

*New Federal Initiatives Project*

**The Obama Administration's Budget  
Proposal for Health and Human Services**

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## THE OBAMA ADMINISTRATION'S BUDGET PROPOSAL FOR HEALTH AND HUMAN SERVICES

On February 26, 2009, President Barack Obama issued his Budget Message, setting forth his Administration's budget policies and priorities.<sup>1</sup> The budget details were more fully set out on May 7, 2009, when the Obama Administration released the Budget of the United States Government for Fiscal Year 2010.<sup>2</sup> One of the policy areas that the Obama Administration highlighted in the budget overview and the budget is health care and health care reform. The Obama FY 2010 budget allocated \$879 billion for the Department of Health and Human Services, including \$758.9 billion for the Medicare and Medicaid programs.<sup>3</sup>

### *Health Care Reform*

One of the most anticipated parts of the Obama budget was its health care reform proposals, particularly the reform proposals, the anticipated costs to the federal government, and how the Obama Administration proposed to fund health care reform. The Obama budget "set[s] aside a reserve fund of more than \$630 billion over 10 years . . . [for] financing reforms to our health care system," yet still recognizes that this amount "is not sufficient to fully fund comprehensive reform."<sup>4</sup> The Budget Overview sets forth President Obama's eight general principles for health care reform:<sup>5</sup>

- "*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."<sup>6</sup>
- "*Aim for Universality.* The plan must put the United States on a clear path to cover all Americans."<sup>7</sup>
- "*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 preexisting 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."<sup>8</sup>
- "*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 Care.* The plan must ensure the implementation of proven patient safety measures and provide incentives for changes in the delivery system to reduce unnecessary variability in patient care. It must support the widespread use 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."

President Obama's Budget proposes to pay for health care reform, in part, by increasing taxes on certain Americans and by instituting certain reforms which it suggests will achieve health care savings in three areas: "promoting efficiency and accountability, aligning incentives towards quality and better care, and encouraging shared responsibility."<sup>9</sup>

President Obama's budget proposes to raise \$318 billion (over 10 years) by limiting the tax rate at which families with incomes over \$250,000 can take itemized deductions (including mortgage interest deductions and charitable contributions) to 28 percent, thus increasing the taxes paid by these Americans. The Budget labels this as "rebalancing the tax code, so that the wealthiest pay more."<sup>10</sup>

The Obama Administration's budget also proposes statutory changes to cut payments to Medicare Advantage (MA) plans, or as the Budget Overview puts it, to "[r]educ[e] Medicare overpayments to private insurers through competitive payments"; it states that Medicare overpays MA plans by 14 percent on average as compared to what Medicare spends for beneficiaries in the traditional Medicare fee for service program, and cites \$175 billion in savings from such reform.<sup>11</sup> Medicare Advantage plans provide more varied packages of benefits (and more benefits) than are available under traditional Medicare.

The proposed budget also contains several initiatives that purport to reduce prescription drug costs, which savings would be used to fund health care reform, including prescription drug importation, establishment of a regulatory, scientific and legal pathway for generic biologics, the prohibition of agreements between brand name and generic drug manufacturers regarding the marketing of generic drugs, and changes to the Medicaid drug rebate program. The Budget Overview notes that the budget "supports [the Food and Drug Administration's (FDA's)] new efforts to allow Americans to buy safe and effective drugs from other countries."<sup>12</sup> Under current law, the importation of prescription drugs by persons other than the manufacturer can occur only if the Secretary of HHS "certifies to the Congress that the implementation of this section [creating a mechanism by which such importation could occur] will— (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer."<sup>13</sup> To date, no Secretary of HHS has made this certification or any similar certification. Thus, such importation could occur only through exercise of enforcement discretion by FDA or by a change in the law.

Through the Budget, the Obama Administration also proposes that it "will accelerate access to make affordable generic biologic drugs available through the establishment of a workable regulatory, scientific, and legal pathway for generic versions of biologic drugs", which would include a period of exclusivity for the original innovator biologic product, "[i]n order to retain incentives for research and development for the innovation of breakthrough products," consistent with Hatch-Waxman law for traditional products.<sup>14</sup> Under current law, FDA may only approve generic versions of innovator drugs (and biologic products approved as drugs under section 505 of the Federal Food, Drug and Cosmetic Act) through the abbreviated new drug application process; there is no legal pathway for approval of generic versions of biological products which are licensed under section 351 of the Public Health Service Acts.<sup>15</sup>

The Administration's budget also proposes to "prevent 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."<sup>16</sup> Current law requires that drug companies file, with the Assistant Attorney General for the Antitrust Division and the Federal Trade Commission, copies of certain agreements reached between brand name and generic drug manufacturers regarding the manufacture, sale, or marketing of brand name or generic drugs,<sup>17</sup> and the Department of Justice and/or the Federal Trade Commission can currently pursue legal action against innovator and generic drug manufacturers if they believe that such agreements violate current antitrust law. Most courts addressing the issue have concluded that the agreements are not anticompetitive; such agreements allow generic drugs on the market before an innovator's patent ends, while also eliminating the risks, uncertainties, and costs of patent litigation. Finally, the Obama Administration's budget proposes to "bring down the drug costs of Medicaid by increasing the Medicaid drug rebate for brand-name drugs from 15.1 percent to 22.1 percent of the Average Manufacturer Price, apply the additional rebate to new

drug formulations, and allow States to collect rebates on drugs provided through Medicaid managed care organizations.”<sup>18</sup> This would have the impact of decreasing the amount of reimbursement that pharmaceutical companies receive for participating in Medicaid, and potentially shift more costs to private sector insurance.

The Obama budget also proposes to reduce Medicare and Medicaid expenditures by improving Medicare and Medicaid payment accuracy. The Budget Overview further states that the Centers for Medicare and Medicaid Services (CMS) will address vulnerabilities presented by Medicare and Medicaid, including Medicare Advantage and the prescription drug benefit (Part D), and “will be able to respond more rapidly to emerging program integrity vulnerabilities across these programs through an increased capacity to identify excessive payments and new processes for identifying and correcting problems.”<sup>19</sup>

In a proposal that has drawn criticism from hospital groups, the Obama Administration proposes to improve care after hospitalizations and reduce hospital readmission rates by changing the reimbursement methodology such that “hospitals will receive bundled payments that cover not just the hospitalization, but care for certain post-acute providers the 30 days of care after the hospitalization, and hospitals with high rates of readmission will be paid less if patients are re-admitted to the hospital within the same 30-day period.” The Administration states that this would lead to better care, and estimates that this would save approximately \$26 billion over 10 years (if it leads to better care and results in fewer readmissions).

The Obama budget also proposes to expand the hospital quality improvement program by “link[ing] a portion of Medicare payments for acute in-patient hospital services to hospitals’ performance on specific quality measures.”<sup>20</sup> The Obama Administration believes that the higher quality that is expected to result from the program will save over \$12 billion over 10 years.

Finally, the Obama budget proposes to reform the physician payment system to improve quality and efficiency by making certain, unspecified reforms so that “physicians are paid for providing high-quality care rather than simply for more procedures and exams.”<sup>21</sup>

### *Budget Initiatives*

The Administration’s health and human services budget overview and budget contain a number of other Obama Administration initiatives, some of which are discussed herein.<sup>22</sup>

The budget includes a number of new or existing user fees for FDA, including a food inspection and food facility registration user fee, “to support and improve inspections, surveillance, laboratory capacity and response to prevent and control foodborne illnesses”<sup>23</sup>; generic drug user fees; user fees for the re-inspection of FDA-regulated facilities; and user fees for the issuance of export certificates for food and animal feeds.<sup>24</sup>

The budget requests \$5 million for the Health Resources and Services Administration (HRSA) to carry out section 319F-4 of the Public Health Service Act, which created a “Covered Countermeasure Process Fund”.<sup>25</sup> The Covered Countermeasure Process Fund is a fund/account in the Treasury that was created to provide compensation for injuries, illnesses or death, or losses arising from the administration or user of a covered countermeasure for which the Secretary of HHS has issued a declaration pursuant to the Public Readiness and Emergency Preparedness Act (PREP Act), PHS Act section 319F-3(b).<sup>26</sup> The budget also expands the loan repayment programs for health care providers (doctors, nurses, dentists) who agree to practice in medically underserved areas.<sup>27</sup>

The budget includes over \$6 billion within the National Institutes of Health to support cancer research, part of a multi-year plan to double cancer research.<sup>28</sup> The budget also includes \$211 million for research on autism spectrum disorders (ASD) causes and treatment, screenings for ASD, public awareness, and support services.<sup>29</sup> Some legislators have noted that, historically, they tend to avoid appropriating money to research cures for specific diseases, in favor of leaving those decisions to scientists.

The Budget proposes two new fees for the Centers for Medicare and Medicaid Services (CMS): (1) to cover the costs of follow-up visits to health care facilities found to be out of compliance with Medicare standards; and (2) to cover some of the costs of normal recertification surveys.<sup>30</sup> The budget also proposes to devote additional funds to “improve[e] oversight and program integrity activities” for the Medicare Part D, Medicare Advantage, and Medicaid programs.<sup>31</sup> This appears to be the same initiative outlined above as part of the down payment on health care reform.<sup>32</sup> It also claims to strengthen the Medicare program “by encouraging high quality and efficient care, and reducing excessive Medicare payments”, initiatives that also appear in the down payment on health care reform.<sup>33</sup> The budget also proposes new funding to broaden the Medicare and Medicaid research agenda.<sup>34</sup>

The Budget references several proposals for the Administration for Children and Families (ACF), the stated purposes of which are to improve child support collection processes and to increase resources to support and facilitate non-custodial parents’ access to, and visitation with, their children.<sup>35</sup> With respect to the Low Income Home Energy Assistance Program (LIHEAP) – which makes grants to States and Indian Tribes to aid low-income households with high energy costs – the Administration proposes through the Budget to create “a new mandatory trigger mechanism to provide automatic increases in energy assistance in response to energy price spikes.”<sup>36</sup> By creating such a mandatory trigger mechanism, this proposal would seem to decrease the Congress’s ability to determine and control the amount of funding for LIHEAP. Moreover, the Budget proposal does not suggest a corresponding mechanism to decrease the amount provided for the program if energy prices decrease, thus creating a one-way ratchet for spending for LIHEAP. The Administration also proposes to create a new, mandatory program in ACF – and to fund it at \$8.6 billion over 10 years – to provide funds to States for “evidence-based home visitation programs for low-income families.”<sup>37</sup> The Obama Administration anticipates that trained nurses would provide home visits to first-time low income mothers and mothers-to-be and that the program could serve as a “foundation for a program that could ultimately serve all eligible mothers who seek services.”<sup>38</sup> The Budget estimates that the program would save Medicaid \$664 million over 10 years.<sup>39</sup> The Budget also proposes funding for a new ACF child welfare initiative and a human services case management system for federally declared disasters.<sup>40</sup> In addition, the Obama Administration’s Budget proposes to eliminate most federal funding for abstinence education programs, and replace it with “teen pregnancy prevention programs”, including programs that replicate elements of teenage pregnancy prevention programs that have been proven “to delay sexual activity, increase contraceptive use (without increasing sexual activity), or reduce teenage pregnancy” and demonstration grants “to develop, replicate, refine, and test additional models and innovative strategies for preventing teenage pregnancy”.<sup>41</sup> The Obama Administration’s Budget “eliminates funding for Community-Based Abstinence Education, the mandatory Title V Abstinence Education program, the Compassion Capital Fund, and Rural Community Facilities.”<sup>42</sup>

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<sup>1</sup> See “A New Era of Responsibility: Renewing America’s Promise”, <http://www.whitehouse.gov/omb/budget/Overview/>, hereafter cited as “Budget Overview”.

<sup>2</sup> See <http://www.whitehouse.gov/omb/budget/>, hereafter cited as “Budget”.

<sup>3</sup> See Janet Adamy, “Budget Plans for Health-Care Overhaul,” *The Wall Street Journal*, [wsj.com](http://online.wsj.com/article/SB124170566917296143.html), May 7, 2009, <http://online.wsj.com/article/SB124170566917296143.html>.

<sup>4</sup> See Budget Overview at 27.

<sup>5</sup> See Budget Overview at 27-28.

<sup>6</sup> The administrative costs of a health plan usually include costs incurred to combat waste (including overutilization), fraud, and abuse. [Many commentators note that extant public health plans (Medicare and Medicaid) are subject to significant waste, fraud, and abuse, and do not spend enough to curb such conduct.] It should be noted that the Obama Budget proposes to increase funding for efforts to combat waste, fraud, and abuse in the Medicare and Medicaid programs. See Budget Overview at 28, 40-41, 69; Budget at 480-481.

<sup>7</sup> While Candidate Obama had been opposed to a mandate that every individual purchase health insurance, President Obama has recently indicated that he is open to such an individual health insurance mandate. See President Obama’s June 2, 2009 Letter to Senators Kennedy and Baucus at 2, <http://www.whitehouse.gov/blog/The-President-Spells-Out-His-Vision-on-Health-Care-Reform/>.

<sup>8</sup> While neither this principle nor any other expressly requires a public (or government-run) health insurance plan, Candidate Obama supported such a public health plan, and President Obama has recently reiterated that position. See Letter to Senators Kennedy and Baucus at 2.

<sup>9</sup> Budget Overview at 28.

<sup>10</sup> See Budget Overview at 29-30, 28.

<sup>11</sup> Whether Medicare overpays Medicare Advantage plans (and, if so, the extent of such overpayment) is an issue of debate.

<sup>12</sup> Budget Overview at 68.

<sup>13</sup> See Federal Food, Drug and Cosmetic Act § 804(l)(1). Pursuant to Congressional mandate, a task force led by the then Surgeon General issued a Report on Prescription Drug Importation in December 2004 (“Task Force Report”). See <http://archive.hhs.gov/importtaskforce/Report1220.pdf>. It concluded, among other things, that: (1) there are significant risks associated with the way individuals are currently importing drugs; (2) it would be extraordinarily difficult and costly for “personal” importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs; (4) regulating personal importation could be extraordinarily costly, on the order of \$3 billion a year based on 2003 estimates of the volume of packages entering the U.S.; (4) overall national savings from legalized commercial importation will likely be a small percentage of total drug spending, and developing and

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implementing such a program would incur significant costs and require significant additional authority; (5) public expectation that most imported drugs are less expensive than American drugs is not generally true, especially in the case of generic drugs marketed in the U.S.; (6) legalized importation of now-unapproved drugs will likely adversely affect the future development of new drugs for American consumers; (7) the effects of legalized importation on intellectual property rights are uncertain but likely to be significant; and (8) legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities. See Task Force Report at XII-XIII. The Congressional Research Service has similarly concluded that such prescription drug importation initiatives would save less than 1 percent of America's spending on prescription drugs.

<sup>14</sup> Budget Overview at 28; Budget at 454.

<sup>15</sup>The Administration also proposes that innovator biologic manufacturers be prohibited "from reformulating existing products into new products to restart the exclusivity process, a process known as ever-greening." Budget Overview at 28.

<sup>16</sup> Budget Overview at 28.

<sup>17</sup> See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1112.

<sup>18</sup> Budget Overview at 28.

<sup>19</sup> Budget Overview at 28-29.

<sup>20</sup> Budget Overview at 29.

<sup>21</sup> Budget Overview at 29. In addition, President Obama has recently proposed to save an additional \$313 billion in Medicare and Medicaid health care spending over 10 years by, among other things, reducing Medicare and Medicaid payments to hospitals and other health care providers, reducing reimbursements to drug manufacturers, and reducing or slowing payment increases to medical device manufacturers and others that provide services to Medicare patients. See *The Wall Street Journal*, June 15, 2009, at A3. The apparent theory behind the proposed reductions in payments to hospitals is that if all Americans have health insurance coverage, the portion of Medicare and Medicaid payments to hospitals that help them treat uninsured patients can be reduced or eliminated. See <http://www.whitehouse.gov/MedicareFactSheetFinal/>. Similarly, President Obama proposes to incorporate "productivity adjustments" into Medicare payment updates, which adjustments would be based on "the economy-wide productivity factor estimated by the Bureau of Labor Statistics." *Id.* According to the Administration, this "would encourage greater efficiency in health care provision." *Id.*

<sup>22</sup> This does not include discussion of any measures that were previously adopted in the reauthorization of the Children's Health Insurance Program or in the American Recovery and Reinvestment Act of 2009, although the Budget Overview makes frequent reference to such measures.

<sup>23</sup> Budget at 454.

<sup>24</sup> *Id.* The Budget also includes user fees associated with prescription drugs, medical devices, new animal drugs, generic animal drugs, mammography, export certification, and priority review. *Id.* at 453.

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<sup>25</sup> Budget at 458.

<sup>26</sup> Under the PREP Act, Secretarial Declarations provide certain immunity with respect to the administration and use of the countermeasures specified in the declarations.

<sup>27</sup> Budget Overview at 69.

<sup>28</sup> Budget Overview at 68. During the Bush Administration, funding for NIH was doubled.

<sup>29</sup> Budget Overview at 69.

<sup>30</sup> Budget at 477.

<sup>31</sup> See Budget Overview at 40-41, 69; Budget at 480.

<sup>32</sup> Cf. Budget Overview at 28.

<sup>33</sup> Budget Overview at 69; cf. Budget Overview at 28-29.

<sup>34</sup> Budget Overview at 69.

<sup>35</sup> Budget at 485.

<sup>36</sup> Budget at 486; Budget Overview at 70.

<sup>37</sup> Budget at 488; Budget Overview at 70.

<sup>38</sup> Budget Overview at 70.

<sup>39</sup> Budget at 488.

<sup>40</sup> Budget at 491.

<sup>41</sup> Budget at 490 (funding through ACF), 494 (funding through General Departmental Management funds).

<sup>42</sup> Budget at 491.