PUBLICATION

The 21st Century Cures Act [Ober|Kaler]

2016

Signed into law by President Obama on December 13, 2016, the 21st Century Cures Act (Act) was overwhelmingly supported in both houses of Congress and comprises a dizzying array of provisions aimed to improve and modernize various aspects of the health care system, especially in areas of biomedical research and mental health. From funding projects for addressing opioid addiction to providing exceptions to the site-of-service differential under the Outpatient Prospective Payment System for off-campus provider-based departments, the Act is arguably the most comprehensive health care legislation to be enacted since the Patient Protection and Affordable Care Act of 2010. Given its scope, only a few notable provisions of the Act are covered below.

Site-Neutrality Payment Policy for Off-Campus Provider-Based Departments (OPBDs)

- *Section 16001*: Section 603 of the Bipartisan Budget Act of 2015 bars CMS from continuing to pay hospitals the outpatient prospective payment services (OPPS) rates for services furnished in OPBD beginning January 1, 2017, with some exceptions. One exception is for OPBDs that billed for services furnished as of November 2, 2015 (the date the law was enacted). Section 16001 of the 21st Century Cures Act expands this exception:

  - For 2017, providers are deemed to have been billing under OPPS for OPBD services furnished prior to November 2, 2015, if the Secretary received a properly filed provider-based attestation for the site from the provider prior to December 2, 2015.
  - For 2018 and subsequent years, OPBDs that were in mid-build status as of November 2, 2015, may continue to be reimbursed under OPPS if they timely filed a provider-based attestation, were included on the provider's enrollment form, had a binding agreement for construction with an unrelated entity prior to November 2, 2015, and timely filed a related certification with CMS. For a more in-depth discussion of this issue, see our earlier article here.

Promoting Biomedical Research

- *Section 2034*: The Secretary of Health and Human Services (Secretary) is to confer with the Office of the Inspector General for Health and Human Services (OIG) to reduce the administrative burden related to financial conflicts of interest for researchers. Additionally, the Office of Management and Budget is required to establish a Research Policy Board to advise on the effects of regulation related to federal research requirements in order to streamline and administrative simplify research policy and regulations to the greatest extent possible.
- *Section 3012*: This section seeks to leverage data from previously approved drug applications to facilitate the development, review, and approval of genetically targeted drugs that treat rare diseases or conditions that are serious or life-threatening.

- *Section 3022*: The Secretary is to establish a program where data from other than randomized clinical trials, defined as "real world evidence," can be used to support a new indication for a previously approved drug.
- *Section 3051*: The Secretary is to establish a program for "breakthrough devices" that operates, essentially, as a fast lane for device review and approval, so long as certain requirements are met.

Revising Documentation Related to the Delivery of Health Care

- *Section 4001*: The Secretary will establish goals to reduce the regulatory and administrative burdens relating to the use of electronic health records. Providers also may delegate certain regulatory documentation requirements in electronic medical records to scribes.
- *Section 4003*: This section establishes standards for "interoperability" for health information technology.
- *Section 4006*: The Secretary will encourage the development and availability of electronic health information to patients in a single, longitudinal format that is updated automatically.
- *Section 4009*: Each Medicare Administrative Contractor (MAC) is required to publish local coverage determinations 45 days prior to implementation. Each local coverage determination must contain a summary of the evidence used by the MAC in its determination, a copy of the public comments to the local coverage determination, and the MAC's responses to those comments.

New OIG Civil Monetary Penalties for Grant Funding or Contracts

- *Section 5003*: This section provides the OIG additional civil monetary penalties for fraud related to grant funding and other agreements that include federal funding from the Department of Health and Human Services.

Mental Health and Substance Abuse

- *Titles VII through XIV*: The Act provides a litany of provisions to improve services related to mental health and substance abuse. Such provisions include (among several others):

  - $1 billion in grant funding to states for addressing opioid abuse and addiction;
  - Several incentive grants for promoting the integration of mental health services with primary care services;
  - Providing the Attorney General the authority to create mental health and drug treatment alternatives to incarceration; and
  - Require the Secretary to develop an action plan for enforcing mental health parity requirements.