CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 23, 2015

H.R. 6
21st Century Cures Act

As ordered reported by the House Committee on Energy and Commerce on May 21, 2015

SUMMARY

H.R. 6 would authorize appropriations for the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and other agencies within the Department of Health and Human Services (HHS) for programs aimed at promoting the discovery and development of drugs and other technologies that prevent, diagnose, and treat disease or to support activities authorized by the legislation. The bill also would make related changes to those agencies' programs.

In addition, H.R. 6 contains provisions that would:

- Grant additional periods of exclusivity for certain brand-name drugs approved for a new indication that treats a rare disease or condition;
- Require Medicare to make an additional payment to hospitals when Medicare beneficiaries use certain antimicrobial drugs during the course of their hospital stay;
- Direct the sale of 8 million barrels of oil from the Strategic Petroleum Reserve (SPR) in each of the fiscal years 2018 through 2025;
- Delay monthly reinsurance payments to stand-alone prescription drug plans in Medicare Part D by shifting payments between certain fiscal years; and
- Limit federal Medicaid reimbursement to states for durable medical equipment (DME).

CBO estimates that implementing the legislation would cost $106.4 billion over the 2016-2020 period, assuming the appropriation of the authorized and necessary amounts.

CBO estimates that enacting H.R. 6 would reduce direct spending, on net, by $11.9 billion over the 2016-2025 period. (Of that amount, CBO estimates that off-budget costs for the U.S. Postal Service would total $6 million over the 2016-2025 period.) Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. Enacting H.R. 6 would not affect revenues.

H.R. 6 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). However, because the bill would delay entry into the market of some generic drugs and limit Medicaid payments to states for DME, the bill could increase state Medicaid costs by $2.6 billion over the 2016-2025 period, CBO estimates. States have flexibility in that program to adjust their financial and programmatic responsibilities, so those costs would not result from an intergovernmental mandate.

The bill would impose private-sector mandates, as defined in UMRA, on drug manufacturers. CBO estimates that the aggregate cost of the mandates would fall below the annual threshold established in UMRA ($154 million in 2015, adjusted annually for inflation) in each of the first five years that the mandates are in effect.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effects of H.R. 6 are shown in Table 1. The effects of the legislation fall primarily within budget functions 270 (energy), 550 (health) and 570 (Medicare).

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 6 will be enacted near the start of fiscal year 2016 and that authorized amounts will be appropriated each year. Outlay estimates are based on historical spending patterns for affected programs.

TABLE 1. BUDGETARY EFFECTS OF H.R. 6

	By Fiscal Year, in Millions of Dollars						
	2016	2017	2018	2019	2020	2016-2020	2016-2025
CHANGES IN SPENDING SUBJECT TO APPROPRIATION							
Department of Health and Human Services							
National Institutes of Health							
Authorization Level	33,811	35,331	36,851	2,000	2,000	109,993	n.a.
Estimated Outlays	8,576	27,473	33,679	26,687	8,625	105,040	n.a.
Food and Drug Administration[a]							
Estimated Authorization Level	194	223	240	256	257	1,171	n.a.
Estimated Outlays	59	127	178	234	274	872	n.a.
Centers for Disease Control and Prevention							
Estimated Authorization Level	17	6	6	6	6	41	n.a.
Estimated Outlays	6	10	7	6	6	35	n.a.
Other HHS Programs[b]							
Estimated Authorization Level	112	104	106	109	111	543	n.a.
Estimated Outlays	35	82	97	104	109	427	n.a.
Other Departments and Agencies							
Estimated Authorization Level	1	*	4	6	9	21	n.a.
Estimated Outlays	1	*	4	6	9	21	n.a.
Subtotal							
Estimated Authorization Level	34,135	35,665	37,207	2,378	2,384	111,768	n.a.
Estimated Outlays	8,677	27,692	33,964	27,037	9,024	106,395	n.a.
CHANGES IN DIRECT SPENDING[c]							
Estimated Budget Authority	1	-12	-571	-532	-4,005	-5,119	-11,888
Estimated Outlays	1	-12	-571	-532	-4,005	-5,119	-11,888

Notes: * = less than $500,000; n.a. = not applicable; HHS = Health and Human Services.

Numbers may not add up to totals because of rounding.

a. Amounts include authorizations of appropriations of $110 million for each of fiscal years 2016 through 2020 from the Cures Innovation Fund established in title IV of the bill. Estimated outlays from the Cures Innovation Fund are also reported here, assuming appropriation action consistent with the bill.

b. H.R. 6 would provide authorizations of appropriations of $10 million for each of fiscal years 2016 through 2023 for the Council for 21st Century Cures.

c. In addition, CBO estimates that enacting H.R. 6 would increase off-budget costs for the U.S. Postal Service by $6 million over the 2016-2025 period.

Spending Subject to Appropriation

H.R. 6 would authorize funding and modify programs within HHS that support medical research, oversee the development and marketing approval for drugs, and monitor the use of drugs in the United States. The legislation also would change the regulatory framework surrounding medical devices and oversight of technology by FDA. As shown in Table 2, CBO estimates that implementing H.R. 6 would cost $106.4 billion over the 2016-2020 period, assuming appropriation of the authorized and estimated amounts. Of that amount, $105.5 billion would be spent from amounts specifically authorized by H.R. 6. CBO estimated other authorizations based on information from NIH, FDA, Centers for Disease Control and Prevention (CDC), and other government agencies.

Assuming appropriation action consistent with the bill, CBO estimates that over the 2016-2020 period:

- Provisions implemented by NIH would cost $105.0 billion;
- Provisions administered by FDA would cost $872 million;
- Provisions administered by CDC would cost $35 million;
- Provisions affecting discretionary spending by other HHS programs would cost $427 million; and
- Provisions affecting discretionary spending by other Departments and agencies would cost $21 million.

TABLE 2. ESTIMATED AUTHORIZATIONS OF APPROPRIATIONS IN H.R. 6

	By Fiscal Year, in Millions of Dollars					
	2016	2017	2018	2019	2020	2016-2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION[a]						
TITLE 1 - DISCOVERY						
NIH Reauthorization						
Authorization Level	31,811	33,331	34,851	0	0	99,993
Estimated Outlays	8,190	25,750	31,781	24,735	6,645	97,100
NIH Innovation Fund						
Authorization Level	2,000	2,000	2,000	2,000	2,000	10,000
Estimated Outlays	386	1,723	1,897	1,952	1,980	7,939
Other Provisions[b]						
Estimated Authorization Level	21	22	22	21	21	107
Estimated Outlays	7	17	19	20	21	84
Subtotal, Title I						
Estimated Authorization Level	33,832	35,353	36,873	2,021	2,021	110,100
Estimated Outlays	8,583	27,490	33,698	26,707	8,646	105,124
TITLE ll - DEVELOPMENT						
Development and Approval of Prescription Drugs and Biologics						
Estimated Authorization Level	51	55	66	69	73	315
Estimated Outlays	22	45	62	69	73	270
Development and Regulation of Medical Devices and Technology						
Estimated Authorizations Level	44	58	65	82	82	331
Estimated Outlays	31	51	61	75	80	299
Subtotal, Title II						
Estimated Authorization Level	95	113	131	151	155	646
Estimated Outlays	52	96	123	145	153	569

(Continued)

TABLE 2. Continued

	By Fiscal Year, in Millions of Dollars					
	2016	2017	2018	2019	2020	2016-2020
Title III - DELIVERY						
Health Information Technology and Other Provisions						
Estimated Authorization Level	12	2	2	2	2	19
Estimated Outlays	6	4	3	3	2	18
Title IV - MEDICAID, MEDICARE, AND OTHER REFORMS						
Cures Innovation Fund[c]						
Authorization Level	110	110	110	110	110	550
Estimated Outlays	11	36	58	94	129	327
SPR Drawdown						
Estimated Authorization Level	0	0	2	2	2	6
Estimated Outlays	0	0	2	2	2	6
Lyme Disease and Other Tick-borne Diseases						
Estimated Authorization Level	86	87	90	92	94	448
Estimated Outlays	25	67	81	87	92	351
Subtotal, Title IV						
Estimated Authorization Level	193	197	202	204	206	1,004
Estimated Outlays	36	102	141	182	223	684
Total						
Estimated Authorization Level	34,135	35,665	37,207	2,378	2,384	111,768
Estimated Outlays	8,677	27,692	33,964	27,037	9,024	106,395

Notes: NIH = National Institutes of Health; SPR = Strategic Petroleum Reserve.

Numbers may not add up to totals because of rounding.

a. Estimated outlays for specified authorizations of appropriations in H.R. 6 are shown for the title in which the authorization of appropriation is identified in the bill, assuming appropriation action is consistent with the bill.

b. Includes authorizations of appropriations of $10 million for each of fiscal years 2016 through 2023 for the Council for 21st Century Cures.

c. Reflects estimated outlays from the Cures Innovation Fund, including any amounts disbursed by the Fund for activities that also are associated with separate authorizations identified in titles I and II of the bill.

Title I—Discovery. Title I would reauthorize NIH, make several programmatic changes to the agency's research and loan repayment programs, and authorize other initiatives aimed at promoting medical research. CBO estimates that implementing title I would cost $105.1 billion over the 2016-2020 period, assuming the availability of appropriated funds.

*NIH Reauthorization***.** Section 1001 would authorize the appropriation of almost $100 billion over the next three years for NIH. The authority for research programs at NIH that are subject to future appropriations expired at the end of fiscal year 2009. Since then, however, the Congress has appropriated an average of about $30 billion annually to continue operating those programs across all areas of research at NIH. CBO estimates that reauthorizing NIH would cost $97.1 billion over the 2016-2020 period.

*NIH Innovation Fund***.** Section 1002 would direct the Secretary of HHS to establish an "NIH Innovation Fund" in the U.S. Treasury to support biomedical research. The bill would authorize the appropriation of $2 billion from that fund for each of fiscal years 2016 through 2020. CBO estimates that spending from the NIH Innovation Fund would total $7.9 billion over the 2016-2020 period.

Other Provisions. Other provisions of title I would aim to promote medical research and accelerate the availability of new therapies. CBO estimates that implementing those provisions of title I would cost $84 million over the 2016-2020 period. That amount includes:

- $45 million for the Council for 21st Century Cures, a public-private partnership intended to help accelerate the discovery, development, and delivery of treatments for patients in the United States. (The bill would authorize the appropriation of $10 million for each of fiscal years 2016 through 2023 for such activities.);[1]

- $21 million for CDC to develop a surveillance system for neurological diseases. (The bill would authorize the appropriation of $5 million for each of fiscal years 2016 through 2020 for such activities.)

- $12 million for the Secretary of HHS to participate in public-private partnerships and award grants to facilitate the collection, analysis, and availability of data on diseases. (The bill would authorize the appropriation of $5 million for each of fiscal years 2016 through 2020 for such activities.);[1] and

1. The legislation also would authorize the appropriation of additional funds for such purposes from the Cures Innovation Fund established in title IV of the bill. See discussion of spending by the Cures Innovation Fund later in the cost estimate.

- $6 million for FDA to establish a pilot program to create a research sharing system (in coordination with NIH) that would give third parties direct access to data generated from clinical trials funded exclusively by the federal government and to assist NIH with standardizing certain information in the registry data bank involving eligibility for clinical trials.

Title II—Development. Title II of H.R. 6 would modify FDA's approach to regulating prescription drugs, biologicals, medical devices, and health-related technology. It also would make changes to certain surveillance activities by the CDC relating to antimicrobials and to CDC's vaccine-related activities. CBO's estimates reflect the expected number of personnel and investment in information technology required to implement the bill based on information provided by the affected agency. (Provisions in title II primarily affect regulatory activities by FDA.) We estimate that implementing Title II would cost $569 million over the 2016-2020 period, assuming the appropriation of the necessary amounts. As discussed below, Title II would affect two regulatory areas: 1) prescription drugs and biologics and 2) medical devices and health-related technology.

*Development and Approval of Prescription Drugs and Biologics***.** Title II of H.R. 6 contains several provisions that would modify FDA's regulatory framework for overseeing the development and approval process of drugs and biologics. The title also would establish a grant program for institutions of higher education and nonprofit organizations to study improvements in the process of continuous manufacturing and other production-related techniques. Finally, this title would make changes to CDC's administrative procedures involving antibiotics and vaccines. Taken together, CBO estimates that implementing provisions relating to drugs and biologics in title II would cost $270 million over the 2016-2020 period. That amount includes:

- $33 million to establish a process to qualify or validate certain drug development tools, such as biomarkers, for use in certain applications. That funding would also allow FDA to enter into cooperative agreements and to award grants to assist the agency with the review of such qualification submissions. (The bill would authorize the appropriation of $10 million for each of fiscal years 2016 through 2020 for such activities.);[1]

- $33 million to identify and publish a list of interpretive criteria for tests that characterize the susceptibility of particular bacteria, fungi, or other microorganisms to drugs;

- $31 million to facilitate approval for certain antibacterial and antifungal drugs used by a limited population of patients;

- $25 million to issue and update guidance to industry, including documents that would assist sponsors in the development of precision drugs and biologics, provide guidelines on responsible communication of certain types of information, and clarify agency procedures regarding its review of combination drug products;

- $21 million to administer a new grant program to study continuous drug manufacturing and production-related technologies. (The bill would authorize the appropriation of $5 million each of fiscal years 2016 through 2020 for that program.);[1]

- $21 million to implement a program that would aim to provide incentives to drug companies to develop new indications for drugs and biologics that target rare diseases and conditions and to extend the voucher program for rare pediatric diseases through December 31, 2018;

- $20 million to develop a regulatory structure that would allow the use of new protocols for statistical modeling and trial designs to support marketing applications for drug and biological products;

- $18 million to devise a plan with sponsors of drug and biological products eligible for accelerated approval to agree on certain details of the design of clinical studies in a manner that would expedite approval of such products;

- $14 million, which reflects the costs for a range of federal programs generated by a provision that would extend exclusivities for certain brand-name drugs. (See discussion of the effect of that provision on mandatory costs for federal health programs below.);

- $14 million to establish a "streamlined data review program" that would allow sponsors to submit qualified summaries of clinical data to support the approval or licensure of new indications under certain circumstances;

- $14 million to conduct pilot demonstrations that would expand the use of FDA's existing surveillance program (that allows the agency to query electronic data systems and proactively evaluate safety issues with medical products) to also capture additional evidence of clinical experiences associated with marketed drug products. (The bill would authorize the appropriation of $3 million for each of fiscal years 2016 through 2020 for such activities.);[1]

- $13 million for CDC to monitor and track usage of antibiotic and antifungal drugs; and

- $14 million for miscellaneous provisions of title II that would affect discretionary spending by various federal agencies, primarily FDA, CDC, and the Government Accountability Office.

Development and Regulation of Medical Devices and Technology. Title II of the bill also contains provisions that would modify the regulatory framework surrounding medical devices and oversight of technology by FDA. Assuming appropriation of the necessary amounts, CBO estimates that implementing those provisions would cost $299 million over the 2016-2020 period, primarily for FDA's personnel-related expenses. That amount includes:

- $158 million to establish a program to provide expedited review for certain devices that represent breakthrough technologies where no approved alternatives exist and that technology offers significant advantages over existing alternatives;

- $68 million to establish a new accreditation program for third parties to expedite the approval process for certain devices, review and recognize national and international standards, and develop and update several guidances and regulations;

- $68 million to implement a new framework for the regulation of medical software based on a new definition of health software, and exempting such software from most regulation; and

- $4 million for FDA's Center for Devices and Radiological Health to issue final guidance regarding its review of combination products within 18 months after the date of enactment of H.R 6, and to update that guidance regularly.

Title III—Delivery. CBO estimates that implementing title III would cost $18 million over the 2016-2020 period, assuming appropriation of the necessary funds. That amount reflects:

- $10 million for contracts with organizations that develop standards to make recommendations for new interoperability standards for electronic health records. (The bill would authorize the appropriation of $10 million in 2016 for such activities.);

- $5 million for the Office of the National Coordinator of Health Information Technology to administer the adoption of those interoperability standards and to publish reports on interoperability;

- $2 million for the Centers for Medicare and Medicaid Services (CMS) and the Medicare Payment Advisory Commission to provide information to the Congress on the use and limitations of telehealth services; and

- $1 million for the Secretary of HHS to establish a Medicare pharmaceutical and technology ombudsman within CMS.

Title III also contains provisions that would affect direct spending. Those provisions are discussed in the direct spending section below.

Title IV—Medicaid, Medicare, and Other Reforms. H.R. 6 would create a fund to pay for new initiatives and administrative costs associated with regulatory requirements established by the bill. It would also direct the Department of Energy (DOE) to sell 64 million barrels of oil from the SPR, and would expand research activities on Lyme disease and other tick-borne diseases. CBO estimates that implementing the provisions in title IV would cost $684 million over the 2016-2020 period, assuming appropriation of the necessary funds. (Title IV also contains provisions that would affect direct spending.)

Cures Innovation Fund. Section 4041 would direct the Secretary of HHS to establish a "Cures Innovation Fund" in the U.S. Treasury. The legislation would authorize the appropriation of $110 million a year from the fund for fiscal years 2016 through 2020. Such authorizations would be in addition to any amounts made available from other authorizations of appropriations identified specifically in titles I and II for the following activities:

- Participating in public-private partnerships and awarding grants that foster the collection, analysis, and availability of data on the natural history of disease;

- Supporting initiatives of the Council for 21st Century Cures;

- Creating a regulatory framework at FDA that incorporates information about patients' experiences with a specific condition or disease, including the risks and benefits of new drug treatments;

- Establishing a process to qualify or validate certain drug development tools, such as biomarkers, for use in certain applications and allowing FDA to enter into cooperative agreements and to award grants to assist the agency with reviewing such qualification submissions;

- Establishing a regulatory framework at FDA to allow information from clinical experiences to support the approval or licensure of a new indication for a drug or biologic, or to fulfill requirements for post-approval study; and

- Administering a new FDA grant program that promotes the study of continuous drug manufacturing and other production-related technologies.

CBO estimates that spending from the Cures Innovation Fund would total $327 million over the 2016-2020 period, assuming appropriation of the authorized amounts.

SPR Drawdown. The bill would direct the DOE to sell 64 million barrels of oil from the SPR, subject to certain conditions. Based on information from DOE, CBO estimates that the transaction costs associated with selling oil from the SPR would average about 21 cents per barrel. Thus, assuming the appropriation of the necessary amounts, CBO estimates that implementing the sales would cost $6 million over the 2016-2020 period. That estimate includes the incremental cost of power, storage, labor, and various other logistical expenses. According to DOE, selling a total of 64 million barrels from the SPR—which would reduce the current inventory by roughly 9 percent—would not require any decommissioning activities or expenses. (See discussion of the effect of the provision on mandatory costs in the direct spending section of the cost estimate.)

Lyme Disease and Other Tick-borne Diseases. Section 4081 would amend the Public Health Service Act to require the Secretary of HHS to conduct or support research on Lyme disease and other tick-borne diseases. Currently, several federal agencies fund research on tick-borne diseases including NIH and CDC. The bill also would require the Secretary to establish a permanent interagency working group on Lyme disease and other tick-borne diseases and to periodically submit to the Congress a strategic plan for conducting and supporting research in that area. Based on a 2011 study by the Institute of Medicine that reported the average annual funding level for Lyme disease and other tick-borne diseases totaled almost $90 million, CBO estimates that implementing section 4081 would cost $351 million over the 2016-2020 period.

Direct Spending

Several provisions in H.R. 6 would affect direct spending. Taken together, CBO estimates that enacting H.R. 6 would reduce on-budget direct spending, on net, by about $11.9 billion over the 2016-2025 period (see Table 3); off-budget costs for the U.S. Postal Service would increase by $6 million over the same period.

TABLE 3. ESTIMATED CHANGES IN ON-BUDGET MANDATORY COSTS FOR H.R. 6

	By Fiscal Year, in Millions of Dollars											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016-2020	2016-2025
CHANGES IN ON-BUDGET DIRECT SPENDING[a]												
TITLE II - DEVELOPMENT												
Encouraging the Development and Use of New Antimicrobial Drugs	0	0	49	60	63	66	71	72	73	81	172	535
Extension of Exclusivity Periods for Certain Drugs Approved for a New Indication for a Rare Disease or Condition	0	0	14	47	84	114	142	147	149	172	145	869
Subtotal, Title II	0	0	63	107	147	180	213	219	222	253	317	1,404
TITLE III - DELIVERY												
Treatment of Certain Items and Devices	0	-4	-8	-11	-15	-17	-23	-27	-30	-37	-38	-172
Medicare Site-of-service Price Transparency	1	5	0	0	0	0	0	0	0	0	6	6
Programs to Prevent Prescription Drug Abuse under Medicare Parts C and D	0	-8	-10	-11	-12	-13	-15	-15	-15	-16	-41	-115
Subtotal, Title III	1	-7	-18	-22	-27	-30	-38	-42	-45	-53	-73	-281
TITLE IV - MEDICAID, MEDICARE, AND OTHER REFORMS												
Limiting Federal Medicaid Reimbursement to States for DME	0	0	0	0	-274	-391	-417	-444	-473	-504	-274	-2,503
Medicare Payment for X-rays and Other Imaging Services	0	-5	-16	-17	-17	-18	-19	-18	-17	-18	-55	-145
Delay Certain Payments to Medicare Prescription Drug Plans	0	0	0	0	-3,184	-301	-4,139	-708	3,786	-417	-3,184	-4,963

(Continued)

TABLE 3. Continued

	By Fiscal Year, in Millions of Dollars											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016-2020	2016-2025
SPR Drawdown	0	0	-600	-600	-650	-650	-700	-700	-750	-750	-1,850	-5,400
Subtotal, Title IV	0	-5	-616	-617	-4,125	-1,360	-5,275	-1,870	2,546	-1,689	-5,363	-13,011
Total, Changes in On-budget Direct Spending[b]	1	-12	-571	-532	-4,005	-1,210	-5,100	-1,693	2,723	-1,489	-5,119	-11,888

Notes: DME = durable medical equipment; SPR = Strategic Petroleum Reserve.

Numbers may not add up to totals because of rounding.

a. Budget authority equals outlays for all direct spending provisions. Medicare provisions include interactions with Medicare Advantage payments, the effect on Medicare Part A and Part B premiums, and TRICARE.

b. CBO estimates that enacting H.R. 6 also would increase off-budget costs for the U.S. Postal Service by $6 million over the 2016-2025 period.

Title II—Development. Title II of the bill would require Medicare to make additional payments to hospitals for using qualifying antimicrobial drugs. It also would extend exclusivity periods for certain drugs approved for a new indication that pertains to treating a rare disease or condition. CBO estimates that implementing such provisions would increase on-budget direct spending for mandatory health programs by $1.4 billion over the 2016-2025 period.[2]

Encouraging the Development and Use of New Antimicrobial Drugs. The bill would require Medicare to make an additional payment to hospitals when Medicare beneficiaries use certain new antimicrobial drugs during the course of their hospital stay. To qualify for the additional payment, a drug would have to meet certain criteria, including: the drug must be approved to treat certain infections for which existing antibiotics are not sufficient and the drug must receive approval for use or for a new indication on or after December 1, 2014. A qualifying drug would be eligible for the additional payment for a period of five years. Each year, the Secretary would establish payment rates for eligible drugs based on payment rates under Part B of Medicare, subject to the pro rata reduction, if any, that the Secretary estimates is needed to limit total payments for such drugs to 0.03 percent of

2. Extending exclusivity periods for certain drugs would affect off-budget spending by the U.S. Postal Service (USPS) for health insurance premiums for its workers and retirees who are covered under the Federal Employees Health Benefits program. CBO estimates that the bill would increase USPS costs (which are classified as off-budget) by $6 million over the 2016-2025 period.

expected Medicare spending for hospital inpatient services. Based on information about drugs currently in the development pipeline that would be likely to satisfy the specified criteria and data from the CDC on rates of antibiotic-resistant infection, CBO estimates that enacting that provision would increase direct spending by about $535 million over the 2016-2025 period.

Extension of Exclusivity Periods for Certain Drugs Approved for a New Indication for a Rare Disease or Condition. Section 2151 of the bill would authorize the FDA to extend exclusivity periods for certain brand-name drugs already on the market by six months if, after enactment of the bill, the drug is approved for a new indication that pertains to treating a rare disease or condition. Such extensions could delay the timing of market entry by lower-priced generic drugs or biosimilars. In addition, the provision would add six months of exclusivity to the patents of select drugs; such provision only would apply to certain designated drugs previously approved under the Federal Food, Drug, and Cosmetic Act (FDCA) and not to biologics previously licensed under the Public Health Service Act.

In order to be eligible for the six month exclusivity period, a drug manufacturer would have to demonstrate safety and efficacy for treatment of a rare disease or condition for which the drug had not been previously approved. CBO expects that approval for the new indication would hinge on successfully completing new clinical trials. While many manufacturers could benefit over the next 10 years from such an extension of exclusivity, CBO expects that only certain drugs that meet all of the following criteria likely would receive one. First, a drug must have the potential to treat a rare disease or condition for which it was not originally approved. Second, the expected value of returns from undertaking the additional research to obtain approval for the new indication must offset the costs. And finally, sufficient time must be available for the manufacturer to conduct the necessary trials, prepare a marketing application, undergo regulatory review, and obtain approval before facing generic competition.

CBO estimates that about 15 percent of the share of brand-name sales for drugs previously approved under the FDCA that are expected to first experience generic competition before 2025 would have such competition delayed by 6 months under this provision. By delaying the timing of market entry of lower priced generics or biosimilars, CBO expects the provision would increase the drug-related costs of federal health programs (both mandatory and discretionary programs) that pay for prescription drugs and biological products. CBO estimates that the provision would increase on-budget spending on prescription drugs by mandatory health programs by $869 million over the 2016-2025 period. Beyond 2025, the potential for the legislation to delay the entry of generic drugs or biosimilars is greater and the federal budgetary effect would increase in later years.

Title III—Delivery. Title III of the bill also contains provisions that would affect direct spending for Medicare. CBO estimates that enacting those provisions would reduce direct spending, on net, by $281 million over the 2016-2025 period.

Treatment of Certain Items and Devices. Under current law, Medicare beneficiaries may receive negative pressure wound therapy (NPWT), which uses a vacuum pump and special dressings to promote wound healing. NPWTs are available using either a durable pump or a disposable pump that can be used at home. If a home health agency (HHA) furnishes a beneficiary with NPWT using a durable form of the device, Medicare makes a payment to the HHA for the visit and to a DME supplier for the NPWT. If the HHA uses a disposable NPWT, Medicare does not make an additional payment and the HHA absorbs the cost of the NPWT. H.R. 6 would establish a new add-on payment to HHAs when they furnish disposable NPWT; that payment would be lower than the payment for durable NPWT. CBO estimates that there would be some switching from durable NPWT to disposable NPWT and thus this provision would save about $172 million over the 2016-2025 period.

Medicare Site-of-service Price Transparency. H.R. 6 would require CMS to create a new database and website that would enable beneficiaries to compare the estimated Medicare payment and cost-sharing amounts for items and services provided in hospital outpatient departments and ambulatory surgical centers. The bill would appropriate $6 million for this purpose and CBO estimates that all of the funding would be spent by the end of fiscal year 2017.

Programs to Prevent Prescription Drug Abuse under Medicare Parts C and D. The bill would permit private drug plans that administer the Medicare Part D prescription drug benefit to establish a program to limit the number of physicians and pharmacies allowed to prescribe and dispense certain drugs to enrollees identified as being at high risk for prescription drug abuse. Under H.R. 6, plans that implement such a program would use clinical guidelines established by the Secretary of HHS to target certain beneficiaries who use controlled substances the Secretary determines are frequently abused or diverted. For example, restrictions might be placed on beneficiaries suspected of abusing or reselling certain controlled substances, but not placed on beneficiaries with cancer or other conditions for which those drugs are considered appropriate. Based on information from HHS and other stakeholders, CBO estimates that enacting that provision would reduce direct spending by $115 million over the 2016-2025 period.

Title IV—Medicaid, Medicare, and Other Reforms. Title IV of the bill contains provisions that would reduce direct spending. CBO estimates that enacting those provisions would reduce direct spending by $13.0 billion over the 2016-2025 period.

Limiting Federal Medicaid Reimbursement to States for DME. Under current law, states have broad flexibility to set coverage and payment policies in their Medicaid programs. Generally, the federal government reimburses states for a portion of the amount they spend

on Medicaid. Section 4001 would limit the amount of spending by states to purchase DME that is eligible for federal reimbursement to the amount that would be paid by the Medicare program. Twelve states have adopted similar policies as of 2014. CBO estimates that enacting DME payment limits in the remaining states beginning January 2020 would reduce direct spending for Medicaid by approximately $2.5 billion over the 2016-2025 period.

Medicare Payments for X-rays and Other Imaging Services. The legislation would reduce Medicare's payment rates under the physician fee schedule for x-ray and other imaging services that do not use digital imaging technology, beginning in 2017. Payment rates for imaging services that use film would be reduced by 20 percent. The reduction for imaging services that use computed radiography would be 7 percent in 2018 through 2022, then 10 percent in 2023 and subsequent years. Based on a review of Medicare claims, CBO estimates that about 1 percent of current spending for imaging services paid under the physician fee schedule would be subject to the reductions in 2017. CBO expects that implementation of the payment reductions would spur adoption of digital technology, and that less than 0.2 percent of spending would be subject to those reductions by 2025. This provision would reduce direct spending about $145 million over the 2016-2025 period, CBO estimates.

Delay Certain Payments to Medicare Prescription Drug Plans. Under current law, most Medicare payments to Part D plans (including capitated payments and reinsurance payments for beneficiaries whose spending exceeds the threshold for the catastrophic portion of the prescription drug benefit) are made on either the first day of the month or the last day of the preceding month (when the first day is a weekend or holiday). Beginning in calendar year 2020, the legislation would delay monthly reinsurance payments to stand-alone prescription drug plans in Medicare Part D. Starting with a payment shift from 2020 to 2021, the provision would shift spending between fiscal years and would shift an estimated $5.0 billion from fiscal year 2025 to fiscal year 2026.[3]

SPR Drawdown. Section 4061 would direct the DOE to sell 8 million barrels of oil from the SPR in each of the fiscal years 2018 through 2025, subject to certain conditions. Under this bill, the proceeds from such sales would be deposited in the general fund of the Treasury by the end of each fiscal year and could not be spent to purchase oil for the reserve. CBO estimates that enacting that provision would increase offsetting receipts (which are certain collections that are treated as reductions in direct spending) by $5.4 billion over the 2016-2025 period.

3. For example, $3.2 billion would be shifted from fiscal year 2020 to 2021, thereby reducing direct spending in 2020 by that amount. For 2021, that $3.2 billion would be shifted into 2021, but $3.5 billion would be shifted into 2022. As a result, the net change in spending in 2021 would amount to $0.3 billion. By 2025, $4.5 billion would be shifted in (from 2024) and almost $5.0 billion would be shifted out (to 2026); the net effect in 2025 would amount to $0.4 billion.

The estimated receipts reflect CBO's March 2015 projection of oil prices, adjusted for the technical characteristics of the oil being sold from the SPR (those adjusted prices range from about $75 to $96 per barrel over the sales period). Based on information from the Energy Information Administration, CBO estimates that the volume of crude oil in the SPR after these sales would exceed an amount equivalent to a 90-day supply of net imports crude oil and petroleum products, as required by the bill.

PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the table below. Only on-budget changes to outlays are subject to pay-as-you-go rules. Enacting H.R. 6 would not affect revenues.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 6, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON MAY 21, 2015

	By Fiscal Year, in Millions of Dollars												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015-2020	2015-2025
NET DECREASE IN THE ON-BUDGET DEFICIT													
Total Changes	0	1	-12	-571	-532	-4,005	-1,210	-5,100	-1,693	2,723	-1,489	-5,119	-11,888
Less:													
Adjustment for Timing Shift[a]	0	0	0	0	0	0	0	0	0	0	-4,963	0	-4,963
Statutory Pay-As-You-Go Impact	0	1	-12	-571	-532	-4,005	-1,210	-5,100	-1,693	2,723	3,474	-5,119	-6,925

Source: Congressional Budget Office.

a. Section 4 of the Statutory Pay-As-You-Go Act of 2010 provides for adjustments related to certain shifts in the timing of spending or revenues. The provision in H.R. 6 that would delay certain payments to Medicare prescription drug plans would create such a timing shift. That provision would shift payments in each year beginning with 2020. The adjustment for timing shifts under pay-as-you-go procedures is only applied to the spending that is shifted from 2025 to 2026.

INCREASE IN LONG TERM DIRECT SPENDING: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 6 contains no intergovernmental mandates as defined in UMRA. The bill would delay entry into the market of some generic drugs resulting in an increase of state Medicaid spending for prescription drugs of $50 million over the 2016-2025 period. In addition, the bill would limit the amount that is eligible for federal matching payments to states for DME in Medicaid to the amount that Medicare would pay. That limitation could increase state Medicaid costs by about $2.5 billion over the 2016-2025 period. However, because states have flexibility in Medicaid to adjust their financial and programmatic responsibilities, including the ability to reduce the amounts they would pay vendors for DME, those costs would not result from an intergovernmental mandate.

ESTIMATED IMPACT TO THE PRIVATE SECTOR

H.R. 6 would impose private-sector mandates, as defined in UMRA, on drug manufacturers. CBO estimates that the aggregate cost of the mandates would fall below the annual threshold established in UMRA ($154 million in 2015, adjusted annually for inflation) in each of the first five years that the mandates are in effect.

The bill would impose a mandate on manufacturers of generic drugs and biosimilars by extending by six months the periods of marketing exclusivity for products that receive a new indication for the treatment of a rare disease. Granting drugs additional marketing exclusivity would delay the entry of lower-priced versions of products in those markets. The cost of the mandate for manufacturers of generic products and biosimilars would be the annual net loss of income resulting from the delay, which could be significant depending on the drugs granted an extension. However, based on information about the sales of drugs that could be affected in the first five years that the mandate is in effect, CBO estimates that the cost of the mandate would amount to about $50 million or less in each of those years.

The bill would impose two additional mandates, and CBO estimates that the cost of each of those mandates would be small. The bill would require manufacturers of investigational drugs to make public their policy for reviewing and responding to requests for access to those drugs under compassionate use policies. The bill would allow manufacturers to comply with the mandate by posting a general policy applicable to all its investigational drugs. The bill also would require manufacturers of antimicrobial drugs to submit an application to FDA for changes to the product's label sooner than they would need to under current law. The bill would require that labels for all antimicrobial drugs include a reference to an FDA website which would contain the updated criteria for determining the effectiveness of such drugs. The mandate would result in savings to the affected manufacturers in later years because they would not need to change a product's label each time those criteria are updated.

ESTIMATE PREPARED BY:

Federal Costs:

National Institutes of Health—Ellen Werble
Food and Drug Administration—Julia Christensen, Anna Cook, and Ellen Werble
Centers for Disease Control and Prevention—Rebecca Yip
Health Information Technology—Zoë Williams
Medicaid—Daniel Hoople
Medicare—Lori Housman, Kevin McNellis, Jamease Miles, Andrea Noda, Lara Robillard, and Rebecca Yip
Strategic Petroleum Reserve—Kathy Gramp

Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy

Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis