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21st Century Cures Act Grants Additional Grandfathered Status to Some Off-Campus Hospital Outpatient Departments

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After being on hold for nearly two years and receiving rare bipartisan support, President Obama signed the 21st Century Cures Act (the “Act”) into law December 13, 2016. Although the Act, as the name suggests, largely sponsors medical innovation, it also includes two exceptions to the site neutrality requirements under Section 603 of the Bipartisan Budget Act of 2015 (“Section 603”). The new exceptions provide temporary grandfather status to certain off-campus hospital outpatient departments (“HOPDs”) that filed voluntary attestations before December 2, 2015 and permanent, but delayed, grandfather status to HOPDs that were in “mid-build” at the time Section 603 was enacted.¹

Under Section 603, only HOPDs that furnished items or services and billed the Centers for Medicare & Medicaid Services (“CMS”) under the Outpatient Prospective Payment System (“OPPS”) prior to November 2, 2015, are eligible to continue billing under OPPS in 2017 and beyond. Reimbursement rates for services provided in an HOPD are generally much higher under OPPS than under alternative fee schedules, such as the Medicare Part B Physician Fee Schedule (“MPFS”). HOPDs that did not qualify for an exception under Section 603 are required to accept the lower MPFS payment rates starting January 1, 2017.

The Act creates two new exceptions, one more limited than the other, allowing certain HOPDs to receive reimbursement under the OPPS. Under the first new exception, HOPDs that furnished services but had not billed for those services under OPPS as of November 2, 2015 are nonetheless eligible for OPPS reimbursement beginning on January 1, 2017 if the hospital submitted a voluntary attestation in accordance with 42 C.F.R. Section 413.65(b)(3) for the HOPD prior to December 2, 2015.² The exception comes on the heels of CMS’s recently published OPPS Final Rule that, in part, clarified Section 603. It made HOPDs that *furnished* OPPS covered services prior to November 2, 2015 still eligible for grandfather status and continued higher reimbursement so long as the items or services were ultimately billed within the timely filing requirements.³

Therefore, this first new exception is unlikely to have any significant impact on HOPDs.

The second new exception provides OPPS reimbursement to HOPDs for items or services furnished on or after January 1, 2018, which had a contract for the actual construction of the HOPD before November 2, 2015 (the “mid-build requirement”).⁴ To be entitled to grandfathered status under this second exception, the hospital must also:

- Submit a provider-based attestation that the HOPD meets all the qualifications for HOPD status by February 11, 2017 (within 60 days of enactment of the Act);
- Include the required information about the HOPD on the provider’s CMS enrollment application; and
- Have the Chief Executive Officer or the Chief Operating Officer of the main provider provide a written certification to the Department of Health and Human Services (HHS) that the HOPD meets the mid-build requirement by February 11, 2017.⁵ This certification should state that the hospital had a binding written agreement with an outside unrelated party for the actual construction of such HOPD before November 2, 2015. The addressee of this certification is yet to be determined.

While the first exception provides OPPS reimbursement only for 2017, OPPS reimbursement under the second exception is available starting on January 1, 2018. Thus, HOPDs that meet the requirements for the second, permanent exception and may be ready for operation before January 1, 2018, will be subject to lower reimbursement in the interim 2017. The Act also charges HHS with the authority to audit compliance with the attestation and certification requirements of the second exception.⁶

1 H.R. 34, 114th Cong., §16001(a)(1)(B)(iii)-(iv).

2 H.R. 34, 114th Cong., §16001(a)(1)(B)(iii).

3 81 Fed. Reg. 79708.

4 H.R. 34, 114th Cong., §16001(a)(1)(B)(iv)-(v).

5 H.R. 34, 114th Cong., § 16001(a)(1)(B) (iv)(I)-(III).

6 H.R. 34, 114th Cong., § 16001(a)(1)(B)(vii).

These new exceptions will help ring in a happy new year for many hospitals across the country with HOPDs that would otherwise have been forced to accept lower reimbursement rates for future services provided in their HOPDs. [The full text of the 21st Century Cures Act is available here.](#)

If you have any questions about the implications of the Act, please contact any member of Drinker Biddle's Health Care team.

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