



# Medicaid and the State Children's Health Insurance Program (CHIP): FY2010 Budget Issues

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## Summary

The President is required each year to submit a comprehensive federal budget proposal to Congress before the first Monday in February. The House and Senate Budget Committees then develop their respective budget resolutions. Based on these budget resolutions, House and Senate Appropriations committees reconcile their budget resolutions and file a joint budget agreement. Although not binding, the resolution provides a framework for consideration of the 12 separate appropriations bills that would fund FY2010 federal spending, beginning October 1, 2009.

In presidential transition years, the timeline for the administration to submit a budget proposal is altered. President Obama was inaugurated on January 20, 2009. An outline of the President's first budget was submitted on February 26, 2009. The Obama Administration issued a detailed FY2010 budget appendix May 7, 2009. The remaining budget documents were released May 12, 2009.

President Obama's FY2010 budget outline described five major policy initiatives including economic recovery, health care reform, education, infrastructure improvements, and clean energy. The health care reform and economic recovery initiatives contained provisions that would affect Medicaid and the State Children's Health Insurance Program (CHIP). Some budget proposals would require legislative action, while others could be implemented administratively (e.g., via regulatory changes, program guidance, or other methods). President Obama has indicated that health care reform will be a major goal for his Administration's first year. The President's FY2010 budget reflects this emphasis, as the Medicaid and CHIP initiatives for FY2010 were aimed primarily at reducing expenditures to help fund a broader health care reform initiative. Medicaid savings, in particular, would help to fund a proposed \$635 billion Health Reform Reserve Fund, which is to be available for the next 10 years. The total Medicaid and CHIP savings from the President's legislative and administrative proposals were estimated to exceed \$1.45 billion in FY2010, \$8.8 billion over the period FY2010 to FY2014.

The Senate Budget Committee approved its budget resolution (S.Con.Res. 13) on March 26, 2009. The House Budget Committee approved its budget resolution (H.Con.Res. 85) on March 25, 2009. The House and Senate agreed to their respective budget resolutions April 2, 2009. A joint conference agreement on the budget resolution (S.Con.Res. 13 accompanied by H.Rept. 111-60) was passed in the House and in the Senate on April 29, 2009. Among other provisions, the conference agreement provides for 20 Senate and 14 House deficit-neutral reserve funds, as well as seven Sense of the Congress provisions. The FY2010 Budget Resolution provides for \$2,322 billion in revenue and \$3,555 billion in expenditures, which would result in a deficit of \$1,233 billion.

This report will be updated to reflect relevant legislative activity.

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## Introduction

Each year, the President is required to submit a comprehensive federal budget proposal to Congress no later than the first Monday in February.<sup>1</sup> Once the budget is submitted, the Congressional Budget Office (CBO) analyzes the proposal using its own economic assumptions and estimation techniques. The House and Senate Budget Committees also develop their respective budget resolutions after reviewing the President's budget, the views of other committees, and information from CBO. Differences between the Senate and House versions are supposed to be reconciled by April 15, but this deadline rarely is met. Although not binding, the budget resolution provides a framework for subsequent legislative action.

This report provides information on Medicaid and the State Children's Health Insurance Program (CHIP). It will be updated to reflect relevant legislative activity. Congressional Research Service (CRS) staff contact information by topic area is provided in **Table 2** at the end of the report.

## Medicaid and CHIP in the President's FY2010 Budget

In January 2009, there was grave concern among policymakers over the widening economic slowdown, bankruptcy in the real estate, automobile, and financial industries, and rapidly increasing unemployment.<sup>2</sup> The economic conditions that prevailed in January 2009 helped to shape the President's FY2010 budget proposal, as well as major legislation passed by Congress that was aimed at underpinning weak economic segments, boosting overall spending, and helping to prevent further economic deterioration.

The severe economic conditions and congressional consensus on the need to address the eminent expiration of CHIP led to emergency legislation for these initiatives that otherwise might have been included in the President's budget proposal and addressed later in the year. The American Recovery and Reinvestment Act (ARRA, P.L. 111-5) and the Children's Health Insurance Program Reauthorization Act (CHIPRA, P.L. 111-3) were passed early in 2009, while the Obama Administration was developing its FY2010 budget proposal. ARRA provided an additional \$89.3 billion in federal Medicaid funding to states over five years.<sup>3</sup> The additional Medicaid funding included enhanced federal financial participation percentages (FMAP), reauthorization of selected Medicaid benefits, extension of regulatory moratoriums, and expansion of coverage for certain

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<sup>1</sup> Current law (31 U.S.C. 1105(a)) requires the President to submit a budget no earlier than the first Monday in January, and no later than the first Monday in February. This timeline often is altered during presidential transition years. President Obama submitted a budget overview document on February 26, 2009. A detailed budget submission was issued May 7, 2009. President Obama's budget timeline and process was consistent with the last three incoming Presidents who also did not submit detailed budget proposals in February. For more information see CRS Report RS20752, *Submission of the President's Budget in Transition Years*, by (name redacted), and CRS Report R40085, *Consideration of Budgetary Legislation During Presidential Transition Years: A Brief Overview*, by (name redacted) and Momoko Soltis.

<sup>2</sup> For more detail on the economic crisis, see CRS Report R40198, *U.S. Economy in Recession: Similarities To and Differences From the Past*, by (name redacted).

<sup>3</sup> CRS Report R40223, *American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111-5): Title V, Medicaid Provisions*, coordinated by (name redacted).

beneficiary groups.<sup>4</sup> CHIPRA reauthorized the CHIP program through FY2013 which provided, among other provisions, \$44 billion in additional funds to states, while permitting states to expand CHIP coverage and benefits.

The President's FY2010 Medicaid and CHIP budget proposals contain no spending increases. Rather, the FY2010 Medicaid and CHIP budget proposals are intended to reduce Medicaid, and indirectly, CHIP expenditures. In the short-term, cost savings through greater efficiency and accountability could help states to maintain Medicaid coverage during the financial crisis by cushioning the program's countercyclical impact.<sup>5</sup> In the longer-term, the Obama Administration envisions Medicaid cost savings to help fund a \$635 billion Health Reform Reserve Fund. For each of the FY2010 Medicaid and CHIP budget proposals, this report provides

- background,
- a description of the proposal based on available information,<sup>6</sup> and
- relevant CRS reports.

## Legislative Versus Administrative Proposals

**Table 1** displays a list of proposals that would require legislative action. With passage of two major health care bills, ARRA and CHIPRA, some budget initiatives (both legislative and administrative) may not be necessary.

In their analyses of the President's budget, both CBO and executive branch agencies such as the Health and Human Services Department (HHS) and the Office of Management and Budget (OMB) provide baseline (current law) estimates of Medicaid and CHIP spending along with estimated costs and savings of proposed changes. However, CBO and the executive branch differ in their treatment of legislative and administrative proposals.

In executive branch documents describing the President's budget, implementation of proposed administrative changes is assumed in estimates of baseline Medicaid and CHIP<sup>7</sup> spending, and estimates for legislative proposals are presented separately. In general, CBO assesses the likelihood that a particular administrative action will take place before adjusting its baseline,<sup>8</sup> and

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<sup>4</sup> The Children's Health Insurance Program Reauthorization Act (CHIPRA, P.L. 111-3) was signed February 4, 2009 and The American Recovery and Reinvestment Act (ARRA, P.L. 111-5) was signed February 17, 2009. For more detail, see CRS Report R40226, *P.L. 111-3: The Children's Health Insurance Program Reauthorization Act of 2009*, by (name redacted) et al. and CRS Report R40223, *American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111-5): Title V, Medicaid Provisions*, coordinated by (name redacted).

<sup>5</sup> See CRS Report RS22849, *Medicaid Financing*.

<sup>6</sup> Sources include Department of Health and Human Services (HHS), *Fiscal Year 2010 Budget in Brief*, available at <http://www.hhs.gov/asrt/ob/docbudget/2010budgetinbrief.pdf>; the Office of Management and Budget, *Budget of the United States Government, Fiscal Year 2010*, available at <http://www.whitehouse.gov/omb/budget/>; and HHS, Centers for Medicare and Medicaid Services, *Fiscal Year 2010 Justification of Estimates for Appropriations Committees*, available at <http://www.cms.hhs.gov/PerformanceBudget/Downloads/CMSFY10CJ.pdf>.

<sup>7</sup> For a description of adjustments made to arrive at baseline Medicaid expenditures, see HHS, *Fiscal Year 2008 Justification of Estimates for Appropriations Committees*, pp. 135-141 <http://www.cms.hhs.gov/PerformanceBudget/Downloads/CMSFY10CJ.pdf>.

<sup>8</sup> CBO, letter to the Honorable John M. Spratt Jr., May 2, 2007, available at <http://www.cbo.gov/ftpdocs/80xx/doc8060/05-02-LetterOnRegs.pdf>.

only provides separate estimates for legislative proposals. For this reason and others, CBO and executive branch estimates of Medicaid and CHIP spending often differ.

**Table I. Cost (Savings) of Medicaid and CHIP Proposals in the President's FY2010 Budget**

Proposal	HHS Estimate of Outlays (in \$ millions)	
	FY2010	FY2010-FY2014
<b>Medicaid</b>		
Legislative proposals		
Increase Medicaid Brand-name Drug Rebate from 15.1% to 22.1%	(250)	(2,120)
Extend Drug Rebates to Medicaid Managed Care Organizations	(770)	(3,810)
Apply Additional Rebate to New Formulations of Existing Drugs	(150)	(1,270)
Mandate National Correct Coding Initiative	(10)	(175)
Expand Medicaid Family Planning Services		(5)
Pathway for FDA Approval of Generic Biologics: Medicaid Impact		(10)
Reallocate Medicaid Improvement Fund		(100)
Subtotal, Medicaid Legislative Proposals	(1,180)	(7,490)
Medicaid Interactions		
Medicaid Drug Rebate Proposals	(270)	(1,320)
Subtotal, Medicaid Interactions	(270)	(1,320)
Total, Medicaid Legislative Proposals	(1,450)	(8,810)
<b>CHIP</b>		
Subtotal, CHIP Legislative Proposals	0	0
<b>Other Medicaid and CHIP Interactions</b>		
Phase-in Home Visitation: Children & Families	(1)	(81)
<b>Total Medicaid and CHIP Legislative Proposals</b>	<b>(1,451)</b>	<b>(8,891)</b>

**Source:** Department of Health and Human Services, *Fiscal Year 2010 Budget in Brief*, available at <http://www.hhs.gov/asrt/ob/docbudget/2010budgetinbrief.pdf> and Congressional Budget Office, *CBO Estimates of Medicaid and CHIP Proposals in the President's Budget for Fiscal Year 2010*, available at <http://www.cbo.gov/budget/factsheets/2009b/medicaid.pdf>.

**Notes:** Numbers in parentheses represent savings. Estimates for proposals that do not show a dollar figure were not provided in the documents cited above. In executive branch documents describing the President's budget, implementation of proposed administrative changes is assumed in estimates of baseline Medicaid and CHIP spending, and estimates for legislative proposals are presented separately. In general, CBO only adjusts its baseline estimates to account for administrative changes as they are implemented—rather than as they are proposed—and only provides separate estimates for legislative proposals.

## Medicaid Legislative Proposals

### Medicaid: Increase Medicaid Brand-name Drug Rebate from 15.1% to 22.1%

**Background.** Prescription drug manufacturers are required to give states rebates on outpatient drugs purchased for Medicaid beneficiaries.<sup>9</sup> Under Medicaid law, manufacturers must enter into agreements with the Secretary of the Department of Health and Human Services (HHS) that guarantee Medicaid their best price. Under these agreements, drug manufacturers must offer for sale to Medicaid programs their entire prescription drug product line. The drug manufacturers also must pay a rebate equal to 15.1% of the purchase price of brand name (single source) products to each state.<sup>10</sup> The purchase price for these brand name products is based on the average manufacturer price (AMP) which excludes certain discounts, free products, and drugs that are delivered through other channels, such as through managed care contracts and other capitation agreements (see the next proposal for a discussion of Medicaid outpatient drugs covered by managed care organizations). Drug manufacturer rebates vary depending on the state and other factors. In 2007, CBO estimated that actual manufacturer rebates were 22.1% of AMP.<sup>11</sup>

**Proposal.** This proposal would increase the fixed rebate paid by prescription drug manufacturers from 15.1% to 22.1% of AMP for single source, brand-name drugs. HHS estimated that by increasing the Medicaid rebate on brand-name prescription drugs to 22.1% of AMP federal expenditures would be reduced by \$250 million in FY2010 and \$2.1 billion over the period FY2010 to FY2014.

**Reports.** For more information, see CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*.

### Medicaid: Extend Drug Rebates to Medicaid Managed Care Organizations

**Background.** Medicaid programs deliver services to beneficiaries through a variety of service delivery options, which range from fee-for-service (FFS) to full risk-bearing managed care/capitation contracts, but also include hybrid approaches that combine elements of both managed care and FFS. Under full risk contracts, managed care organizations (MCOs) accept financial responsibility for Medicaid beneficiaries' medical care needs in exchange for a negotiated, but fixed payment amount. Expenditures for beneficiaries' care that exceeds the agreed to amount are the responsibility of the MCO, but when beneficiaries' care cost less than

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<sup>9</sup> The Social Security Act, Section 1927(a), Payment for Covered Outpatient Drugs.

<sup>10</sup> The rebates are paid in aggregate for all drugs sold by a manufacturer to each state rather than separately for each product. Prescription drug manufacturers also pay rebates to states on multiple-source (generic) drugs. Generic drug rebates are 11% of the manufacturer's Average Manufacturer Price (AMP). AMP is defined as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail class of trade.

<sup>11</sup> Budget Options Volume 1, Health Care, Option 74, Congress of the United States, Congressional Budget Office, December 2008.

the contracted amount, the MCO retains the excess as profit. Medicaid programs have increasingly relied on MCO contracts, particularly to cover children and nondisabled adults.

Prescription drug manufacturers that want to sell drug products to Medicaid programs must agree to pay states discounts on both brand and generic outpatient prescription drug products purchased on behalf of Medicaid beneficiaries (see the previous proposal on increasing Medicaid's rebate to 22.1% and the next proposal on applying the Medicaid rebate to new formulations of existing drugs). Under Medicaid law, prescription drug manufacturers are exempted from paying discounts on outpatient prescription drugs that are delivered by MCOs, Part D, and some other distribution channels. With Medicaid's increasing use of managed care to deliver services to beneficiaries, the loss of prescription drug discounts has become substantial. It is estimated that between 35-40% of all Medicaid beneficiaries are covered under full capitation agreements where prescription drugs are included in the contracts.<sup>12</sup> Estimates of the percentage of Medicaid beneficiaries covered under some form of managed care, including partial risk contracts and modified FFS delivery approaches, are considerably higher. States often "carve-out" prescription drugs from full risk capitation agreements in order to receive the full benefit of Medicaid's rebates.<sup>13</sup>

**Proposal.** This proposal would authorize states to collect rebates from drug manufacturers on outpatient drugs purchased for Medicaid beneficiaries under Medicaid MCO and other health plan contracts. The rebate structure for beneficiaries covered under managed care contracts would be the same as under Medicaid's FFS process and percentage. HHS estimated that this proposal would reduce federal expenditures by \$770 million in FY2010 and \$3.8 billion over the period FY2010-2014.

**Reports.** CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*.

## Medicaid: Apply Additional Rebate to New Formulations of Existing Drugs

**Background.** Under Medicaid's fee-for-service (FFS) prescription drug pricing rules, drug manufacturers must enter into agreements with the Secretary of HHS for their products to be covered by Medicaid. Manufacturers must agree to sell their brand name products to state Medicaid programs at the best price offered to all purchasers, with a few exceptions.<sup>14</sup> As part of

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<sup>12</sup> Estimates of the percentage of Medicaid beneficiaries that receive services through full capitation contracts vary from 35% to 60% or more. The reason for this seemingly large disparity is that some Medicaid managed care contracts are not considered risk bearing contracts. Under primary care case management (PCCM) contracts providers (mostly physicians) are paid a per member per month management fee, but do not assume any risk for the services that beneficiaries will need. PCCM is essentially a type of fee-for-service delivery approach. When all Medicaid managed care enrollment is adjusted for partial capitation and prescription drug carve-outs, the percentage of Medicaid enrollment in managed care was approximately 37% in 2006. These data are based on CRS analysis of CMS' Managed care Reports <http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/Downloads/mmcer06.pdf>.

<sup>13</sup> Of the 41 states with some form of full risk Medicaid capitation contracts, 14 states carve-out prescription drugs, while another 9 states carve out selected drug classes.

<sup>14</sup> Best price is the lowest price for brand name products sold under new drug applications (as defined in the Federal, Food, Drug, and Cosmetic Act) to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity, with some exclusions. Exclusions include drugs sold to the Indian Health Service, the Veterans Administration, the 340B program, State Pharmacy Assistance Programs (SPAPs), Medicare Part D, and Federal Supply Schedule (FSS) sales. Best price also includes cash and volume discounts, other rebates, and free goods.



the agreement with HHS and to help the Secretary monitor Medicaid's and other drug pricing policies, drug manufacturers that participate in Medicaid must report two drug prices to CMS: the average manufacturer price (AMP) and the best price.<sup>15</sup> AMP and best price are used to calculate drug manufacturers' rebates.

On single source, brand name drugs, drug manufacturers pay two different rebates to states, a basic and an additional rebate. The basic rebate is the greater of either 15.1% of AMP or the difference between AMP and best price. The additional rebate helps to offset rapid price increases that manufacturers might use as a way of reducing the value of the required basic rebate. Manufacturers owe the additional rebates on drugs when the AMP exceeds the original Medicaid base price established for each drug (and each formulation/dosage) when the drug is first brought to market and annually adjusted for inflation. The additional rebate would be equal to the amount each drug increased above the inflation adjusted base price.

Drug manufacturers sometimes create new products by modifying existing drugs, such as by creating new dosages or formulations, but include minor changes such as extended-release versions, which often are accompanied by substantial price increases. Under current law, even minor changes to existing products can be designated as new products, which result in new base prices. New products have new base prices assigned. With new base prices, manufacturers are able to increase prices and avoid paying the additional Medicaid rebate that they would owe if they raised the price on the original version of the drug.

**Proposal.** Under this proposal, extended-release versions of existing products would be classified as the original product for the purpose of calculating the additional Medicaid drug rebate, which would reduce the ability of prescription drug manufacturers to avoid paying additional rebates to state Medicaid programs by introducing new versions of existing drugs and charging higher prices for these reformulated products. In the President's FY2010 budget, it was estimated that this proposal would reduce federal Medicaid expenditures by \$150 million in FY2010 and \$1.3 billion over the period from FY2010 to FY2014.

**Reports.** Currently, no other CRS reports address this topic.

## Medicaid: Mandate National Correct Coding Initiative

**Background.** Unlike Medicaid, where states administer the program, the Medicare program is national and is administered by CMS. Working through contractors, primarily health insurance companies, CMS processes Part B Medicare claims, including payments for physician, laboratory, and radiology services. To help ensure correct payment for claims, CMS implemented a Correct Coding Initiative (CCI) for Medicare in 1996. Under Medicare's CCI, CMS' contractors review claims from Part B health care providers, before payment, using automated edits. These automated edits scan each claim to detect inconsistencies that would make the claims invalid or ineligible for payment. Reimbursement claims submitted by providers follow standard formats and the vast majority are submitted and processed electronically. Reimbursement claims must all contain numeric codes that classify the patient's condition as well as the services performed during a visit (encounter) to a health care provider. The Healthcare Common

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<sup>15</sup> The average manufacturer price (AMP) is the average price that drug manufacturers receive for sales to retail pharmacies and mail-order establishments.

Procedure Codes (HCPCS) system<sup>16</sup> is a classification system used to describe physician office visits and outpatient claims. CCI edits review the HCPCS codes contained on health care claims to identify coding inconsistencies such as, duplicate services delivered to the same beneficiary on the same date of service; individual services billed erroneously as service bundles (when individual services are grouped together, but cheaper comprehensive codes are available to describe the same services); and also when bundled services are submitted for payment which should have been billed individually, not as bundled services.

**Proposal.** This proposal would mandate that Medicaid participate in a national CCI, presumably similar to Medicare's correct coding initiative. HHS estimated that a CCI would reduce Medicaid expenditures in FY2010 by \$10 million and would further decrease Medicaid spending by \$175 million for the period FY2010 to FY2014.

**Reports.** Currently, no other CRS reports address this topic.

## Medicaid: Expand Medicaid Family Planning Services

**Background.** In 2003, Medicaid paid for approximately 40% of all U.S. births.<sup>17</sup> Thus, the federal government and states paid for the prenatal care, delivery, and postpartum care for approximately 1.5 million children and their families. In addition, studies suggest that nearly half of all pregnancies in this country are unplanned and that unplanned pregnancy rates may be as much as four times higher for low-income women.<sup>18</sup> Medicaid coverage of family planning services is a mandatory benefit for women whose income is not more than 133% of poverty. Family planning is covered for these women for 60 days postpartum. Approximately half of the states and the District of Columbia have used waivers to extend family planning coverage for women up to 200% of poverty. In addition to family planning services, many women, up to 200% of poverty, would be eligible for Medicaid if they became pregnant. The federal government's share of most Medicaid service costs is based on the Federal Medical Assistance Percentage (FMAP)<sup>19</sup>. FMAP rates vary among states, but certain Medicaid services are matched for all states at higher rates. States receive a 90% FMAP rate for family planning services.

**Proposal.** This proposal would require states to cover family planning services for women between the ages of 15 and 44 who were not pregnant and whose family income was not more than 200% of poverty. A rationale for this proposal is that it would reduce the number of unplanned pregnancies and reduce Medicaid expenditures for the federal government and states. CBO estimated that 2.4 million women would be covered under this proposal in 2014.<sup>20</sup> In the

<sup>16</sup> HCPCS codes are used to bill for physician and outpatient services.

<sup>17</sup> See Births Financed by Medicaid, The Henry J. Kaiser Family Foundation, State Health Facts, Medicaid and CHIP, accessed on May 20, 2009, <http://www.statehealthfacts.org/profileind.jsp?cat=4&sub=57&rgn=1>.

<sup>18</sup> *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, Perspectives on Sexual and Reproductive Health, Vol. 38, No.2, June 2006, Lawrence Finer and Stanley Henshaw.

<sup>19</sup> The Federal Medical Assistance Percentage (FMAP) is calculated annually based on a statutory formula which can range from 50% to 83%. Rates vary for each state, based on per capita income and other variables. State FMAP rates are published annually in the *Federal Register* at the end of each year for the next FY so states have time to prepare their budgets and fund their share of Medicaid expenditures (FY2010 FMAP rates appeared in the November 21, 2008 *Federal Register*, see <http://edocket.access.gpo.gov/2008/pdf/E8-28233.pdf>). However, under Sec. 5001 of the American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111-5) FMAP rates for FY2009-2011 were increased. The enhanced FY2010 FMAP rates were published in the *Federal Register* on April 21, 2009.

<sup>20</sup> Budget Options, Volume I, Health Care, Congress of the United States, Congressional Budget Office, December (continued...)

President's FY2010 budget it was estimated that this proposal would have no effect on federal expenditures in FY2010, but would decrease federal expenditures by \$5 million over the period FY2010 to FY2014.

**Reports.** CRS Report R40223, *American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111-5): Title V, Medicaid Provisions*, coordinated by (name redacted), CRS Report RS21054, *Medicaid and SCHIP Section 1115 Research and Demonstration Waivers*, by (name redacted), and CRS Report RL32950, *Medicaid: The Federal Medical Assistance Percentage (FMAP)*.

## Medicaid: Pathway for FDA Approval of Generic Biologics: Medicaid Impact

**Background.** A biologic is a drug or a vaccine that is made from living organisms. Spending on biologic products has increased and was estimated to exceed \$40 billion in 2007. Approximately 75% of biologic spending was on brand-name products that will lose patient protection over the next 10 years.

Generic non-biologic products (made from chemicals or other non-biologic compounds) are covered under the federal Food, Drug, and Cosmetic Act. This law authorizes the Food and Drug Administration (FDA) to use an abbreviated regulatory process to approve generic versions of single source, innovator drugs based on FDA's approval for the brand-name versions of these products. FDA's authority to approve generic drug products is possible because the generic products are chemically the same as the approved brand named products. As patents on single source non-biologic drug products approach expiration, generic drug manufacturers compete to offer the first generic version of these branded products, especially for drugs with significant sales potential. For the growing number of biologic products, however, FDA lacks abbreviated regulatory authority to license follow-on or biosimilar versions of biologic products.<sup>21</sup> Thus, even after patents on biologics expire, there is little competitive pressure on brand name biologic drug companies to reduce prices, because there are no alternative products. In most cases it would be illegal and cost prohibitive for generic drugmakers to fully replicate safety and efficacy research and the manufacturing processes used to make biologic products in order to introduce biosimilar products.

**Proposal.** This proposal would establish a new abbreviated regulatory pathway for biosimilars analogous to the FDA's existing authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 P.L. 98-417. FDA would be permitted to use data and research submitted to support the original single source biologic's approval as the basis for approving follow-on biologic products. An abbreviated approval process would encourage other manufacturers to develop similar competitive products as patents on the original biologic products expired. Additional competition from multiple manufacturers of follow-on biologics would help to decrease prices and lower prescription drug spending for Medicaid and

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2008.

<sup>21</sup> Generic drugs contain the same active ingredients as the original patented drugs, but may contain different inactive ingredients. In contrast, biosimilars are much more complex molecules that are often dependent on specific manufacturing processes.

other payers. In the President's budget, HHS estimated that this proposal would not have an effect on federal Medicaid expenditures in FY2010, but would reduce federal outlays by \$10 million over the period FY2010 to FY2014.

**Reports.** CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, by (name redacted), and CRS Report RL33901, *Follow-On Biologics: Intellectual Property and Innovation Issues*, by (name redacted) and (name redacted).

## Medicaid: Reallocate Medicaid Improvement Fund

**Background.** Under Sec. 7002 of the Supplemental Appropriations Act, 2008 (War Supplemental, P.L. 110-252), Congress required the Secretary of HHS to establish the Medicaid Improvement Fund.<sup>22</sup> The Medicaid Improvement Fund (MIF) would be available for the Centers for Medicare and Medicaid Services (CMS) to use to improve the management of the Medicaid program, including oversight of contracts and contractors and evaluation of demonstration projects. The MIF was to have \$100 million available in FY2014, and \$150 million in FYs 2015-2018. Funds for the Medicaid Improvement Fund were redirected from the Physician Assistance and Quality Initiative (PAQI) created under the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA, P.L. 110-173).<sup>23</sup>

**Proposal.** This proposal would eliminate the MIF and reallocate these savings to support the President's broader health care reform initiative. This proposal was estimated in the President's budget to have no effect on FY2010 Medicaid expenditures, but would decrease federal spending by \$100 million over the period FY2010 to FY2014.

**Reports.** Currently, no CRS reports address this topic.

## Medicaid: Expand Home Visitation Programs

**Background.** With a number of exceptions, Medicaid is available only to children, adult members of families with children, pregnant women, and to aged, blind, or disabled people. People who do not fall into these categories—such as childless, single adults and couples—generally do not qualify for Medicaid regardless of their income level. Historically, Medicaid eligibility has been divided into two basic classes, the “categorically needy” and the “medically needy.” The two terms once distinguished between welfare-related (categorically needy) beneficiaries and those qualifying under special Medicaid rules which allow states to cover people whose incomes are too high to qualify for cash welfare support, but who nevertheless need help with medical bills (medically needy). As non-welfare groups have been added to the “categorically needy” list over the years, the terms categorically and medically needy have become less meaningful in describing the various populations for whom mandatory or optional Medicaid coverage is available. Nonetheless, the distinction can be useful when considering Medicaid benefits. Some benefits are considered mandatory for categorically needy individuals; that is, states must cover those benefits for the categorically needy, but they are optional for medically needy individuals. Other benefits are optional for both groups of beneficiaries. Some states provide those optional benefits only to categorically needy individuals, while some states

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<sup>22</sup> See Social Security Act, Sec. 1941 (42 U.S.C. 1396w-1).

<sup>23</sup> Sec. 1848(l)(2) of the Social Security Act (42 U.S.C. 1395w-4(l)(2)).

provide optional benefits to both groups, and still other states provide optional benefits to selected subcategories of the medically needy as well as to all categorically needy beneficiaries.

Although home visitation services are not specifically required benefits under Medicaid law, these services could potentially be covered by states under mandatory and optional benefit categories. Under current Medicaid law, many states may not routinely cover home visitation or would only cover these services in selected situations where beneficiaries or their providers were able to demonstrate a need. Some states may be providing services similar to home visitation under existing Medicaid authorities, but not describing these activities in their state plans as home visitation services. Under Early and Periodic, Screening, Diagnosis, and Treatment (EPSDT)<sup>24</sup> requirements, Medicaid must cover an array of services for eligible children. Depending on the specific services needed by beneficiaries, home visitation services could be considered EPSDT services and covered by a state Medicaid program. Home visitation might be viewed as services related to home health care.<sup>25</sup> Even though home health is a mandatory Medicaid benefit, these services are mandatory only for individuals entitled to nursing facility levels of care.<sup>26</sup> In other words, states must cover home health services for categorically eligible individuals, whose medical conditions would warrant placement in a nursing facility, but are not required to cover home health for medically needy individuals, or beneficiaries who do not require nursing facility levels of care.<sup>27</sup> Some groups claim that home visitation services could be covered by Medicaid as optional targeted case management and administrative case management.<sup>28</sup>

**Proposal.** The President's FY2010 Budget includes a legislative proposal to create a mandatory new program which would provide funds to states to establish and expand evidence-based home visitation programs for low-income families. This program would primarily be intended to provide services to children to improve: child health and development, readiness for school, child maltreatment, and parenting abilities to support children's optimal cognitive, language, social-emotional, and physical development. Although the home visitation initiative would be administered by the Administration for Children and Families, the Obama Administration envisions that the home health visitation program would have substantial interaction with Medicaid and CHIP. Under this proposal, future Medicaid and CHIP expenditures are expected to decrease because low income children would receive preventive and early treatment that would reduce the incidence of more serious health and social problems. The Administration estimated that the interaction of the home visitation initiative with Medicaid and CHIP would reduce federal expenditures by \$1 million in FY2010 and \$81 million over the period FY2010 to FY2014. The

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<sup>24</sup> Early and Periodic, Screening, Diagnosis, and Treatment services include medical services for individuals under age 21 to discover and diagnose physical and mental illnesses or conditions and to correct or ameliorate any illnesses or chronic conditions discovered. Services include periodic comprehensive unclothed physical examinations at appropriate intervals, a comprehensive health and developmental history, pediatric immunizations, laboratory tests appropriate for the child's age, health and risk factors, vision services, dental services, hearing services, and any other health care necessary to correct or ameliorate defects, illnesses or conditions discovered through screening.

<sup>25</sup> Home health care services include part-time intermittent nursing, home health aide services, medical supplies and medical equipment and appliances suitable for home use, provided to a recipient at his or her residence, other than a skilled nursing facility, when ordered by the recipient's physician as part of a written plan of care that is reviewed by the physician every 60 days.

<sup>26</sup> See the Centers for Medicare and Medicaid Services, Medicaid at a Glance, 2005, at <http://www.cms.hhs.gov/MedicaidEligibility/Downloads/MedicaidatAGlance05.pdf>.

<sup>27</sup> States that cover nursing facility services for the medically needy would also be required to cover home health services for those individuals.

<sup>28</sup> See the National Governors Association, The Benefits and Financing of Home Visitation Services, June 2002, at <http://www.nga.org/Files/pdf/BENEFITSFINANCINGHOME.pdf>.

Administration estimated the interaction with Medicaid would reduce federal expenditures by \$77 million over five years, with the remaining \$4 million expenditure reduction attributable to CHIP.

**Reports.** Currently, no other CRS reports address this topic.

## CHIP Legislative Proposals

### CHIP: Phase-in Home Visitation Impact

**Background.** See the Medicaid discussion of this proposal above.

**Reports.** For more information on the CHIP, see CRS Report R40444, *State Children's Health Insurance Program (CHIP): A Brief Overview*, by (name redacted), (name redacted), and (name redacted), and CRS Report RS22739, *FY2008 Federal SCHIP Financing*, by (name redacted).

## Congressional Budget Action

The House and Senate began considering the FY2010 federal budget in March 2009. The House and Senate Budget Committees produced their versions of the budget resolution which incorporated most of the President's budget proposals as submitted in President Obama's budget outline of February 26, 2009. The two houses adopted their respective FY2010 budget resolutions on April 2, 2009. The Senate and House agreed to a Conference Agreement Report on April 29, 2009 (H.Rept. 111-60, accompanying S.Con.Res. 13).

Although the budget resolution does not become law, it establishes spending and revenue targets for discretionary spending. The resolution also creates a framework for the budget subcommittees to follow in developing 12 annual appropriations bills that will fund FY2010 (discretionary) federal programs and operations. With adoption of the budget proposal, Appropriations subcommittees for both chambers may initiate legislation authorizing funding for Cabinet departments and federal agencies.

### Senate

On March 26, 2009, the Senate Budget Committee reported a budget resolution (S.Con.Res. 13), which the Senate passed April 2, 2009. The Senate budget resolution includes 24 deficit-neutral reserve funds, including provisions that could affect Medicaid and CHIP.

### House

The House Budget Committee reported a budget resolution (H.Con.Res. 85) on March 25, 2009, which the House passed on April 2, 2009. On March 27, 2009, the House filed a report (H.Rept. 111-60) to accompany the concurrent budget resolution (H.Con.Res. 85). The House's budget resolution contained 14 deficit-neutral reserve funds, including provisions could affect Medicaid and CHIP.

## Conference Agreement

On March 27, 2009 the Senate and House filed a Conference Agreement Report on the budget resolution (H.Rept. 111-60 which accompanied the Senate S.Con.Res. 13 and House H.Con.Res. 85). On April 29, 2009 the Senate and House both adopted the Conference Report (H.Rept. 111-60, accompanying S.Con.Res. 13). The following major provisions affecting Medicaid and CHIP are included in the Conference Agreement.

- **Reconciliation Instructions.** In the Senate, both the Committee on Finance and Committee on Health, Education, Labor, and Pensions were required to reduce the federal budget deficit for programs under their jurisdictions by \$1 billion over the period from FY2009 to FY2014. Similarly, in the House, the Committees on Energy and Commerce and Ways and Means were required to reduce the federal budget deficit for programs under their jurisdictions by \$1 billion for the period FY2009 to FY2014.
- **Senate Reserve Funds.** The Joint Budget Resolution contained both Senate and House Budget Neutral Reserve Funds. The Senate provisions included two deficit-neutral funds that could affect Medicaid and CHIP: (1) to transform and modernize America's health care system, and (2) to improve the well-being of children.
- **House Reserve Funds.** The House budget-neutral reserve fund provisions also included two proposals that could affect Medicaid and CHIP: (1) a deficit-neutral fund for health care reform, and (2) a deficit-neutral fund to improve the well-being of children.
- **Budget Enforcement.** In the Senate, a point of order rule can be applied if the cost of legislation increases the budget deficit by more than \$10 billion in any fiscal year covered by the concurrent budget resolution, unless the proposed expenditures are offset by spending reductions in other programs.

## Appropriations

In general, Medicaid and CHIP spending are not controlled through the annual appropriations process. As an entitlement program, Medicaid's spending level is determined by the underlying benefit and eligibility criteria established in law. Thus, federal Medicaid expenditures vary depending on the amount of services required and the number of beneficiaries that enroll in any federal fiscal year. CHIP is a grant program, so federal spending is capped, with annual CHIP appropriations specified by law. The Medicare, Medicaid, and CHIP Extension Act of 2007 (MMSEA, P.L. 110-173) provided FY2008 and FY2009 CHIP allotments through March 31, 2009, with enough additional funding to cover the federal share of CHIP spending through March 31, 2009. As noted above, with passage of the Children's Health Insurance Reauthorization Act of 2009 (CHIPRA, P.L. 111-3), CHIP funding was extended through FY2013.

Even though annual Medicaid and CHIP appropriations are not controlled through the appropriations process, Congress can exercise some authority over Medicaid and CHIP spending through the appropriations process by limiting funds for specified activities. For example, the Labor, Health and Human Services, and Education appropriations bill regularly contains restrictions that limit circumstances when federal funds may be used to pay for abortions.

**Table 2. CRS Staff Contact Information, by Medicaid and CHIP Topic Area**

Topic	Staff member	Phone number
<b>Medicaid</b>		
Administration	(name redacted)	7-....
<b>Benefits and eligibility</b>		
Aged	(name redacted)	7-....
Children, families, immigrants, other non-disabled adults	Evelyne Baumrucker Elicia Herz	7-.... 7-....
Individuals with disabilities, medically needy	(name redacted) (name redacted)	7-.... 7-....
Dual eligibles	(name redacted)	7-....
Expenditures	(name redacted)	7-....
<b>Financing</b>		
Disproportionate share hospital payments	Elicia Herz	7-....
Federal medical assistance percentage	(name redacted) Evelyne Baumrucker	7-.... 7-....
General issues	(name redacted) Elicia Herz	7-.... 7-....
Intergovernmental transfers	Elicia Herz	7-....
Upper payment limits	Elicia Herz	7-....
HCBS & Section 1915(i) SPAs	(name redacted)	7-....
Integrity (waste, fraud, and abuse)	(name redacted)	7-....
Long-term care	(name redacted)	7-....
Managed care	Elicia Herz	7-....
Prescription drugs	(name redacted)	7-....
Provider payment issues	Elicia Herz	7-....
Regulations	Elicia Herz (name redacted)	7-.... 7-....
Territories	Evelyne Baumrucker	7-....
Waivers		
Section 1115	Evelyne Baumrucker	7-....
Section 1915(c)	(name redacted) (name redacted)	7-.... 7-....
<b>CHIP</b>		
Financing	Evelyne Baumrucker Chris Peterson	7-.... 7-....
General issues	Evelyne Baumrucker Elicia Herz	7-.... 7-....
Section 1115 waivers	Evelyne Baumrucker	7-....



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