Summary of Major Changes to H.R.6 - The 21st Century Cures Act

June 2, 2015

- Amended the National Institutes of Health and Cures Innovation Fund to clarify the availability of a $9.3 billion advanced appropriation for FY2016-FY2020. $1.75 billion is made available for NIH activities annually from FY2016-FY 2020. $110 million is made available for FDA regulatory modernization activities annually from FY2016-FY2020.

- Struck Section 1101, "Sharing of data generated through NIH-funded research"

- Amended Section 2123, "Encouraging the development and use of DISARM drugs," to clarify intent by reducing to .02 the amount of additional incentive for lifesaving antibiotic drugs.

- Amended Section 3001, "Ensuring interoperability of health information technology," to clarify standards regarding the development of health information technology. The changes also clarify the role that federal agencies, including the National Institute of Standards and Technology, under the program going forward.

- Amended Section 3021, "Telehealth services under the Medicare program," to amend deadlines for MedPAC, modify the Sense of Congress and make technical changes.

- Added 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.

- Struck previous Section 4003, "Implementation of Office of Inspector General Recommendation to Delay Certain Medicare Prescription Drug Plan Prepayments."

- Added Section 4004, "Treatment of infusion drugs furnished through durable medical equipment." This section would set payment amounts for Part B drugs infused through Durable Medical Equipment (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.

- Added Section 4005, "Extensions and expansions 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 commercial sector prior authorization efforts, this section includes several targeted policies to improve CMS's use of prior authorization for DME. First, this section creates 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 expands the geographic scope and extends the duration of CMS's current DME power mobility device (PMD) demo. Third, in implementing this section, this policy require CMS to consider various factors (access to care, commercial best practices, timeliness of payments, etc.) in prior authorization efforts.

- Added Section 4006, "Civil monetary penalties for violations related to grants, contracts, and other agreements." Currently, HHS is the largest grant-making organization in the federal government, with over 79,000 grants

totaling $389 billion awarded in FY 2014. HHS is also the third largest contracting agency in the federal government. In FY 2013, HHS awarded over $20 billion in contracts across all program areas. Although HHS is authorized under certain circumstances by the Program Fraud Civil Remedies Act of 1986 (PFCRA) to impose civil penalties against grantees and contractors that commit fraud, procedural and jurisdictional barriers limit PFCRA's effectiveness for the Department. Since the 1980s, OIG has successfully used its Civil Monetary Penalty (CMP) authorities for Medicare and Medicaid fraud to collect millions of dollars in hundreds of cases involving fraud. OIG has used this administrative tool to complement DOJ's civil and criminal enforcement authorities and to promote compliance in the health care industry. However, if HHS OIG had CMP authorities for grant and contract fraud, OIG could promote greater compliance with HHS grant and procurement requirements and recover appropriate amounts that would include repayment of damages to the government. 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.

- Amend Section 4041 related to the Strategic Petroleum Reserve (SPR) to adjust the drawdown of excess capacity within the SPR.