H.R. 6 SECTION-BY-SECTION – JULY 2, 2015

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SEC. 2 – NIH AND CURES INNOVATION FUND

The section would establish a temporary, fully offset innovation fund for National Institutes of Health (NIH) and Food and Drug Administration (FDA) for research and researchers (including young scientists) that plan to tackle the major challenges in biomedical research and have the potential to lead to breakthroughs. Unlike most mandatory spending, or entitlements, this funding is set forth for a specific and limited period of time and sunsets after five years, the amount is clearly defined, and the regular appropriations process is used to direct $1.75 billion per year to NIH and $110 million to FDA.

And while every dollar of spending in the bill is offset with other reforms (detailed below), experts suggest that money spent in the short-term to develop new treatments and cures will yield dramatic savings to the federal budget in the long-term, allowing the 21st Century Cures investment to produce savings for taxpayers that could grow exponentially over time.

An example of these long-term savings can be observed through the creation of the polio vaccine through American innovation in the 1950s. When the menace of polio peaked in the early 1950s, more than 20,000 Americans contracted the disease and some 3,000 died from it in one year.[1] However, in the early 1950s, a vaccine for polio was discovered. Polio has been eliminated in the United States through the widespread adoption of a safe and effective vaccine. Some estimate that this vaccine has saved the United States $800 billion since 1955."[2] While we have a vaccine for polio, we do not have cures for many other diseases, which pose a substantial threat to patients and our health care system. For example, as the President's Council of Advisors on Science and Technology has noted, Alzheimer's disease, which already afflicts more than 5 million people in the United States, accounts for nearly $140 billion in Medicare and Medicaid payments. One study noted that over the next forty years, caring for patients with Alzheimer's could cost the federal government as much as $15 trillion dollars.[3] Finding cures and treatments for diseases like Alzheimer's can help us innovate our way out of the entitlement crisis.

TITLE I - DISCOVERY

SUBTITLE A- NATIONAL INSTITUTES OF HEALTH FUNDING

SECTION 1001 – NATIONAL INSTITUTES OF HEALTH REAUTHORIZATION

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[1] Brian Resnick, *The Atlantic,* January 20, 2012, available online: http://www.theatlantic.com/national/archive/2012/01/what-america-looked-like-polio-children-paralyzed-in-iron-lungs/251098/

[2] Michael Milken, in the Foreword of *The Upside of Aging: How Long Life Is Changing the World of Health, Work, Innovation, Policy and Purpose,* by Paul Irving, 2014.

[3] Alzheimer's Association, March 2013, available online: http://act.alz.org/site/DocServer/2012_Trajectory_Fact_Sheet.pdf?docID=1922

This section would reauthorize the National Institutes of Health (NIH) for three years: Fiscal Year FY 2016 through FY 2018.

SUBTITLE B – NATIONAL INSTITUTES OF HEALTH PLANNING AND ADMINISTRATION

SECTION 1021 – NIH RESEARCH STRATEGIC PLAN

This section would require NIH to issue a strategic plan.

SECTION 1022 – INCREASING ACCOUNTABILITY AT NIH

This section would increase accountability at NIH, including with respect to the award of grants.

SECTION 1023 – REDUCING ADMINISTRATIVE BURDENS OF RESEARCHERS

This section would direct the NIH to compile research and implement recommendations on how to streamline the grant process for researchers and reduce administrative burdens.

SECTION 1024 – EXEMPTION FOR NIH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS

This section would exempt certain NIH research activities from the Paperwork Reduction Act.

SECTION 1025 – NIH TRAVEL

This section would set forth a sense of Congress to reiterate the importance of scientific conferences and meetings to the mission of NIH.

SECTION 1026 – OTHER TRANSACTIONS AUTHORITY

This section would provide the National Center for Advancing Translational Science (NCATS) at NIH with more flexibility on the use of Other Transaction Authority (OTA) so it can operate like the Defense Advanced Research Projects Agency (DARPA).

SECTION 1027 – NCATS PHASE IIB RESTRICTION

This section would remove a restriction on NCATS' conduct of, or grants for, phase II and III clinical trials.

SECTION 1028 – HIGH-RISK, HIGH-REWARD RESEARCH

This section would support research that pursues innovative approaches to major challenges in biomedical research that involve inherent high risk, but have the potential to lead to breakthroughs.

SECTION 1029 – SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED COMMUNITIES IN CLINICAL TRIALS

This section would encourage the National Institute on Minority Health and Health Disparities (NIMHD) to include within their strategic plan ways to increase representation of underrepresented communities in clinical trials.

SUBTITLE C – SUPPORTING YOUNG EMERGING SCIENTISTS

SECTION 1041 – IMPROVEMENT OF LOAN REPAYMENT PROGRAMS OF NIH

This section would improve loan repayment programs for NIH researchers.

SECTION 1042 – REPORT

This section would require the NIH Director to submit a report to Congress on programs for young emerging scientists at NIH.

SUBTITLE D – CAPSTONE GRANT PROGRAM

SECTION 1061 – CAPSTONE AWARD

This section would create a capstone grant program to support outstanding scientists who have been funded by NIH.

SUBTITLE E – PROMOTING PEDIATRIC RESEARCH THROUGH THE NATIONAL INSTITUTES OF HEALTH

SECTION 1081 – NATIONAL PEDIATRIC RESEARCH NETWORK

This section would require NIH to establish a national pediatric research network. It would be composed of research institutions that would operate as a consortium in order to pool resources and coordinate activities related to pediatric rare diseases or birth defects.

SECTION 1082 – GLOBAL PEDIATRIC CLINICAL STUDY NETWORK SENSE OF CONGRESS

This section would set forth a sense of Congress that NIH and FDA should work with the European Union, industry, and others to establish a global pediatric clinical study network.

SECTION 1083 – APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH

This section would help ensure appropriate age groupings are included in research studies involving human subjects.

SUBTITLE F – ADVANCEMENT OF NIH RESEARCH AND DATA ACCESS

SECTION 1101 – STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS

This section would enhance patient searches for ongoing trials by requiring NIH to standardize certain patient inclusion and exclusion information across all trials housed in ClinicalTrials.gov.

SUBTITLE G – FACILITATING COLLABORATIVE RESEARCH

SECTION 1121 – CLINICAL TRIAL DATA SYSTEM

This section would create a third-party scientific research sharing system for trials solely funded by the federal government in order to allow the use and analysis of data beyond each individual research project.

SECTION 1122 – NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM

This section would require the Centers for Disease Control and Prevention (CDC) to set up a surveillance system for neurological diseases like Parkinson's disease and Multiple Sclerosis.

SECTION 1123 – DATA ON NATURAL HISTORY OF DISEASES

The section would establish a public-private partnership to establish or enhance and support an information technology system, including staffing, to collect, maintain, analyze, and interpret data on the natural history of diseases, with a particular focus on rare diseases.

SECTION 1124 – ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

This section would require the Secretary of HHS to revise several provisions in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to clarify certain permissible uses of protected health information.

SUBTITLE H – COUNCIL FOR 21ST CENTURY CURES

SECTION 1141 – COUNCIL FOR 21ST CENTURY CURES

This section would establish a public-private partnership in the United States to accelerate the discovery, development, and delivery of innovative cures, treatments, and preventive measures for patients.

TITLE II - DEVELOPMENT

SUBTITLE A – PATIENT-FOCUSED DRUG DEVELOPMENT

SECTION 2001 – DEVELOPMENT AND USE OF PATIENT EXPERIENCE DATA TO ENHANCE STRUCTURED RISK-BENEFIT FRAMEWORK

This section would require FDA, in the context of the new drug review process, to implement a structured framework to facilitate the incorporation of patient experiences in the consideration of a drug's benefits and risks.

SUBTITLE B – QUALIFICATION AND USE OF DRUG DEVELOPMENT TOOLS

SECTION 2021 – QUALIFICATION OF DRUG DEVELOPMENT TOOLS

This section would codify a structured framework at FDA for the submission, review, and qualification of biomarkers and other drug development tools for specific contexts of use that, if qualified, can be relied on by any person for such purposes.

SECTION 2022 – ACCELERATED APPROVAL DEVELOPMENT PLAN

This section would enable the sponsor of a drug that FDA determines may be eligible for accelerated approval to request voluntarily that FDA agree to an accelerated approval development plan.

SUBTITLE C – FDA ADVANCEMENT OF PRECISION MEDICINE

SECTION 2041 – PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION

This section would require FDA to issue and periodically update guidance defining the term "precision drug or biological product" and authorize the agency, in the case of a drug or biological product for the treatment of a serious or life-threatening disease or condition designated as a drug for a rare disease or condition, to rely upon data or information previously submitted by the sponsor for a different drug or biological product that incorporates or utilizes the same or similar underlying approach.

SUBTITLE D – MODERN TRIAL DESIGN AND EVIDENCE DEVELOPMENT

SECTION 2061 – BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS

This section would require FDA to hold a public meeting and issue guidance documents that would assist sponsors in incorporating adaptive designs and Bayesian statistical modeling into their proposed clinical protocols and applications for new drugs and biological products.

SECTION 2062 – UTILIZING EVIDENCE FROM CLINICAL EXPERIENCE

This section would require FDA to establish a program to evaluate the potential use of evidence from clinical experience to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements. In parallel, FDA would identify and execute pilot demonstrations to extend existing use of the Sentinel System to, among other things, support these efforts.

SECTION 2063 – STREAMLINED DATA REVIEW PROGRAM

This section would require FDA to establish a program authorizing the holder of an approved application to submit a summary of clinical data intended to support the approval or licensure of the drug for a new indication for the treatment of cancer or other types of indications.

SUBTITLE E – EXPEDITING PATIENT ACCESS

SECTION 2081 – SENSE OF CONGRESS

This section reaffirms that FDA should continue to expedite the approval of drugs designated as breakthrough therapies as early as possible in the clinical development process, provided that the application for a drug meets the required evidentiary standards of safety and effectiveness.

SECTION 2082 - EXPANDED ACCESS POLICY
SECTION 2083 - FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS

These sections would require certain manufacturers or distributors of an investigational drug to make publicly available, such as through a manufacturer or distributor's web site, basic information on their expanded access policy. In addition, they would require the FDA to expedite guidance providing clarity to sponsors seeking drug approval regarding the consideration during the drug review process of adverse events experienced by patients receiving a drug through an expanded access program.

SUBTITLE F – FACILITATING RESPONSIBLE MANUFACTURER COMMUNICATIONS

SECTION 2101 - FACILITATING DISSEMINATION OF HEALTH CARE ECONOMIC INFORMATION

This section would clarify the scope of health care economic information drug manufacturers can permissibly disseminate to payors, formulary committees, or other similar entities.

SECTION 2102 - FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS

This section would require FDA to issue draft guidance, no later than eighteen months from the date of enactment, to clarify how drug and device manufacturers can permissibly disseminate truthful and non-misleading scientific and medical information about a drug or device that is not included in the approved labeling for the product.

SUBTITLE G – ANTIOBIOTIC DRUG DEVELOPMENT

SECTION 2121 - APPROVAL OF CERTAIN DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS
SECTION 2122 - SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS
SECTION 2123 - ENCOURAGING THE DEVELOPMENT AND USE OF DISARM DRUGS

These sections would build off of the progress Congress made with the passage of the GAIN Act as a part of the Food and Drug Safety and Innovation Act (FDASIA) in 2012 by facilitating the development of new antibacterial or antifungal drugs through a new FDA approval pathway and creating economic incentives for new drug development.

SUBTITLE H – VACCINE ACCESS, CERTAINTY, AND INNOVATION

SECTION 2142 - TIMELY REVIEW OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Following FDA licensure of a new vaccine, the Advisory Committee on Immunization Practices (ACIP) convenes working groups to review data available on the vaccine in order to make recommendations to ACIP. ACIP consists of fifteen voting members who vote on their working groups recommendations before forwarding them to the Director of the CDC for approval.

This section would ensure that the working groups have enough time to review the data and information to make an informed recommendation to ACIP and that ACIP votes on such recommendations in a timely way to ensure patient access to these lifesaving vaccines.

SECTION 2142 - REVIEW OF PROCESSES AND CONSISTENCY OF ACIP RECOMMENDATIONS

This section would require the Director of the CDC to conduct a review of the process used by ACIP in order to evaluate ACIP's consistency in formulating and issuing recommendations pertaining to vaccines. Following such review, the CDC Director shall publish a report on the results of the review, including recommendations on improving the consistency of the process.

SECTION 2143 - MEETINGS BETWEEN CDC AND VACCINE DEVELOPERS

This section would create and formalize processes for the making of vaccination scheduling recommendations by ACIP, for CDC review of ACIP recommendations, and for meetings between CDC and vaccine developers. These meetings will provide companies investing in vaccines more certainty and understanding when establishing investment and development plans.

SUBTITLE I – ORPHAN PRODUCT EXTENSIONS NOW; INCENTIVES FOR CERTAIN PRODUCTS FOR LIMITED POPULATIONS

SECTION 2151 – EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION

This section would incentivize the repurposing of major market drugs for rare diseases – advancing safe and effective treatments and cures to patients facing these rare diseases. The provision would provide a one-time, six month extension of certain exclusivity periods and patent protection for an already-approved drug if the drug's sponsor obtains approval of a new indication for the drug for a rare disease or condition.

SECTION 2152 – REAUTHORIZATION OF RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER INCENTIVE PROGRAM

This section would reauthorize the rare pediatric disease priority review voucher (PRV) program through December 31, 2018. In addition, it would broaden the definition of a rare pediatric disease to ensure that pediatric oncology drugs and treatments for sickle cell disease are eligible for designation. Further, it would require the U.S. Government Accountability Office to complete a report evaluating the effectiveness of the program for encouraging drug development for rare pediatric diseases.

SUBTITLE J – DOMESTIC MANUFACTURING AND EXPORT EFFICIENCIES

SECTION 2161 - GRANTS FOR STUDYING THE PROCESS OF CONTINUOUS DRUG MANUFACTURING

This section would allow FDA to award grants to higher education and non-profit organizations to study and recommend improvements to the process of continuous manufacturing (and other similar innovative monitoring and control techniques) of drugs and biologics.

SECTION 2162 - RE-EXPORTATION AMONG MEMBERS OF THE EUROPEAN ECONOMIC AREA

This section would allow U.S. pharmaceutical companies to re-export controlled substances similar to foreign pharmaceutical manufacturers, providing a level-playing field regarding controlled substances exports.

SUBTITLE K – ENHANCING COMBINATION PRODUCTS REVIEW

SECTION 2181 - ENHANCING COMBINATION PRODUCTS REVIEW

This section would require FDA to issue a final guidance document describing the role of all agency centers when reviewing a combination product

SUBTITLE L – PRIORITY REVIEW FOR BREAKTHROUGH DEVICES

SECTION 2201 - PRIORITY REVIEW FOR BREAKTHROUGH DEVICES

This section would require FDA to establish a program to provide priority review for qualifying medical devices. It would provide FDA with sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

SUBTITLE M – MEDICAL DEVICE REGULATORY PROCESS IMPROVEMENTS

SECTION 2221 – THIRD-PARTY QUALITY SYSTEM ASSESSMENT

This section would establish a voluntary third-party quality system assessment program where device companies could have their quality system certified by an FDA-authorized third party and, once certified, gain certain efficiencies in the FDA pre-market review process.

SECTION 2222 – VALID SCIENTIFIC EVIDENCE

This section would clarify that, in the context of FDA evaluation of medical devices, valid scientific evidence may include registry data, studies published in peer-review journals, and data collected in countries other than the United States so long as certain criteria are met.

SECTION 2223 – TRAINING AND OVERSIGHT IN LEAST BURDENSOME APPROPRIATE MEANS CONCEPT

This section would ensure that each FDA employee involved in the review of medical device submissions receives adequate training in the meaning and implementation of the least burdensome means concept.

SECTION 2224 – RECOGNITION OF STANDARDS

This section would establish a clear process at FDA for the submission, review, and recognition of standards established by a nationally or internationally recognized standard organization for purposes of medical device review.

SECTION 2225 – EASING REGULATORY BURDEN WITH RESPECT TO CERTAIN CLASS I AND CLASS II DEVICES

This section would allow FDA to focus its oversight on those devices that pose more risks to patients.

SECTION 2226 – ADVISORY COMMITTEE PROCESS

This section would improve the medical device classification panel review process at FDA to ensure adequate expertise among panel members to assess the device and allow for presentation by the device sponsor to the panel, among other things.

SECTION 2227 – HUMANITARIAN DEVICE EXEMPTION APPLICATION

This section would provide FDA with the authority to apply the humanitarian device exemption to diseases and conditions that affect up to 8,000 individuals in the U.S.

SECTION 2228 – CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS

This section would require FDA to issue guidance clarifying CLIA waiver study design.

SUBTITLE N – SENSIBLE OVERSIGHT FOR TECHNOLOGY WHICH ADVANCES REGULATORY EFFICIENCY

SECTION 2241 – HEALTH SOFTWARE
SECTION 2242 – APPLICABILITY AND INAPPLICABILITY OF REGULATION
SECTION 2243 – EXCLUSION FROM DEFINITION OF DEVICE

Technological innovation around health software and wireless platforms such as smartphones hold great promise for our 21st century health care system. However, there are concerns related to the current regulatory approach for health technologies. Sections 2241-2243 would support further development in this field by updating the regulatory laws around software and creating clarity for developers and reviewers alike.

SUBTITLE O – STREAMLINING CLINICAL TRIALS

SECTION 2261 – PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES

This section would require the Secretary of HHS to harmonize differences between the human subject regulations under the Common Rule and the Federal Food Drug and Cosmetic Act (FFDCA). Further, this section would streamline the institutional review board (IRB) process for trials that are being conducted at multiple sites.

SECTION 2262 – USE OF NON-LOCAL INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS AND HUMAN DEVICE EXEMPTIONS

This section would remove the limitation on the use of central IRBs in medical device trials.

SECTION 2263 – ALTERATION OR WAIVER OF INFORMED CONSENT FOR CLINICAL INVESTIGATIONS

This section would amend certain provisions governing the informed consent process for enrolling patients in medical device tests that poses no more than minimal risk and include appropriate safeguards to protect the rights, safety, and welfare of the participants.

SUBTITLE P – IMPROVING SCIENTIFIC EXPERTISE AND OUTREACH AT FDA

SECTION 2281 – SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE

This section would enable FDA to hire more efficiently and ensure that the agency has the staff required to ensure they keep up with the pace of innovation.

SECTION 2282 – ENABLING FDA SCIENTIFIC ENGAGEMENT

This section expresses congressional support for eliminating barriers that prevent agency staff from attending scientific conferences and meetings. Allowing staff travel for their continued training and education will help the agency keep pace with the latest scientific developments.

SECTION 2283 – REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

This section would ensure that the Reagan-Udall Foundation has access to the expertise and human capital it needs to fulfill its statutory mission of advancing FDA's scientific priorities.

SECTION 2284 – COLLECTION OF CERTAIN VOLUNTARY INFORMATION EXEMPTED FROM PAPERWORK REDUCTION ACT

This section would exempt FDA from the Paperwork Reduction Act with respect to the collection from patients, industry, academia, and other stakeholders of voluntary information through voluntary surveys and questionnaires. This will enable FDA to more easily and efficiently receive patient input.

SECTION 2285 - HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL

This section would enable FDA to hire more efficiently by giving the agency broad and flexible new authority to recruit and retain the staff required to ensure that the agency keeps up with the pace of innovation. It also includes the ability to offer salaries competitive with those in the private sector and in academia. This authority is essential for FDA be able to hire in an effective manner and to avoid existing inefficient processes.

SUBTITLE Q – EXEMPTING FROM THE SEQUESTRATION CERTAIN USER FEES

SECTION 2301 - EXEMPTING FROM SEQUESTRATION CERTAIN USER FEES

This section would permanently exempt the following FDA user fees from sequestration: fees for medical devices, prescription drugs, generics drugs, biosimilars, animal drugs, and generic animal drugs. This provision would provide certainty regarding access to FDA user fees and provide funding for drug and device review and other critical agency functions.

TITLE III - DELIVERY

SUBTITLE A – INTEROPERABILITY

SECTION 3001 – ENSURING INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY

As evidenced by statements from numerous 21st Century Cures roundtable participants, the ability to share research and clinical data is a cornerstone of our drive for new cures. The Office of the National Coordinator (ONC) for Health Information Technology has led the charge, but recently has identified barriers to nationwide interoperability of health technology. This section would refocus national efforts on making systems interoperable and holding individuals responsible for blocking or otherwise inhibiting the flow of patient information throughout our healthcare system.

SUBTITLE B – TELEHEALTH

SECTION 3021 - TELEHEALTH SERVICE UNDER THE MEDICARE PROGRAM

The Energy and Commerce Bipartisan Telemedicine Member Working Group has been working to find a solution that has plagued Congress and our health system for decades: how to adopt new technologies into our delivery system in ways that promote greater quality care and fiscal

integrity. This section would support the efforts of the working group by requiring specific actions of government bodies identified as critical to developing a long-term solution to this problem.

SUBTITLE C - ENCOURANGING CONTINUING MEDICAL EDUCATION FOR PHYSICIANS

SECTION 3041 - EXEMPTION FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES

This section would exempt certain transfers of value from reporting requirements that providers have noted had a chilling effect on their engagement in important continuing medical education activities.

SUBTITLE D – DISPOSABLE MEDICAL TECHNOLOGIES

SECTION 3061 - TREATMENT OF CERTAIN ITEMS AND DEVICES

Today, seniors who receive their care in a home setting are not able to access certain services afforded others because of the nature of the durable medical equipment (DME) payment system. This section would ensure that those seniors receiving care in the home setting are not denied access to certain treatments that would otherwise be available to them based simply on the location in which they seek care.

SUBTITLE E – LOCAL COVERAGE DECISION REFORMS

SECTION 3081 - IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS

The local coverage determination (LCD) process is an important means by which seniors can access treatments that would not otherwise be covered by Medicare due to the length of time it takes for the national process to conclude its work. However, improvements are needed. This section would increase transparency around the LCD process and begin the process of bringing greater accountability to the actions of those contracting with the Centers for Medicare and Medicaid Services to manage the operation of the Medicare program.

SUBTITLE F – MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN

SECTION 3101 - MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN

This section would create a new technology ombudsman within Medicare to address problems relating to coverage of new and life-saving technologies.

SUBTITLE G – MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY

SECTION 3121 - MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY

The Medicare benefit currently pays varying rates for the same services depending on where they are delivered. As a result, seniors' out of pocket costs can be higher or lower for a given procedure based upon where the service is provided. This section would give seniors the ability to shop among certain sites of service for certain services so that they can identify the most cost-effective treatments.

SUBTITLE H – MEDICARE PART D PATIENT SAFETY AND DRUG ABUSE PREVENTION

SECTION 3141 - PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER MEDICARE PARTS C AND D

This section would allow prescription drug plans in Medicare Part D to develop a safe prescribing and dispensing program for beneficiaries that are prescribed a high volume of controlled substances.

TITLE IV – MEDICAID, MEDICARE, AND OTHER REFORMS

SUBTITLE A – MEDICAID AND MEDICARE REFORMS

SECTION 4001 - LIMITING FEDERAL MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT (DME) TO MEDICARE PAYMENT RATES

This section would limit federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to Medicare reimbursement rates. By limiting federal matching funds for Medicaid to the market-based rates paid by Medicare, it would ensure that federal taxpayers are not over-paying for products and thus save money. This policy would not take effect until the start of fiscal year 2020. This delayed effective date would allow states, plans, providers, industry, and other stakeholders to adjust current practices and plan for the coming changes. The provision also directs the Medicare Beneficiary Ombudsman to evaluate the impact of this limit on federal matching funds on beneficiary health status and outcomes.

SECTION 4002 – EXCLUDING AUTHORIZED GENERICS FROM CALCULATION OF AVERAGE MANUFACTURER PRICE

Under current law, brand manufacturers are able to include the sales of authorized generics in the calculation of average manufacturer price, thereby artificially lowering their brand-name rebate obligations. This section would exclude authorized generics from Average Manufacturers' Price (AMP) calculations for determining Medicaid brand name rebates. Under this section, the primary drug manufacturer must exclude sales of authorized generic products from their calculation of the antecedent brand name drugs AMP. This policy would have the effect of increasing the AMP of brand drugs and thus increasing the rebates drug manufacturers would owe to the states and federal government. Drug manufacturer's sales and reporting of brand products would not be affected by this proposal. Under this policy, certain drug manufacturers

would be liable for Medicaid rebates on their products based on the AMP for the existing brand, but calculated without including sales of the lower priced authorized generic drug.

SECTION 4003 - MEDICARE PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY AND OTHER MEDICARE IMAGING PAYMENT PROVISION

This section would improve patient safety and encourage the adoption of innovative medical technologies by implementing a differential Medicare reimbursement for film x-ray and computed radiography to incentivize the transition to digital radiography. This policy would encourage providers' transition to modern digital technologies and improve patient safety and care as providers' transition away from older technology, which may produce less detailed images, thus requiring another image to be taken which exposes patients to the negative clinical effects of additional scans. Additionally, as a matter of basic fairness and transparency, this policy would eliminate application of the multiple procedure payment reduction unless the Secretary conducts and publishes empirical analysis within the Medicare Physician Fee Schedule Proposed Rule in the prior year.

SECTION 4004- USE OF AVERAGE SALES PRICE FOR MEDICARE PART B PAYMENT AND METHODOLOGY FOR DME DRUGS

This section would set payment amounts for Part B drugs infused through DME items using the methodology used for most physician-administered drugs: Average Sales Price (ASP) plus 6 percent. Applying the ASP+6 percent methodology to DME infused drugs would result in payment amounts that reflect actual transaction prices. The Department of Health and Human Services Office of Inspector General recommends this legislative change, noting that the current payment methodology based on manufacturer sticker prices that were in effect in 2003 *over pays* many drugs and under pays others.

SECTION 4005 – EXTENSIONS AND EXPANSION OF PRIOR AUTHORIZATION FOR POWER MOBILITY DEVICES (PMDS) AND ACCESSORIES AND PRIOR AUTHORIZATION AUDIT LIMITATIONS

Prior authorization programs determine medical necessity before payments are approved, thus improving payment integrity for payers, providing payment predictability for suppliers, and reducing costly pay-and-chase efforts after payments are made. Building on current CMS and private sector prior authorization efforts, this section includes several targeted policies to improve CMS's use of prior authorization for DME. First, this section would create a new kind of safe harbor for suppliers who receive a prior authorization approval for medical necessity, so that such suppliers would not be unduly burdened by duplicative audits –though they could still be subject to audit in cases of suspected fraud. Second, this policy would expand the geographic scope and extend the duration of CMS's current DME power mobility device (PMD) demo. Third, in implementing this section, this policy would require CMS to consider various factors (access to care, commercial best practices, timeliness of payments, etc.) in prior authorization efforts.

SECTION 4006 – CIVIL MONETARY PENALTIES FOR VIOLATIONS RELATED TO GRANTS, CONTRACTS, AND OTHER AGREEMENTS

This section would clarify and expand the HHS Office of the Inspector General's authority to use civil monetary penalties (CMPs) in cases of proven HHS grant or contract fraud. HHS OIG and CBO believe this tool would help save the federal government millions of dollars and have a positive sentinel effect by penalizing proven bad actors.

SUBTITLE B – OTHER REFORMS

SECTION 4041 - SPR DRAWDOWN

This section would direct the Department of Energy to drawn down and sell crude oil from the Strategic Petroleum Reserve (SPR).

SUBTITLE C – MISCELLANEOUS

SECTION 4061 - LYME DISEASE AND OTHER TICK-BORNE DISEASES

This section would help to accelerate improved methods for prevention, diagnosis, and treatment of Lyme disease. It would establish a working group to prepare a report that would summarize federal research efforts related to Lyme disease and other tick-borne diseases. Informed by the report prepared by the working group, the Secretary would develop a strategic plan to improve health outcomes.