ROPES & GRAY ALERT

FDA Regulatory ▪ Health Care ▪ Digital Health

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21st Century Cures Act – Provisions Relating to Reimbursement & Fraud and Abuse

On December 13, 2016, President Obama signed into law the 21st Century Cures Act (the Act), just days after it passed in the U.S. House of Representatives and Senate. With an overarching goal of advancing biomedical innovation, the Act makes numerous changes to laws that govern Food and Drug Administration (FDA) programs, clinical research regulations, and Medicare coverage and reimbursement rules.

To see Ropes & Gray's analysis of key provisions of the Act, please click on the hyperlinks below:

- Promoting Drug Development
- Development Incentives for Certain Classes of Drugs
- Medical Device Innovation
- Digital Health
- Regulation of Clinical Research

Partners in Ropes & Gray's FDA Regulatory practice have also recorded a podcast to discuss some key implications of the Act for biopharmaceutical and medical device manufacturers. Click here to listen to the podcast.

This Alert notes key changes to the Medicare and Medicaid programs, including changes to coverage and reimbursement rules affecting hospitals, ambulatory surgery centers, DME suppliers, and other providers. It also highlights a change to the Civil Monetary Penalties Law providing for penalties in cases of fraud involving HHS grants, contracts, or other agreements.

Greater Transparency of Local Coverage Determinations [Section 4010].[1]

Effective six months after enactment, the Act requires each Medicare administrative contractor that develops a local coverage determination to publish the following information on the contractor's website and on the Medicare website: (i) the determination in its entirety; (ii) where and when the proposed determination was first made public; (iii) hyperlinks to the proposed determination and responses to comments submitted; (iv) a summary of the evidence considered, along with a list of the sources; and (v) an explanation of the rationale supporting the determination.

Medicare Site-of-Service Price Transparency [Section 4012].

In order to facilitate price transparency of Medicare payment for hospital outpatient and ASC items and services, the Act requires HHS to make available, via a public searchable website, the Medicare estimated payment and beneficiary liability amounts for each item or service. The Act also provides a formula for calculating estimated beneficiary liability. This is expected to benefit ASCs, which generally provide services at a lower cost.

[1] Cited sections refer to the relevant provisions in the Act.

Medicaid Reimbursement to States for DME [Section 5002].

Effective January 1, 2018, the Act limits the amount of federal Medicaid reimbursement to states for durable medical equipment (DME), prosthetics, orthotics and supplies sold pursuant to a Medicaid fee schedule to the Medicare reimbursement rates. This section effectively eliminates federal financial participation for state Medicaid DME fee schedule payments that exceed the amount Medicare would have paid for the item, including in states that have launched competitive acquisition programs.

Reducing Overpayments of Infusion Drugs [Section 5004].

The Act changes the reimbursement methodology for infusion drugs furnished through an item of DME to the methodology used for the majority of physician-administered drugs: Average Sales Price (ASP) plus six percent. The Act also removes infusion drugs furnished through DME from competitive acquisition areas designated by the Secretary. This pricing structure is intended to reflect actual transaction prices in an attempt to remedy the over- and underpayment of certain drugs.

Allowing Physical Therapists to Utilize Locum Tenens Arrangements [Section 16006].

The Act allows physical therapists furnishing outpatient physical therapy services in certain underserved areas to use locum tenens arrangements, in the same manner as such arrangements apply to physicians.

Continuing Medicare Payment under HOPD Prospective Payment System for Services Furnished by Mid-build Off-campus Outpatient Departments of Providers [Section 16001].

Under Section 603 of the Bipartisan Budget Act of 2015 and implementing regulations issued by HHS in November 2016, most new hospital off-campus provider-based departments (HOPDs)—*i.e.*, those that began furnishing services on or after the date of enactment of the Bipartisan Budget Act, or November 2, 2015—would be subject to payment reforms that provide for Medicare reimbursement under a modified fee schedule rather than the more favorable Hospital Outpatient Prospective Payment System (OPPS). In response to complaints from hospitals that had undertaken significant capital projects for HOPDs with the expectation of Medicare payments under the more favorable OPPS, the Act provides an exception for HOPDs defined as "mid-build" prior to November 2, 2015. The Act defines "mid-build" as a provider that had a binding written agreement with an outside, unrelated party for the actual construction of the HOPD. To qualify, each HOPD would submit a certification from the CEO/COO that it meets the "mid-build" requirements and an attestation that it is provider-based. The attestation would be subject to audit by the HHS Secretary. Qualifying HOPDs would receive the full OPPS payment rate beginning in 2018 rather than the lower physician fee schedule or ambulatory surgical center payments required under the Bipartisan Budget Act of 2015.

Penalties for Violations of Grants, Contracts and Other Agreements [Section 5003].

The Act adds several new violations to the list for which penalties are available under the Civil Monetary Penalties law. The newly added violations include: misrepresentations of "specified claims" under an HHS grant or contract; misrepresentations in a document required to receive or retain funds under an HHS grant or contract; misrepresenting a material "obligation" to transmit funds under an HHS grant; and failing, upon reasonable request, to grant timely access for audits or other statutory functions involving such grants or contracts.

If you have any questions, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.