



PHARMACY BENEFIT MANAGER COMPLIANCE CHECKLIST

State Form 57243 (3-23)

INDIANA DEPARTMENT OF INSURANCE

INSTRUCTIONS: Complete this form in its entirety.

The attestation must be completed by an officer of the Pharmacy Benefit Manager.

In the Location/Comments box, indicate where the required information can be found in the document(s) (e.g., "Auditing Procedures, Page 4, Article VI, B(1)"). Highlight the document(s) accordingly. If more space is required, reference any additional attachments in the Location / Comments box.

Pharmacy Benefit Manager Name	
Title(s) of Document(s)	

Attestation: As a duly appointed officer of the above Pharmacy Benefit Manager, I attest that the attached document(s) meet(s) the requirements of Indiana Code 27-1-24.5 and 760 IAC 5. I further attest that any agreement with a 340B covered entity meets the requirements of Indiana Code 27-1-24.5-19.5.

Officer Signature			
Officer Name			
Title		Date (mm/dd/yyyy)	

Statute / Regulation	Location / Comments	IDOI Use Only
IC 27-1-24.5-22 (a)(1) (See also IC 27-1-24.5-23) A pharmacy benefit manager shall identify to contracted pharmacy services administrative organizations or pharmacies (...) the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health plan administered by the pharmacy benefit manager.		
IC 27-1-24.5-23 (See 760 IAC 5-4-1) 760 IAC 5-4-1 (a) In a contract between a pharmacy benefit manager and a pharmacy, or a pharmacy benefit manager and a pharmacy services administrative organization, the pharmacy or the pharmacy services administrative organization must be given the right to obtain from the pharmacy benefit manager, within ten (10) calendar days after a request, a current list of the sources used to determine maximum allowable cost pricing. The pharmacy benefit manager must update the maximum allowable cost list at least every seven (7) calendar days and provide a means by which contracted pharmacies and pharmacy services administrative organizations may promptly review maximum allowable cost list updates in a format that is readily available and accessible.		

Statute / Regulation	Location / Comments	IDOI Use Only
<p>IC 27-1-24.5-22 (a)(2)</p> <p>A pharmacy benefit manager shall (...) establish an appeal process for contracted pharmacies, pharmacy services administrative organizations, or group purchasing organizations to appeal and resolve disputes concerning the maximum allowable cost pricing.</p>		
<p>IC 27-1-24.5-22 (a)(3)</p> <p>A pharmacy benefit manager shall (...) update and make available to pharmacies:</p> <p>(A) at least every seven (7) days; or</p> <p>(B) in a different time frame if contracted between a pharmacy benefit manager and a pharmacy;</p> <p>the pharmacy benefit manager's maximum allowable cost list.</p>		
<p>IC 27-1-24.5-22 (a)(4)</p> <p>A pharmacy benefit manager shall (...) determine that a prescription drug:</p> <p>(A) is not obsolete;</p>		
<p>(B) is generally available for purchase by pharmacies in Indiana from a national or regional wholesaler licensed in Indiana; and</p>		
<p>(C) is not:</p> <p>(i) temporarily unavailable;</p> <p>(ii) listed on a drug shortage list; or</p> <p>(iii) unable to be lawfully substituted;</p> <p>before the prescription drug is placed or continued on a maximum allowable cost list.</p>		
<p>IC 27-1-24.5-22 (b)(1)</p> <p>The appeal process [to appeal and resolve disputes concerning the maximum allowable cost pricing] must include (...) [t]he right to appeal a claim not to exceed sixty (60) days following the initial filing of the claim.</p>		
<p>IC 27-1-24.5-22 (b)(2) (See 760 IAC 5-4-2 (2))</p> <p>760 IAC 5-4-2 (2)</p> <p>A pharmacy benefit manager shall establish a process for contracted pharmacies, pharmacy services administrative organizations, and group purchasing organizations to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes (...) a requirement that the appeal be investigated and resolved within thirty (30) calendar days after the appeal is received.</p>		

Statute / Regulation	Location / Comments	IDOI Use Only
<p>IC 27-1-24.5-22 (b)(3)</p> <p>The appeal process [concerning the maximum allowable cost pricing] must include (...) a requirement that the pharmacy benefit manager do the following [if an appeal is denied]:</p> <p>(A) Provide the reason for the denial.</p>		
<p>(B) Provide the appealing contracted pharmacy, pharmacy services administrative organization, or group purchasing organization with the national drug code number of the prescription drug that is available from a national or regional wholesaler operating in Indiana.</p>		
<p>IC 27-1-24.5-22 (b)(4)</p> <p>The appeal process [concerning the maximum allowable cost pricing] must include (...) a requirement that the pharmacy benefit manager do the following [if an appeal is approved]:</p> <p>(A) Change the maximum allowable cost of the drug for the pharmacy that filed the appeal as of the initial date of service that the appealed drug was dispensed.</p>		
<p>(B) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the same network of the pharmacy benefit manager that filled a prescription for patients covered under the same health plan beginning on the initial date of service the appealed drug was dispensed.</p>		
<p>(C) Notify each pharmacy in the pharmacy benefit manager's network that the maximum allowable cost for the drug has been adjusted as a result of an approved appeal.</p>		
<p>(D) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost, if applicable.</p>		
<p>(E) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled the prescriptions for patients covered under the same health plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed.</p>		
<p>(F) Make retroactive price adjustments in the next payment cycle unless otherwise agreed to by the pharmacy.</p>		

<p>IC 27-1-24.5-22 (b)(5)</p> <p>[Claims] auditing procedures:</p> <p>(A) may not use extrapolation or any similar methodology;</p>		
<p>(B) may not allow for recovery by a pharmacy benefit manager of a submitted claim due to clerical or other error where the patient has received the drug for which the claim was submitted;</p>		
<p>(C) must allow for recovery by a contracted pharmacy for underpayments by the pharmacy benefit manager; and</p>		
<p>(D) may only allow for the pharmacy benefit manager to recover overpayments on claims that are actually audited and discovered to include a recoverable error.</p>		
<p>760 IAC 5-3-3</p> <p>An auditor conducting [a claims] audit must comply with all of the following:</p> <p>(1) The contract under which an onsite or remote audit is performed must provide a description of audit procedures that will be followed.</p>		
<p>(2) For an onsite audit conducted at a pharmacy's location, the auditor that conducts the audit must provide written notice to the pharmacy or pharmacist at least fourteen (14) calendar days before conducting the initial onsite audit for each audit cycle.</p>		
<p>(3) The auditor must not interfere with the delivery of pharmacist services to a patient and must use every effort to minimize inconvenience and disruption to pharmacy operations during the audit. This subdivision does not prohibit audits during normal business hours of the pharmacy.</p>		
<p>(4) If the audit requires use of clinical or professional judgement, the audit must be conducted by or in consultation with an individual licensed as a pharmacist under IC 25-26.</p>		
<p>(5) The auditor must allow the use of written or otherwise transmitted hospital, physician, or other health practitioner records to validate a pharmacy record.</p>		
<p>(6) The auditor must perform the audit according to the same standards and parameters that the auditor uses to audit all other similarly situated pharmacies.</p>		

<p>760 IAC 5-3-3 (continued)</p> <p>(7) The period covered by the audit must not exceed twenty-four (24) months after the date on which the claim that is the subject of the audit was submitted to or adjudicated by the pharmacy benefit manager, unless a longer period is required under federal or state law. The pharmacy must be permitted to resubmit electronically any claims disputed by the audit. Audit procedures must provide for a period of at least thirty (30) calendar days during which the pharmacy may resubmit a disputed claim.</p>		
<p>(8) An auditor must not schedule an audit to begin during the first seven (7) calendar days of a month without the voluntary consent of the pharmacy. The consent may not be mandated by a contract or other means.</p>		
<p>(9) Payment to the auditor for conducting the audit must not be based on a percentage of any amount recovered as a result of the audit.</p>		
<p>(10) Within twenty-four (24) hours of receiving the notice of an audit, a pharmacy may reschedule the audit to a date not more than fourteen (14) calendar days after the date proposed by the auditor. However, if the auditor is unable to reschedule within the fourteen (14) calendar day period, the auditor must select and reschedule the audit for a date after the fourteen (14) calendar day period.</p>		
<p>(11) The auditor must allow a pharmacy or pharmacist to produce documentation to address a discrepancy found during the audit.</p>		