CMS FINALIZES CHANGES IN CY 2018 OPPS AND PFS FINAL RULES

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Health Care Alert

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On November 1, 2017, the Centers for Medicare & Medicaid Services ("CMS") released its final rule with comment period revising the Medicare Hospital Outpatient Prospective Payment System ("OPPS") and the Medicare Ambulatory Surgical Center ("ASC") payment system for Calendar Year ("CY") 2018 ("OPPS Final Rule"). [1] A day later, CMS released its final rule addressing changes to the Medicare Physician Fee Schedule ("PFS") and other Medicare Part B payment policies, such as changes to the Medicare Shared Savings Program ("MSSP") and policies necessary to begin offering the expanded Medicare Diabetes Prevention Program ("MDPP") model ("PFS Final Rule"). [2] These final rules contain a number of important changes for providers and suppliers, including substantial changes to reimbursement that is scheduled to become effective January 1, 2018. We have highlighted some key aspects of these final rules below and will follow-up with additional detail and analysis in subsequent alerts on a number of these areas.

OPPS FINAL RULE

- *340B Reimbursement* – As discussed in greater detail in our recent alert, one of the major and potentially controversial changes in the OPPS Final Rule is a dramatic cut to reimbursement for drugs purchased through the 340B Drug Pricing Program. While separately payable drugs purchased under the 340B Program are currently reimbursed at average sale price ("ASP") plus 6%, the OPPS Final Rule cuts reimbursement to ASP minus 22.5% beginning in CY 2018, as it originally proposed in July of this year. [3] It is anticipated there will be significant pushback from providers in this area, as several hospital groups immediately vowed to pursue legal action against CMS related to this change, [4] which is expected to reduce reimbursement by a total of $1.6 billion to eligible 340B hospitals. [5]

- *Site of Service Price Transparency* – Pursuant to Section 4011 of the 21st Century Cures Act, [6] CMS intends to create a searchable website which will provide the estimated payment amount for items and services under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service in an effort to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or ASC. CMS anticipates that the website and additional subregulatory guidance will be made publicly available in early 2018. [7]

- *Supervision of Outpatient Therapeutic Services in Critical Access Hospitals ("CAHs") and Small Rural Hospitals* – CMS has extended its non-enforcement instruction for Medicare Administrative Contractors ("MACs") to not evaluate or enforce direct supervision requirements for therapeutic services provided to outpatients in CAHs and small rural hospitals with 100 or fewer beds. [8] Though the direct supervision requirement has been applicable to CAHs and small rural hospitals for a number of years, the

requirement has not historically been enforced due to CMS instructions or legislative action and stakeholder concerns regarding the difficulty in staff recruiting, particularly with specialty services, for these types of providers. [9]

- *Laboratory 14-Day Rule* – Under the date of service ("DOS") policy also known as the "14-Day Rule," payment for laboratory tests are generally bundled into the hospital payment, unless certain criteria are met allowing such laboratory tests to instead be paid separately under Part B. [10] In the OPPS Final Rule, CMS adds a new exception to the 14-Day Rule that will enable laboratories performing Criterion (A) ADLTs and molecular pathology tests excluded from the OPPS packaging policy to bill Medicare directly for those tests instead of requiring them to seek payment from the hospital for tests ordered within 14 days of a patient's discharge if the specimen was collected from a hospital outpatient during a hospital outpatient encounter and the test was performed following the patient's discharge from the outpatient department. [11]
- *Hospital Outpatient Quality Reporting ("OQR") Program* – CMS has finalized its proposals to remove and delay certain measures for the CY 2020 payment determination and subsequent years one year earlier than originally proposed. [12] CMS also finalized other related proposals, with corresponding regulatory changes, beginning with CY 2020: (1) to codify the previously finalized process for targeting hospitals for validation of chart-abstracted measures; (2) to formalize the educational review process and use it to correct incorrect validation results for chart-abstracted measures; (3) to align the first quarter for which hospitals must submit data for all hospitals that did not participate in the previous year's Hospital OQR Program; and (4) to align the naming of the Extraordinary Circumstances Exceptions ("ECE") policy. [13] However, CMS declined to finalize its proposal to change the Notice of Participation ("NOP") deadline due to operational constraints, but noted that this issue may be revisited in future rulemaking. [14]

PFS FINAL RULE

- *Site-Neutral Payment Rule* – The site-neutral payment rule is addressed in both the OPPS and PFS Final Rules. As discussed in greater detail in our November 2016 alert, pursuant to Section 603 of the Bipartisan Budget Act of 2015, on January 1, 2017 CMS began implementing a site-neutral payment policy for off-campus outpatient Provider-Based Departments ("PBDs") that were not furnishing services prior to November 2, 2015. Generally, off-campus PBDs that were furnishing services prior to this date are considered "excepted" and may continue to furnish services and bill under OPPS as traditionally done. For CY 2017, nonexcepted PBDs were required to submit claims on the institutional claim form and append a "PN" modifier in order to flag the claim for the reduced site-neutral payment, which was generally 50% of the OPPS rate (the "PFS Relativity Adjuster"). [15] As noted in our August 2017 alert, CMS had initially proposed to reduce the PFS Relativity Adjuster to 25%. [16] In responding to commenters' concerns regarding the proposed PFS Relativity Adjuster, CMS has instead adopted a PFS Relativity Adjuster of 40% for CY 2018. [17] That is, payment for items and services furnished by nonexcepted PBDs will generally be reimbursed at a rate of 40% of the applicable OPPS rate for CY 2018. CMS noted that it will have a full year of data (CY 2017) available when it undertakes PFS ratesetting for CY 2019 and that it intends to use that data to ensure that Medicare payment to hospitals billing for nonexcepted items and services furnished by nonexcepted off-campus PBDs under the PFS

would reflect the relative resources involved in furnishing the items and services relative to other PFS services. [18]

- *Payment for Biosimilar Biological Products under Part B* – CMS finalized a policy change regarding how it will pay for biosimilar biological products under Medicare Part B to provide for separate HCPCS coding and payment for each individual biosimilar product. [19] The existing policy groups all biosimilar products with a common reference product together into codes such that they are subject to the same payment calculation. In determining that the policy change was appropriate, CMS noted that it intends for the new policy to address concerns about a stronger biosimilar marketplace, including access and physician and patient choice. [21] CMS also noted that the new payment policy will encourage the innovation needed to bring more biosimilar products to market. [22] CMS notes that the policy change in the PFS Final Rule will not require any change to the regulatory text at 42 C.F.R. § 414.904(j), but it does anticipate issuing detailed subregulatory guidance on coding by mid-2018. [23]
- *Medicare Shared Savings Program* – CMS also finalized a number of updates to the MSSP in the PFS Final Rule. These changes include: changes to the ACO beneficiary assignment methodology, changes to quality reporting requirements, relaxed application submission requirements, changes to TIN exclusivity rules and modifications to how the calculation of MSSP payments will interact with other CMS demonstration projects. [24]
- *Medicare Diabetes Prevention Program* – Lastly, CMS finalized a number of changes to the MDPP in the PFS Final Rule. These changes include: delay of effective date of MDPP services in order to permit MDPP suppliers sufficient time to enroll, changes to the set of MDPP services and changes related to beneficiary eligibility. [25]

Notes:

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (to be published Nov. 13, 2017) *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf [hereinafter "OPPS Final Rule"].

[2] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (to be published Nov. 15, 2017) *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23953.pdf [hereinafter "PFS Final Rule].

[3] OPPS Final Rule at 607. For more information on the initial proposal and its potential impact, please see our July 2017 alert titled "340B Update: CMS Proposes to Reduce 340B Drug Reimbursement; Draft Executive Order Could Mean Further Changes to the 340B Program," available at http://www.klgateshub.com/details/?pub=340B-Update-CMS-Proposes-to-Reduce-340B-Drug-Reimbursement-Draft-Executive-Order-Could-Mean-Further-Changes-to-the-340B-Program-07-17-2017.

[4] *See e.g.* Press Release, American Hospital Association, Statement on Final CY 2018 OPPS Rule (Nov. 1, 2017) (available at http://www.aha.org/presscenter/pressrel/2017/110117-pr-opps.shtml).

[5] OPPS Final Rule at 1076.

[6] Pub. L. 114-255.

[7] OPPS Final Rule at 689.

[8] *Id.* at 692.

[9] *Id.* at 693.

[10] OPPS Final Rule at 707. Under the 14-Day Rule, the DOS included on a claim for a laboratory test is the date the test was performed, instead of the date of specimen collection, when the test meets certain criteria, including that the test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital. Id. at 706-707; 42 C.F.R. § 414.510(b)(2)(i).

[11] *Id.* at 737.

[12] *Id.* at 47.

[13] *Id.* at 1111.

[14] *Id.* at 894.

[15] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital, 81 Fed. Reg. 79,562, 79,725 (Nov. 14, 2016).

[16] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, 82 Fed. Reg. at 33,950 33,982–83 (July 21, 2017).

[17] Final Rule at 200-201.

[18] *Id.* at 196-197.

[19] *Id.* at 573.

[20] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 80886, 71096 (Nov. 16, 2015).

[21] PFS Final Rule at 574.

[22] *Id.*

[23] *Id.* at 574-575.

[24] *Id.* at 659.

[25] *Id.* at 754.

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