

February 26, 2009

Summary of the President's Budget for FY 2010

The White House released the President's budget today, "A New Era of Responsibility: Renewing America's Promise," which includes approximately \$43 billion in new revenue from biopharmaceutical companies -- \$29 billion to the federal government and an estimated \$14.5 billion to state governments over 10 years:

- \$19.5 billion in new federal revenue by: (1) increasing the Medicaid flat rebate from 15.1% to 22.1%, (2) extending the rebate to Medicaid managed care organizations, and (3) applying the additional inflation-based Medicaid rebate to new formulations of existing medicines. State government would also receive approximately \$14.5 billion in new revenues from these policies (These state revenues are not included in the President's budget).
- \$9.2 billion by creating an abbreviated pathway to approve follow-on biologics.

These new revenues are included in a "Health Reform Reserve Fund," which totals \$634 billion over 10 years, and will be used to fund a "very substantial down-payment" toward comprehensive healthcare reform. The fund includes \$316 billion from reductions in health care spending, 55 percent (\$176 billion) of which comes from reductions in payments to Medicare Advantage plans, 9 percent (\$29 billion) from the biopharmaceutical industry, and the remainder comes from reductions to other providers (e.g. hospitals, home health) – and related health-system and payment reforms. The other half of the reserve fund (\$318 billion over 10 years) would be financed by increases in taxes on affluent individuals and families (those families earning over \$250,000 annually) including a provision capping itemized deductions for Americans in the top income bracket.

The following list of policy proposals summarizes OMB's estimates of federal budgetary savings or spending over five-year and 10-year periods as they appear in the President's Budget. Where indicated, the five-year period includes fiscal years 2010 through 2014; the 10-year period includes fiscal years 2010 through 2019.

Key Provisions Affecting the Biopharmaceutical Industry

Medicaid:

The Administration is proposing three significant policy initiatives on Medicaid's payment for prescription drugs:

- (1) Increasing Medicaid's flat drug rebate for brand name medicines from 15.1% to 22.1% of the average manufacturers price (AMP);
- (2) extending and collecting rebates on behalf of Medicaid managed care plans (MCOs); and
- (3) applying Medicaid's CPI-based inflation rebate to new formulations of existing drugs.

OMB estimates these provisions would save the federal government **\$8.2 billion over 5 years and \$19.5 billion over 10 years**. When combined with the states' corresponding increased share of rebates, these combined proposals would **yield \$14 billion over 5 years and \$34 billion over 10 years**.

Medicare:

The President's budget does not repeal the noninterference provision and does not include mandatory rebates or government negotiation that would alter the competitive structure of the Medicare prescription drug program (Part D). Options to achieve savings in the Medicare program include implementing an income-related Part D premium and establishing a competitive system for Medicare Advantage plans. Other Medicare options include aligning hospital and physician payments with quality, promoting coordinated care, and assuring Medicare payments are accurate.

Follow-On Biologics:

Establishment of an abbreviated regulatory pathway for follow-on biologics (FOBs): \$9 billion in savings to the Federal Government over 10 years. While no detail is provided in the President's budget regarding the assumptions used to derive the estimated cost-savings from FOBs, it is likely that OMB drew heavily from the CBO Budget Options Book as the scoring appears consistent with CBO's score of \$9.2 billion over the same 10-year period for last year's Senate bill. That bill, which was voted out of the HELP Committee in 2008, would "establish an abbreviated regulatory pathway for approving follow-on biologics under the Public Health Services Act" and "would grant brand-name biologics 12 years of exclusivity during which time no follow-on biologic could be approved." With no detailed policy specifics other than a reference to an undefined period of data exclusivity and a reference to "evergreening," we cannot say definitively that the budget estimate is based on CBO's scoring of the Senate bill. However, based on triangulation of the scores, the President's Budget estimate is consistent with scoring of a HELP-type bill. We believe that had a very different DE period been considered in the President's Budget that the estimated cost-savings would have been very different. The President's Budget defines "evergreening" as "prohibiting brand biologic manufacturers from reformulating existing products into new products to restart the exclusivity process," which the President's Budget refers to as "ever-greening." No additional details nor estimates of potential cost savings are provided. It also should be noted that the CBO Budget Options Book had estimated an additional \$2.8 billion in savings if the pathway included a modification of Medicare Part B payment rates; this option does not appear to be included in the President's Budget assumptions.

Comparative Effectiveness Research (CER):

Generally Expand CER. The budget "expands research comparing the effectiveness of medical treatments to give patients and physicians better information on what works best." Linking results of CER to electronic medical records by instituting "user friendly pop-up alerts" will help better inform physician "clinical decision making". The budget does not provide detailed cost or saving amounts for CER.

Food and Drug Administration (FDA) Issues:

General Support for Importation. The budget supports the FDA in "new efforts to allow Americans to buy safe and effective drugs from other countries."

Investments in Inspections/Import Safety. The budget proposes an investment of \$1 billion to "increase and improve inspections, domestic surveillance, laboratory capacity, and domestic response to prevent and control food borne illness."

National Institutes of Health (NIH) Issues:

Includes over \$6 billion for the NIH to support cancer research. This funding “is central to the President’s sustained, multi-year plan to double cancer research. These resources will be committed strategically to have the greatest impact on developing innovative diagnostics, treatments, and cures for cancer. This initiative will build upon the unprecedented \$10 billion provided in the recovery Act, which will support new NIH research in 2009 and 2010.”

Intellectual Property Issues:

Patent Settlement Agreement. Prevents “drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.” No additional details nor estimates of potential cost savings are provided.

The President’s budget proposal seeks to protect intellectual property rights created through patents and trademarks. This option would give the U.S. Patent and Trademark Office “full access to its fee collections, which will provide resources to strengthen the Office’s ability to encourage innovation and safeguard the value of intellectual property through more efficient and higher quality patent and trademark examinations.”

Research Tax Credit:

The President’s Budget would make the research and experimentation (R&E) tax credit permanent. The tax credit would encourage technology-based companies to invest additional resources in the research, development, and testing of various products and services. While there is no narrative on this proposal within the budget, it is included as a line item in the budget tables. The budget tables indicate that between 2010 and 2019 this tax credit would increase the federal deficit by \$74.5 billion.

Global Health Initiative:

The President’s budget proposes to increase investments in global health programs, but provides no specific funding amounts. The budget cites increased investments in HIV/AIDS, malaria, and tuberculosis through global health initiatives such as the President’s Emergency Plan for AIDS Relief (PEPFAR) and the Malaria Initiative. The budget proposal indicates a continued focus on improving “the health status of the world’s poorest populations.”

Other Key Health Provisions in the President’s Budget

Below is a high-level summary of the other major healthcare-related proposals contained in the President’s Budget.

Health Reform Provisions:

The budget proposal includes a new **\$634 billion reserve fund** for comprehensive healthcare reform over the next decade aimed providing a “major commitment” toward putting the United States on a “clear path to cover all Americans.” About half of the reserve fund (**\$318 billion over 10 years**) would be financed by increases in taxes on affluent individuals and families (those families earning over \$250,000 annually) including a provision capping itemized deductions for

Americans in the top income bracket. The other portion of financing is from reductions in payments to insurers, doctors, hospitals and prescription MEDICINE manufacturers under Medicare and Medicaid (**\$316 billion over 10 years**) – including a proposal to reduce payments to private plans in Medicare (Medicare Advantage plans) by establishing a new competitive bidding structure (**\$177 billion over 10 years**).

The President’s budget proposal acknowledges that the \$634 billion funding commitment is “not sufficient to fully fund comprehensive reform,” but rather a “first crucial step” and pledges to work with “Congress to find additional resources to devote to health care reform.” The budget proposal also considers – but does not specially endorse – other potential financing mechanisms including “capping the tax exclusion for employer-sponsored health insurance, a value-added tax, or additional offsets in existing health care programs.” The budget proposal does not include specific initiatives to expand insurance coverage, but includes eight principles for health care reform, including:

- **Protect families’ financial health.** The plan “must reduce the growing premiums and other costs American citizens and businesses pay for health care. People must be protected from bankruptcy due to catastrophic illness.”
- **Make health coverage affordable.** The plan “must reduce high administrative costs, unnecessary tests and services, waste, and other inefficiencies that consume money with no added health benefits.”
- **Aim for universality.** The plan “must put the United States on a clear path to cover all Americans.”
- **Provide portability of coverage.** “People should not be locked into their job just to secure health coverage, and no American should be denied coverage because of pre-existing conditions.”
- **Guarantee choice.** The plan “should provide Americans a choice of health plans and physicians. They should have the option of keeping their employer-based health plan.”
- **Invest in prevention and wellness.** The plan “must invest in public health measures proven to reduce cost drivers in our system – such as obesity, sedentary lifestyles, and smoking – as well as guarantee access to proven preventive treatments.”
- **Improve patient safety and quality.** The plan “must ensure the implementation of proven safety measures and provide incentives for changes in the delivery system to reduce unnecessary variability in patient care. It must **support the widespread adoption of health information technology and the development of data on the effectiveness of medical interventions to improve the quality of care delivered.**”
- **Maintain long-term fiscal sustainability.** The plan “must pay for itself by reducing the level of cost growth, improving productivity, and dedicating additional sources of revenue.”

Other Medicare Provisions:

Reducing Medicare Overpayments to Private Insurers Through Competitive Payments would save \$176 billion over 10 Years. This option would establish a competitive system for Medicare Advantage plans in which payments would be based upon an average of plans' bids submitted to Medicare. This budget notes this would allow the market, not Medicare, to set the reimbursement limits, as well as reduce Part B premiums.

Implementing an Income-Related Medicare Part D Premium would save \$8 billion over 10 Years. This option would require certain higher-income beneficiaries enrolled in Medicare Part D to pay higher premiums according to their income, as is currently required for physician and outpatient services in Medicare Part B.

Encouraging Coordinated Care for Medicare Beneficiaries would produce negligible savings over 10 Years. This option would enable physicians to form voluntary groups that coordinate care for Medicare beneficiaries and to receive performance-based payments for the coordinated care.

Providing Private Sector Enhancements to Ensure Medicare Pays Accurately and Reallocating Medicare and Medicaid Improvement Funds would save \$25 billion over 10 Years. This option would dedicate additional resources that will initially be targeted to improving oversight and program integrity activities for the Medicare Part D, Medicare Advantage, and the Medicaid Program.

Promoting Flu Vaccines for Medicare Beneficiaries would produce negligible savings over 10 Years. This option would encourage primary care physicians to administer the flu vaccine to Medicare beneficiaries.

Improving Medicare Home Health Payments would save \$37 billion over 10 Years. This option would improve Medicare home health payments to align with costs.

Addressing physician-owned specialty hospitals would produce negligible savings over 10 Years. This option would address financial conflicts of interest in physician-owned specialty hospitals.

Health Care Quality Provisions:

Improving Care after Hospitalizations and Reduce Hospital Readmission Rates would save \$26 billion over 10 Years. This option would require that hospitals receive bundled payment for the hospitalization and care rendered by certain post-acute providers for 30 days after the hospitalization. Payment would be reduced to hospitals with high re-hospitalization rates within the 30-day post-release time frame.

Expanding the Hospital Quality Improvement Program would save \$12 billion over 10 Years. This option would require that a portion of Medicare payment for acute in-hospital services would be linked to performance on selected quality measures.

Reforming the Physician Payment System to Improve Quality and Efficiency. This section states that the current physician payment system should be reformed to provide incentives to physicians to improve quality and efficiency whereby physicians are paid for quality rather than

quantity. No specific dollar amounts are assigned to this section, as this proposal would be included in health reform.

Health Information Technology Issues (HIT):

The President's budget proposal seeks to accelerate the adoption of health information technology and utilization of electronic health records. The budget states it will continue efforts to further the adoption and implementation of health IT and use of electronic health records in an effort to “facilitate improvements in the quality of health care, prevention of unnecessary health care spending, and a reduction in medical errors.” No additional funding is indicated for these activities in the budget.