhaler	26GM	300	2 inh every four hours	12	25
Maxair AutoInhaler	14GM	400	2 inh every four hours	12	33
Miacalcin Nasal Spray	4ML	30	1 spray in each nostril once daily-alternate nostrils	1	30
Nasacort Nasal Spray	10GM	100	2 sprays in each nostril twice a day	8	13
Nasacort AQ Nasal Spray	17GM	120	2 sprays in each nostril once daily	4	30
Nasal crom Nasal Spray	13ML	100	1 spray in each nostril every four to six hours	12	8
Nasal crom Nasal Spray	26ML	200	1 spray in each nostril every four to six hours	12	17
Nasalide Nasal Spray	25ML	200	2 sprays in each nostril twice daily - max 8 sprays/nos a day	16	13
Nasarel Nasal Spray	25ML	200	2 sprays in each nostril twice daily - max 8 sprays/nos a day	16	13
Nasonex Nasal Spray	17GM	120	2 sprays in each nostril 1 to 2 times a day	8	15
Proventil Inhaler	17GM	200	2 inh every four hours	12	17
Proventil HFA Inhaler	7GM	200	2 inh every four hours	12	17
Pulmicort Turbuhaler	1	200	4 inh twice a day	8	25
Rhinocort Nasal Spray	7GM	200	2 sprays in each nostril twice a day	8	25
Rhinocort Aqua Nasal Spray	9GM	120	max 4 sprays per nostril once daily	8	15
Serevent Diskus	1	60 blisters	1 inh every 12 hours - max 2 inh a day	2	30
Servent Inhaler	7GM	60	2 inh every four hours	4	15
Servent Inhaler	13GM	120	2 inh every four hours	4	30
Stadol Nasal Spray	3ML	14 to 15	1 - 2 sprays in each nostril prn - may rpt prn q 3 to 4 hours	12	1
Synarel Nasal Spray	10ML	60	1 spray in one nostril twice a day	2	30
Tilade Inhaler	17GM	104	2 inh four times a day	8	13
Tornalate Inhaler	17GM	300	3 inh every six hours	12	25
Vancenase AQ DS Nasal Spray	19GM	120	2 sprays in each nostril once daily	4	30
Vancenase Pockethaler	7GM	200	1 spray in each nostril four times a day	8	25
Vanceril Inhaler	17GM	200	4 inh five times a day	20	10
Vanceril DS Inhaler	13GM	120	2 inh five times a day	10	12
Ventolin Inhaler	7GM	80	2 inh every four to six hours	12	7
Ventolin Inhaler	17GM	200	2 inh every four to six hours	12	17
Ventolin HFA Inhaler	18 GM	200	2 inh every four to six hours	12	17

Accutane[®], Amnestein, Clavaris and Sortet guidelines

The yellow self-adhesive sticker, known as the Accutane[®] Qualification Sticker indicates that the physician and the patient have complied with the FDA mandated risk management program called S.M.A.R.T — System to Manage Accutane[®] Related Teratogenicity. Effective April 10, 2002, all Accutane[®] prescriptions must have a properly completed yellow sticker. What does this mean? It means that the prescriber and the patient have taken the necessary safety precautions and requirements to “qualify” the patient to take the medication.



Important information for pharmacists

Accutane[®] (Isotretinoin) may only be dispensed as follows:

- Only on presentation of an Accutane[®] prescription with a completed yellow self-adhesive Accutane[®] Qualification sticker for female and male patients
- No telephone or computerized prescriptions are permitted or accepted
- Prescription written and filled within previous seven (7) days of the date of “qualification” on the Accutane[®] Qualification sticker. The first day does count as day no.1.
- Dispense no more than a 30-day supply
- No refills — refills require a new prescription with an Accutane[®] Qualification sticker
- A copy of the Accutane[®] Medication Guide must be provided to patients with each dispensed prescription, as required by law.

Female Accutane® (Isotretinoin)

patient requirements:

- Must have two (2) negative urine or serum pregnancy tests before an Accutane® prescription is written and an additional test each month during treatment.
- Must have selected and committed to use two (2) forms of effective contraception for one month prior, during and after Accutane® treatment.
- Must have signed a patient information/consent form.
- Must have been informed of the purpose and the importance of participation in the Accutane® Survey. (The Accutane® Survey will collect data to help Roche Laboratories and the FDA decide if S.M.A.R.T is helping to prevent exposure on unborn babies to Accutane®.)

Male Accutane® (Isotretinoin)

patient requirements:

- Must be aware of the possibility of birth defects if an unborn child is exposed to Accutane®.
- Must be instructed to not share Accutane® or donate blood while they are taking Accutane®.

If pregnancy does occur during treatment, the prescriber and patient should discuss the desirability of continuing the pregnancy. Prescribers are strongly encouraged to report all cases of pregnancy to a Roche pregnancy prevention specialist at 800.526.6367 or the FDA MedWatch program at 800.FDA.1088.

Amnesteem, Clavaris and Sotret are generic versions of Isotretinoin and may be dispensed for any valid Accutane® prescription. As with the dispensing of Accutane®, a yellow self-adhesive qualification sticker must be affixed to the patient's prescription for Amnesteem, Clavaris and Sotret.

Ophthalmic drops days supply guidelines

Bottle size	Drops per day	Days supply
2.5 ml	1 gtt	30
2.5 ml	2 gtts	25
5 ml	1 gtt to 3 gtts	30
5 ml	4 gtts	25
5 ml	5 gtts	20
5 ml	6 gtts	16
5 ml	7 gtts	14
5 ml	8 gtts	12
5 ml	9 gtts	11
5 ml	10 gtts	10
5 ml	12 gtts	8
10 ml	1 gtt	200
10 ml	2 gtts	100
10 ml	3 gtts	66
10 ml	4 gtts	50
10 ml	5 gtts	40
10 ml	6 gtts	33
10 ml	8 gtts	25
10 ml	10 gtts	20
10 ml	12 gtts	15
15 ml	1 gtt	300
15 ml	2 gtts	150
15 ml	3 gtts	100
15 ml	4 gtts	75
15 ml	5 gtts	60
15 ml	6 gtts	50
15 ml	8 gtts	37
15 ml	10 gtts	30
15 ml	12 gtts	25

Based on 20 gtts per 1 ml

Be sure to calculate the number of drops per day by the bottle size (total ml) to get the days supply

= More than a 30 day supply and may not be covered due to plan limitations

Contacts

Contacts

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staff — audits

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Roster of Boards of Pharmacy *executives* Pharmacy

State and federal guidelines are kept on file and will be accessible on myleader.com and mcareconnect.com

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