ROPES & GRAY ALERT

Health Care ▪ Government Enforcement / White Collar Crime

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Medicare, Medicaid, and Enforcement Implications of the 21st Century Cures Act Recently Passed by the House

On July 10th, the U.S. House of Representatives passed the 21st Century Cures Act – medical innovation reform legislation that has been in the works for over a year – by a wide margin (344-77). As Ropes & Gray previously reported, the House Energy & Commerce Committee ("E&C Committee") released an initial discussion draft in January 2015 and a revised discussion draft in April 2015.

The bill aims to bring new drugs to market faster by encouraging medical innovation, and grants additional funding to the NIH and Food and Drug Administration. The bill also would make several significant changes to the Medicare and Medicaid programs with implications for a wide range of stakeholders across the health care industry, including payors, home health agencies, drug and device manufacturers, hospitals, and ambulatory surgery centers.

Several key provisions relevant to Medicare and Medicaid have been summarized below.

Provisions Related to Drugs and Biological Products

- *Programs to Prevent Prescription Drug Abuse (Section 3141).* The bill would permit Part D Prescription Drug Plan ("PDP") sponsors to establish drug management programs for at-risk beneficiaries under which the PDP sponsors may limit access to coverage for frequently abused drugs prescribed by one or more prescribers and dispensed by one or more pharmacies. Several due process protections for affected beneficiaries also are put in place, including strict notice requirements and a process for appeal and termination.
- *Inclusion of Infused Biological Products in DME Payment Methodology (Section 4004).* The bill would add infusion biological products to the payment methodology for infusion drugs furnished through durable medical equipment ("DME").
- *Modification to Calculation of Average Manufacturer Price (Section 4002).* The bill would exclude generic drugs from the calculation of the average manufacturer price ("AMP"), which manufacturers must report to CMS for all Medicaid-covered drugs on a quarterly basis as a requirement of the Medicaid drug rebate program. The AMP is used to calculate Medicaid rebates.

Provisions Related to Durable Medical Equipment and Disposable Medical Technologies

- *Payment Reductions for Durable Medical Equipment (Section 4001).* The bill would limit federal Medicaid reimbursement to states for DME to Medicare payment rates. In other words, the bill eliminates federal financial participation for state Medicaid DME fee schedule payments that in the aggregate exceed the amount Medicare would have paid, including in states that have launched competitive acquisition programs. Probably as a concession to industry concerns that competitive bidding will drive down quality and access, the bill also would require that a Medicare ombudsman monitor the effects of competitive acquisition programs on beneficiary health status and outcomes.
- *Extension of Prior Authorization for Power Mobility Devices (Section 4005).* The bill would exclude from Recovery Audit Contractor ("RAC") audits any claim for Power Mobility Devices ("PMDs") that has received a provisional affirmation under an advance determination. However, the bill specifies that such claims may be subject to audits for potential fraud in areas not covered by the advance determination, such as inappropriate

utilization, changes in billing patterns, or information that could not have been considered during the advance determination such as proof of item delivery.

- *New Medicare Payment for Disposable Medical Technologies Used in Home Health (Section 3061).* The bill would establish separate payment to home health agencies for any disposable medical device used in Medicare home health delivery for which there is (1) a separate Healthcare Common Procedure Coding System ("HCPCS") code for which the description for a professional service includes the furnishing of such device; and (2) a separate Level I HCPCS code for a professional service that uses durable medical equipment instead of the device.

Provisions Related to Pricing Process and Transparency

- *Greater Transparency of Local Coverage Determinations (Section 3081).* Effective six months after enactment, each Medicare administrative contractor that develops a local coverage determination would be required to publish the following information on the contractor's website and on the Medicare website: (1) the determination in its entirety; (2) where and when the proposed determination was first made public; (3) hyperlinks to the proposed determination and responses to comments submitted; (4) a summary of the evidence considered along with a list of the sources; and (5) an explanation of the rationale supporting the determination.
- *Medicare Site-of-Service Price Transparency (Section 3121).* In order to facilitate price transparency of Medicare payment for hospital outpatient and ambulatory surgery center items and services, the bill would mandate that the Secretary make available via a public searchable website the Medicare estimated payment and beneficiary liability amounts for each item or service. The bill also provides a formula for calculating estimated beneficiary liability.

Provisions Related to Radiology

- *Incentives to Transition to Digital Radiography (Section 4003).* The bill would create incentives for the transition from traditional x-ray imaging to digital radiography. First, the bill would reduce the technical component of the payment amount for x-rays taken using film by 20%. Second, the bill would limit payment for computed radiography imaging services using an incremental approach: the technical component of the payment amount would be decreased by 7% for services furnished during 2018-2022 and by 10% for services furnished during or after 2023. Additionally, a multiple procedure payment reduction would not be applied to the professional component of apparently all imaging services unless the Secretary has published an empirical analysis demonstrating efficiencies.

Provisions Related to Federal Grants, Contracts, and Funding Agreements

- *New Civil Monetary Payments for Grant and Contract Violations (Section 4006).* The bill would add several new violations to the list for which penalties are available for imposition by the Office of Inspector General of the Department of Health and Human Services ("HHS OIG") under the Civil Monetary Penalties statute. Additionally, the bill would authorize the government to impose an "assessment" on the majority of these actions, which, depending on the nature of the violation, could require liable persons to pay an assessment of three times the amount claimed or three times the amount of HHS funds or property at issue. Among others, the newly added actions include: knowingly presenting or causing to be presented a false or fraudulent "specified claim" under an HHS contract or grant; knowingly making, using, or causing to be made or used a false statement, omission, or misrepresentation of material fact in a document required to be submitted to receive or retain funds under an HHS contract or grant; and failing to grant timely access to HHS OIG upon reasonable request for audits or to carry out other statutory functions in matters involving an HHS grant or contract.

Prospects for the Legislation

Although the Cures Act has cleared the hurdle of the House, the prospects of passage in the Senate remain uncertain. The Senate Health, Education, Labor & Pensions Committee ("HELP Committee") has held numerous hearings over

the past several months as it considers its own medical innovation legislation. However, the HELP Committee has not yet released even a discussion draft of its legislation, and one is not expected until at least the end of the Senate recess in August. Following the House's passage of the Cures Act, HELP Committee Chairman Lamar Alexander (R-TN) stated that the Senate's work would continue "on a parallel track . . . to produce a bill that [the Senate] can combine with 21st Century Cures and send to the President's desk."

Prior passage of the Cures Act, the White House, via a statement of administration policy, objected to the bill's use of the government's Strategic Petroleum Reserve to offset the bill's funding increases. The White House would have preferred that the bill directly address sequestration and ensure that FDA has sufficient funding to support all the programs established in the bill. The White House also expressed concern regarding the proposals relating to drug exclusivity and drug manufacturer communications with payors. Whether the Senate's proposed legislation will address the White House's concerns remains to be seen.

Re-authorization of the Prescription Drug User Fee Act ("PDUFA VI") is slated to occur in 2017. Given that PDUFA VI is considered "must-pass" legislation, it is possible that a number of issues under consideration in the Cures Act, particularly those issues lacking consensus, will be deferred until that latter debate.

Ropes & Gray will continue to monitor legislative developments in this area. If you have any questions, please contact any member of Ropes & Gray's health care, FDA regulatory, or government enforcement practices or your usual Ropes & Gray advisor.