

## Top 18 Solutions for High Drug Costs

1. **Address Part D's protected classes.** Designating “classes of clinical concern” where all or substantially all drugs in a class must be covered allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage. A CMS plan to only moderate the effect of protected classes—not eliminate them—would save \$2 billion over 10 years.
2. **Encourage greater use of generics for Part D LIS enrollees.** MedPAC recommended allowing the Secretary to lower cost sharing on generics and raise it for brands that have generic competition. Allowing plans to lower generic cost sharing for these beneficiaries would save money for beneficiaries, taxpayers, and the Medicare program.
3. **Modify the requirement for two drugs per class.** The requirement that Part D plans cover two drugs per class is outmoded. It has encouraged manufacturers to argue for ever more granular classes and reduced competition, increasing Part D costs. Modifying the requirement by requiring plans to ensure access to therapies based on conditions or disease states instead would reduce costs without reducing access to needed drugs.
4. **Build on existing efforts to apply Part D management tools to Part B drugs.** PBM tools such as value-based formularies, manufacturer negotiation, prior authorization, and step-therapy have proven indispensable for improving patient safety and lowering costs in outpatient prescription drug plans like Part D. Adding Part D management tools to the Medicare fee-for-service program and building on efforts in Medicare Advantage for Part B drugs would make drugs more affordable on Medicare's medical side.
5. **Encourage use of mail-order pharmacy in Part D.** Mail-order pharmacy: vastly reduces errors in dispensing; increases convenience for beneficiaries on maintenance medications; improves adherence; and offers a lower cost sharing option to beneficiaries in most cases. With much of the country using home-delivery for a wide range of goods, CMS should begin encouraging home delivery of maintenance medications.
6. **Repeal any willing pharmacy provisions.** Requirements that all pharmacies be included in Part D networks drives up costs and are unnecessary, given the network adequacy requirements. Congress should repeal the provision. A recent study showed that greater use of limited network pharmacies in Part D could generate \$35 billion in savings over 10 years.
7. **Give Part D plans meaningful access to Part A and B claims data.** To coordinate care and make the best coverage decisions for beneficiaries, plans need to be able to use medical data as well as prescription data. Existing prohibitions on using A and B data to inform coverage design and decisions are misguided and keep plans from using claims data to improve care coordination and coverage. Researchers suggest combined data sets of Parts A, B, and D claims can be a “rich resource” for comparative effectiveness data.

8. **Inform patients when a drug is prescribed how much they will pay.** Patients would benefit from knowing at the time a physician prescribes a drug what their cost-sharing will be, based on where they are in their benefit structure (in the deductible, catastrophic phase, etc.) and the pharmacy they select. Providing this information through the use of real-time benefit tools will encourage patients to make the most cost-effective decisions on their care.
9. **Eliminate “pay-for-delay” agreements.** Patent settlements, or “pay-for-delay” agreements, allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic or biosimilar drug. These anticompetitive agreements should be eliminated.
10. **Eliminate risk evaluation and mitigation strategy (REMS) abuses.** Brand drug manufacturers have withheld drug samples from would-be generic manufacturers by citing REMS compliance as an excuse. Enacting the CREATES Act or similar legislation would prohibit these abusive practices used by a small minority of brand drug manufacturers.
11. **End orphan drug exclusivity abuses.** Orphan drug exclusivities are meant to encourage research on rare diseases, but manufacturers have gamed the policy to apply to blockbuster drugs with script volume in the tens of millions. Orphan exclusivity periods should apply to only those drugs originally approved by FDA under an orphan indication and only for the orphan indication itself.
12. **Revise innovator biologic exclusivity to seven years.** Seven years of data exclusivity would still provide a sufficient return to manufacturers, while also speeding more affordable biosimilars to market.
13. **Allow for FDA accelerated approval of me-too brands.** Accelerated review is granted to new drug applications that address “unmet need.” The economic need for competition to lower prices should be a criterion of unmet need.
14. **Improve biosimilar labeling and naming.** Substitutable biosimilars should bear identical names and labels to their innovator analogs. Use of different names will only create confusion among patients and providers and inhibit prescribing of biosimilars.
15. **Create a safe harbor for value-based drug price negotiations from Medicaid Best Price.** Today any drug manufacturer must offer state Medicaid programs the lowest price it offers any other payer. This provision is seen as a price floor and is inhibiting creative value-based pricing arrangements.
16. **Eliminate the tax deduction for direct-to-consumer (DTC) drug ads.** While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of drug benefits. Tax deductions should end for ads mentioning a specific product.

17. **Require use of electronic prescribing (eRx) where appropriate.** eRx helps increase patient safety and medication adherence while impeding the fraud and abuse that more easily happens with traditional paper or oral prescriptions. Many states have already smoothly adopted mandatory eRx for opioids and Congress last year required eRx for controlled substances under Medicare. To decrease fraud and diversion and increase patient access and safety, Congress should require eRx for all prescriptions, subject to certain exceptions.
  
18. **Expand drug coverage options for Health Savings Account (HSA)-eligible high-deductible health plans (HDHPs).** HDHPs associated with HSAs should have the option of covering prescription drugs with low or no cost-sharing prior to reaching the deductible, especially drugs that qualify for a preventive drug list. This policy can be achieved by expanding the current preventive drug list used by HDHPs.