

KEY PROVISIONS: COMPREHENSIVE STATE PBM REGULATION (1/11/2021)

- I. Compensation and reimbursement provisions: in response to *Rutledge v. PCMA* SCOTUS case, make these regulations applicable to PBMs serving all commercial and Medicaid managed care plans.
 - a. E.g., MAC transparency, PBM-affiliated pharmacy reimbursements, limits on retroactive reimbursement reductions/denials.
- II. Require PBM registration/licensure
 - a. Define “pharmacy benefit manager,” including their role as both a drug benefits manager and a pharmacy.
 - b. Enforcement of PBM regulations by the Insurance Commissioner
 - i. Authority to promulgate rules.
 - ii. Authority to impose penalties, levy fines, and revoke/suspend license.
 - iii. Establish a private right of action for pharmacies/pharmacists to ensure compliance.
- III. Reimbursement transparency
 - a. Make transparency laws applicable to all reimbursement methods (e.g., MAC, GER, etc.)
 - b. Require disclosure of basis of methodology to determine reimbursements.
 - c. Establish an appeal process.
 - i. Permit PSAO to file appeal on behalf of pharmacy
 - ii. If appeal is denied, disclose source where drug can be acquired at or below cost.
 - iii. If upheld, price adjustment should be retroactive and should apply to all network pharmacies.
 - d. Prohibit a PBM from reimbursing below acquisition cost benchmarks, such as NADAC.
 - e. Permit pharmacies to decline to dispense when reimbursement is below the pharmacy’s acquisition cost.
 - f. Prohibit arbitrary, retroactive claim adjustments and adjudication fees.
 - g. Prohibit a PBM from reimbursing non-affiliated pharmacies less than PBM-owned pharmacies.
 - h. Include pharmacy reimbursement in EOB.
 - i. Require PBMs to implement a pass-through pricing model.
- IV. Fair audit: addressing audit procedures and guardrails on recoupments.
- V. Network adequacy and patient access
 - a. Require a PBM to secure the participation in its network of a sufficient number of retail pharmacies to ensure convenient access.
 - b. Require a PBM to contract with any willing pharmacy.
 - c. Prohibit the requirement that a patient receive prescription drugs from a mail-order pharmacy.
 - d. Ensure patients may access “specialty” medications at the pharmacy of their choice.
 - e. Prohibit arbitrary accreditation standards as a condition of network participation.
- VI. Medicaid managed care reform
 - a. Carve pharmacy benefits out of the opaque managed care program and into the transparent fee-for-service program.
 - b. Increase oversight for PBMs serving managed care programs.
 - i. Utilize the pharmacy benefit administrator (PBA) model with pass-through pricing.
 - ii. Contract with only one PBM to serve all Medicaid managed care enrollees.
 - iii. Require the PBM to allow the state access to PBM’s drug pricing data and provide for state audits.
 - c. Require the state’s PBMs to utilize the objective, evidence-based reimbursement rates applicable to the fee-for service program.
 - d. Protect patient choice (e.g., any willing pharmacy, and anti-mandatory mail-order protections)