September 8, 2020

- **Time to pay the piper? Medicare's Accelerated Payment Program: Will the Center for Medicare & Medicaid Services ("CMS") recoup, or not? If so, when? Is executive action warranted, or must Congress act?**
  - Before the CARES Act began pushing COVID-19 relief funds into hospital bank accounts, CMS doled out $60 billion in accelerated payments to participating hospitals using its statutory authority (42 U.S.C. § 1395g(e)(3)) to address what the *Medicare Financial Management Manual* terms "highly exceptional situations where CMS deems an accelerated payment is appropriate."
  - Unlike relief funds, which are not repaid, CMS recoups accelerated payments through payment offsets implemented by the applicable Medicare Administrative Contractor ("MAC"). Before COVID-19, repayment would start 90 days after advance payment issuance, but with Congress' blessing, CMS extended that to 120 days and gave hospitals up to one year to repay the balance.
  - As the August 1 deadline came and went, ending the 120 day period for some hospitals, provider groups clamored for Congress to step in and extend the recoupment period or recast the accelerated payments as forgivable loans.
  - With Congress failing to act as of this writing and prospects for a COVID-19 relief package before Election Day looking doubtful, it seems unlikely that an extension or forgiveness will be addressed if Congress limits its focus to a streamlined stopgap funding bill to avoid a federal government shutdown.
  - Absent Congressional action, MACs are required to initiate recoupment ("shall attempt to recover") unless CMS steps in to further extend the timeline for recoupment. Several obstacles may preclude administrative relief:
    - Under the CARES Act, Congress directed the Secretary of HHS to extend the time before claims are offset to recoup accelerated payments to 120 days and allow not less than 12 months from the date of the first accelerated payment before requiring the outstanding balance to be paid in full. 42 U.S.C. § 1395g(f)(2)(C).
    - The Secretary has already extended the onset of recoupment by the authorized 120 days, so CMS may not have statutory authority to further extend the start of recoupment.
    - Presumably, the Secretary could allow substantially more time for repayment – Congress directed "not less than 12 months" and set no outside limit – but the statutory language implies that once the 120 days run, the hospital's claims for Medicare payment "are offset to recoup the accelerated payment," and recoupment means 100 percent offset until repayment is achieved.
    - The CMS Fact Sheet, *Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency*, tells us that the recoupment process is automatic: "every claim submitted by the provider/supplier will be offset from the new claims to repay the accelerated/advanced payment [so] … instead of receiving payment for newly submitted claims, the provider's/supplier's outstanding accelerated/advance payment balance is reduced by the claim payment amount."

- **Key Takeaway:** Absent Congressional action to forgive or extend repayment, hospitals that received accelerated payments should anticipate the initiation of 100 percent offsets by MACs to recoup those payments once the 120 day window expires.

- **Health care providers reportedly will not be penalized in future Medicare payment calculations for their receipt of Provider Relief Fund ("PRF") payments or Small Business Administration ("SBA") loans, but providers must be mindful of CMS's warning to ensure such funds are used only for permissible purposes.**
  - On August 26, 2020, CMS released additional FAQs, "COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing," (the "FAQs") to Medicare providers, addressing how to report PRF payments and SBA Loan Forgiveness amounts on the Medicare Cost Report.
  - **PRF Payments**
    - In the FAQs, CMS states that all providers must report PRF payments on the Medicare Cost Report's statement of revenues for informational purposes.
    - In addition, CMS advises that providers should not adjust the expenses on the Medicare Cost Report based on PRF payments received. The PRF payment amounts that are not attributable to patient-specific claims and are not PRF payment amounts from the Uninsured Program should not be used to offset expenses on the Medicare Cost Report.
    - CMS warns providers that they must ensure PRF payments are used for "permissible purposes" and "that the uses of PRF payments do not violate the prohibition on using PRF money to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse."
  - **SBA Loans**
    - In the FAQs, CMS provides that, if a provider receives forgiveness for an SBA loan, the provider must report the forgiven amount on the Medicare Cost Report's statement of revenues for informational purposes. Alternatively, if a provider does not receive forgiveness for the SBA loan, there are no forgiven amounts to report on the Medicare Cost Report.
    - CMS also states that if a provider pays interest on any portion of an SBA loan, such interest payments may be reported as interest expenses on the Medicare Cost Report.
    - CMS advises that providers should not offset SBA loan forgiveness amounts against expenses unless such amounts are attributable to specific claims, such as payments for the uninsured.
    - CMS warns providers that "[t]he terms and conditions of the SBA loan forgiveness overseen by the SBA include employee retention criteria, and the funds must be used for *eligible expenses*." (emphasis added).
  - **Key Takeaway:** CMS's clarification that neither PRF payments nor SBA loan forgiveness amounts should be offset against expenses on provider cost reports is welcome news. PRF payments and SBA loans continue to serve as a lifeline for health care providers during the COVID-19 pandemic; however, such funds are not distributed without strings attached. Therefore, providers must ensure PRF payments and SBA loans are utilized only in accordance with applicable restrictions.

- **In a potential sign of things to come, the CMS seeks to fast track Medicare coverage for breakthrough medical devices approved by the Food & Drug Administration ("FDA"), requesting comment on whether availability of its proposed pathway should be broadened to include certain additional categories for diagnostics, drugs and/or biologics.**
    - In response to directives contained in President Trump's October 3, 2019 Executive Order 13890, CMS is proposing the Medicare Coverage of Innovative Technology ("MCIT") pathway to accelerate Medicare coverage of FDA-approved breakthrough medical devices. Details are set forth in a September 1, 2020 proposed rule published in the *Federal Register*.
    - The new MCIT pathway applies to devices that are part of the FDA's Breakthrough Devices Program, FDA market authorized, and used according to FDA approved or cleared indications for use (*i.e.*, excluding "off-label" use).
        - If the MCIT pathway is finalized as proposed, national Medicare coverage of a breakthrough device would begin immediately upon the FDA market authorization date and continue for 4 years. Coverage also would be available for breakthrough devices that received FDA market authorization in the 2 years prior to the final rule's effective date for claims submitted on or after the effective date. The 4-year coverage period, however, would continue to tie back to the FDA market authorization date, resulting in coverage under the MCIT pathway for some period short of 4 years.
        - All breakthrough devices that receive coverage under the MCIT pathway would be eligible for coverage under existing pathways at conclusion of the MCIT pathway coverage period.
    - While CMS states the MCIT pathway would be voluntary – device manufactures would notify CMS if they want to use it – it is difficult to envision a scenario where a device manufacturer would decline the opportunity to accelerate Medicare coverage for their medical devices. As CMS observes, National Coverage Determinations ("NCDs") and Local Coverage Determinations ("LCDs") typically take 9 to 12 months to finalize due, in part, to statutorily prescribed timeframes. CMS is proposing the MCIT pathway for the purpose of eliminating variable coverage as well as coverage uncertainties that can arise between FDA market authorization and CMS's finalization of an NCD or a MAC's finalization of an LCD.
    - Importantly, the MCIT pathway would be not be available for medical devices that do not meet the FDA's standards under the Breakthrough Devices Program. Furthermore, breakthrough devices that CMS determines during the MCIT pathway process that do not have a Medicare benefit category or are statutorily excluded from Medicare coverage under Parts A or B also would be excluded from coverage.
    - **Key Takeway:** If finalized as proposed, the MCIT pathway will streamline and accelerate Medicare coverage for breakthrough medical devices, making them accessible to Medicare beneficiaries nationwide more quickly than is feasible under existing coverage pathways. There would seem to be little reason not to extend the MCIT pathway to include categories for some or all diagnostics, drugs and/or biologics. Coverage delays and variability would be eliminated, and there appears to be little downside to manufacturer participation in the MCIT pathway. Comments on the proposed rule are due no later than November 2, 2020.

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