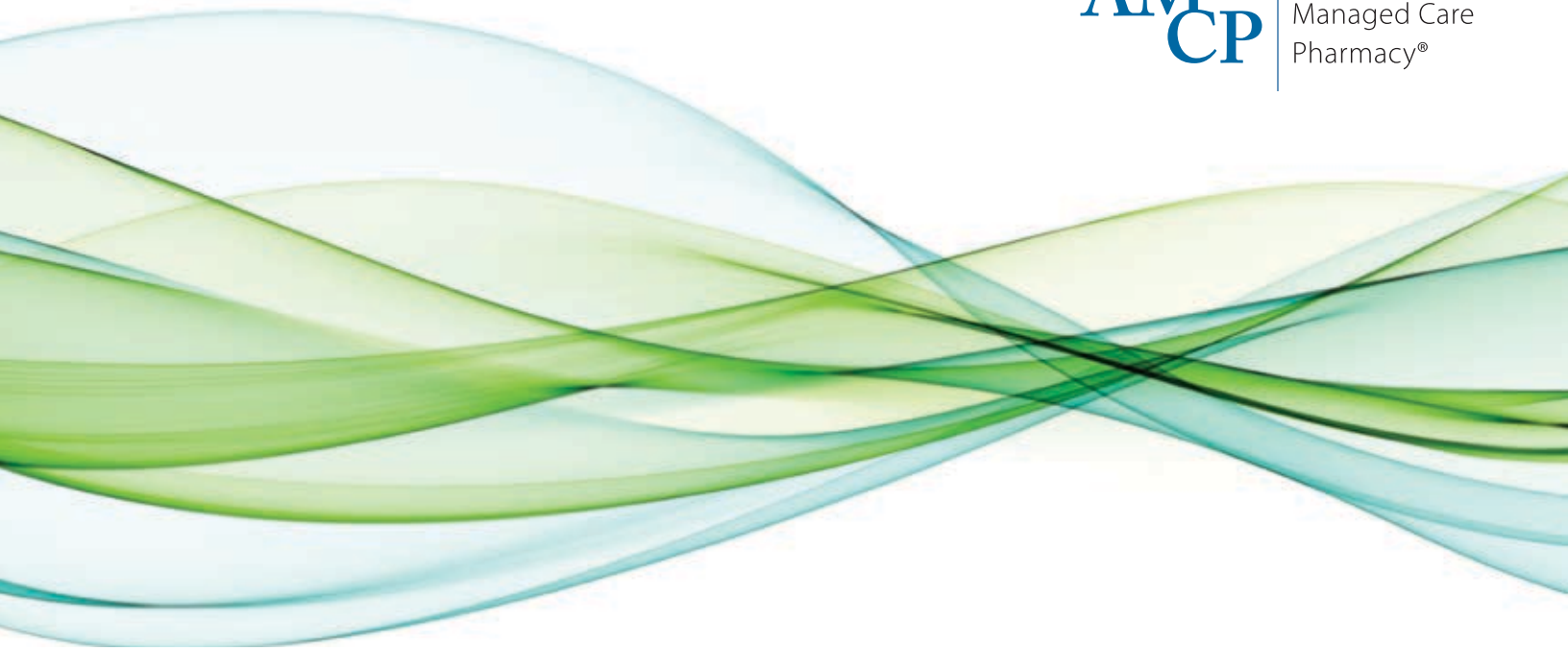

# Model Audit Guidelines

## *for Pharmacy Claims*


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NOTE: The *AMCP Model Guidelines for Pharmacy Claims* do not necessarily represent the views of the individual Task Force members or their organizations.

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# INTRODUCTION

In 2009, the Academy of Managed Care Pharmacy (AMCP) established the Community Pharmacy Outreach Advisory Council to address issues that managed care pharmacy and community pharmacy share and that would lead to an enhanced relationship. The Council identified auditing of pharmacy claims as a high priority issue largely because of the friction it causes for both community and managed care pharmacy. The Council conducted a poll to learn about the issues that both practices had with auditing and determined that model guidelines for pharmacy claims auditing could serve as the foundation to address the issue.

The *AMCP Model Audit Guidelines for Pharmacy Claims* are the result of over a year-long effort by a Task Force comprised of pharmacists in managed care organizations[1] (MCOs), community practice and law; auditing administration; third party management; and, network administration.

It is important to note that while these *Guidelines* were developed for MCOs and community pharmacies as a way to improve the relationship between the parties, the contract between the MCO and the pharmacy should define the actual audit process. These *Guidelines* are offered to assist MCO's in developing a pharmacy claims audit program, and to help pharmacy providers to better understand the audit requirements and process.

# THE ROLE OF AUDITS

Historically, health care services, including prescription medications, were paid by the patient as an out of pocket expense. These payments may then have been reimbursed by a third party or self-funded insurance plan. Over the twentieth century health care insurance evolved from indemnity pre-paid insurance, to managed care emerging as a major mechanism of coverage. The growth of plan design, administration and payment by third-party entities, coupled with increases in the total costs of care, have required oversight of plans and their financial services. Audits of claims made by pharmacies and payments made to pharmacies are included in the oversight process.

The auditing of pharmacy claims serves two main purposes: 1) detecting fraud, waste and abuse, and 2) validating data entry and documentation to ensure they meet regulatory and contractual requirements.

## Fraud, Waste and Abuse

While a pharmacy may find audits unpleasant and disruptive as they are currently conducted, all providers need to recognize that audits remain the primary method presently available for MCOs to determine network pharmacy compliance and to identify fraud, waste and abuse (FWA) within the prescription drug benefit, as these contribute to the rising cost of health care.

With the launch of Medicare Part D in 2006 came an increase in federal funding of pharmacy benefits and a corresponding increase in the scrutiny of pharmacy claims and billing practices. Under the Centers for Medicare and Medicaid's (CMS) oversight of federally funded programs, plans and provider networks are subject to performance monitoring for compliance with and adherence to fraud, waste and abuse requirements that are well defined in federal law. The federal standards have led to an increasing level of oversight of pharmacy claims in commercial plans as well, and are reaching into the specialty pharmacy practices associated with long term care and home infusion pharmacies. Regardless of professional setting, an appreciation of the changing environment in which MCOs operate is essential for contemporary pharmacy practice and operation.

[1] Managed Care Organization (MCO) is used throughout the *Guidelines* and is defined as all types of MCOs including, but not limited to, health plans, PBMs, HMOs and contracted agents.

### Data Entry and Documentation

Another purpose of audits is to validate the correct entry of required pharmacy claims information. These are the audits most commonly experienced by MCOs and pharmacies, and are among those that cause the most difficulties.

The misunderstandings that arise from data verification are often preventable. The MCO should supply the pharmacy provider with a document that defines the requirements on which it may base an audit. This document must be updated and communicated as changes occur. The actual audits should be conducted in a manner that leads to continuous quality improvement of the services of the provider, rather than as a source of revenue. Further, the provider must review and be comfortable with these documents before it agrees to a contract. Once a contract is entered into, it is incumbent on the provider to commit to review and comply with the requirements.

## PHILOSOPHY and RESPONSIBILITIES

The audit is both a contract management essential and a public relations opportunity for the MCO. It is possible that the in-pharmacy audit is the only time the pharmacy provider and a representative of a MCO will ever meet in an official capacity. The way in which an audit is conducted can contribute substantially to the pharmacy staff's attitude about the MCO, and the MCO representative's attitude about the pharmacy's practice, and can affect the ongoing working relationship between the two parties and ultimately, patient care.

The audit experience, regardless of outcome, is often shared broadly with colleagues in the pharmacy practice community and back to the MCO. Experiences the pharmacy staff has with auditing, drug benefit design, benefit management, and help desk interaction can affect the attitude of the pharmacy staff towards the MCO. Therefore, the pharmacy staff is in a position to affect consumer perception of the health benefit broadly and the MCO's drug benefit specifically.

The audit provides an important opportunity for the MCO to market itself to the pharmacy staff by sharing the goals of the benefit design, discussing the importance of adherence to the contract, and gathering important market information from the pharmacy. The net result can be an improved relationship between the parties.

It is much easier for the pharmacy staff to understand the requirements of a MCO subject to audit if the goals of the drug benefit are shared. In many cases these goals are quite simple, e.g., target generic dispensing rates, adherence to formulary and compliance.

The audit process is a means of ensuring that pharmacy procedures and reimbursement mechanisms are consistent with regulatory and MCO contractual requirements. With increasing oversight of the cost of the many elements of health care, the frequency and nature of audits of pharmacy claims can only be expected to increase.

It is imperative that pharmacists-in-charge, and their staff, understand the dispensing and billing requirements and the implications of non-compliance. The pharmacy organization should consider appointing a "compliance officer" for the purpose of monitoring regulatory and MCO requirements and to ensure optimal performance of pharmacies.

A properly designed audit process should be transparent and have a fair design and implementation. Such a structure goes a long way towards fulfilling its purpose of assuring the performance of the pharmacy network. The auditors and the pharmacy staff must understand the elements of the audit process.

There are several considerations that will positively affect audit performance outcomes:

## PHILOSOPHY and RESPONSIBILITIES

*continued*

***Bilateral understanding and adherence to contract obligations:*** Both parties to the contract, and their representatives, should understand the obligations under the contract. This requires affirmative action of both parties.

***Transparency of audit guidelines, dispensing requirements and process:*** It is important to the process that the MCO makes the audit elements and audit process available to the network in a clearly defined usable manner, and updates this information when changes are made. If included in the contract, it is helpful if these porocesses appear in a separate section labeled as "audit elements." Without this transparency, the pharmacy may be left with the assumption that the audit is merely a way for the MCO to make more money. In the interest of compliance with the requirements, the MCO should routinely offer audit tips to its pharmacy network.

***Risk- or Incentive-based Auditing:*** Auditing of pharmacy claims that are paid for as a percentage of findings may lead to overzealous interpretation and frivolous recoupment of payment. It is strongly recommended that MCOs should avoid contracting pharmacy claims auditing based upon this practice.

***State dispensing regulations and published MCO claim submission requirements must work in concert:*** Audit requirements should not require the pharmacy staff to act contrary to state regulations. However, the claim submission requirements regarding plan benefit design, and the audit of same, may be additive to state laws, rules and regulations to the extent that the MCO requires it to correctly administer its defined benefit.

***Prescription Order Documentation:*** Pharmacy practice often requires modifications to the original prescription order after consultation with the prescriber or patient. These consultations must be documented by the pharmacist on the prescription order or electronic record. For example, a "use as directed" instruction on the prescription order needs further clarification to support appropriate billing of the claim.

***Electronic documentation and records:*** With an ever increasing shift to electronic prescribing and record keeping, it is imperative that electronic documentation (e.g. prescription orders, transaction notes, etc.) become acceptable for audit purposes. It is, however, critical that electronic documentation and records are complete, secure and of high quality to ensure their readability and authenticity.

***All participants to an audit need to be informed and professional:*** When an audit is seen as reasonable, transparent and fair in design and implementation, the entire process is raised to a professional and quality improvement level. On the part of the MCO this would include timely notice of pending audit and its purpose, timely arrival to conduct the audit, timely notification of results, and a reasonable appeals process, as well as professional demeanor by the auditors. On the part of the pharmacy it would be understanding of the contract, audit requirements and dispensing requirements, being prepared for the audit, providing a member of the pharmacy staff to assist the auditor, as well as a professional demeanor of the pharmacy staff. A bilateral professional level of performance can make the audit process run smoothly, be educational and improve quality.

# THE AUDIT PROCESS

Over the years different types of audits have been developed to address changes in benefit and billing processes. Concurrent Daily Review Auditing was developed to attempt to make immediate changes to a claim before payment was made to the pharmacy. Another type, Retrospective Audits (desk, mail or in person) were designed to validate appropriate service by the pharmacy and help to detect FWA. And finally, an Investigative Audit is used after the normal audit processes have led to fraud.

## Description of Audit Types

***Concurrent Daily Review Audit*** is an audit of claims that may trigger the MCO to review them for various reasons (e.g. atypical quantities or excessive dosage). This type of audit focuses on the rationality of quantity and dosage form pairing. Once identified, typically a telephone call is made or an email is sent, usually immediately (generally within the same day but no later than 72 hours of claim submission), to the dispensing pharmacy to obtain an understanding of the claim submission. The claim concern is usually resolved at the time of notification by the pharmacy's electronic resubmission of the claim.

***Retrospective Audit*** is a retrospective, usually quite detailed, analysis of the total volume of claims submitted by a pharmacy. Retrospective audits may be conducted using one of three different types of pharmacy claims audits:

- **Desk Top Audit** is conducted by contacting the pharmacy via fax, email, the U.S. mail or contracted mail services as defined in the contract between the parties. The pharmacy may be asked to provide photocopies of the specific prescription orders, signature logs, wholesaler invoices or other documentation within a date range of claims paid to the pharmacy. The pharmacy will be given a due date to submit the requested information. The requested information may be returned by fax, email or U.S. Mail.
- **In-Pharmacy Audit** is conducted by contacting the pharmacy via email, U.S. mail, or other channel as defined in the contract between the parties, prior to the scheduled on-site audit date. The notification may include the audit time frame and types of documents that will be reviewed during the on-site audit and optimally blinded prescription order number ranges that will be reviewed. These audits may be conducted during regular business hours and the auditor should make reasonable efforts to minimize disruptions to the pharmacy. The pharmacy may be expected to have the documentation to support the audit period readily retrievable and accessible. A member of the pharmacy staff should be dedicated to assist the auditor. When the audit is complete, the auditor should provide general feedback to the assigned pharmacy staff member.
- **Investigational Audit** differs from MCO to MCO, but typically it is broader than a pharmacy claims audit and may be initiated from a medical, dental or another type of claim. An investigational audit is usually a more extensive audit and can involve regulatory and law enforcement. Typically this type of audit commences when there is clear evidence based upon preliminary reviews or audits that reveal fraud or abuse by patient or provider. This type of audit will not be addressed by these Guidelines due to the individual nature of this type of audit.

## Audit Process: Outline of Procedures

### I. Concurrent Daily Review Audits

Concurrent Daily Review Audits are a great way for a MCO to monitor its network and work with pharmacy to identify claims that were submitted incorrectly so that these claims can be corrected prior to payment by the MCO. Pharmacy claims audits, with retroactive recovery of prior payments, may lead to friction between a pharmacy and MCO. The Concurrent Daily Review Audit process is a way to ease this friction by identifying claims immediately, and allowing for correction of the claims through a reversal and rebilling process. Pharmacy can appreciate this audit process as it avoids the notion that pharmacy claims audits are merely a revenue source for a MCO. This audit process creates more of a partnership between a MCO and pharmacy.

#### Documentation

When a relationship is established between a pharmacy and an MCO, there should be formal written documentation either included as contractually defined in the body of the contract or in the provider manual that includes specific information on the audit process. For Concurrent Daily Review Audits the following information[2] may be pertinent:

- Documentation of the audit process
- Documented list of items necessary to satisfy the audit which can include some or all of the following:
  - Prescription order copies
    - Original prescription orders or
    - Electronic scanned images

    Note: Regardless of the copy type, it is important that the prescription order copy must be able to be verified as a legitimate order with legible content and containing pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important to be sure that all the necessary information related to the prescription order dispensing is provided. Usually, it is to the benefit of the community pharmacy to make sure its prescription copies are legible and all supporting documentation is presented.
  - Physician Notes
  - Additional Documentation
    - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
    - Written documentation on the dispensing of the prescription order that is dated as to when the documentation occurred.
- Timeframes should be outlined
  - Timeframe for a pharmacy to submit audit documentation for a concurrent audit. *Suggested timeframe:* At least 10 to 14 calendar days.
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 24 to 48 hours after receiving initial documentation.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 10 to 14 calendar days.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 24 to 48 hours after receiving any additional supporting documentation.

[2] There may be state laws regarding auditing pharmacy claims that differ from the Model Guidelines outlined.

## Audit Process: Outline of Procedures

*continued*

- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may adopt its own unique policies regarding documents that are acceptable for additional review
- Documented appeals process
- Process for resolution of issues raised by the audit. This is typically handled through a reversal and rebilling process.

**Procedures**

1. The MCO identifies claims for audit.
   *Guidance: The number of prescription orders to be audited typically ranges from 1 to 5. The prescription orders audited are typically no more than 7 to14 calendar days old and dependent on payment cycles.*
2. The MCO can deliver the audit notification to the pharmacy via encrypted email or telephone call.
   *Guidance: The audit notification should include the following information:*
   *a. Pharmacy response time*
   *b. Documentation needed to satisfy the audit request*
   *c. Contact within the auditing department at the MCO to answer any questions*
   *d. Expectation of when the pharmacy will receive initial results*
3. The pharmacy is required to compile all audit documentation for submission to the MCO. The documentation should include everything necessary to satisfy the audit.
   *Guidance: All documentation should be emailed or faxed back to the MCO within 14 calendar days. It may be to the benefit of the pharmacy if the pharmacy is able to provide the documentation right away. This may allow for prescription orders to be corrected prior to the prescription sale. Typically the pharmacy is given the opportunity to reverse the original claim and rebill the claim correctly. This process allows for corrections to be made prior to the payment of the claim which prevents any audit chargebacks from occurring.*
4. The MCO then reviews all audit documentation submitted by the pharmacy, and creates an initial findings report for the pharmacy.
   *Guidance: This report would typically be emailed to the pharmacy within 24 to 48 hours of receipt of the original documentation. The initial results should include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.*
5. The pharmacy will typically receive the initial audit results via email. At this time all claims should be reviewed to determine the following:
   a. No discrepancies are found.
   b. Pharmacy agrees with the audit discrepancy. The pharmacy may find that the prescription has not yet been dispensed to the customer and pharmacy can correct the prescription and prepare it for future fills. If the prescription has been dispensed, the pharmacy can make the correction in the system to prepare for future refills.

## Audit Process: Outline of Procedures

*continued*

c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation supporting the prescription order dispensing. The pharmacy is required to collect all additional documentation to be submitted to the MCO to support the original dispensing.
*Guidance: Supporting documentation should be submitted within 14 calendar days of receiving the initial results.*

6. The MCO will typically receive the supporting documentation via email or fax. At this time the MCO reviews the supporting documentation to determine the final audit results. The MCO will typically send final audit results to the pharmacy within 24 hours of receipt of supporting documentation. With the final audit results, the MCO should communicate the amount that the pharmacy is to expect on the next remittance advice as payment for the prescription order.
7. The pharmacy will then verify that the proper payment was received on the claim when the corresponding remittance advice is received.

### II. Desktop Audits

Desktop Audits (a retrospective audit) are a method of auditing that MCOs use which many pharmacies prefer because they may be less disruptive to the day-to-day pharmacy operations when compared to an in-pharmacy audit. Typically these audits utilize a process where community pharmacy may provide copies of prescriptions along with additional documentation to satisfy the audit.

### Documentation

When a relationship is established between a pharmacy and a MCO, there should be formal written documentation contractually defined either included in the body of the contract or in the provider manual that includes specific information on the process. It is strongly recommended that pharmacy staff responsible for approving contracts read the provider manual prior to signing any contracts. For desktop pharmacy audits the following information may be pertinent:

- Documentation of the audit process
- Documented list of items necessary to satisfy the audit which can include some or all of the following:
  - Prescription order copies — either original prescription orders or electronic scanned images
    *Regardless of the copy type, it is important for the prescription copy to be legible and contain any pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important that all necessary information related to the prescription order dispensing is provided.*
  - Proof of pick up or delivery of the prescription. Pharmacy is most often allowed to provide one of the following:
    - Electronic date and time stamp in the pharmacy software system of the sold prescription
    - Electronic signature
    - Paper signature
  - Physician Notes
    - Notes should be on the written copy which is what will be reviewed in an audit.

## Audit Process: Outline of Procedures

*continued*

- Additional Documentation
  - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
  - Written documentation on the dispensing of the prescription order that is dated as to when the documentation occurred.

- Timeframes should be outlined
  - Timeframe for a pharmacy to submit audit documentation for a desktop or mail audit. *Suggested timeframe:* At least 14 to 21 calendar days.
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of the audit.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 14 to 21 calendar days after receipt of initial results.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of receiving any follow up documentation.

- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may have different policies regarding documents that are acceptable for additional review

- Documented appeals process
- Process for chargebacks or recoupment of payment defined.

### Procedures

1. The MCO identifies claims for audit.
   *Guidance: The number of prescription orders audited typically ranges from 1 to 50 unique prescription claims and from 1 to 12 months old.*
2. The MCO can deliver the audit notification to the pharmacy via mail or encrypted email.
   *Guidance: The audit notification should include the following information:*
   *a. Pharmacy response time*
   *b. Documentation needed to satisfy the audit request*
   *c. Contact within the auditing department at the MCO to answer any questions*
   *d. Expectation of when the pharmacy will receive initial results*
3. The pharmacy needs to compile all audit documentation for submission to the MCO. The documentation should include everything necessary to satisfy the audit.
   *Guidance: All documentation should be faxed, emailed or mailed back to the MCO within the specified time which typically ranges from 14 to 21 calendar days.*
4. The MCO will then review all audit documentation submitted by the pharmacy and create an initial findings report for the pharmacy.
   *Guidance: This report is typically mailed or sent via secure email to the pharmacy within 30 to 45 calendar days after the receipt of the original documentation. The initial results typically include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.*

## Audit Process: Outline of Procedures

*continued*

5. The pharmacy may receive the initial audit results via mail or secure email. At this time all claims should be reviewed to determine the following results:
   a. No discrepancies are found.
   b. Pharmacy agrees with the audit discrepancy.
   c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation. The pharmacy will collect all additional documentation to be submitted to the MCO to support the original dispensing.
   *Guidance: Supporting documentation is typically submitted 14 to 21 calendar days after reception of initial results.*
6. The MCO will typically receive the additional documentation via fax, mail or email. At this time the MCO reviews the additional documentation to determine the final audit results.
   *Guidance: The MCO will typically send final audit results to the pharmacy within 30 to 45 calendar days. With the final audit results, the MCO will typically give the pharmacy the choice to pay any chargeback amounts with a separate check or an automatic deduction from a future remittance to the pharmacy.*
7. Once the pharmacy receives the final audit results, it can do the following:
   a. Appeal the audit results via the appeals process
   b. Agree with the results and select a payment method.
   *Guidance: Alternatives include pharmacy submitting payment via check to the MCO within the period of time specified contractually, typically agreed to by the parties but generally within 30 calendar days of receipt of final audit results. The pharmacy may also opt to allow the MCO to complete an automatic deduction on a future remittance advice typically at least 30 calendar days from the date the pharmacy received the final audit results.*

### III. In-Pharmacy Audits

In-Pharmacy Audits (a retrospective audit) are used widely by MCOs because they provide the most comprehensive view of operational practices and procedures yet they are most intrusive to pharmacy practice as they can interrupt daily operations and patient care. MCOs should be sensitive to scheduling this type of audit to minimize disruption. It is also advisable for the pharmacy to provide dedicated pharmacy staff to the auditor to minimize exposure of health information and ascertain that the best effort is made to find all documentation. From a pharmacy perspective, Concurrent Daily Audits or Desktop Audits are typically preferred methods, but reality is that the In-Pharmacy Audit gives a MCO the opportunity to interact directly with members in the pharmacy network.

### Documentation

When a relationship is established between a pharmacy and a MCO, there should be formal written documentation contractually defined either included in the body of the contract or in the provider manual that includes specific information on the process. It is strongly recommended that pharmacy staff responsible for approving contracts read the provider manual prior to signing any contracts.

For In-pharmacy audits the following information is pertinent:

- Documentation of the audit process
- Documented list of items and documentation necessary to satisfy the audit which can include some or all of the following:

## Audit Process: Outline of Procedures

*continued*

- Prescription order copies — either original prescription orders or electronic scanned images

  Regardless of the copy type, it is important for the prescription copy to be legible and contain any pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important that all necessary information related to the prescription order dispensing is provided.
- Proof of pick up or delivery of the prescription. Pharmacy may be allowed to provide as documentation, as defined in the pharmacy contract, one of the following:
  - Electronic date and time stamp in the pharmacy software system documenting the delivery of the sold prescription
  - Electronic signature
  - Paper signature
- Prescriber Notes
- Additional Documentation
  - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
  - Written documentation concerning the dispensing of the prescription order that is dated as to when the documentation occurred.

- Timeframes should be outlined
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of the audit.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 14 to 21 calendar days after receipt of initial results.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of receiving any follow up documentation.
- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may have different policies regarding documents that are acceptable for additional review
- Documented appeals process
- Process for chargebacks or recoupment of payment defined.

### Procedures

1. The MCO identifies claims for audit.
   *Guidance: The number of prescription orders audited typically ranges from 25 to 125 unique prescription claims and from 1 to 12 months old, however, Medicare Part D audits by the MCO or CMS (or its OIG) may require the review of claims substantially older than this general timeframe.*
2. The MCO can deliver the audit notification to the pharmacy via mail or encrypted email.
   *Guidance: The audit notification should include the following information:*
   a. *Date and time of the In-Pharmacy audit. Guidance: The MCO would typically notify the pharmacy at least 14 to 21 calendar days prior to the audit date. In the event*

## Audit Process: Outline of Procedures

*continued*

*the pharmacy is not available for an In-Pharmacy audit on the date the MCO selected, there should be flexibility to reschedule the audit at a time when both parties are available. Effort should be made by the MCO to avoid the holiday timeframes, weekends, Mondays, or the first week of the month when pharmacies are experiencing high prescription volumes.*

   b. *Documentation needed to satisfy the audit request along with the timeframe of the records to be audited. Guidance: All documentation should be within the rules and regulations of the State Board of Pharmacy, DEA, state regulatory/enforcement agencies, and HIPAA/HITECH.*
   c. *Contact within the auditing department at the MCO to answer any questions.*
   d. *Expectation of when the pharmacy will receive initial results after the In-Pharmacy audit is completed.*

3. The pharmacy must prepare for the In-Pharmacy audit. Preparation would include obtaining the appropriate records for review. Note: The MCO will typically provide a date range or masked prescription number for the community pharmacy to begin pulling appropriate records if they are in storage. Community pharmacy should also prepare from a staffing standpoint so that their day-to-day workflow is not impacted by the In-Pharmacy audit.

4. The MCO will then review all audit documentation submitted by the pharmacy and create an initial findings report for the pharmacy.
   *Guidance: This report is typically mailed or emailed to the pharmacy within 30 to 45 calendar days after the receipt of the original documentation. The initial results typically include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.*

5. The pharmacy will receive the initial audit results via mail or email depending on agreement between MCO and pharmacy. At this time all audit reports detailed by claim should be reviewed to determine the following:
   a. No discrepancies were found
   b. Pharmacy agrees with the audit discrepancy
   c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation. The pharmacy will collect all additional documentation to be submitted to the MCO to support the original dispensing.
      *Guidance: The MCO may accept supporting documentation that is submitted by the pharmacy up to 21 calendar days after reception of initial results.*

6. The MCO will typically accept the additional documentation via fax, mail, or email. At this time the MCO reviews the additional documentation to determine the final audit results.
   *Guidance: The MCO will typically send final audit results to the pharmacy within 30 to 45 calendar days. With the final audit results, MCO will typically give the pharmacy the choice to pay any chargeback amounts with a separate check or an automatic deduction on a future remittance advice.*

7. Once the pharmacy receives the final audit results, it can do the following:
   a. Appeal the audit results via the appeals process.
   b. Agree with the results and select a payment method.
      *Guidance: The pharmacy typically would then send a check to the MCO within 30 calendar days of receipt of final audit results. The pharmacy may also opt to allow the MCO to complete an automatic deduction on a future remittance advice typically at least 30 calendar days from the date the pharmacy received the final audit results.*

## THE APPEAL PROCESS

Once the pharmacy receives the audit results, it is recommended that the pharmacy be given the opportunity to submit a formal appeal to the MCO. This is typically completed and received by the MCO no later than 30 calendar days from the date that the final audit report is communicated to the pharmacy.

If the pharmacy files an appeal, it should be filed according to the procedures and timeline as detailed in the contract between the parties. Many MCOs require the pharmacy to complete a formal appeal form and send it with the required documentation.

The pharmacy should provide appropriate additional documentation to substantiate the appeal of the final audit results. The MCO should provide a written determination of the appeal within 30 calendar days of the expiration of its specified review period.

*Guidance:*

1. *Reasonable documentation from a prescriber or a patient to substantiate the dispensing of a prescription should be accepted by the MCO.*
2. *The type of acceptable documentation should be outlined in the contract between the pharmacy and the MCO.*
3. *Regardless of what is required in the contract, the pharmacy should always submit the appeal by a secure mail service.*

## COMPOUNDED MEDICATION: GENERAL DISCUSSION AND GUIDANCE

A compounded prescription order is a unique, nonstandard order for the preparation of a medication or medications in a form that is not commercially available; therefore, not standardized with a single specific NDC number describing the product dispensed. For this reason, billing for compounded medications is often confusing and inconsistent for MCOs and pharmacies. Most MCOs have their own specific process for pharmacies to submit a compounded prescription order claim. Pharmacies may be in many different MCO networks and not familiar with all the different processes. The pharmacy will choose one process and use it to bill all MCOs for compounded prescription orders resulting in an inappropriately billed claim because it is not the proper process.

There are pharmacies that prepare compounded prescription orders as a small percentage of the practice, and because they are members of MCO networks, they will direct bill to the MCO. However, there are others that specialize in compounding prescription orders. These pharmacies are commonly referred to as compounding pharmacies. Many of these compounding pharmacies do not participate in MCO networks, which will require patients to seek reimbursement by submitting a claim directly to the MCO.

It is important for pharmacy and MCOs to come together to develop model guidelines that specifically address billing for compounded prescription medications. Due to the lack of model guidelines addressing compounded prescription orders, there are inconsistencies in the way compounded prescription orders are submitted. The number that are inaccurately billed may result in auditors targeting compounded prescription claims disproportionately and more frequently than other types of claims. To a pharmacy submitting a high percentage of compounded prescription claims, this targeting appears unfair.

NCPDP recognized this and developed a new telecommunication standard (v D.0) that was adopted and its use will be required on January 1, 2012. Once MCOs and pharmacies adopt and implement the new standard, there will be a more accurate means of billing c ompounded prescription claims.

*Guidance: Pharmacy and MCOs should develop model audit guidelines based on the implementation of the new vD.0 telecommunication standard for compounded prescription billing.*

## LONG TERM CARE: GENERAL DISCUSSION AND GUIDANCE

Auditing of Long Term Care (LTC) pharmacies is one of the more challenging areas of pharmacy practice for auditing. The volume of claims by the LTC pharmacy, the issue of medical orders versus prescription orders, state-by-state regulatory differences in the storage of prescription order documentation and physical accessibility of stored documents are just some of the underlying factors that make it so challenging. These Model Guidelines can provide only limited help in resolving the existing problems for LTC pharmacy audit processes. It is recommended that pharmacy and MCOs seek to develop a model audit process specific to LTC pharmacy. Further, it is recommended that the National Association of State Boards of Pharmacy (NABP) and state boards of pharmacy develop a national standard for the retention and storage requirements for LTC prescription orders.

The demographics of patients, the prescribers and the LTC facility make it difficult for pharmacies to get, verify and store what MCOs view as the appropriate documentation to validate appropriate filling and billing of a prescription order. It is recommended that the audit process should allow an extended period of time, perhaps 30 calendar days, for LTC pharmacies to locate and present the appropriate documentation; however, often the expected documents are simply not available. This is due primarily to physicians writing medication orders in a patient chart rather than writing prescription orders as is typical for ambulatory care patients. The lack of appropriate documentation onsite often leads to what auditors and MCOs today view as inappropriate documentation (such as a "bar code scan" for a reorder) as proof of a prescription order. The result is often a citation for recoupment of the claim payment which can frustrate the pharmacy. The LTC pharmacy may view this as a legitimately dispensed prescription order. The recoupment of the claim may result in the patient/beneficiary being denied the value of the benefit to which they are entitled. In turn, the MCO may then become frustrated by its inability to properly conduct its drug utilization review process and validation of a paid claim to meet the requirements of government and private payor programs. Each believes they are following best practices and regulations; however, the documentation requirements to fill a prescription order and to bill a prescription order are inconsistent. It is recommended that further discussion by the profession is needed to bridge this documentation gap.

*Guidance: Pharmacies, MCOs and government regulatory entities should develop audit processes specific to LTC pharmacy practice. The processes should consider:*

1. *The types of documentation that are legally accepted to support medication orders in the LTC pharmacy. Audit findings should be consistent with legal requirements under state laws, and until documentation requirements are standardized and clarified, pharmacies should ensure that documentation properly supports the dispensing and billing of prescription orders;*
2. *Proper execution of MCO DUR programs, which are an integral part of drug benefit management and utilization controls;*
3. *Government program documentation requirements that impose obligations on both MCOs and pharmacies; and,*
4. *Preservation of the drug benefit to which the patient/beneficiary is entitled.*

## PRIVACY CONCERNS

Pharmacies are considered to be Covered Entities under the Federal HIPAA law as well as under state privacy laws. Amendments to HIPAA contained in the HITECH law passed in 2009 included expansion of several requirements to Business Associates, which include the MCO and audit contractors. In addition, there may be state privacy laws that place similar or separate privacy requirements on pharmacies, MCOs, and audit contractors. Audit procedures should incorporate any requirements contained in these laws to ensure that the audit does not place the MCO, audit contractor and pharmacy being audited in violation of these laws.

*Guidance: Audit Procedures should include provisions to ensure that privacy protections required by federal and state law are met. Procedures should also include provisions to assist audited pharmacies in complying with their obligations under these laws.*

*In developing audit procedures, the MCO should analyze Federal and State laws to:*

1. *Identify privacy issues and responsibilities of the MCO*
2. *Identify privacy issues and responsibilities of Pharmacy*
3. *Identify privacy issues and responsibilities of the Audit Contractor (if outside of the MCO)*
4. *Address compliance issues of all parties*
    a. *Patient Consent and Auditor authority regarding personal health information (PHI)*
    b. *Authorized disclosures*
    c. *Unauthorized disclosures*
    d. *Accounting of all disclosures*
    e. *Allowed exclusion of PHI*

## STATE and FEDERAL OVERSIGHT

### State and Federal Pharmacy Laws and Regulations

State and federal laws reflect a wide variety of requirements and regulatory oversight that apply to the practice of pharmacy, the distribution of federal legend drugs, the operation of pharmacies and the sale and administration of health benefit plans inclusive of prescription drug benefit coverage in each state and throughout the country. The pharmacy and pharmacist are required to comply with the law that applies to the location of the pharmacy, or, on occasion, the pharmacy law of the locale where the patient resides. In general, interpretation of, and compliance with, the applicable law is a matter that is left to a Board of Pharmacy, Department of Insurance, CMS or another regulatory agency with jurisdiction over the issue. Auditors are often asked to evaluate the legitimacy and legality of prescription drug orders as part of their auditing procedure. There have been wide complaints from audited pharmacies that auditors are not qualified to interpret the state laws, or that they make interpretations that are inconsistent with those of the state board of pharmacy.

Audit and appeal procedures should include provisions that prevent claim recoupment based on interpretations of law that are inconsistent with the law under which the pharmacy filled the prescription order.

In developing audit procedures and training for auditors, the MCO should outline the following federal and/or state laws and regulations:

- Related to Health Plans
    - General ERISA and non-ERISA
    - Medicare
    - Medicaid

## State and Federal Pharmacy Laws and Regulations *continued*

- Related to Pharmacies
  - Dispensing
  - Controlled Substances
  - Compounding
  - Other Drug Laws
- Specific laws related to insurance other plans and/or audit standards
- Laws related to Pharmacy Practice
  - Board of Pharmacy
    - General Practice
    - Practice Site Specific (LTC, assisted living, home infusion, etc.)
    - Compounding
  - Other
- Laws related to Health Plans
- General laws related to contracts

*Guidance*

1. *Audit procedures should acknowledge that differences exist between:*
   a) *Contractual requirements of network participation in a variety of plans with defined benefits as one component of audit evaluation, and*
   b) *Various federal and state laws and regulations that govern the practice of pharmacy and the operation of pharmacies.*
2. *It is recommended that auditors be pharmacists or certified pharmacy technicians that have had experience in community pharmacy practice.*

# PHARMACY AUDIT TRANSACTION STANDARDS

In 2009, NCPDP[3] sponsored audit focus groups including representatives from pharmacies, MCOs, and audit companies to develop the scope of a project on pharmacy audit transaction standards. With participants from all segments of the industry within and outside of the NCPDP membership, focus groups were conducted which resulted in the three goals of the project:

- Create an electronic audit transaction file with requests, responses, and final outcome transmissions for both Desk Top claim audits and for In-Pharmacy audit notices.
- Create a forum to discuss and resolve audit issues with government programs and state regulation
- Create a forum to discuss and resolve common prescription conflict/dispensing events that may be non-compliant with the plan coverage criteria.

An NCPDP Task Group within the Telecom Workgroup was assigned this project and the Implementation Guide was approved by NCPDP as a standard in May 2011.

The new NCPDP Pharmacy Audit Transaction Standard was developed to help guide those involved with the community pharmacy claims audit process and was intended to meet two needs:

- To provide practical guidelines for software developers throughout the industry as they implement the Audit Transaction Standard, and
- To ensure a consistent implementation of the Audit Transaction Standard.

[3] NCPDP (National Council of Prescription Drug Programs) is a not-for-profit ANSI-Accredited Standards Development Organization representing virtually every sector of the pharmacy services industry.

## PHARMACY AUDIT TRANSACTION STANDARDS

*continued*

This Standard should facilitate a specific type of business communication among diverse parties within the audit process. However, the use of this standard may be too burdensome on both pharmacies and MCOs because a process to upload documentation that is so critical in the audit process has not been selected and HIPAA standards for this type of information exchange have not yet been released. These factors may slow its adoption.

*Guidance*

1. *The adoption of this new transaction standard should remain voluntary.*
2. *A mechanism to upload documentation needs to be determined to assist in the adoption of this new transaction standard.*

## CONCLUSION

Pharmacy claims auditing has been a source of contention in pharmacy, and, to some degree, MCOs and pharmacies have been positioned as adversaries. It became necessary for the profession to develop a stakeholder-based process to address the pharmacy claims audit process.

The *AMCP Model Audit Guidelines for Pharmacy Claims* will assist stakeholders in taking the first steps in understanding the perspectives of the MCO and pharmacy to ensure the audit process policies and procedures are sensitive to all stakeholders.

It is encouraged that all stakeholders review the presented *Model Guidelines* and use them when developing or reviewing current audit processes to ensure that they are fair and balanced. If both MCOs and pharmacies objectively review and embrace these Model Guidelines, the result will be a transparent audit process, a better understanding of the audit process and a more cooperative relationship between the parties.

# APPENDIX: GLOSSARY

**Appeal:** As it relates to pharmacy claims audits, a formal request by the pharmacy for reconsideration on the audit findings.

**Audit Notification:** A communication via US mail or electronic means that is sent by the MCO to notify the pharmacy of an audit.

**Audit Process:** A means of ensuring that pharmacy procedures and reimbursement mechanisms are consistent with regulatory and MCO contractual requirements.

**Audit Types:** There are different types of audits that apply to pharmacy claims or conducted by an MCO:

- **Concurrent Daily Review:** An audit that is conducted by telephone or email usually immediately (within the same day but no longer than 72 hours of claim submission). The claim concern is usually resolved at the time of notification by the pharmacy's electronic resubmission of the claim.
- **Retrospective Audit** is a retrospective detailed analysis of the total volume of claims submitted by a pharmacy. A retrospective audit can be conducted using one of three types of pharmacy claims auditing:
  - **Desk Top Audit** is conducted after notification by the MCO to the contracting pharmacy as defined in the contract between the parties. The audit is conducted electronically. See *Guidelines* for process.
  - **In Pharmacy Audit** is conducted after notification by the MCO to the contacting pharmacy via email, U.S. mail, or other channel as defined in the contract between the parties. This audit is conducted onsite in the pharmacy. See *Guidelines* for process.
  - **Investigational Audit** differs from MCO to MCO, but typically it is broader than a pharmacy claims audit and may be initiated from a medical, dental or another type of claim. An investigational audit is usually a more extensive audit and can involve regulatory and law enforcement. Typically this type of audit commences when there is clear evidence based upon preliminary reviews or audits that reveal fraud or abuse by patient or provider.

**Adjudication:** The process of completing all validity, process and file edits necessary to prepare a claim for final payment or denial.

**Claim:** A submission by the pharmacy to the MCO for payment of prescription dispensed to an MCO plan member.

**Documentation:** Items (i.e., prescription order, signature logs, purchasing invoices, etc) required to satisfy an audit and/or appeal process. These items should be listed in the provider manual under the audit process.

**Employee Retirement Income Security Act of 1974 (ERISA):** A federal law that regulates employer-sponsored benefit plans and restricts state government from regulating these plans. The law mandates reporting and disclosure requirements for group life and health plans with relevant guidance on the sponsorship, administration, minimum records retention period, servicing of plans, some claims processing, appeals regulations and minimum mandatory clinical benefits.

# APPENDIX: GLOSSARY

*continued*

**Fraud, Waste and Abuse (FWA)**

- **Fraud:** It is the illegal acquisition of prescription drugs for personal use or profit. This definition excludes theft, burglary, backdoor pharmacies and illegal importation or distribution of prescription drugs (i.e., purposeful billing for non-existent prescriptions (phantom claims), billing for brand drugs when generics are dispensed)
- **Waste:** To consume, spend, or employ uselessly or without adequate return; use to no avail or profit (i.e., prescription medications ordered when not needed (auto fill or hoarding), filled after patient death or discontinuation of treatment, large day supplies filled when drug has not been shown effective for patient and medications automatically given because patient says they've been taken in the past yet there is no demonstrated need.
- **Abuse:** The use of a prescription medication in a way not intended by the prescriber.

**HIPAA:** The Health Insurance Portability and Accountability Act of 1996, a Federal law and subsequent regulations that include protection of personally identifiable health information and gives HHS the authority to mandate the use of electronic standards for the electronic exchange of health care data.

**HITECH:** The Health Information Technology for Economic and Clinical Health (HITECH) Act, was enacted as part of the American Recovery and Reinvestment Act of 2009 to promote the adoption and meaningful use of health information technology. It also addresses the privacy and security concerns associated with the electronic transmission of health information that strengthen the civil and criminal enforcement of the HIPAA regulations.

**Incentive-based Auditing:** Auditors are paid for their services based on a percentage of incorrectly or inappropriately submitted pharmacy claims.

**Long Term Care (LTC) Pharmacy:** Long term care typically refers to individuals who require health care either in an institutional facility on a long-term basis, but can also refer to those requiring services at home. Pharmacy services may be provided by the institutional facility or through an offsite pharmacy providing services to the facility.

**Managed Care Organization (MCO):** For the purposes of this document this term is used generically to include all types of MCOs including health plans, pharmacy benefit managers (PBM), health maintenance organizations (HMO), contracted agents, etc.

**NDC Number (National Drug Code):** A unique 11 digit code given to drugs that identifies the labeler, product and package size.

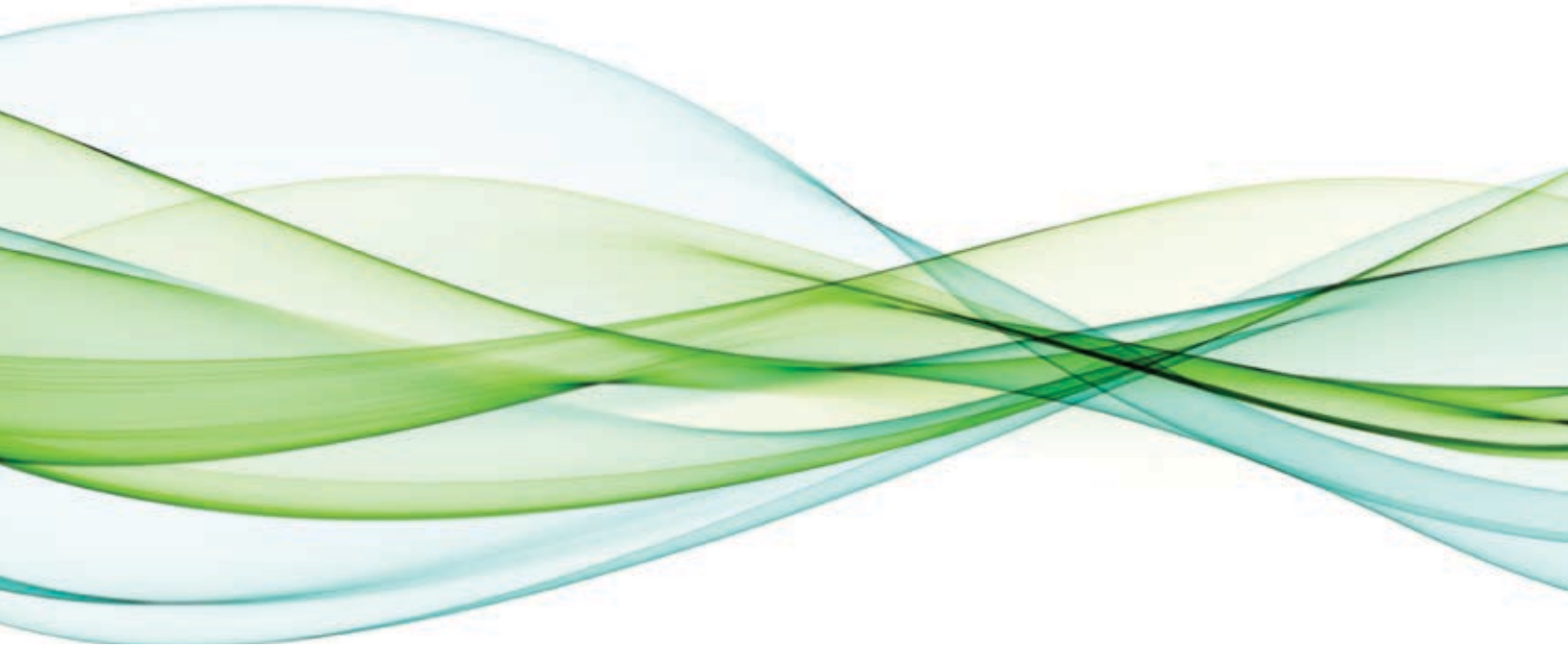
**National Council of Prescription Drug Programs (NCPDP):** National Council of Prescription Drug Programs is a not-for-profit ANSI-Accredited Standards Development Organization representing virtually every sector of the pharmacy services industry.

**Pharmacy Benefits Manager (PBM):** PBMs are hired by the health plan, employer, or PDP to orchestrate the development of the pharmacy network and adjudicate claims for the health plan.

**Pharmacy Network:** Pharmacies that are contracted by a MCO in order to service the members of the health plan by providing convenient sites to fill their prescriptions.

**Provider:** An entity who has contracted with an MCO to deliver care to a covered person. In the case of pharmacy services, it is typically the pharmacy, rather than the pharmacist, that contracts with the MCO.

**Provider Manual:** A manual issued by the MCO and distributed to the pharmacy that outlines its processes, procedures, etc., as it relates to drug benefit and pharmacy claims.



**This document is available electronically at**
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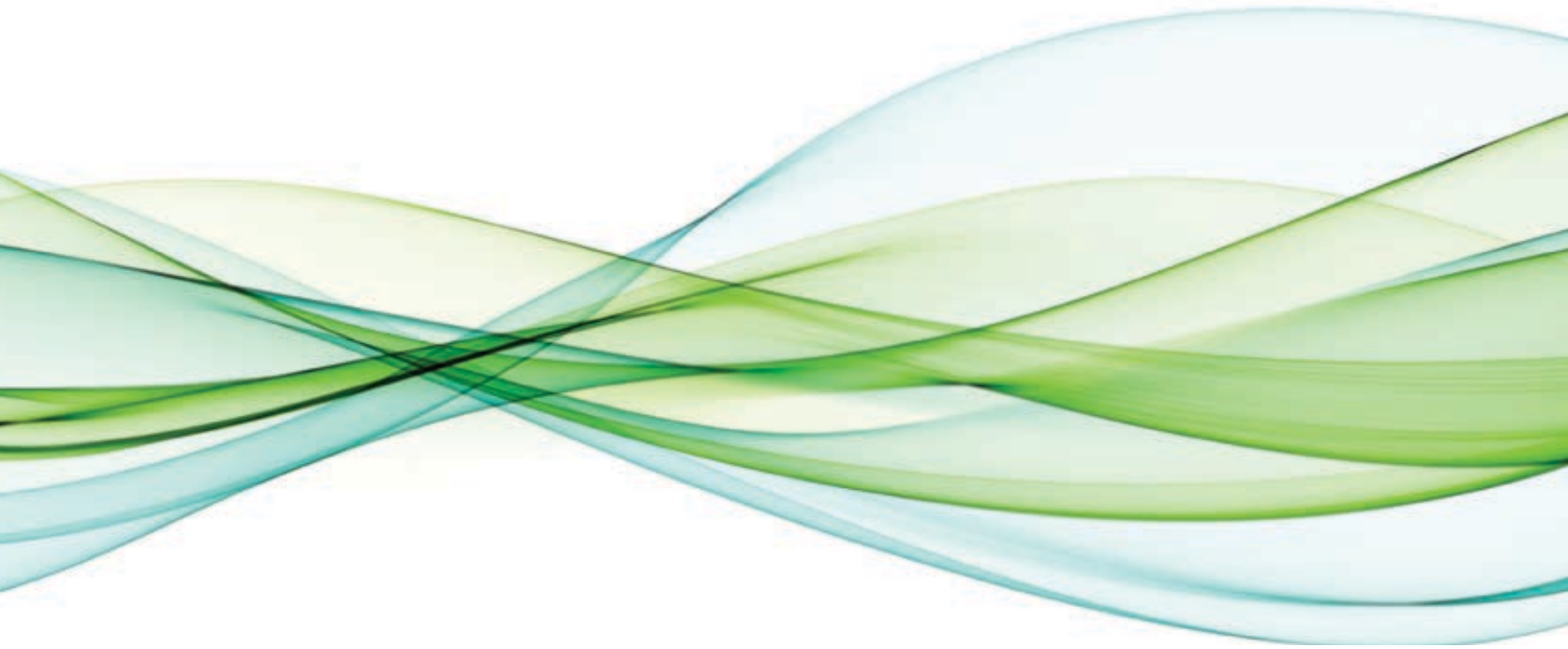

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