

## **Note Regarding Implementation of Sections 16001 and 16002 of the 21<sup>st</sup> Century Cures Act**

On December 13, 2016, the 21<sup>st</sup> Century Cures Act was enacted into law. Sections 16001 and 16002 amended section 1833(t)(21) (as added by section 603 of the Bipartisan Budget Act of 2015) of the Social Security Act (the Act) and provide additional criteria by which off-campus departments of a provider will be excepted from payment under section 1833(t)(21)(C) of the Social Security Act. Preliminary guidance on sections 16001 and 16002 of the 21<sup>st</sup> Century Cures Act is included below. Additional guidance will be forthcoming at a later date.

### **Section 16001: Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.**

**For 2017:** If the Secretary received from a provider prior to December 2, 2015, an attestation that a department was a department of a provider in accordance with the regulations at 42 CFR 413.65(b)(3), such department will be deemed to be “excepted” from payment under section 1833(t)(21)(C) of the Act. Accordingly, such departments will be paid for covered outpatient services under the Hospital Outpatient Prospective Payment System (OPPS) and should not use modifier ‘PN’ which would trigger payment under the Medicare Physician Fee Schedule (MPFS). Such departments shall continue to report the ‘PO’ modifier as appropriate.

For calendar year 2017, all other applicable off-campus departments of a provider that did not meet the attestation requirement to be deemed excepted for 2017, shall use modifier ‘PN’ as described in the CY 2017 OPPS final rule with comment period and interim final rule with comment period, including those that anticipate meeting the exception requirements for 2018 and subsequent years.

**For 2018:** An off-campus department of a provider that meets the requirements outlined below will be excepted from payment under section 1833(t)(21)(C) of the Act for items and services furnished on or after January 1, 2018. Hospitals should submit these materials to their Medicare Administrative Contractor:

- (I) The Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than February 13, 2017, that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;
- (II) The provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and
- (III) The department met the mid-build requirement (as defined at section 1833(t)(21)(B)(v)) and the Secretary receives, not later than February 13, 2017, a

written certification signed by the chief executive officer or chief operating officer of the main provider (as defined by 42 CFR 413.65(b)(2)) (or equivalent if such titles are not used by the main provider) that the department met such requirement.. Email submissions are acceptable.

The mid-build requirement defined at section 1833(t)(21)(B)(v) of the Act is that before November 2, 2015, with respect to a department of a provider, the main provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

**Section 16002: Treatment of cancer hospitals in off-campus outpatient department of a provider policy.**

Section 16002 of the 21<sup>st</sup> Century Cures Act provides that applicable items and services furnished during 2017 or a subsequent year, by an off-campus outpatient department of a hospital paid under section 1886(d)(1)(B)(v) of the Act are excepted and such department will be excluded from payment under section 1833(t)(21)(C) if the department met the requirements of 42 CFR 413.65 after November 1, 2015 and before December 13, 2016, and the Secretary receives an attestation that such requirements were met no later than February 13, 2017.

Alternatively, in the case of an off-campus outpatient department of a hospital paid under section 1886(d)(1)(B)(v) of the Act that meets the requirements of 42 CFR 413.65 after December 13, 2016, such applicable items and services furnished by such department will be excepted and such department will be excluded from payment under section 1833(t)(21)(C) if the Secretary receives from the provider an attestation that such requirements were met no later than 60 days after the date such requirements are first met by such department.

Off-campus departments of a provider that meet these statutory criteria for an exception or exclusion should not use modifier “PN” on hospital outpatient claims.