MEDICARE PART D

- Change Part D formulary standards: Would allow plans to cover one drug per class
 instead of two, while also expanding utilization management tools for specialty drugs and
 protected classes. Estimated budget impact: -\$5.52 billion
 - o PCMA supports eliminating the two-drugs-per-class requirment and the classes of clinical concern and letting plans' pharmacy and therapeutic (P&T) committees determine formularies. At the very least, plans should be able to cover only one drug in a category with only two drugs in it, allowing for exceptions for medical necessity.
- Eliminate cost sharing for generics for low-income enrollees: Estimated budget impact: -\$0.21 billion
 - PCMA supports widening the distinction between brands and generic cost-sharing for LIS beneficiaries. In the past, PCMA members have not supported setting generic costsharing to zero, preferring to have the option to do that themselves.

MEDICARE PART B

- Coverage of certain Part B drugs under Part D: Would authorize HHS to consolidate coverage of certain drugs under Part D that are currently covered under Part B. *Estimated budget impact: not available*
 - OPCMA supports the application of cost management techniques used in Part D to managing drugs in Part B. In particular, PCMA recommends the use of formularies in Part B to enable private sector entities to negotiate prices with manufacturers, apply utilization management techniques, and direct care to the most appropriate site.

MEDICAID

- Five State Demonstration to Utilize Private Sector Tools in Medicaid: Participating states would determine their own drug formularies, establish a medical necessity appeals process, and negotiate drug prices directly with manufacturers. Prices negotiated under the demonstration would be excluded from Best Price. Estimated \$85 million in savings
 - PCMA supports using private-sector drug price negotiation in place of government price controls and the use of independent P&T committees to determine drug formularies.
- Reforming Medicaid Best Price:
 - PCMA supports lifting Medicaid best price requirements for plans in the Exchanges.
 Medicaid Best price laws should not stand in the way of value-based negotiations for drug prices.
- Value-Based Purchasing:
 - PCMA supports removing barriers to value-based negotiations, such as Medicaid Best Price. PCMA supports safe harbors in the anti-kickback statutes for value-based purchasing.

FDA

- Curbing R.E.M.S. abuses by brand manufacturers:
 - o PCMA supports ending manufacturers' anticompetitive abuse of R.E.M.S. programs.
- FDA Should Issue Final and Simple Biosimilar Interchangeability Guidance:
 - o PCMA encourages FDA to issue final interchangeability guidance that is understandable and presents no unnecessary obstacles to approval in a timely manner.

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

PCMA supports mandatory use of e-prescribing for controlled substances.