March 9, 2022

Audit Results of Mid-Build Exception Requests for Off-Campus Outpatient Departments

Section 603 of the Bipartisan Budget Act of 2015 (BBA of 2015), enacted on November 2, 2015, amended section 1833(t) of the Social Security Act (the Act) to change the way items and services furnished by certain off-campus outpatient departments of providers are paid. Under the law, off-campus outpatient departments of providers that were billing for covered outpatient department (OPD) services under the Outpatient Prospective Payment System (OPPS) prior to the date of enactment of the BBA of 2015 could continue to be paid under the OPPS. Items and services furnished to Medicare beneficiaries by new off-campus outpatient departments of providers (those that were not billing for covered OPD services under the OPPS prior to the date of enactment of the BBA of 2015) would no longer be considered covered OPD services payable under the OPPS and would be paid under the Physician Fee Schedule.

On December 13, 2016, the 21st Century Cures Act (Pub. L. No. 114-255) (the Cures Act) was enacted. Section 16001(a) of the Cures Act amended section 1833(t)(21) to add an alternative exception for items and services furnished in 2018 or a subsequent year by off-campus outpatient departments of providers that met the "mid-build requirement" before the date of enactment of the BBA of 2015.

Section 1833(t)(21)(B)(iv) excluded departments of providers from the definition of off-campus outpatient department of a provider for purposes of payment under the OPPS if:

- 1. The Secretary receives from the provider an attestation (pursuant to 42 CFR 413.65(b)(3)) not later than February 13, 2017, that such department met the requirements of a department of a provider specified in 42 CFR 413.65;
- 2. The provider includes the department on its enrollment form in accordance with the enrollment process under section 1866(j) by submitting a change to its 855A enrollment form; and
- 3. The provider met the mid-build requirement (that it had, before November 2, 2015, a binding written agreement with an outside, unrelated party for the actual construction of such department) and the chief executive officer or chief operating officer of the provider submits a certification prior to 60 days after the date of enactment of the Cures Act, stating that the off-campus outpatient department of the provider meets the mid-build requirement.

Section 1833(t)(21)(B)(vii) requires the Secretary to audit the compliance with the requirements in section (t)(21)(B)(iv) of each department of a provider that applied for the mid-build exception. For 334 departments of providers that requested the mid-build exception, CMS audited their compliance with these requirements and issued its audit determinations in January of 2021. Of the 334 providers that applied for the mid-build exception, 132 qualified and 202 failed to qualify.

Out of an abundance of caution in response to questions raised by providers regarding the accuracy of the audits, in September 2021, the audit determinations of all providers that failed to qualify for the mid-build exception were rescinded. CMS oversaw the continuation of these audits, which were conducted by an independent audit firm. To be certain that all providers were given a full opportunity to provide all relevant evidence to support their mid-build exception requests, the independent audit firm requested and considered any additional documentation providers chose to submit to support their eligibility for the mid-build exception or to address findings contained in the rescinded audit determinations. In addition, CMS broadened its interpretation of a construction contract to include certain lease agreements. As a result of these audits, it was determined that 119 additional providers met the mid-build exception requirements.

All departments of providers that failed to qualify for the mid-build exception based on the January 2021 audit determinations, which were subsequently rescinded, have now been sent final audit determination letters informing them either that they now qualify for the mid-build exception, or continue to fail to qualify for the exception, based on the findings of the audit. Pursuant to section 1833(t)(21)(E)(ii) and (iv), the determination of whether a department of a provider meets the term described in subparagraph (B) and the determination of the audit are not subject to administrative or judicial review.

Providers with off-campus provider-based departments that failed to qualify for the mid-build exception and have billed for the services provided by their off-campus provider-based departments under the OPPS during any period beginning on January 1, 2018, likely have received overpayments. Also, providers with off-campus provider-based departments that have been determined to qualify for the mid-build exception and have not been billing for the services provided by their off-campus provider-based departments under the OPPS during the aforementioned period, likely have been underpaid. The audit determination letters provide the appropriate point of contact information and further instructions to address potential overpayments and underpayments.

In accordance with section 1128J(d) of the Social Security Act and its implementing regulation at 42 CFR 401.305, a provider or supplier who has received an overpayment must report and return the overpayment within 60 days after having identified the overpayment. The regulation gives providers and suppliers a benchmark of 180 days to conduct a timely investigation/review to identify an overpayment. Consequently, CMS will afford all providers a total of 240 days from the date of their final audit determination letters to address any overpayments resulting from the findings of the audit. All affected providers should refer to their final audit determination letters for more specific instructions and, upon request, providers may be eligible for an Extended Repayment Schedule (ERS) for any overpayments per standard procedure if they meet applicable statutory and regulatory criteria.