

Manager's Amendment Summary: Major Changes

The manager's amendment includes a number of technical and conforming changes to H.R. 6. Detailed below is a summary of some of the major substantive changes included in the amendment. Read a section-by-section of H.R. 6 online [here](#).

- The amendment would modify Section 2123 (“Encouraging the development and use of new antimicrobial drugs”), including clarification regarding eligibility for consideration as a DISARM drug and the process for securing reimbursement.
- This amendment would enable FDA to expedite the hiring process by using direct hiring authority, similar to the hiring authority that is available to the National Institutes of Health.
- The amendment would exempt the following FDA user fee programs from sequestration: medical devices, prescription drugs, generics drugs, biosimilars, animal drugs, and generic animal drugs.
- The amendment would limit Medicaid reimbursement to States for Durable Medical Equipment (DME) to Medicare rates. Through the Durable Medical Equipment Competitive Bidding Program, Medicare is in the process of implementing market-based reforms to how taxpayers pay for DME. These reforms are estimated to amount to more than \$30 billion over 10 years. This provision, based on the President's FY 2016 Budget proposal, would extend these reforms to Medicaid by limiting federal reimbursement for a state's Medicaid spending on certain durable medical equipment to what Medicare would have paid. Unlike the President's FY2016 Budget proposal which envisioned immediate adoption of this policy, this proposal does not take effect until 2020.
- The amendment would accelerate the modernization of x-ray imaging and improve patient safety by reforming the Medicare reimbursement system for outdated film x-ray imaging services.
- The amendment would alter the timing of reinsurance payments to prescription drug plan sponsors.
- This amendment would establish a \$110 million annual fund from FY2016-2020 to provide dedicated resources for FDA regulatory modernization and other activities authorized by the 21st Century Cures Act.
- Because the Strategic Petroleum Reserve (SPR) is well in excess of required reserves, this amendment would direct DOE to draw down and sell crude oil from the SPR.
- The amendment includes the language from H.R. 789, the Tick-Borne Disease Research Accountability and Transparency Act of 2015.