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21st Century Cures Act provides relief to qualifying hospitals with off-campus outpatient departments

By Carolyn Jacoby Gabbay and Jena Grady

On December 13, 2016, President Barack Obama signed H.R. 34, the 21st Century Cures Act (the “Act”), the largest piece of health care legislation since the Affordable Care Act. It makes sweeping changes to medical research, approval of drugs and mental health care delivery and funding. The Act (Sections 16001 and 16002) revises the site-neutral payment policy that was enacted by Section 603 of the Bipartisan Budget Act of 2015 (the “BBA”) to expand the categories of off-campus provider-based departments (“PBDs”) that may receive payments under the Medicare Outpatient Prospective Payment System (“OPPS”), rather than being limited to receiving payments under modified physician fee schedule or ambulatory surgery center reimbursement rates.

The Centers for Medicare and Medicaid Services (“CMS”) [finalized regulations](#) implementing the BBA, providing that only the following PBDs would be “grandfathered” and excepted from the site-neutrality payment requirement so they could continue to receive OPPS on and after January 1, 2017:

- A PBD that is “on the campus” or within 250 yards of the hospital or a remote location of the hospital;
- Off-campus dedicated emergency departments; and
- Off-campus PBDs that were billing under OPPS for covered outpatient department services prior to November 2, 2015 (i.e., the enactment date of Section 603 of BBA 2015), provided that the PBD has not impermissibly relocated or undergone a change of ownership since that date.

The site-neutrality payment rule adversely affected many hospitals, including many that were well down the road toward implementing their planned off-campus outpatient projects. Some of those hospitals have now obtained at least partial relief under the Act.

Partial relief for completed off-campus departments

Some off-campus outpatient projects that had been completed and were about to start to render services, but had not yet started to bill under OPPS on November 2, 2015, fell just shy of qualifying for the BBA’s grandfathering provision that would have allowed them to qualify for payment under

OPPS. Under the Act, if the PBD filed a voluntary provider-based attestation in accordance with 42 C.F.R. Sec. 413.65 by December 2, 2015, it will be permitted to receive payments under OPPS in 2017.

Partial relief for “mid-build” off-campus departments

Hospitals that had off-campus outpatient projects under way but not yet completed also were caught by surprise by the BBA site-neutrality provision. Many such hospitals asked CMS to create an exception for off-campus PBDs that were “mid-build” on November 2, 2015. CMS stated in the final regulations implementing Section 603 of the BBA that the law did not provide authority for an exception for mid-build off-campus PBDs and, therefore, CMS could not grandfather them. The Act has provided partial relief for mid-build off-campus PBDs, permitting them to be paid under OPPS if they qualify for relief by meeting certain requirements:

- The hospital must have had a binding, written agreement with an outside, unrelated party for the actual construction of the off-campus PBD on November 2, 2015.
- Each off-campus PBD must submit both:
 - a certification from the hospital’s Chief Executive Officer or Chief Operating Officer that the off-campus PBD meets the “mid-build” definition, and
 - a provider-based attestation in accordance with 42 C.F.R. Sec. 413.65 within 60 days of the enactment of the Act.
- The hospital must include the PBD as part of the hospital on its 855A enrollment form.

Hospitals that meet the applicable requirements for the partial relief for “mid-build” projects will still be paid on a site-neutral basis during 2017, but they will be able to receive payments under OPPS beginning January 1, 2018.

Hospitals with completed projects that qualify for relief for 2017 also should be able to qualify for the relief allowing them to continue to be paid under OPPS in 2018.

The Act requires CMS to audit each hospital’s compliance with the mid-build requirements not later than December 31, 2018.

Relief for off-campus departments of cancer hospitals

The Act also exempts the off-campus outpatient departments of cancer hospitals from the impact of Section 603 of the BBA if they file provider-based attestations (a) within 60 days of the date of the Act’s enactment, if they met provider-based requirements between November 2, 2015 and December 13, 2016, or (b) within 60 days of the date of meeting provider-based requirements.

Conclusion

Hospitals that qualify for the relief from the site-neutrality payment provisions afforded by the Act must act promptly and file the required paperwork within the allotted period of time.

The 60th day following enactment of the Act falls on a Saturday. Rather than relying on the “next business day” convention, to assure that they are filing the paperwork that is required “within” 60 days from the Act’s enactment, hospitals should plan to make those filings by Friday, February 10, 2017.

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