The President's FY 2014 Budget is Bad for Patients, Innovation, and the Economy

Undermining Medicare Part D

- The President's FY 2014 Budget proposes to impose Medicaid-style rebates in Medicare Part D for beneficiaries who receive the low-income subsidy beginning in 2014. The proposal would require manufacturers to pay the difference between rebate levels they already provide to Part D plans and Medicaid rebate levels.[i]
- Mandated Part D rebates will harm patients by leading to more expensive beneficiary premiums, copays and more restrictive access to medicines.[ii] Analysis from a former CBO director found that imposing these rebates in the Part D program could increase beneficiary premiums by 20 to 40 percent.[iii]
- The President's Budget also proposes to increase manufacturer discounts for brand name medicines from 50% to 75% in the Part D coverage gap in 2015.
- The cumulative impact of the Budget's proposed Part D policies could jeopardize tens of thousands of jobs in the U.S. biopharmaceutical sector and across the entire economy, in addition to slowing the pace of R&D investment to develop tomorrow's cures.
- The biopharmaceutical sector accounts for 650,000 jobs in the U.S. Each of these jobs supports nearly five additional jobs.[iv] This translates into a total of 4 million jobs across our economy, including industries like manufacturing, child care and retail. Analysts estimate that a $10 to $20 billion per year reduction in sector revenue -- the same magnitude as policies to impose a Part D rebate -- would result in 130,000 to 260,000 lost jobs.[v]
- Part D's success is largely attributable to its unique competition-based structure. Part D plans negotiate discounts and rebates directly with manufacturers, keeping program costs far below projections, while achieving high satisfaction marks from seniors. Injecting government-mandated rebates into Part D will undermine this beneficial structure.
- Recent CBO estimates have found that total Part D spending is 45 percent lower than initial projections,[vi] and CBO has also reduced its 10-year forecast of Part D spending by more than $100 billion in each of the past three years.[vii]
- Read more about Medicare Part D

Reducing Data Protection for Innovator Biologics

- Under current law, innovator biologics are entitled to 12 years of data protection. This data protection is intended to incentivize manufacturers to invest in the research and development of life-saving biologic medicines. The President's FY 2014 Budget proposal would reduce the 12 years of data protection to 7 years.
- The current 12 years of data protection for innovator biologics is critical to keeping the high-value U.S. jobs offered by the biopharmaceutical sector and spurring the R&D investment needed to seize the extraordinary opportunities for medical advances against our most costly and challenging diseases.
- 12 years of data protection for innovator biologics is one of the only provisions in the health reform law that received broad bipartisan support in both the House and Senate.
- Current law, which also established an approval pathway for biosimilars, provides a careful balance between incentivizing innovation and helping ensure long-term access and competition.

Restricting Patent Settlements That Bring Generic Medicines to Patients

- Patent settlements allow innovator and generic companies to avoid some of the costly and lengthy litigation related to patent disputes. History shows that patent settlements between innovator and generic companies generally permit generics on the market before patent expiration, leading to significant savings for consumers.[viii]
- Innovator and generic companies may pursue patent settlements because there can be benefits for both parties, and ultimately, for consumers. Litigating a patent dispute to final judgment can result in substantial costs to both innovator and generic companies, create business uncertainty, and can also result in a later generic entry.

- According to one generic company's estimate, patent settlements on 10 products alone allowed generic launches an aggregate of 83.4 years before patent expiration, resulting in more than $67 billion in savings to consumers.[ix]
- Discouraging or limiting patent settlements, as the FY 2014 Budget proposes to do, would increase the cost of patent enforcement, decrease the value of patent protection generally, and decrease incentives for taking the risks necessary to develop new medicines.[x]
- The FTC and Department of Justice already receive information on patent settlements, can review them on a case-by-case basis, and can challenge them in court.

Expanding the Unaccountable IPAB

- Under current law, if the projected Medicare per capita growth rate exceeds a predetermined target growth rate, the Independent Payment Advisory Board (IPAB) will recommend policies to Congress to reduce the Medicare growth rate to meet the target -- and those recommendations will automatically go into effect unless blocked by new legislation. The President's FY 2014 Budget proposes to lower the target rate applicable for 2020 and after from GDP per capita growth plus 1 percentage point to GDP per capita growth plus 0.5 percentage points.[xi]
- IPAB can enact sweeping Medicare changes without Congressional oversight, and their implementation would not be subject to judicial or administrative review.
- As it is structured, IPAB will likely result in reduced access to medical treatments for Medicare beneficiaries.
- PhRMA joins with over 500 organizations nationwide, including hospital and physician groups that have publicly expressed either concern or outright opposition to IPAB.
- Members of both parties in Congress have expressed their opposition to retaining the board as it currently stands, and bipartisan bills have been introduced in the House and Senate to repeal IPAB.[xii]

Increasing Part D Brand Prescription Copayments for Low Income Seniors

- This proposal unfairly targets low-income beneficiaries, who have complex health care needs and require access to a wide variety of medicines. According to CBO, even among drugs approved to treat the same condition, some drugs in a class may be more effective than others, for different patients.[xiii] Yet higher copayments on brand medicines would limit patient choices and force changes in prescribed treatment, even when not medically appropriate.
- On average, LIS beneficiaries fill more prescriptions each month than non-LIS beneficiaries, making an increase in cost-sharing particularly burdensome for LIS beneficiaries.[xiv]
- Increasing copays for low-income patients could lead to poor health outcomes and increased total health spending. Research shows that cost sharing is an important factor affecting adherence among low- income patients, potentially impacting health outcomes and potentially costing Medicare and Medicaid more in unnecessary hospitalizations and other medical care.
    - For example, research has shown that responsiveness to price increases for prescription drugs is significantly greater than for emergency room (ER) and hospital visits among low-income populations.[xv]
    - According to one study, low-income patients with high cholesterol were disproportionately impacted by an increase in cost-sharing for statins, resulting in larger declines in adherence relative to higher-income patients.[xvi]
    - Additionally, other researchers found that even small copay increases for low-income cancer patients in Medicaid reduced their use of necessary medicines while significantly increasing the probability of having an ER visit and raising their health care costs.[xvii]
- Generic use among low-income seniors is already high and increasing. MedPAC data shows similar generic utilization rates for both LIS and non-LIS beneficiaries, and that generic utilization has been increasing in recent years.[xviii]

Changes in Payment for Physician-Administered Medicines in Medicare Part B

- The President's FY 2014 Budget proposes to lower reimbursement for Part B drugs to 103 percent of Average Sales Price (ASP).
- MedPAC reports that physician margins for Part B drugs are already slim, and in some cases physicians cannot purchase drugs at the current 106 percent of ASP payment rate.[xix] Therefore, cuts to Part B payment for medicines could jeopardize access to critically important medications for many beneficiaries by reducing reimbursement to less than a physician's acquisition cost.
- Maintaining access to Part B medicines is crucial for vulnerable patients who suffer from serious illnesses such as cancer, end-stage renal disease, cerebral palsy, immune deficiency disease, and multiple sclerosis. Seven of the top 10 therapies covered by Part B in 2010 are used to treat cancer or the side effects of chemotherapy. [xx]
- Part B's market-based reimbursement approach is working well, and Part B medicines account for a declining share of overall spending. Average price growth in Medicare Part B is less than medical inflation, and volume weighted ASP for all Part B drugs has remained flat since 2006.[xxi] Smaller physician practices and/or rural practices with less purchasing power would be particularly at risk if payment is cut. Some of these physician practices are the sole provider of critical medical services in the local community.
- A reduction in the ASP payment rate could also be particularly burdensome for certain specialties, like oncology, that rely significantly on Part B drugs to treat their patients. A recent survey shows that payment cuts could force 72 percent of community cancer clinics to stop taking new Medicare patients, severely restricting access to vital medicines and services.[xxii]

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[i] HHS FY2014 Budget in Brief, p. 52.
[ii] Antos & King, "Tampering with Part D Will Not Solve Our Debt Crisis," *American Enterprise Institute Health Studies Working Paper*, June 2011.
[iii] Douglas Holtz-Eakin and Michael Ramlet, "Real versus Illusory Entitlement Solutions: Medicare Part D Rebates Would Dramatically Increase Drug Premiums." American Action Forum, July 2011.
[iv] Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation*, July 2011, p. 6.
[v] Op cit Battelle, p. 7.
[vi] See CBO Medicare baselines for 2004 through 2012 available at www.cbo.gov
[vii] See CBO, "Preliminary Analysis of the President's Budget for 2012," March 18, 2011, p. 12. http://www.cbo.gov/ftpdocs/121xx/ doc12103/2011-03-18-APB-PreliminaryReport.pdf and CBO, "Updated Budget Projections: Fiscal Years 2012 to 2022," March 2012, p. 9.
[viii] Generic Pharmaceutical Association, Press Release, Appeals Court Ruling Threatens Consumer Access to Safe and Effective Generic Drugs. July 16, 2012.
[ix] Testimony of Theodore C. Whitehouse of Wilkie, Farr, & Gallagher LLP on behalf of Teva Pharmaceuticals USA, Inc., for House E&C Comm., Subcommittee on Commerce, Trade, and Consumer Protection Hearing on H.R. 1706, "Protecting Consumer Access to Generic Drugs Act of 2009," Mar. 31, 2009.
[x] *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,* 344 F. 3d 1294, 1309 (11th Cir. 2003); *Schering-Plough*, 402 F.3d at 1075
[xi] HHS FY2014 Budget in Brief, p. 56.
[xii] 113th Congress, H.R. 351 and S. 351, "Protecting Seniors' Access to Medicare Act of 2013"
[xiii] "Effects of Using Generic Drugs on Medicare's Prescription Drug Spending" CBO. September 2010 http://www.cbo.gov/ftpdocs/118xx/doc11838/09-15-PrescriptionDrugs.pdf
[xiv] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy" March 2012. Ch. 13. www.MedPAC.gov
[xv] A. Chandra et al. "Patient Cost Sharing in Low Income Populations" *American Economic Review,* May 2010.
[xvi] ME Chernew et al. "Effect of Increased Patient Cost Sharing on Socioeconomic Disparities in Health Care," *Journal of General Internal Medicine*, August 2008.
[xvii] S Subramanian, "Impact of Medicaid Copayments on Patients with Cancer: Lessons for Medicaid Expansion under Health Reform," *Medical Care,* September 2011.
[xviii] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy" March 2013. www.MedPAC.gov
[xix] MedPAC, Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs 5 (Jan. 2007), available at http://www.medpac.gov/documents/jan07_partb_mandated_report.pdf.
[xx] MedPAC. Health Care Spending and the Medicare Program Data Book. June 2012, p 158.
[xxi] Weiss, K. Trends in Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2012. The Moran Company, December 2012.
[xxii] The American Society of Clinical Oncology, Community Oncology Alliance, International Oncology Network/AmerisourceBergen, The US Oncology Network. Joint Letter to The Honorable Kathleen Sebelius. April 1, 2013.