ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: November 4, 2022

RE: A&B Topline Summary – Calendar Year 2023 Medicare Physician Fee Schedule (PFS) Final Rule

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released its *Calendar Year (CY) 2023 Medicare Physician Fee Schedule (PFS)* Final Rule.[1] The 2,953-page annual final rule includes numerous policy updates. CMS released separate fact sheets focusing on different aspects of the proposed rule including: the final rule overall,[2] the CY 2023 Quality Payment Program changes,[3] and the Medicare Shared Savings Program changes.[4] This major final rule also implements certain provisions of *the Consolidated Appropriations Act, 2022*, *Protecting Medicare and American Farmers from Sequester Cuts Act*, *Infrastructure Investment and Jobs Act*, *Consolidated Appropriations Act, 2021*, *Bipartisan Budget Act of 2018*, and *the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*, related to Medicare Part B payment.

These regulations are effective on **January 1, 2023**. Among others, the rule includes the following key provisions:

Rate Setting and Conversion Factor

- The final CY 2023 PFS conversion factor is $33.06, a decrease of $1.55 to the CY 2022 PFS conversion factor of $34.61.

Determination of Practice Expense (PE) Relative Value Units (RVUs)

- The final rule implements a series of standard technical changes involving PE, including the implementation of the second year of the clinical labor pricing update.
- CMS is also seeking public input while developing a more consistent, predictable approach to incorporating new data in setting PFS rates.
- Per statutory requirements, the data that is used to develop the geographic practice cost indices (GPCIs) and malpractice RVUs has also been updated.

Potentially Misvalued Services under PFS

- Interested parties nominated several codes for review, including those for home-based physician visit, cataract surgery, retinal procedures, and spinal surgery. These recommendations were reviewed on a code-by-code basis and CMS developed appropriate adjustments to the RVUs.

[1] The public display copy of this final rule is available here: https://public-inspection.federalregister.gov/2022-23873.pdf. It is scheduled to be published in the Federal Register on November 18, 2022.
[2] This fact sheet is available here: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule.
[3] This fact sheet is available here: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule-medicare-shared-savings-program.
[4] This fact sheet is available here: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule-medicare-shared-savings-program

- CMS intends to continue examining potentially misvalued codes over the upcoming years. Nominations for consideration in the next annual rule cycle should be received by February 10, 2023.

Payment for Medicare Telehealth Services under Section 1834 of the Social Security Act

- The services temporarily included on the Medicare Telehealth Services List on a Category 3 basis will continue to be included through the end of CY 2023. In the event that the COVID-19 public health emergency (PHE) extends well into CY 2023, this policy may be revised.
- On the 152nd day after the end of the PHE, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Social Security Act, and telehealth claims for these services furnished on or after the date the codes are removed from the list will be denied.

Valuation of Specific Codes

- The final rule makes numerous changes to RVUs for dozens of codes.

Evaluation and Management (E/M) Visits

- The final rule adopts revised coding and updated guidelines regarding E/M visits from the American Medical Association and other interested parties in efforts to: better reflect the current practice of medicine, decrease administrative complexity, and pay more accurately under the PFS.
- Implementation of the policy to define the substantive portion of a split (or shared) visit based on the amount of time spent by the billing practitioner is delayed until January 1, 2024.

Geographic Practice Cost Indices (GPCI)

- New GPCIs for CY 2023 are finalized and a geographic adjustment factor (GAF) for each PFS locality is calculated.
- Half of the proposed GPCI adjustments will be phased in for CY 2023 and the remaining half of the adjustments will be phased in for CY 2024.
- The CY 2023 GPCIs and GAFs reflect the 1.0 work floor, and as required, also reflect the 1.5 work GPCI floor for Alaska and the 1.0 practice expense GPCI floor for Frontier States.

Determination of Malpractice RVUs

- The final rule implements a risk index rather than risk factors, changing data imputation strategy by mapping to service risk group/class.
- There is a 3-year phase-in for specialties with a reduction in risk value of 30 percent or more in an effort to reduce burden, maintain stability in reimbursement for practitioners, and maintain access to services for beneficiaries.

Remote Therapeutic Monitoring (RTM) Services

- CMS decided there should be continued discussion on these topics before finalizing changes to the current RTM coding and payment policies that go beyond refinements to supervision and documentation requirements for RTM.

Payment for Skin Substitutes

- CMS proposed several changes to the policies for skin substitute products to streamline the coding, billing, and payment rules and to establish consistency with these products across various settings, such as physician offices and hospital outpatient departments.
- After reviewing comments on the proposals, CMS decided it would be beneficial to provide interested parties more opportunity to comment prior to finalizing these proposals.

  - There will be a Town Hall session in early CY 2023 for interested parties to provide additional feedback.

Allowing Audiologists to Furnish certain Diagnostic Tests Without a Physician Order

- Beneficiaries are allowed direct access to an audiologist without an order from a physician or nonphysician practitioner for non-acute hearing conditions.
- The services can be billed using the codes audiologists already use and include only those personally furnished by the audiologist. The finalized direct access policy will allow beneficiaries to receive care by audiologists for non-acute hearing assessments that are unrelated to disequilibrium, hearing aids, or examinations for the purpose of prescribing, fitting, or hearing aids.

Payment for Dental Services

- CMS finalized policies intended to clarify and codify certain aspects of current Medicare fee-for-service payment policies for dental services.
- The final rule allows payment for other dental services, such as dental exams and necessary treatments prior to organ transplants, cardiac valve replacements, and valvuloplasty procedures that may be inextricably linked to, and substantially related and integral to, the clinical success of an otherwise covered medical service.
- CMS is also finalizing payment for dental exams and necessary treatments prior to the treatment for head and neck cancers starting in CY 2024.

Updating the Medicare Economic Index (MEI)

- CMS finalized rebasing and revising the MEI using the 2017 MEI.
- The final CY 2023 MEI update is 3.8 percent based on the most recent historical data available.
- The rebased and revised MEI weights were not used in CY 2023 PFS rate setting, but CMS provided examples of the potential impact of implementation and alternatives considered.

Requiring Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

- CMS finalized policies to implement section 90004 of the *Infrastructure Investment and Jobs Act*, which requires manufacturers to refund payments for unused amounts of separately payable, Part B single-use vials and single-use packages where payments for such unused amounts exceed 10 percent of the total allowed charges for the drug, subject to exceptions.
- The final rule defines a refundable single-dose container or single-use package drug as a drug or biological for which payment is made under Part B and that is furnished from a single-dose container or single-use package.
  - There are exclusions to this definition as required by statute.
- CMS finalized an increased applicable percentage of 35 percent for a drug that is reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys.
- CMS plans to collect additional information about drugs that may have unique circumstances along with what increased applicable percentages might be appropriate for each circumstance. CMS will revisit additional increased applicable percentages through future rulemaking.
- CMS will issue a preliminary report on estimated discarded drug amounts based on claims from the first two calendar quarters of 2023 and will revisit the timing of the first report in future rulemaking.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- The final rule adds new Chronic Pain Management and Behavioral Health Integration Services to the RHC- and FQHC-specific general care management Healthcare Common Procedure Coding System (HCPS) code.
- CMS finalized policies implementing the RHC and FQHC telehealth provisions in the *Consolidated Appropriations Act, 2022*.
- CMS clarified that a 12-consecutive month cost report should be used to establish a specified provider-based RHC's payment limit per visit.

Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-In of Payment Reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests

- The final rule makes certain conforming changes to data reporting and payment requirements.
    - This includes conforming changes for phase-in of payment reductions.
- The final rule increases the nominal fee for specimen collection and will update the fee annually based on the Consumer Price Index for all Urban Consumers.
- CMS codified and clarified the Medicare CLFS travel allowance policy.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

- The final rule expands Medicare coverage policies for colorectal cancer screening to align with United States Preventive Service Task Force recommendations.
    - This includes expanding Medicare coverage for certain colorectal cancer screening tests by reducing the minimum age from 50 years to 45 years.
    - The final rule expands the regulatory definition of colorectal cancer screening tests to include a complete colorectal cancer screening, where a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result.
    - As a result, for most beneficiaries, cost sharing will not apply for either the initial stool-based test or the follow-on colonoscopy.

Modifications Related to Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

- The methodology is revised for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone.
    - The final rule includes basing the payment amount for the drug component of HCPCS codes G2067 and G2078 for CY 2023 and subsequent years on the payment amount for methadone in CY 2021 and updating this amount annually to account for inflation using the Producer Price Index for Pharmaceuticals for Human Use.
- The use of audio-only communication technology is permitted to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary and all other applicable requirements are met.
- Locality adjustments for services furnished via mobile units will be applied as if the service were furnished at the physical location of the OTP registered with Drug Enforcement Agency and certified by Substance Abuse and Mental Health Services Agency.

Medicare Shared Savings Program

- CMS sought to provide organizations new to accountable care arrangements greater flexibility in the progression to performance-based risk and allowing these organizations more time to redesign their care processes to be successful under risk arrangements.

- CMS expanded opportunities for certain low revenue accountable care organizations (ACOs) participating in the BASIC track to share in savings even if they do not meet the minimum savings rate to allow for investments in care redesign and quality improvement activities among less capitalized ACOs.

Medicare Part B Payment for Preventive Vaccine Administration Services

- The final rule refines the payment amount for preventive vaccine administration under the Medicare Part B vaccine benefit.
- The payment amount will be annually updated based upon increase in the MEI and adjusted for the geographic locality, based on the PFS locality where the preventive vaccine is administered.

Payment for COVID-19 Vaccinations

- The payment amount for COVID-19 vaccinations is $41.52. This price will remain through the end of the calendar year in which the current EUA declaration for drugs and biologicals with respect to COVID-19 remains in place. Thereafter, the payment amount for COVID-19 vaccine administration will be adjusted to align with the payment rate for the other Medicare Part B preventive vaccines.

Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services

- CMS clarified in the final rule that a signed physician certification statement with additional documentation from the medical record may be used to support medical necessity.

Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment

- The final rule expands authority to deny or revoke enrollment based on Office of the Inspector General exclusions, felony convictions, and other statutory authorities.

State Options for Implementing Medicaid Provider Enrollment Affiliation Provision

- The final rule permits states to move from a more limited implementation option to a more robust option with regard to affiliation disclosures with Medicaid suppliers and providers.
    - States will not be allowed to move from the more robust option to the more limited one.

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

- The existing non-compliance action of sending letters to non-compliant prescribers for the EPCS program implementation year (January 1, 2023 through December 31, 2023) is extended to the following year (January 1, 2024 through December 31, 2024).
- The final rule changed the year from which prescription drug event data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions.
- The system used for determining a prescriber's valid address when establishing qualification for the emergency or disaster exception changed.

Medicare Ground Ambulance Data Collection System (GADCS)

- The final rule updates regulations to provide necessary flexibility to specify how ground ambulance organizations should submit the hardship exemption request and informal review requests.
- CMS also finalized and clarified elements of the Medicare Ground Ambulance Data Collection Instrument. CMS described these changes as falling under four categories: editorial changes for

clarity and consistency; updates to reflect the web-based system; clarifications responding to feedback from questions from interested parties and testing; and typos and technical corrections.

Origin and Destination Requirements Under the Ambulance Fee Schedule

- CMS clarified the interim final policy (85 FR 19276) stating that the expanded list of covered destinations for ground ambulance transports was for the duration of the COVID-19 PHE only.
- When the COVID-19 PHE ends, these relevant regulations will reflect the long-standing ambulance services coverage for the following destinations only: hospital; critical access hospital; skilled nursing facility; beneficiary's home; and dialysis facility for an end-stage renal disease patient who requires dialysis. In addition to these long-standing covered destinations, rural emergency hospitals (REH) will also be an allowed destination, in accordance with the *Consolidated Appropriations Act, 2021*.

HCPCS Level II Coding Procedures for Wound Care Management Products

- After consideration of public comments, CMS did not finalize the proposed revisions to the payment methodology for skin substitutes. CMS also did not finalize any change in terminology regarding wound care management.
    - There will be a Town Hall session in early CY 2023 to discuss alternative payment solutions and nomenclature ahead of CY 2024 rulemaking.

Updates to the Quality Payment Program

- The final rule permanently establishes the 8 percent generally applicable revenue-based nominal amount standard for Advanced Alternative Payment Models (APMs).
- The final rule also broadens opportunities for public feedback on viable Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs).

Behavioral Health Services

- There is an added exception to the direct supervision requirement under the "incident to" regulation at 42 CFR 410.26 to allow behavioral health services to be provided under the general supervision of a physician or non-physician practitioner (NPP), rather than under direct supervision, when these services or supplies are furnished by auxiliary personnel, such as licensed professional counselors and licensed marriage and family therapists, incident to the services of a physician (or NPP).
- CMS also clarified that any service furnished primarily for the diagnosis and treatment of a mental health or substance use disorder can be furnished by auxiliary personnel under the general supervision of a physician or NPP who is authorized to furnish and bill for services provided incident to their own professional services.
- CMS indicated in the final rule the intention to address payment for new codes that describe caregiver behavioral management training in CY 2024 rulemaking.

Chronic Pain Management

- CMS finalized new HCPCS codes and valuation for Chronic Pain Management and Treatment Services for CY 2023.

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We hope this summary was helpful to you. Please do not hesitate to contact us if you have any questions.