Reimbursement End-of-Year Newsletter

NEWSLETTER FROM THE REIMBURSEMENT PRACTICE GROUP

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Select Highlights from CY 24 Medicare Physician Fee Schedule Final Rule

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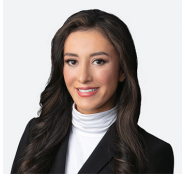

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The CY 24 Medicare Physician Fee Schedule ("PFS") final rule was published in the November 16, 2023 Federal Register. The rule addresses updated payment for physician and other practitioner services, and also sets out new rulemaking with respect to certain other suppliers and items, such as ambulances, laboratories and other diagnostic facilities, and prescription drugs. Following is a summary of certain key regulatory changes outlined in the rule. The PFS final rule is available here.

1. New E/M Code for Visit Complexity

CMS is implementing a new code, G2211, as an add-on to office or outpatient E/M visits to reflect complex visits where the billing provider is the focal point of care for a patient's complex or serious condition. As a result of this add-on code, other codes have been revalued to maintain budget neutrality, but CMS has indicated that the overall effect of the revaluation on existing codes has been less than it anticipated in the proposed rule.

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2. Split/Shared Visits.

For CY 2024, CMS is implementing that the choice of which provider can bill a split/shared visit can either be made based on which provider spent the majority of the time with the patient or based on whether the provider participated substantively in the medical decision-making as defined in CPT guidelines. Previously, CMS had stated that split/shared visits would be based on time exclusively starting on January 1, 2024.

3. Telehealth Services under the Physician Fee Schedule

For CY 2024, CMS is adding health and wellness codes 0591T, 0592T, and 0593T (health and well-being coach, individual session, group session) on a temporary basis as telehealth services. While CMS considered several comments requesting the permanent addition of these codes to the Medicare Telehealth Services List, CMS did not find sufficient evidence at this time. Additionally, CMS found that the evidence presented by the commentors was anecdotal, and instead, requested that commentors submit qualified, peer-reviewed data in future submissions. Lastly, for CY 2024, CMS is restoring the binary multicategory classification for telehealth services. Instead of categories one, two, and three, CMS is moving to a two-category, permanent versus provisional system.

4. Telehealth Services Furnished in Teaching Settings

In CY 2021, CMS allowed teaching physicians to have a virtual presence in all teaching settings for clinical purposes, but only when the service is provided virtually. This allows teaching physicians and residents to provide telehealth services when (1) the interaction is audio-visual, not only audio, and (2) does not require the teaching physician and resident be co-located when the patient is located in an area that is not a Metropolitan Statistical Area ("MSA"). The non-MSA requirement allows CMS to continue prioritizing access of care for individuals located in a rural or remote areas. For CY 2024, CMS will continue allowing the above as described.

5. Medicare Part B Payment for Preventive

Vaccine Administration Services. CMS increased the reimbursement rate for HCPCS M0201, which allows home administration of the COVID–19 vaccine, so long as it is not administered in a hospital outpatient department, rural health clinic, or federally qualified health center, and added coverage of pneumococcal, influenza, and hepatitis B vaccines (the "Part B preventatives"). The reimbursement rate for CY 2023 was $35.50, while the CY 2024 rate will be $36.85. Please note that these are baseline figures subject to annual updates and geographical adjustments.

To qualify for M0201, the patient must be hard-to-reach due to either disability, or barriers to care, including clinical, socioeconomic, or geographical barriers. Note, however, that with the addition of Part B preventives, multiple vaccines may be administered in a single visit. This changes the current requirement that the sole purpose of the visit was to administer the COVID–19 vaccine. However, only one M0201 code may be billed for a visit. The in-home payment for Part B preventives will be effective January 1, 2024.

6. Telehealth Proposals for Diabetes Self-Management Training ("DSMT") Services

During the COVID-19 Public Health Emergency ("PHE"), CMS allowed certain specialty providers, including those who provide DSMT services, to telecommunicate with patients. Providers were allowed to bill for DSMT telecommunications, as were institutions billing for institutional staff. These institutions included hospital outpatient departments, skilled nursing facilities, and home health agencies. CMS used waiver authority to expand the definition of distant site practitioners to include DSMT providers, and further used its waiver authority to expand the Medicare originating site requirements, as these definitions apply to telehealth. CMS also used its waiver authority to implement Hospitals Without Walls ("HWW"), which expanded hospitals' ability to bill for telecommunication and telehealth services rendered to patients in their homes. But hospital outpatient departments were to bill for services using modifier 95, indicating telehealth.

For CY 2024, CMS is continuing the current DSMT system defined above. The notable amendment is changing the HWW requirement. Instead, hospitals and all other institutional providers, with an exception for some critical access hospitals, must include modifier 95 on the claim.

7. Dental and Oral Health Services

CMS allows for payment of certain dental services that are inextricably linked to covered Medicare Part A or B procedures. In CY 2023, CMS finalized this concept, with inextricably linked defined as dental procedures proven to mitigate risks associated with covered Part A or B procedures. In CY 2024, CMS will expand the definition of inextricably linked procedures to include (1) chemotherapy, (2) CAR T-cell therapy, and (3) high-dose bone modifying therapy. CMS explained its rationale as preventing serious and imminent risks caused by dental infections, such as delaying or preventing the primary medical service. Instead, and dental or oral examination performed as part of the comprehensive work-up may mitigate risks, infections, and delays.

8. Coverage for Certain Therapy Services Rendered Through Telehealth

For CY 2024, CMS will allow outpatient hospitals and other providers of physical therapy, occupational therapy, speech-language pathology, Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) services that remain on the Medicare Telehealth Services List for CY 2024 to bill for these services when furnished remotely in the same way they have been during the PHE and through the end of CY 2023.

9. Clarification on DSMT Services Furnished by Registered Dietitians and Nutrition Professionals

CMS finalized clarifications that a Registered Dietician (RD) or nutrition professional is required to personally perform DSMT services they bill for, but that, when billing as or on behalf of a DSMT entity, they can bill for the DSMT entity regardless of which professional furnishes the actual services.

10. Expanded Diabetes Screening

CMS added Hemoglobin A1C testing to as a covered diabetes screening test. CMS also finalized rules for expanding and simplifying frequency limitations for diabetes screening coverage and removed specific clinical test criteria from the definition of "diabetes."

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11. Medicare Diabetes Prevention Program (MDPP) Expanded Model

CMS finalized proposed amendments to the MDPP Expanded Model, including extending flexibilities for MDPP services under the PHE through December 31, 2027.

12. Electronic Prescribing for Controlled Substances (EPCS) Program

CMS finalized regulatory provisions relating to prescriber notices of non-compliance, the same entity exception, prescribing during a recognized emergency, and other provisions under the EPCS Program.

Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B

CMS codified provisions of the Inflation Reduction Act (IRA) affecting limits on beneficiary out-of-pocket costs for certain drugs payable under Part B.

13. Ambulance Fee Schedule – Ambulance Extenders Provisions

CMS extended the ambulance fee schedule amounts for ground ambulance services, as well as the Super Rural Bonus, through December 31, 2024.

14. Supervision of Outpatient Therapy Services in Private Practices

CMS added language to the outpatient occupational therapy and physical therapy service conditions to permit occupational therapy assistants and physical therapy assistants to furnish remote therapeutic monitoring (RTM) under general supervision of an occupational therapist in private practice or a physical therapist in private practice, and require direct supervision for RTM services performed by unenrolled occupational therapists and physical therapists.

15. KX Modifier Thresholds

CMC finalized the CY 2024 KX modifier threshold amounts as $2,330 for physical therapy, SLP, and OT services. The KX modifier is required when aggregate therapy services exceed the threshold amount to confirm that the medical necessity of the services is appropriately documented in the patient's medical record.

16. Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS rescinded the current AUC program regulations, and plans to continue working to identify a workable implementation approach, which will be reflected in future rulemaking.

IPPS Highlights

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Changes to Payment Rates Under IPPS

CMS finalized an increase of 3.1% to the IPPS payment rates. This reflects a projected FY 2024 IPPS hospital market basket update of 3.3%, reduced by a 0.2% productivity adjustment. The update reflects the most recently available forecasts of the price proxies underlying the market basket, including projected increases in compensation. Hospitals may be subject to the following IPPS payment adjustments: payment reductions for excess readmissions; payment reduction (1%) for the worst-performing quartile; and upward and downward adjustments under the Hospital Value-Based Purchasing (VBP) Program.

Graduate Medical Education (GME)

For cost reporting periods beginning on or after October 1, 2023, a hospital may include full-time equivalent (FTE) residents training at a rural emergency hospital (REH) in its FTE counts as long as the hospital incurs the costs of the resident training. Alternatively, a REH can choose to operate as a non-provider training site where another hospital incurs the costs for the training and counts the resident FTEs on the other hospital's cost report. These changes were enacted to support medical education training programs in rural areas.

Uncompensated Care / Disproportionate Share (DSH)

With respect to the DSH calculation, CMS finalized how Section 1115 waiver patients are included in the DSH calculation. These patients include only those who receive rfrom the demonstration either (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100% of the premium cost to the patient for inpatient hospital services, provided that the patient is not also entitled to Medicare Part A for each case. Moreover, CMS excluded from the DSH calculation the days of patients for whom hospitals are paid from waiver-authorized uncompensated or undercompensated care pools. This change could have a meaningful impact on hospitals in states that use Section 1115 demonstration funds for uncompensated care pools, including California, Florida, Massachusetts, and Texas, among others.

For the uncompensated care program, CMS will distribute approximately $5.94 billion in uncompensated care payment (UCP) to eligible DSH hospitals for FY 2024, which is a decrease of about $940 million from the prior year.

Hospital Quality Reporting

For FY 2024, CMS adopted three new measures, removed three existing measures, and modified three current measures for the Hospital Inpatient Quality Reporting (IQR) Program, including several electronic clinical quality measures (eCQMs). First, CMS is adding the following three eCQMs: (1) Hospital Harm – Pressure Injury; (2) Hospital Harm – Acute Kidney Injury; and (3) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient). Second, CMS is removing the following three measures: (1) Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty; (2) Medicare Spending Per Beneficiary (MSPB) Hospital; and (3) Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Third, CMS is modifying the following three measures: (1) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality to include Medicare Advantage (MA) admissions; (2) Hybrid Hospital-Wide All-Cause Readmission to include MA admissions; and (3) COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) to include the cumulative number of HCP who are up to date with recommended COVID-19 vaccinations in accordance with the Centers for Disease Control and Prevention guidance. Hospitals that fail to submit quality data or to meet all Hospital IQR Program requirements are subject to a one-fourth reduction in their Annual Payment Update under the IPPS. The new measures have reporting periods beginning in CY 2025 and payment determination impacts in FY 2027.

Hospital-Acquired Conditions (HAC) Reduction Program

CMS made several changes to the HAC Reduction Program, including the establishment of a validation reconsideration process for hospitals that failed to meet data validation requirements. This process begins with the FY 2025 program year, affecting CY 2022 discharges and the modification of the targeting criteria for data validation to include hospitals that received an Extraordinary Circumstances Exception during the data periods validated beginning with the FY 2027 program year, affecting CY 2024 discharges.

Hospital Readmissions Reduction Program

CMS did not propose or finalize any changes to the Hospital Readmissions Reduction Program. All previously finalized policies under this program will continue to apply.

CY 2024 OPPS Final Rule Summary for RI Year-End Review

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In the Calendar Year (CY) 2024 Medicare Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems Final Rule, the Centers for Medicare & Medicaid Services (CMS) increased OPPS and ASC payment rates by 3.1% for hospitals and ASCs that meet quality reporting requirements.

Below we highlight select policy updates from the Final Rule. The full Final Rule, released on November 2, 2023, is available here. Several important topics from the Final Rule (including price transparency, increased access to hospital outpatient behavioral health, and 340B updates) are addressed elsewhere in this [End-Of-Year Review].

1. Site neutrality / Intensive Cardiac Rehabilitation

Under Section 603 of the Bipartisan Budget Act of 2015 ("Section 603"), Congress directed CMS to establish "site neutral" payment for services furnished in certain new off-campus hospital outpatient settings. To implement Section 603, CMS applied a 60% cut to OPPS payments for services furnished in off-campus hospital outpatient departments, except for certain sites "excepted" from Section 603. This first wave of hospital outpatient site neutrality took effect on January 1, 2017. In a second wave of site neutrality, in 2019 CMS extended its neutrality policy to outpatient clinic (E&M) visits furnished in "excepted" off-campus hospital outpatient departments (HCPCS code G0463).

In the Final Rule, CMS is continuing its policy of "site neutral" payments. However, in a significant update for hospitals that offer intensive cardiac rehabilitation services ("ICR"), CMS finalized its proposal to exempt hospital outpatient ICR services from site neutrality. ICR services (HCPCS codes G0422 and G0423) will be paid at 100% of the OPPS rate in any hospital outpatient setting.

2. Dental Services

Although Medicare rarely pays for dental services, CMS has, in recent years, developed the position that some dental services are substantially related and integral to a medical service and may be paid for under Part A or Part B. As part of this effort, CMS finalized, in the CY 2024 Final Rule, payment rates under OPPS for over 240 dental codes, and added dental surgical procedures to the ASC Covered Procedures List and list of covered ancillary services.

3. Quality Reporting

Hospitals and ASCs must comply with quality reporting measures to avoid payment reductions. For CY 2024, CMS modified reporting measures related to COVID-19 vaccination, cataract surgery, and colonoscopy follow-up. CMS also adopted new measures regarding total hip and/or total knee arthroplasty and radiation doses and adopted separate quality measures specific to Rural Emergency Hospitals.

4. Inpatient Only List

Medicare's "Inpatient Only" ("IOP") list identifies services that CMS has determined can only be safely furnished in an inpatient setting. In the Final Rule, CMS finalized its proposal to add to the IOP list 9 services for which codes were newly created by the AMA CPT Editorial Panel for CY 2024. CMS did not remove any services from the IOP. See Table 102 of the Final Rule for the list of new IOP service.

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5. Drugs and Devices

a. Transitional Pass-Through Payment for Medical Devices

The CMS transitional pass-through payment policy for new devices aims to ensure adequate payment for innovative technology while necessary cost data is collected. Devices meeting certain criteria are eligible for this payment, including those in the FDA Breakthrough Device Program. In response to COVID-19's impact, CMS extended pass-through status for certain devices. For CY 2023, CMS returned to regular updates, but the Consolidated Appropriations Act, 2023 extended pass-through for five devices until December 31, 2023. For CY 2024, CMS evaluated six device applications for pass-through payments in its quarterly review, approving four, including two breakthrough devices. No changes were proposed to the qualification criteria for these payments.

b. Drugs, biologicals and radiopharmaceuticals without pass-through payment status

CMS finalized the drug packaging threshold as $135 per day, instead of the proposed $140 to determine if a drug is separately payable. For CY 2024, CMS calculated the per day cost of non-pass-through drugs and biologicals using CY 2022 claims to determine their packaging status. The change is not a result of a change in methodology but rather recalculating updated data. Biosimilars are excepted from the threshold packaging policy when their reference products are paid separately to avoid financial incentives.

c. Diagnostic Radiopharmaceuticals

In the CY 2024 proposed rule, CMS considered various recommendations to modify its packaging policy for diagnostic radiopharmaceuticals under the OPPS. Stakeholders had expressed concerns that the current bundled payment approach, which includes several categories of non-pass-through drugs and biologicals regardless of cost, often falls short, especially for high-cost, low-utilization diagnostic radiopharmaceuticals. Alternatives suggested included separate payments for diagnostic radiopharmaceuticals exceeding the $140 OPPS drug packaging threshold, restructuring APCs for high cost uses, and specific payment policies for those used in clinical trials. However, due to a lack of consensus among stakeholders and the issue's complexity, CMS decided not to implement any changes for the upcoming year, choosing to continue evaluating stakeholder feedback for future rulemaking.

d. Request for Comments – Essential Medicine Stock

Due to concerns over the supply chain, CMS intends to propose new hospital Conditions of Participation addressing hospital's processes for maintaining a supply of essential medicines. CMS considered policies for separate payment under the OPPS (as well as IPPS) for a hospital's costs to establish and maintain access to a buffer stock of essential medicines. CMS did not adopt separate payment policies at this time, but CMS indicated that it will continue to consider feedback from interested parties, including potential payment policies.

2023 OIG Releases New General Compliance Program Guidance

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The Office of Inspector General (OIG) released new General Compliance Program Guidance (GCPG) on November 6, 2023. This is the first major update to the OIG's compliance guidance in 15 years and is meant to serve as a comprehensive reference guide for the health care compliance community and all other health care stakeholders. While the GCPG is considered voluntary guidance that describes best practices for compliance programs, healthcare entities should be cautious of adopting processes that are a departure from the GCPG's recommendations.

Some key take aways from the OIG's guidance:

False Claims Act

The guidance highlights the importance of the False Claims Act and reiterates providers' obligations to identify billing mistakes or other non-compliance with program rules. There is still an obligation to repay the money even when a provider makes an innocent billing error. The OIG reminds providers that failure to repay any overpayment to Medicare and Medicaid can lead to False Claims Act liability of up to three times the programs' loss plus an additional penalty per claim filed. Compliance programs should be tailored and updated regularly to ensure even inadvertent billing errors are identified and repaid.

Financial Incentives: Ownership and Payment – Follow the Money

Compliance officers should be attuned to the varying risks associated with the payment methodologies through which health care entities are reimbursed for the items and services they provide. This could include overutilization and patient steering in volume based or fee-for-service scenarios or stinting on care or discriminating against more costly patients when paid on a capitated basis. When payment incentives and associated risks are fully understood, compliance officers, including those at entities with private investment, are better positioned to design informed audit plans, conduct effective monitoring, detect problems early, and implement effective preventive strategies.

So what can you do to avoid violations of the applicable laws and protect your healthcare entity?

Elements of an Effective Compliance Program

The seven elements of an effective compliance program remain unchanged: (1) Written Policies and Procedures; (2) Compliance Leadership and Oversight; (3) Training and Education; (4) Effective Lines of Communication with the Compliance Officer and Disclosure Program; (5) Enforcing Standards: Consequences and Incentives; (6); Risk Assessment, Auditing, and Monitoring; and (7) Responding to Detected Offenses and Developing Corrective Action Initiatives. It is worth noting several areas highlighted by the OIG that are particularly relevant in the context of reimbursement compliance efforts.

Role of Compliance Officer

The OIG explains that to be effective a compliance officer should maintain a degree of separation from the delivery of health care services and related operations. Compliance officers should not be responsible, either directly or indirectly, for billing, coding or claim submission and involvement in contracting, medical review or administrative appeals can also present potential conflicts.

Small entities that cannot support a compliance officer should consider designating one person as the entity's compliance contact and have them be responsible for ensuring that the entity's compliance activities are completed. Even in this scenario, small entities should still avoid, whenever possible, appointing a person involved in billing, coding or submission of claims.

Risk Assessment & Auditing

The GCPG also emphasizes the value of a formal risk assessment process, recognizing it as an integral part of an effective compliance program that is necessary for fiscal internal controls and enterprise risk management. Compliance committees should educate themselves on industry risk assessment methods when creating their own processes and should also use data analytics to identify risk areas. Entities should be able to compare standards metrics of their operations internally to determine whether there are any outliers. The routine audit program should incorporate the results of the risk assessment and may focus on areas such as high-value billing codes, medical record documentation, and medical necessity of admission.

Small entities should also conduct at least an annual audit and review their own data to identify potential risks, like claims denials, challenges to medical necessity and patient safety data. The OIG recommends generating risk information by, for example, brainstorming during a staff meeting and then addressing and remediating high-priority issues. Remediation can include repayment, process changes and education.

Highlights from the Final Home Health and Hospice Payment Rules

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The Centers for Medicare & Medicaid Services (CMS) released the Fiscal Year (FY) 2024 Hospice Payment Rate Update Final Rule on July 28, 2023 (the "Hospice Final Rule") and the Calendar Year (CY) 2024 Home Health Prospective Payment System Final Rule (the "Home Health Final Rule") on November 1, 2023. Each of the rules included the expected annual payment updates, but also finalized initiatives to combat fraud and abuse in Hospice and Home Health industries. This article highlights key provisions of both Hospice and Home Health Final Rules.

Hospice Updates

CMS continues to pay close attention to the hospice industry under growing concerns regarding fraud and abuse specific to hospice care. Along with the standard annual updates, the 2024 Hospice Final Rule outlines provisions to further its efforts integrity and quality in the hospice industry. The Home Health Final Rule also finalized a few program integrity provisions specific to hospice care and are included in the below Hospice Update. Key provisions of the rulemakings are outlined below.

1. **Payment Adjustment.** The FY 2024 hospice payment update percentage is 3.1% (an estimated increase of $780 million in payments from FY 2023). This is a result of the 3.3% market basket percentage increase reduced by a 0.2 percentage point productivity adjustment. Hospice agencies that fail to submit their required quality data will incur a 4% payment penalty for FY 2023 and therefore will not enjoy the full percentage increase in the payment update.

2. **Annual Hospice Cap.** CMS sets the FY 2024 annual hospice cap at $33,494.01, which was derived from increasing the FY 2023 cap amount by the 3.1% payment increase.

3. **Hospice Quality Reporting Program.** The rule finalizes the codification of the Hospice Quality Reporting Program (HQRP) data submission threshold policy and provides several updates related to the development of a patient assessment instrument, Hospice Outcomes and Patient Evaluation (HOPE), and future quality measures. The primary objectives for HOPE are to provide quality data for the HQRP requirements through standardized data collection and provide additional clinical data that could inform future payment refinements.

4. **Physician Enrollment Requirements.** Under current regulations, the hospice physician and the attending physician, if any, must initially certify the patient's terminal condition. As part of CMS' larger strategy to address hospice program integrity and quality of care, this rule finalizes the requirement that these two categories of physicians must be enrolled in or opted out of Medicare for hospice services to be paid. Requiring enrollment or opt-out will allow CMS to screen the physician to ensure they are qualified to certify the terminal condition. This requirement will be enforce beginning May 1, 2024, to give unenrolled and non-opted-out physicians more time to enroll in or opt-out of the Medicare program.

5. **Hospice Enrollment.** Hospices will be subjected to the highest level of provider enrollment application screening, which includes fingerprinting all 5 percent or greater owners. In addition, a hospice administrators and medical directors who exercise managing control over hospice operations will be defined as "managing employees" and will need to be disclosed on hospice enrollment applications.

6. **Informal Dispute Resolution (IDR).** CMS finalized a new IDR progress, through which hospices have an informal opportunity to refute one or more condition-level deficiencies cited in the Statement of Deficiencies survey report.

7. **Hospice Special Focus Program (SFP).** The Home Health Final Rule provides for the implementation of an SFP for underperforming hospices in 2024. An SFP algorithm will assess data collected from surveys, the Hospice Care Index Overall Score, and Consumer Assessment of Healthcare providers and Systems ("CAHPS") survey measures. Hospices will receive an aggregate score based on these data points, and the lowest 10% of hospices will be subject to the SFP's increased oversight, including surveys to assess condition-level deficiencies. Under the SFP, CMS maintains the authority to terminate noncompliant hospice programs from the Medicare program as well as to impose civil money penalties, in-service trainings, plans of correction, suspension of payments, or appointment of temporary management.

Home Health Final Rule

The 2024 Home Health Final Rule finalized routine, annual payment adjustments, but also finalizes details regarding a several key program integrity and quality initiatives. CMS anticipates that Medicare payments to HHAs in CY 2024 will increase in the aggregate by 0.8% or $140 million compared to CY 2023. Key provisions of the final rule include the following:

1. **Payment Prospective Payment Adjustment.** CMS finalized a permanent prospective payment system (PPS) adjustment to the 30-day period payment to account for changing expenditures. The finalized increase of 0.8% is down from the originally proposed 2.2% increase.

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2. **36-Month Rule.** As first proposed in July, the Home Health Final Rule finalizes CMS' extension of the existing 36-month rule related to a change in majority ownership to hospices. Effective January 1, 2024, if a hospice undergoes a change in majority ownership within 36 months after: (i) the date the hospice was initially enrolled in Medicare; or (ii) the date of the most recent change in majority ownership, and none of the Rule's enumerated exceptions apply, then the hospice's provider agreement and Medicare billing privileges would not convey to the hospice's new owner. As a result, a new Medicare enrollment and certification would be required, thereby necessitating an initial survey by the state survey agency or accrediting organization.

3. **Home Health Quality Reporting Program (HH QRP).** CMS has finalized the addition of two quality measures to the HH QRP: (i) "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date;" and (ii) "Functional Discharge Score (DC Function)." CMS has removed the following measures from the HH QRP: (i) "Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan);" and (ii) both "M0110 – Episode Timing" and "M2220 - Therapy Needs" OASIS items. CMS also finalized the public reporting of four measures: (i) Discharge Function; (ii) Transfer of Health (TOH) Information to the Provider-Post-Acute Care (PAC) Measure; (iii) TOH Information to the Patient-PAC Measure; and (iv) HH QRP COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date.

Key Updates to Telehealth Reimbursement for 2024

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The Center for Medicare and Medicaid Services (CMS) recently issued a final rule for calendar year 2024 under the Medicare Physician Fee Schedule (the "Final Rule") that updates key payment policies and Medicare payment rates for services furnished by physicians and non-physician practitioners to Medicare beneficiaries. Several of the Final Rule provisions relate to Medicare payment for telehealth services, impacting telehealth coverage and reimbursement. Below are key takeaways from the Final Rule related to telehealth coverage in the coming year.

Temporary Extension of Telehealth Flexibilities

The Final Rule implements the telehealth flexibilities passed by the Consolidated Appropriations Act, 2023 (2023 CAA), which extends through December 31, 2024, many of the telehealth waivers and flexibilities that were put in place as a result of the COVID-19 Public Health Emergency ("PHE"). Namely, the current flexibilities include among others:

- Waiving geographic limitations and originating site requirements, which allows beneficiaries to receive telehealth services from their home;
- Expanding the types of providers that may furnish telehealth services to include physical therapists, occupational therapists, speech language pathologists, and audiologists. Beginning in 2024, the expanded provider types will include mental health counselors (MHCs) and marriage and family therapists (MFTs);
- Removing frequency limitations for subsequent nursing facility or inpatient visits and critical care consultations;
- Delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and, again, at subsequent intervals as the Secretary determines appropriate; and
- Extending coverage for audio-only telehealth services in certain limited circumstances. However, CMS notes in the Final Rule that a majority of telehealth visits require the use of audio and video technology.

Virtual Direct Supervision

The Final Rule extends the definition of "direct supervision" to include supervision through the use of real-time audio and video technology through December 31, 2024. Direct supervision generally requires the immediate in-person availability of a supervising physician or practitioner. However, CMS notes in the Final Rule that the extension of virtual direct supervision will help prevent access to care barriers for many services, while giving practitioners the time needed to adjust their practice patters to pre-pandemic policy requirements.

Adoption of New Code for Administering SDOH

Risk Assessment. CMS finalized permanent adoption of a new standalone Social Determinants of Health (SDOH) Risk Assessment HCPCS code and added the code permanently to the Medicare Telehealth List. This addition will allow behavioral health practitioners to conduct SDOH Risk Assessments alongside behavioral health visits for diagnosis and treatment of mental illness and substance use disorders.

Telehealth Provider Enrollment

CMS will continue to allow flexibility related to provider enrollment requirements for practitioners who furnish telehealth services from their homes. During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home

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address on their Medicare enrollment while continuing to bill from their currently enrolled location. This waiver will continue through December 31, 2024.

Telehealth Place of Service 10 and Non-Facility Rate Payment

CMS has modified place of service ("POS") requirements for telehealth services beginning in 2024. Under pre-existing PHE waivers, practitioners were required to report the POS code that would have applied had the service been furnished in person. However, CMS finalized in the Final Rule that beginning in 2024, POS 10 should be reported when the patient is located at home, and POS 02 should be reported when the patient is located somewhere other than their home. Additionally, CMS will reimburse professional telehealth services furnished to patients in the home at the higher "non-facility rate," which covers both professional cost and overhead cost, which CMS notes more accurately reflects the practice expenses for these practitioners. CMS will continue to reimburse claims with POS 02 at the facility rate, as the originating sites of those services will be the same types of sites common for those services before the PHE, and the facility rate will continue to accurately reflect the providers' practice expenses.

Care Management Services

The Final Rule also includes updates to reimbursement for telehealth adjacent services, such as Remote Therapeutic Monitoring (RTM) and Remote Patient Monitoring (RPM).

- CMS clarified that RPM services only apply to "established patients." Patients who received RPM services during the PHE will be considered established patients. However, patients who receive RPM services after May 11, 2023, will need to undergo an initial new patient exam prior to receiving RPM services.
- CMS provided clarity surrounding concurrent billing of RPM or RTM with certain care management services – providers may now bill Medicare for RTM or RPM provided concurrently with Chronic Care Management (CCM), Transitional Care Management (TCM), Behavioral Health Integration (BHI), Principal Care Management (PCM), and Chronic Pain Management (CPM).
- Under the Final Rule, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) may begin separately billing for RPM and RTM services. This practice was previously not authorized, and services were reimbursed via an all-inclusive rate.
- Additionally, previous reimbursement rules required physical and occupational therapists in private practice to provide direct supervision of physical and occupational therapy assistants in order to bill for RTM services. Beginning in 2024, private practice physical therapists and occupational therapists are required only to provide general supervision of assistants in order to bill for RTM services (provided the supervising therapist is individually enrolled in Medicare).

We anticipate additional changes to telehealth reimbursement in 2024 as CMS continues to evaluate the ongoing flexibilities implemented during the COVID-19 pandemic. Evident throughout the commentary from CMS was the sentiment that some flexibilities extended during the PHE may revert to their original form, and providers should be prepared to revert their practices to pre-pandemic Medicare telehealth policy.

A Busy Year for 340B Programs and Covered Entities

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HRSA, CMS, and the courts kept Covered Entities (CEs) busy this past year and struggling to keep up with several 340B program updates, with the biggest changes happening in the final months of the year. Within a span of a week between October – November, the United States District Court, District of South Carolina issued an order that had tremendous implications on the 340B program, CEs filed a lawsuit challenging a HRSA notice regarding 340B child sites, and CMS issued a final rule that will result in billions of dollars of lump sum payments to CEs in 2024. The 340B Program is currently in uncharted territory following the Genesis ruling and the recent lawsuit over child site eligibility requirements. These changes happened very quickly, so we provided a summary of each update to help providers digest the information and determine how to adapt their 340B Programs to the news. We expect upcoming HRSA audits to reveal where the 340B program is headed in the near term.

One key observation is there is a pattern of lawsuits centered around HRSA's unauthorized implementation of requirements from its withdrawn 2015 Mega-Guidance. Given these pending matters and uncertainty in the 340B enforcement landscape, CEs should review their program operations and rely on the 340B statute, the 1994 HRSA notice regarding outpatient facilities, and the 1996 Patient Definition guidance to remain compliant during this time. HRSA has historically implemented its unofficial requirements through audit enforcement mechanisms, so CEs should be mindful of the risks before opting to expand their programs.

Genesis District Court Ruling

In November, the District Court in *Genesis Health Care, Inc. v. Becerra*, No. 4:19-CV-01531-RBH, 2023 WL 7549156 (D.S.C. Nov. 3, 2023) granted summary judgement in favor of a CE, and enjoined HRSA from enforcing its interpretation of a "patient", which required that a prescription originate from a 340B-eligible location of the CE to be eligible for the 340B program. As a result, it is our understanding that the broader language found in HRSA's 1996 guidance ("1996 Patient Definition") applies. CEs should be evaluating their programs and determining how to react to this change. Whether CEs will expand their patient definition to qualify more scripts and how they do it should be a CE-by-CE decision. CEs should also consider jurisdictional issues since *Genesis* is limited to the FQHC plaintiff in South Carolina. CEs may also want to consider contract pharmacy restrictions when determining whether expansion outweighs additional compliance cost and operational risk.

HRSA Notice Child Site Eligibility and Resulting Litigation

HRSA issued a Notice in October Registration Requirements in the 340B Drug Pricing Program ("Notice") reminding providers of when an off-site outpatient facility can qualify as a 340B child site. (88 FR 73859) The Notice addresses HRSA's abrupt change in child site eligibility policy (connecting the flexibility to the Public Health Emergency two days before the expiration of the PHE) and provides CEs with a limited opportunity to qualify scripts as 340B eligible at off-site outpatient facilities prior to being listed on a filed Medicare Cost Report and registered on OPAIS. Depending on when the off-site outpatient facility opened and will be on the CE's MCR, a CE may need to submit a disclosure to HRSA within 90 days of the Notice. CEs should evaluate whether the information in the notice applies to any of their sites and whether the information needs to be submitted to HRSA.

CEs filed a lawsuit (*Albany Med. Health System v. Health Res. and Servs. Admin., No. 1:23-cv-03252* (D.D.C. Oct 31, 2023), Docket No. 1:23-cv-03252 (D.D.C. Oct 31, 2023)) within a week of the Notice being published challenging the validity of the notice. It's possible that the Notice, and any assertion by HRSA that off-site outpatient facilities must be prospectively registered after appearing on a filed Medicare cost report, is unenforceable. If courts follow a similar reasoning as the court did in Genesis, its likely that HRSA's would face an injunction.

CMS 340B Final Remedy Rule

CMS published its 340B Remedy Final Rule in November ("Final Rule") (88 FR 77150), which confirmed it will pay CEs a one-time lump sum payment for the 2018 – 2022 340B Part B Drug underpayments. Background regarding these underpayments can be found here. The Final Rule is welcome news to many CEs who have faced significant underpayments for separately payable 340B drugs for several years.

Due to the substantial lump sum payment, CMS also finalized the proposed budget neutrality component, which will result in a 0.5% reimbursement reduction to the conversion factor for non-drug items and services over the course of 16 years beginning CY 2026. Lastly, CMS noted in the Final Rule that Medicare Advantage drug claims impacted by its 340B Part-B payment policy are out of its scope. CMS referred to its December 2022 memo to Medicare Advantage Organizations (MAOs), which notes CMS cannot interfere with contracts between MAOs and providers, and payment issues are left to the MAOs and providers to resolve. Therefore, CEs with MAO plan rates that relied on CMS' unlawful OPPS drug reimbursement methodology from 2018 through September 2022 may be able to pursue substantial underpayments from the MAOs.

SNF 2024 Forecast

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Skilled Nursing Facilities (SNFs) and other certified long term care providers will see substantial regulatory and compliance changes in 2024.

FY2024 SNF PPS

On July 31, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a final rule updating the Medicare payment rules for SNFs under the Skilled Nursing Facility Prospective Payment System (SNF PPS) to be effective in the coming fiscal year (FY) 2024. The final rule includes these noteworthy updates:

- An estimated overall 4% increase in Medicare Part A payments over the 2023 rates;
- Revisions to PDPM ICD-10 Code Mappings;
- Removing marriage and family therapist (MFT) services and mental health counselor services (MHC) from SNF consolidated billing;
- Significantly changing the SNF Quality Reporting Program including addition and removal of various reporting measures and increasing completion thresholds;
- Imposing financial penalties amounting to a two-percentage-point reduction in annual payment update for failing to comply with the SNF QRP requirements;
- Adopting new quality measures and imposing policy changes to the Value Based Purchasing (VBP) Program to measure staff turnover, quantify the percentage of residents who meet or exceed expected discharge function scoring, assess the hospitalization rate for long-term residents and assess rates of falls with major injuries for long-term residents; and
- CMS will also adopt a Health Equity Adjustment in the SNF VBP program to reward SNFs that provide care to a higher proportion of residents who are dually eligible for Medicare and Medicaid with an increased payback percentage of 66%, beginning in FY 2027.

Automatic Hearing Waivers and CMP Discounts

Additionally, beginning in 2024, CMS has indicated it will implement an administrative procedure to automatically consider a SNF facing penalties for noncompliance with certification requirements to have waived its right to request a hearing in exchange for a 35% Civil Money Penalty (CMP) discount if CMS has not received a request for a hearing within the requisite deadline. CMS intends for this revised and streamlined procedure to reduce administrative burdens on CMS and to shift resources toward other oversight and enforcement activities.

Ownership Transparency Disclosure Rules

CMS also recently published a final rule that becomes effective January 16, 2024 and will require SNFs to identify an expanded array of ownership and control interests on a revised Form CMS 855-A during initial Medicare enrollment, revalidation, and any change of the data reported.

These new disclosure requirements will bring the ownership information of additional interested parties into public view in certain circumstances, such as private equity companies and real estate investment trust ("REITs").

Importantly, CMS states in its commentary that although revalidations normally occur on a five-year cycle, CMS reserves the right to conduct off-cycle revalidations to collect this new data. Thus, SNFs should prepare for CMS to request this information sooner than their next five-year revalidation deadline, and possibly as soon as the new Form 855-A is published.

Significant Policy Updates in Behavioral Health

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2023 was another busy year for federal policymakers trying to improve access and equity in behavioral health services. In addition to significant monetary investments for school- and community-based behavioral health services, the Administration made a number of key policy updates to increase access to quality behavioral health care. The below summarizes key regulatory changes finalized in 2023, as well as rules we are keeping our eye on in 2024.

Coverage for Intensive Outpatient Services

The final 2024 Medicare Outpatient Prospective Payment System ("OPPS") Rule officially approved Medicare payment for intermediate level behavioral health services, also known as "intensive outpatient program" (IOP) services. Under the OPPS final rule, IOP services can be furnished in various healthcare settings, including hospital outpatient departments, Federally Qualified Health Centers, Community Mental Health Clinics, Rural Health Clinics, and Opioid Treatment Programs. IOP services are more intensive than traditional outpatient therapy but less intensive than the inpatient-level of care furnished by partial hospitalization programs or hospitals. Providers furnishing IOP-level of services must have a "distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness or substance use disorder, consisting of a specified group of behavioral health services." IOP services will be billed with specific consolidated services codes and paid on a per diem basis under the relevant payment system based on setting.

Increased Payment for Crisis Psychotherapy Outside Health Care Settings

CMSs finalized the CY 2024 Physician Fee Schedule, which will increase compensation for psychotherapy for crisis services to 150% of the fee schedule rate for non-facility sites. Psychotherapy for crisis services may be furnished in "non-facility rate" settings other than an office setting, including a patient's home or in a mobile unit. CMS also approved heightened payment for psychotherapy conducted alongside an office visit and for Health Behavior Assessment and Intervention (HBAI) services.

MFT/MHC Enrollment

Filling a long-term gap in behavioral health coverage, Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs) are now permitted enroll and, effective January 1, 2024, bill for the diagnosis and treatment of mental illnesses in an outpatient setting. If an individual meets certain qualifications, they may enroll as either an MFT or MHC, even if the state license uses a different name for the counselor (e.g., licensed professional counselor, mental health counselor, addiction counselor, etc.). To be eligible to enroll, an individual must:

1. Possess a master's or doctorate degree that qualifies them for license or certification as either a marriage and family therapist or counselor;

2. Maintain a state license or certification as a MFT or MHC (using the state terminology) in the state in which they will provide services;

3. Have performed at least two years of clinical supervised experience after obtaining their master's or doctorate degree; and

4. Meet any other requirements that CMS determines appropriate.

CMS has provided additional guidance in a Frequently Asked Questions document to address specific questions, such as licensing matters, taxonomy codes, and timing of enrollment, among others.[1]

Compensation for Community Health Workers and Peer Support Specialists

CMS has finalized distinct coding and reimbursement for community health integration services. These services include person-centered planning, health system coordination, promotion of patient self-advocacy, and facilitation of access to community-based resources to address unmet social needs affecting the practitioner's diagnosis and patient treatment. For the first time, Physician Fee Schedule services will include care delivered by community health workers.

General Supervision for Behavioral Health Services "Incident to" at RHCs and FQHCs

CMS has finalized a shift in the required level of supervision for behavioral health services at federally qualified health centers (FQHCs) and rural health clinics (RHCs), allowing for "general" supervision instead of "direct" supervision. This change enables behavioral health practitioners to offer services without the physical presence of a doctor or non-physician practitioner on-site. The change aims to increase access to behavioral health services like counseling and cognitive behavioral therapy, particularly in rural or underserved communities where obtaining care can be challenging.

1 Marriage and Family Therapists (MFT) and Mental Health Counselors (MHC) Provider Enrollment Frequently Asked Questions (FAQs), CMS, Sept. 2023, cms.gov/files/document/marriage-and-family-therapists-and-mental-health-counselors-faq-09052023.pdf

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Continued Telehealth Services for Opioid Treatment Providers

CMS finalized that it is continuing to allow opioid treatment providers to deliver specific services via telephone or audio-only technology.

Mental Health Parity

As part of the Administration's focus on mental health care, the Departments of Labor, Treasury and Health and Human Services published a proposed rule on July 25, 2023, attempting to strengthen the regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act ("MHPAEA"). The proposed rulemaking, if finalized, would provide guidance on provisions of the Consolidated Appropriations Act of 2021 that required all health plans and insurers that impose Non-Quantitative Treatment Limitations ("NQTLs") on mental health and/or substance abuse benefits to conduct and document a comparative analysis of the design, application, and impact of NQTLs to show compliance with MHPAEA.

If the rule is finalized as proposed, it would fill some gaps in understanding the requirements of MHPAEA, generally, and it would identify detailed requirements for health plans and insurers to use in determining whether an NQTL imposes greater limits on access to mental health and substance use disorder benefits as compared to physical health benefits. If material differences are found, it would be a strong indicator that the NQTL violates the MHPAEA, and the plan or insurer would need to take reasonable actions to mitigate those differences or not impose the NQTL.

The proposed rule would also newly require plans and insurers to collect and evaluate network and outcomes data to assess the impact of NQTLs. This would require plans and insurers to collect data regarding, for instance, out-of-network utilization, reimbursement of out-of-network providers, prior authorization requirements, time and distance standards, and denial rates. This data collection would force plans and insurers to actively show parity with respect to access to mental health and substance use disorder treatment services.

The proposed rule would allow for a couple of exceptions, which, if satisfied, would insulate a plan or insurer from liability. Plans and insurers that apply NQTLs that (1) apply generally accepted standards of care and/or (2) are applies used solely for the purpose of detecting or preventing fraud, waste and abuse (as established through objective, unbiased data) would not violate MHPAEA with respect to the specific excepted NQTL.

We anticipate that significant comments were made regarding the proposed rulemaking, with strong dissent from the insurance industry. We will continue to watch for finalized guidance in the next year.

CMS Finalizes Changes to Medicare Provider Enrollment Rules

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CMS made several updates to the Medicare provider enrollment regulations and sub-regulatory guidance in 2023. Overall, the changes continued recent policymaking efforts by CMS to encourage voluntary correction and updating of enrollment profiles as well as efforts to increase the transparency in program integrity efforts. A summary of the major changes affecting providers and suppliers is provided directly below:

CMS Created a New Provider Enrollment Denial and Revocation Authority for Civil False Claims Act Judgments

The 2024 Medicare Physician Fee Schedule Final Rule expanded CMS' denial and revocation authorities to allow a Medicare provider enrollment application to be denied, or an existing enrollment to be revoked if a civil False Claims Act judgment has been entered against a provider or supplier, or any owner, managing employee or organization, officer, or director within the previous 10 years. CMS clarified that the revocation authority would be purely discretionary and that it would consider factors on the nature and scope of the conduct leading to the False Claims Act judgment in making an enrollment determination. The rule will only apply prospectively.

CMS Updated Sever Provider Enrollment Regulatory Definitions

CMS responded to several requests by suppliers and providers to update key provider enrollment definitions and implemented changes or additions to the following:

- Added a definition of "indirect ownership interest" and included guidance on how to calculate the percentage of indirect ownership interest in a provider or supplier.
- Amended the definition of "supplier" at 42 C.F.R. 424.502 to include physical therapists in private practice, occupational therapists in private practice and speech-language pathologists.
- Updated the definition of "authorized official" to clarify that the "organization" referenced in the definition is meant to refer to the enrolling entity, as defined by its legal name and tax identification (rather than the provider or supplier type the entity is enrolling as).

CMS Clarified Change in Location Filing Requirements

CMS required all providers and suppliers to report a change in practice location within 30 days of the change (previously, some must report within 90 days). CMS also clarified that a change in practice location includes adding a new location or deleting an existing location.

CMS Extends the 36 Month Rule to Hospices

CMS finalized a proposal to extend the application of the 36 month rule to Medicare enrolled hospices effective January 1, 2024. The revised rule will forbid any change in majority ownership of a hospice provider during the 36 months after initial Medicare enrollment or its most recent change in majority ownership.

CMS Categorized Hospices as "High-Risk" Providers

Hospices initially enrolling in Medicare will now be deemed "high risk" providers. This means individuals with a 5% or greater indirect or direct ownership interest in a newly enrolling hospice will be required to submit fingerprints for a criminal background check. Further, any new individual owners with 5% or greater indirect or direct ownership in a currently enrolled hospice will be required to undergo fingerprinting.

CMS Modified the Excluded Unit Regulation for IRFs

In its Fiscal Year 2024 IRF Prospective Payment System ("PPS") Final Rule, CMS finalized changes to regulations governing excluded hospital units to allow hospitals to open a new IRF unit and begin being paid under the IRF PPS at any time during the cost reporting period. Hospitals must notify the CMS Regional Office and the Medicare Administrative Contractor in writing at least 30 days before the date of the change and maintain the information needed to accurately determine the costs attributable to the IRF unit.

Four Major Issues Medicaid Providers Need to Know for Fiscal Year 2024

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The Medicaid program remains the largest government program for health care coverage (84.7M Americans in 2021) and a meaningful operational and compliance burden for health care providers. This article discusses a few key issues impacting Medicaid providers based on developments in 2023 and leading in to 2024, including:

1. Uncertainty regarding Medicaid beneficiary enrollment, eligibility, and coverage due to the unwinding of the COVID-19 public health emergency ("PHE");

1. Rate increases and enhanced Medicaid coverage for certain provider types;

2. Increased enforcement activity due to greater post-PHE scrutiny of provider billing practices; and

3. Federal efforts to stabilize the Home and Community-Based Services ("HCBS") provider workforce through mandatory spending ratios for enrolled providers.

Uncertainty Regarding Medicaid Beneficiary Enrollment, Eligibility and Coverage

The Families First Coronavirus Response Act[1] increased federal Medicaid funds to states with the requirement that states maintain Medicaid beneficiary enrollment throughout the PHE. In February 2023, the continuous enrollment requirement ended, and state Medicaid programs began eligibility redeterminations and disenrollment of individuals who no longer met eligibility criteria through a process referred to as "unwinding." As of November 2023, unwinding led to the disenrollment of more than 11 million beneficiaries. It is likely that millions more will lose Medicaid coverage before May 31, 2024, the deadline for states to redetermine eligibility. The mass disenrollment of millions of Medicaid beneficiaries creates significant claims processing, eligibility determination, and other operational issues for Medicaid providers, who must be vigilant about monitoring Medicaid coverage as states systematically disenroll beneficiaries.

The eligibility redetermination process has been bumpy. The Centers for Medicare & Medicaid Services (CMS) has identified significant concerns with state enrollment and redetermination processes that have disenrolled beneficiaries for procedural reasons (e.g., failure to submit paperwork), rather than a substantive failure to meet Medicaid eligibility criteria. This means that (potentially) millions of eligible individuals have been left without coverage in recent months.

In response to these concerns, CMS recently published a final rule to refocus state processes and preserve Medicaid coverage for eligible individuals. The new rule:

1. Requires states to submit a corrective action plan ("CAP") in the event that the state does any of the following:

    a. Fails to meet reporting requirements related to unwinding, such as unwinding data, enrollment in Qualified Health Plans and Basic Health Plans in states that operate a State-based Marketplace, monthly data about activities related to eligibility determinations and redeterminations conducted during that period, and other similar data;

    b. Fails to follow recommended timelines for disenrolling individuals from Medicaid; and

    c. Disenrolls a large number of Medicaid beneficiaries for procedural reasons (i.e., reasons unrelated to a state's determination of whether the individual meets eligibility criteria, including for failure to return a renewal form or documentation needed by the State to make a determination of eligibility)

2. Requires states to suspend Medicaid disenrollment for procedural reasons; and

3. Imposes a penalty of up to $100,000 for each day a state is not in compliance with reporting requirements related to Medicaid eligibility redeterminations and/or fails to submit or implement a CAP.

The interim final rule took effect on December 6, but CMS will accept public comments until February 2, 2024. Regardless of whether CMS ultimately updates its rule, Medicaid providers should exercise diligence when verifying Medicaid eligibility. To avoid significant billing and compliance concerns, and to plan for increased uncompensated care, providers should redouble their efforts to validate Medicaid enrollment, and notify their State Medicaid Agency if they observe significant disenrollments. We recommend providers who care for Medicaid beneficiaries work closely with their State Agencies to adopt CMS approved options to delay or avoid procedural disenrollments, and to adopt ex parte verification practices. States that fail to maintain appropriate Medicaid enrollment risk cuts to federal Medicaid funding, which should interest Agencies and State Legislatures.

1 P.L. 116-127 (Mar. 18, 2020).

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Rate Increases and Expanded Coverage

While state budgets and Medicaid programs deal with constant budget pressure, according to a Kaiser Family Foundation (KFF) survey of State Medicaid Agencies, states have reported fee-for-service (FFS) rate increases for nursing facilities, HCBS providers, primary care physicians, and behavioral health providers.[2] In some cases, such rate increases outpaced FFS rate decreases for FY 2024.[3] While states continue to heavily rely on managed care to deliver Medicaid benefits, FFS reimbursement rates remain significant benchmarks for managed care payments in most states; thus, the rate increases noted in the KFF survey are significant for Medicaid-enrolled providers that participate in managed care plans as well.

In addition to rate increases for select provider types, states are also reporting expanded benefits for a number of service categories, namely the following:

1. Mental health/SUD treatment;
2. Pregnancy and postpartum care;
3. Preventive services;
4. Dental services;
5. Services related to Social Determinations of Health (SDOH), sometimes referred to as Associated Health-Related Social Needs (HRSN); and
6. Community healthcare.[4]

Expanded service coverage presents opportunities for Medicaid providers to not only seek additional sources of revenue, but also to expand partnership with other organizations and address a full spectrum of issues related to beneficiary wellbeing. Benefit enhancements related to SDOH/HRSN are particularly notable. In 2022, CMS launched a new framework for states to cover HRSN services under Section 1115 of the Social Security Act that expanded flexibility for states to add particular short-term housing and nutrition supports as Medicaid benefits.[5] CMS subsequently approved HRSN waivers in six states (Arizona, Arkansas, Massachusetts, New Jersey, Oregon and Washington), prompting one-quarter of state Medicaid directors to name HRSN as a key priority for future benefit enhancements.[6]

Increased Federal, State and Medicaid MCO Enforcement Activity Expected

Both CMS and HHS-OIG have prioritized investigation of health care providers for potentially fraudulent billing practices related to COVID-19 during the PHE, as well as states that collected increases under the enhanced federal match rate, also called the Federal Medical Assistance Percentage (FMAP), during the PHE. As early as May 2020, HHS-OIG launched a strategic plan related to oversight of COVID-19 response and recovery.[7] HHS-OIG is now implementing this plan, initially by focusing on auditing state Medicaid collections of the enhanced FMAP.[8] The following provider types face especially increased attention, because their billing practices are currently of particular interest to enforcement agencies:

1. Applied Behavior Analysis (ABA) providers;
2. Home-based service providers, particularly regarding the furnishing by personal care services (PCS) either furnished by regular personal care aides or by family caregivers;
3. Hospitals, especially with respect to inpatient hospital services; and
4. Non Emergency Medical Transportation (NEMT) providers. CMS and HHS-OIG are also expecting Medicaid MCOs to progressively refer more providers for potential fraud to state Medicaid Fraud Control Units.[9]

Medicaid providers of all types should be prepared for enhanced scrutiny over the coming months, and should take action to ensure their organizations are prepared. Steps to take include: (1) evaluating PHE-related treatment, operational, and billing practices to ensure any flexibilities allowed during the PHE have been appropriately adapted to a post-PHE world, (2) training staff in the receipt of and response to government requests for documents or subpoenas, and (3) reviewing and formalizing procedures to enlist internal and external legal and compliance resources to manage these interactions.

2 See Elizabeth Hinton, et al., Amid Unwinding of Pandemic-Era Policies, Medicaid Programs Continue to Focus on Delivery Systems, Benefits, and Reimbursement Rates: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2023 and 2024, Kaiser Family Foundation (Nov. 14, 2023), avail. at https://www.kff.org/report-section/50-state-medicaid-budget-survey-fy-2023-2024-executive-summary/.

3 *Id.*

4 *Id.*

5 See Ctrs. for Medicare & Medicaid Srvcs., All-State Medicaid and CHIP Call (Dec. 6, 2022), avail. at https://www.medicaid.gov/sites/default/files/2022-12/covid19allstatecall12062022.pdf.

6 See Elizabeth Hinton, et al., Amid Unwinding of Pandemic-Era Policies, Medicaid Programs Continue to Focus on Delivery Systems, Benefits, and Reimbursement Rates: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2023 and 2024, Kaiser Family Foundation (Nov. 14, 2023), avail. at https://www.kff.org/report-section/50-state-medicaid-budget-survey-fy-2023-2024-executive-summary/.

7 See U.S. Health & Hum. Srvcs., Office of the Inspector General, OIG Strategic Plan: Oversight of COVID-19 Response and Recovery (May 2020), avail. at https://oig.hhs.gov/documents/root/166/COVID-OIG-Strategic-Plan.pdf.

8 See HHS-OIG, Audit of Medicaid Collections During COVID-19 Federal Medical Assistance Percentage Increase (Jan. 2023), avail. at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000758.asp.

9 See, e.g., HHS-OIG, State Medicaid Agencies' Perspectives of Managed Care Plans' Referral of Fraud (Jun. 2023), avail. at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000777.asp; HHS-OIG, Medicaid Managed Care Plans' Focus on Fraud Referrals (Sept. 2022), avail. at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000727.asp; see also HHS-OIG, OIG's Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs (2022), avail. at https://oig.hhs.gov/documents/top-unimplemented-recommendations/1102/compendium2022.pdf, at 3 ("CMS should improve Medicaid managed care organizations' (MCOs') identifications and referrals of cases of suspected fraud or abuse").

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Workforce Stabilization

Health care provider turnover and workforce shortages are an area of immense focus for providers, patients, and government agencies alike, and there have been numerous attempts to address these concerns from various regulatory agencies. In May 2023, CMS published a proposed rule intended to stabilize the workforce for Home and Community Based Services (HCBS) through increased regulatory requirements for agencies. CMS proposed HCBS agencies expend a minimum portion of their Medicaid reimbursement on direct care worker compensation.[10] The proposed rule faced meaningful pushback from both the provider community and regulatory agencies, objecting to both the proposed compensation thresholds and numerous potential implementation issues (e.g., what should be considered "compensation" to direct care workers). CMS is still sorting through the thousands of comments they received, and has yet to finalize this rule. We anticipate a final rule could be published as soon as the first quarter of 2024. As a result, HCBS providers should stay nimble when making budgets for the coming year, and be prepared to implement both the substantive requirements CMS imposes and the procedural and reporting rules that will accompany these changes.

The need for HCBS services and providers continues to grow, and providers should evaluate their potential to serve these populations in existing programs and potential, new waiver programs.

1088 FR 27960 (May 5, 2023).

2023 CMS Innovation Center Updates

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The CMS Innovation Center ("CMMI") was formed by Congress in 2010 and tasked with developing and testing new payment and service delivery models, with the goals of improving quality and decreasing costs Medicare, Medicaid and other federal programs. CMMI has overseen and administered over 50 alternative payment models since 2010, which tend to concentrate on specific health conditions or care episodes, including mandatory programs like the Comprehensive Care for Joint Replacement Model, and voluntary programs like the Bundled Payments for Care Improvement model and the Pioneer ACO Model.

CMMI programs which are new, accepting applicants, or which were materially revised or updated in 2023 include the following:

- **Bundled Payments for Care Improvement Advanced ("BPCI Advanced")** was extended for 2 years through 2025, and new applicants were accepted through spring 2023 for a January 1, 2023 start. The extended model offers applicants the option to elect to participate with downside risk, or opt out later before bearing risk; to select individual clinical episode service line groups; and, to analyze historical claims data to understand the financial and clinical opportunities before agreeing to fully participate. During the extension direct risk-bearing entities must be either Medicare providers/suppliers or Medicare accountable care organizations (ACOs), and private convener organizations will be prohibited from playing direct roles in BPCI Advanced, effectively giving power back hospitals and physician group practices from commercial intermediary entities which have now withdrawn from the program.
- **Radiation Oncology Model (the "RO Model")** aims to improve the quality of care for cancer patients by moving towards a simplified and predictable payment model. The RO Model plans to change the way that RT services are currently paid for by shifting from a fee for service model to an outcome based approach, linking payment to quality. There are three elements to the alternative payment structure: (1) Payments will be bundled based on a patient's diagnosis for RT care furnished in 90 day increments; (2) payments will be site-neutral regardless of the setting the care is furnished in; and (3) payments will be split into professional and technical components. Entities eligible to participate in the RO model include PGP (including free standing radiation centers, or an HOPD. Participants have the option of participating in the RO Model as professional participants, technical participants, or dual participants depending on the RT services furnished.
- **States Advancing All-Payer Health Equity Approaches and Development ("AHEAD") Model** On September 5, 2023, CMS announced the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model with goal of cutting rising healthcare costs, improving population health, and advancing health equity. AHEAD is a state total cost of care (TCOC) model under which participating states will use their authority to manage health care quality and costs across all payers. The AHEAD model will provide funding and support to participating states to strengthen primary care. There are three primary participants for the AHEAD Model, states, hospitals, and primary care practices. The Model will operate for a total of 11 years and consist of three cohorts, with an application window scheduled to be opened in the Spring of 2024.

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- **Medicare Intravenous Immune Globulin ("IVIG") Demonstration** was previously extended through December 31, 2023, and continues to accept new enrollments on a rolling basis. The goal of the Medicare IVIG demonstration is to evaluate the benefits of providing payment and items for services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency disease (PIDD). The demonstration uses the national per visit low-utilization payment amount (LUPA) as the standard rate of payment per visit for home-based IVIG administration. Under this demonstration, beneficiaries do not need to be homebound in order to receive the home health care benefits. To participate, beneficiaries must meet eligibility requirements, currently require IVIG for the treatment of PIDD, and complete and sign the application along with their physician.

- **Making Care Primary ("MCP") Model** is a 10.5-year model (running from July 2024 to December 2034) to improve care management and care coordination and better equip primary care providers with tools to form partnerships with health care specialists and leverage community-based connections to address patients' health needs as well as health-related social needs (HRSNs) such as housing and nutrition. CMS is working with State Medicaid Agencies in 8 states – Colorado, North Carolina, New Jersey, New Mexico, New York, Minnesota, Massachusetts, and Washington – to engage in full care transformation across payers with future plans to engage private payers. The MCP Program is geared toward beneficiaries enrolled in Traditional Medicare (FFS), but other payers are encouraged to partner with CMS to address these goals and improve primary care across all patients. The MCP Model accepted applications for the model through December 14, 2023.

- **Guiding an Improved Dementia Experience ("GUIDE") Model** is a model that aims to support people living with dementia and unpaid caregivers to allow those living with dementia to remain in their homes and communities for as long as possible. The GUIDE Model will establish dementia care programs (DCPs) that provide ongoing, longitudinal care and support to people living with dementia through an interdisciplinary team. Guide Participants will be Medicare Part B enrolled providers/suppliers, excluding DME and laboratory suppliers, who are eligible to bill for Medicare Physician Fee Schedule services and agree to meet the care delivery requirements of the model (or contract with Partner Organizations which are other Medicare providers/suppliers, to meet the care delivery requirements). CMS announced this nationwide voluntary model on July 31, 2023 with applications due by January 30, 2024. The GUIDE Model will launch July 1, 2024 (for established programs) and July 1, 2025 (for new programs) and run for 8 years.

- **Medicare Advantage Value-Based Insurance Design ("VBID") Model** aims to remove obstacles to health and healthcare for those enrolled in Medicare Advantage (MA) plans under a participating Medicare Advantage Organization (MAO) by providing patients with supplemental benefits tailored to their needs such as lower costs for prescription drugs, grocery assistance, transportation services, and support managing chronic conditions. There is also a Hospice benefit component to the VBID model. Historically, when a person enrolled in an MA plan enters hospice, FFS Medicare is financially responsible for most services. The Hospice benefit component to the VBID model enables MA plans to be financially responsible for all services, including hospice, which improves care accountability and financial responsibility across the life course. There are currently 69 MAO participants for CY2024. The VBID Model was extended for calendar years 2025 through 2030.

During 2024, it is anticipated that CMMI will provide significant clarity regarding plans for what programs will replace the flagship BPCI Advanced program after 2025. Whether CMMI pursues a mandatory participation strategy, which was the strategy prior to the Trump administration in 2016, or potentially expands a voluntary program similar to the current BPCI Advanced, will be the biggest Innovation Center development of 2024, so be on the lookout for Reimbursement Institute updates as soon as CMMI releases further details on new program development.

Recent Federal Price Transparency Requirements for Hospitals and Plans

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The Center for Medicare and Medicaid Services (CMS) recently implemented certain price transparency requirements for hospitals and health plans through various regulations, Executive Orders, and the federal No Surprises Act. CMS reasons that these requirements help Americans know the cost of an item or service (including covered items / services) before receiving it, and that this information will make it easier for consumers to shop and compare prices. We have not yet seen data indicating transparency has impacted consumer behavior.

Each hospital must disclose on a publicly available website its current standard charges for all items or services, the a) gross charges, b) discounted cash price, and c) payer-specific negotiated charge in a machine-readable format, and for a subset of 300 'shoppable" services, the current standard charges in a consumer-friendly list. These shoppable services are composed of 70 CMS-specified services and 230 hospital-selected services. Many hospitals have chosen to satisfy this shoppable services requirement by providing an online price estimator tool.

Likewise, plans and issuers must disclose on a publicly available website the payment rates for all covered items and services for in-network providers and the allowed amounts for, and billed charges from, all out-of-network providers in a machine-readable format. Further, plans must disclose an online price comparison tool (also available by phone, or in paper form, upon request) allowing an individual to receive an estimate of their cost-sharing responsibility for 500 designated items or services from a specific provider. As of next month, plans and issuers must expand the price estimator to all items and services.

CMS has been reviewing hospital websites and evaluation complaints made by members of the public and sent out over 1000 general warning letters or requests for corrective action plans (CAPs). At least 14 hospitals have been assessed civil monetary penalties. And, while we are aware of activity by researchers to use the data provided by plans and issuers, to date, we are unaware of any audit or enforcement measures by any governmental agency against plans or issuers. Enforcement against plans and issuers may be complicated by the complexity of state insurance regulators and diversity of federal agencies that oversee various types of health insurance coverage.

Additionally, the recently implemented federal No Surprises Act ("NSA"), effective January 1, 2022, imposes some lesser-known price transparency requirements on an individual patient-by-patient basis. These requirements apply to all provider types and regardless of whether the items / services are in- or-out-of-network. For uninsured (self-pay) patients, providers must furnish a good faith estimates (GFE) to the patient within a very short timeframe. The patient may dispute any amount billed that is $400 or more than the GFE amount through the NSA's patient-provider dispute resolution process (PPDRP).

A failure to comply with this requirement is subject to $10,000 monetary penalty for each violation. At this point, we understand that CMS is engaging in inquiries with providers in response to patient complaints regarding the GFE. We are unaware of any financial penalties having been imposed on any provider for failure to comply with this requirement, however.

Similarly, the NSA requires plans to furnish an advanced explanation of benefits (AEOB) to commercially insured patients 3 days before the service or upon request if the service has not been scheduled. This would also require providers to send estimates of the scheduled item / services to the plan so that the plan could furnish the AEOB. CMS is delaying enforcement of these AEOB requirements, however, until subsequent rulemaking. Nonetheless, providers should be prepared to, at some point, send estimates for both uninsured (self-insured) and commercially insured patients.

Medicare Advantage Reimbursement Trends to Watch Including CMS's Proposed Rule

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The Providers should be aware of several recent developments in the Medicare Advantage (MA) program, including the 2025 MA Proposed Rule which addresses predatory marketing and access to behavioral health care, as well as the 2024 MA Final Rule, which made significant changes addressing timely access to care and prior authorization requirements. The Biden Administration's continued focus on increased protections for Medicare beneficiaries continues to impact providers and the reimbursement that flows from the Centers for Medicare & Medicaid Services (CMS) to MA plans to providers.

MA's steady trend of enrollment increases continued in 2023. Now, almost 31 million people are enrolled in an MA plan. That's more than half of the Medicare eligible population. In addition, the average Medicare beneficiary has access to 43 MA plans, a record high. Seeing no end to this trend, Humana announced in 2023 that it will exit the commercial market to focus on its Medicare business.

But among these signs of strong MA growth nationally, there are also signs of discontent among providers. A growing number of hospitals and other providers are declining to participate in MA plans, citing slow payments, disproportionate claim and authorization denial rates, and unacceptable administrative burdens. Some providers are even advising their patients to stay in the original Medicare program.

CMS recently took several steps to curb these MA plan practices, particularly when they jeopardize beneficiary access to care.

Access to Care and Streamlining Prior Authorization Requirements

The 2024 MA Final Rule, which takes effect January 1, 2024, included many key changes and clarifications regarding CMS requirements for beneficiary access to care. For example, an MA plan may no longer use prior authorization policies to delay or discourage care. Rather, a plan may only use prior authorizations to confirm the presence of diagnoses or other medical criteria and to ensure that a service or benefit is medically necessary.[1] CMS also clarified that when an MA plan provides a pre-service medical necessity determination through the prior authorization process, the plan cannot later deny coverage or payment based on medical necessity, absent a specific basis for reopening (e.g. reliable evidence of fraud or other "good cause").

At a high level, the 2024 MA Final Rule also clarifies longstanding CMS policy that MA plans must provide benefits coverage for MA enrollees that is no more restrictive than traditional / FFS Medicare. When Medicare statutes, regulations, National Coverage Determinations, or Local Coverage Determinations create "fully established" coverage criteria for an item or service, the MA plan is required to comply and may not apply additional criteria as part of its coverage determination. In these cases, the MA plan may not deny coverage of the item or service based on "internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies."[2]

CMS also emphasized that an MA plan may not limit how and when covered benefits are furnished in a way that is more limited than Traditional Medicare. If a patient's physician orders post-acute SNF care, for example, the MA plan cannot deny SNF coverage and redirect the patient to home health unless the patient does not meet SNF coverage criteria.[3]

Curbing Predatory Marketing and Inappropriate Steering That Distorts Healthy Competition

CMS previously addressed predatory marketing such as banning misleading advertisements, prohibiting marketing of benefits in a service area where those benefits are not available, and requiring MA plans to have an oversight plan that monitors agent/broker activities. Now, CMS is aiming at the compensation structure that agents and brokers receive. CMS believes some MA Plans are circumventing existing payment rules and inappropriately steering beneficiaries to enroll in plans that do not meet their medical needs, which leads to further consolidation in the MA market and greater negotiating imbalances for providers. As a result, CMS seeks in its 2025 MA Proposed Rule to "prohibit contract terms between MA Plans and agents, brokers or other third party marketing organizations that may interfere with the agent or broker's ability to objectively assess and recommend the plan that best fits a beneficiary's health care needs; set a single compensation rate for all plans; revise the scope of items and services included within agent and broker compensation; and eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services."[4] CMS believes the

1 2024 MA Final Rule, 88 Fed. Reg. 22120, 22200-22205 (April 12, 2023), implementing a new regulation at 42 CFR § 422.138
2 2024 MA Final Rule at 22194.
3 2024 MA Final Rule at 22190, amending 42 CFR § 422.101(c)(1)(i).
4 2025 MA Proposed Rule, 88 Fed. Reg. 78476, 78544 (November 15, 2023).

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proposed changes will ensure that the use of compensation will create incentives to enroll individuals in the plans that best fit their needs, and hopefully reducing denials from MA plans that were never meant to serve a particular beneficiary.

Strengthening Access to Behavioral Health Care

Finally, CMS proposed to build on changes made in the 2024 MA Final Rule to further expand network adequacy requirements for MA plans. Specifically, CMS seeks to add a combined facility-specialty category called "Outpatient Behavioral Health," to its formal network adequacy requirements. This new category may include Marriage and Family Therapists, Mental Health Counselors, Opioid Treatment Program Providers, and other behavioral health and addiction medicine specialists and facilities. CMS believes the proposed addition will ensure that MA beneficiaries can access vital mental health and substance use disorder treatment. Of course, it also provides an opportunity for these providers to seek more favorable participation terms with MA plans.

Conclusion

The Biden Administration is committed to strengthening the MA program. As examples, the 2024 MA Final Rule, as well as the 2025 MA Proposed Rule build on the Administration's existing policies to strengthen beneficiary protections, deter anti-competitive practices, and promote access to other services such as behavioral health. As the MA program's steady trend of enrollment continues, so will additional rules, which providers should know, that aim at ensuring benefits remain strong and stable for beneficiaries.

Key Take-aways for Health Care Providers from the DOL's Lawsuit Against the Nation's Largest TPA

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A recent court case could pave the way for lawsuits against third-party administrators ("TPAs")-- separate from plan sponsors--for denying and underpaying claims in violation of the Employee Retirement and Income Security Act of 1974 ("ERISA") and the Affordable Care Act ("ACA"). In July 2023, the U.S. Department of Labor filed a lawsuit against UnitedHealth Group's subsidiary, UMR Inc., alleging UMR improperly denied thousands of claims in violation of ERISA and ACA. These allegations highlight many emerging and trends in commercial payor provider relations, in particular here reimbursement issues with third party administrators ("TPAs") of ERISA-governed health plans.

In its complaint, the Department alleged UMR improperly denied thousands of claims for (1) emergency room ("ER") visits and (2) urinary drug screening ("UDS") in violation of UMR's obligations under ERISA and the ACA.

To justify its denial of the ER claims, UMR used two lists: the "True ER List" and the "Sudden and Severe List." If an ER claim did not have at least one diagnosis code from either the True ER List or the Sudden and Severe List, UMR automatically denied the claim. The Department alleged UMR violated the ACA through its automatic ER claim denial process because, during the adjudication of the ER claims, UMR did not apply the prudent layperson standard to determine whether the ER claim was proper.

For UDS claims, UMR uniformly denied all UDS claims until 2018 and from 2018 onward uniformly denied all non-ER UDS claims. The Department alleged UMR violated ERISA through its automatic UDS claim denial process because UMR never applied the respective health plan's definition of medical necessity to the denied claims.

Further, the Department argued that UMR's explanations of benefits and their associated denial codes were insufficient to satisfy ERISA's claims procedure regulations. ERISA establishes specific notice requirements when a health plan issues an adverse benefits determination to a claim. Failure to follow the notice requirements constitutes a breach of fiduciary duty. The explanations of benefits for the automatically denied ER claims stated, "the plan excludes benefits for this treatment." The explanations of benefits for

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the automatically denied UDS claims stated "charges not considered medically necessary" and "additional information needed to process your claim." UMR's explanations of benefits did not meet ERISA notice requirements because they (a) provided no clinical or scientific information as to the rational of medical necessity denials, (b) never identified the information needed to overturn the denials, (c) provided no citations to the relevant health plans or the health plans' coverage provisions, and (d) never applied the health plans' definitions of medical necessity.

The Department concluded that UMR was in breach of its fiduciary duties under ERISA, failed to administer the claims or establish an adequate claims handling process in compliance with ERISA, and failed to adequately notify the relevant beneficiaries. Therefore, the Department requested a permanent nationwide injunction preventing UMR from improperly denying claims.

The Department's allegations against UMR are not unique in the commercial reimbursement sphere. TPAs throughout the U.S. have increasingly relied on automatic denial lists, algorithms, or charge audits to immediately deny reimbursement for medical services in both emergent and non-emergent contexts. These TPAs provide limited or vague explanation supporting the denial in their explanations of benefits. In doing so, the TPAs have stepped beyond the protective shield of ERISA preemption by violating ERISA and its claims handling regulations. Nationwide injunctions requiring TPAs to accurately adjudicate claims may be an effective tool moving forward.

Key points to follow during this lawsuit include:

1. TPAs have a duty to follow the prudent layperson standard when adjudicating ER claims.

2. Health plans have a duty to give adequate notice under ERISA of adverse benefits determination (including both underpayments and complete denials).

3. TPAs bear their own liability under a contract when acting on behalf of self-insured plans.

Key actions for providers to address challenge denials and underpayments under ERISA:

1. Review denial explanations of benefits to ensure they satisfy the adverse determination notice requirements outlined in ERISA - such as specific rational noted for the denial and outlining the appeals process.

2. Monitor denials to identify trended denials. In many cases, TPAs employ algorithms or denial lists to uniformly deny a specific code. In recognizing denial patterns, providers can identify where TPAs may be violating their duty to adjudicate claims according the health plan's specific terms on medical necessity and coverage, and/or the prudent layperson standard.

3. Evaluate current assignment of benefits ("AOB") to ensure they accommodate equitable relief. State law varies on whether a general AOB assigns the right to pursue equitable relief to a provider. Adding specific equitable relief language to AOBs is important to ensure a provider's ability to pursue claims against ERISA actions.

The Latest in Government Audits: Six Takeaways from 2023

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Following the trend from last year, government contractors continue to revamp their audit activities after a relative slowdown during 2020 and 2021 at the height of the COVID-19 pandemic and 2023 brought a lot of changes for providers in the audits and reimbursement disputes realm. Significantly, these changes have established patterns that can be expected to endure beyond this year. This article focuses on six notable audit trends from 2023 of which providers should be aware to prepare for 2024.

The End of the Medicare Appeals Backlog

For the better part of the past decade, the Office of Medicare Hearings and Appeals ("OMHA"), which oversees Administrative Law Judge ("ALJ") hearings relating to Medicare audit and overpayment appeals, encountered significant delays over the past in administering and adjudicating ALJ hearings. These delays were so significant that the American Hospital Association with three other regional hospitals and health-care systems sued the Secretary of the Department of Health and Human Services ("HHS") in May 2014 seeking mandamus to compel the HHS to comply with the statutory deadlines the Medicare Act imposes on the appeals process.

In 2018, the U.S. District Court for the District of Columbia issued a mandamus order directing the HHS to clear the Medicare backlog by the end of FY 2022. However, at the end of the first quarter of 2022, OMHA had 52,641 appeals remain pending, which was down from 60,062 appeals at the end of the fourth quarter of 2021. Due to the significant backlog of Medicare appeals, the average wait time for those provider appeals to be heard in 2021 was 1,259 days, or almost four years.

Notwithstanding, the U.S. District Court acknowledged in an October 26, 2022 Order that HHS had achieved admirable results, and the court modified its original mandamus order such that HHS was required reduce the prior pending backlog by 98% by the end of the second quarter of FY 2023 and ordered the parties to submit a new status report on April 7, 2023 setting forth the backlog-reduction percentage as of March 30, 2023 and a summary of their positions on how the court should proceed with the backlog.

In a Joint Status Report filed on April 7, 2023, the parties stated that the as of March 31, 2023, there were only 663 backlogged cases remaining, which the parties asserted surpassed the Court's 98% reduction target set in its October 26, 2022 Order. As a result of HHS' progress, the Court terminated its original mandamus Order compelling HHS to reduce the backlog and withdrew its supervision over the backlog reduction on April 10, 2023.

After almost 10 years since the litigation began, HHS has essentially eliminated the backlog of Medicare appeals. Providers should continue to expect quick turnaround times between the time a provider files a request for ALJ hearing to the ALJ hearing.

Review of Medicare Payments for OTC COVID-19 Test Kits

From April 4, 2022, until the conclusion of the COVID-19 public health emergency (PHE) on May 11, 2023, the Centers for Medicare & Medicaid Services (CMS) conducted a demonstration project under section 402(a)(1)(B) of the Social Security Amendments of 1967. During this period, Medicare provided coverage and payment for over-the-counter (OTC) COVID-19 tests at no cost to beneficiaries with Medicare Part B, including those enrolled in Original Medicare and Medicare Advantage plans. This initiative represented a shift in Medicare policy, addressing the urgent need for accessible COVID-19 testing during the pandemic.

Under the demonstration, eligible providers and entities were authorized to distribute up to eight U.S. FDA-approved or authorized OTC COVID-19 tests per calendar month to each beneficiary. It is important to note that this quantity limit was specific to OTC tests and did not extend to laboratory-performed COVID-19 tests or other related services. CMS set a fixed national payment rate of $12 per OTC COVID-19 test. If a provider's charge for a test was less than this rate, Medicare would pay the lower amount. Notably, beneficiaries could obtain these tests without a physician's order or supervision, simplifying access to testing.

Participating providers were advised to keep records demonstrating a beneficiary's request for the tests, as failure to provide documentation could lead to CMS recouping payments or taking other administrative actions.

During the demonstration, CMS disbursed approximately $1.1 billion for about 101 million OTC COVID-19 tests to about 8 million Medicare beneficiaries. However, CMS notes this period also saw a rise in health care fraud schemes. The Department of Justice ("DOJ") on April 20, 2023, announced criminal charges against eighteen defendants across nine federal districts in the United States for their involvement in various fraud schemes related to health care services during the pandemic, including the distribution of unsolicited OTC COVID-19 tests. Concurrently, CMS reported taking adverse administrative actions against twenty-eight medical providers for their alleged roles in COVID-19 related schemes. In August 2023, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) announced a work plan to evaluate whether Medicare payments to eligible providers for OTC tests complied with the demonstration's guidelines.

Over the past year, there has been a noticeable increase in audits and overpayment demands associated with the provision of OTC COVID-19 test kits. This trend is expected to continue into 2024, as the OIG is slated to publish its findings

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from the work plan. Providers who participated in the demonstration should be diligent in maintaining documentation of a patient's request for COVID-19 tests, in anticipation of potential audit inquiries. This vigilant approach to record-keeping is essential for providers to demonstrate compliance and avoid potential recoupments or other actions by CMS.

FEP, OPM, and Overpayments — Oh My!

Most, if not all, providers have had the frustrating and unfortunate experience of being subjected to overpayment demands issued by various commercial payors. However, in 2023, commercial payor overpayment demands have added new wrinkle.

Specifically, providers contracted with a commercial payor may have, unbeknownst to them, provided services to members under the commercial payor's Federal Employee Program (FEP) such as Blue Cross and Blue Shield's FEP. While this may seem unremarkable, these FEPs are part of the Federal Employee Health Benefit (FEHB) program, which is administered by the United States Office of Personnel Management (OPM). The OPM contracts with certain fee-for-service carriers like Blue Cross and Blue Shield to provide services to eligible federal employees.

So, why does this matter?

Well, in 2023, many providers received overpayment demands from a commercial carrier about services provided to FEP members under that carrier's FEP. However, though these overpayment demands appear to come directly from the commercial carrier, they are actually issued at the direction of the OPM and subject to federal law governing overpayments and recoupments under the FEHB program. Unfortunately, these laws grant the OPM broad authority to seek repayment for overpayments, including by offsetting a provider's future payments from the commercial carrier even if provider's provider or facility agreement does not allow or speak to such offsetting activity. The OPM's ability to seek recoupment of any alleged overpayments is valid even if the overpayment resulted through no fault of the provider, and such overpayments are not limited to determinations of medical necessity for paid claims.

Some of these audits and later overpayment demands issued at the direction of the OPM have reached a national scale and have resulted in commercial carriers engaging large law firms to assist with overpayment collections across the country. The silver lining for providers subjected to such audits and overpayment demands is that, notwithstanding the government's broad authority to instruct the carriers to conduct these audits and collect any resulting overpayments, the scale of these activities and inherent unfairness associated with the overpayment demands (depending upon the basis for such demand) may cause a pathway to negotiation of a settlement.

Still, the successful resolution of these overpayment demands may depend largely on effective communication with the appropriate parties, and affected providers should contact their legal counsel for assistance should they find themselves in receipt of such an overpayment demand.

The Rise of Data-Driven Audits and Investigations

Over the past year, there has been a notable escalation in the efforts of the Department of Justice (DOJ) and the Centers for Medicare & Medicaid Services' Unified Program Integrity Contractors (CMS UPIC) to conduct informal investigations and audits of health care providers driven by using data analytics, also known as data mining. Data mining involves a thorough collection and examination of a provider's data to identify anomalies that may suggest improper payments, health care fraud, or other types of suspicious activities.

CMS has long acknowledged the critical role of data analysis as an initial step in determining whether patterns in claims submissions and payments point to potential issues. This process identifies statistical outliers in billing patterns that might indicate improper billing or payment. Data analysis is conducted as part of general surveillance and review of submitted claims or in response to specific problem indicators, such as complaints, input from providers or beneficiaries, fraud alerts, reports from CMS, other Medicare Administrative Contractors ("MACs"), or information from independent governmental and non-governmental agencies. CMS provides to the DOJ's Health Care Fraud Unit direct access to its data portal. Utilizing this data, DOJ analysts and UPIC auditors scrutinize billing and other health care data to identify suspicious activities.

The past year has seen an increase in hospice-related investigations initiated through independent data analysis by UPIC auditors or the DOJ, rather than traditional methods like provider, beneficiary, or qui tam relator input. This trend is expected to continue, especially after CMS's announcement on August 22, 2023, regarding its intent to address benefit integrity issues related to hospice care. In the last year, CMS has executed site visits to over 7,000 hospices with the goal of identifying fraudulent actors and mitigating fraudulent activities. Following these site visits, approximately 400 hospices are under consideration for potential administrative action as of mid-August. Additionally, we have seen multiple cases where the DOJ has initiated informal investigations into hospice clients, spurred by these site visits and data analyses that identified outliers.

In light of these developments, we advise hospice clients to exercise increased diligence in maintaining their documentation, particularly in aspects related to determining terminal illness and the basis for recertification. This heightened scrutiny underscores the need for health care providers, especially in the hospice sector, to be vigilant and proactive in ensuring compliance and accuracy in their billing and documentation practices.

A New Shiny Object for CMS – Amniotic Fluid Allograft Injections

One area where many providers – especially orthopedic and podiatry practices and practitioners – have found themselves in CMS's crosshairs is a particular pain management service that utilizes amniotic fluid allograft injections. While amniotic fluid allograft products are not novel in the medical space, their use for treatment of pain, particularly for orthopedic and podiatric conditions and ailments, is a relatively recent trend that the CMS has, unfortunately, targeted.

While many are approved by Medicare for wound care treatment with an assigned HCPCS code classified as a Skin Substitute and Biological, the Food and Drug Administration ("FDA") has not cleared these products as safe and effective for alternative uses, including pain management. Therefore, CMS, through

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the Unified Program Integrity Contractors ("UPICs"), has been aggressively auditing providers who utilized this code at a relatively high rate and issuing overpayment demands for these services, which can amount to hundreds of thousands of dollars depending upon the volume of usage for these products – leaving providers bewildered and searching for answers.

While the FDA has not cleared the use of amniotic fluid allograft products for pain management, and though Medicare has taken the stance it will not cover payment for these services, there are myriad clinical studies and medical literature discussing the benefits and effectiveness of amniotic fluid allograft injections for pain management in orthopedic and podiatric conditions. Still, providers subjected to audits for these services should expect to face an uphill battle and seek legal counsel to help navigate these complex – and potentially expensive – audits.

Understanding RAC Audits

A Recovery Audit Contractor (RAC) is a third-party entity tasked by the Centers for Medicare & Medicaid Services (CMS) to carry out post-payment reviews to identify improper payments within Medicare and Medicaid. RACs play a pivotal role in ensuring billing accuracy and compliance in these government health care programs.

There are two principal forms of RAC audits: automated and complex. An automated RAC audit utilizes advanced data analysis techniques to scrutinize claims data. This process does not necessitate the submission of medical documentation from the provider. Instead, the RAC relies solely on their analysis of the available claims data to make determinations. A complex RAC audit is more involved, requiring health care providers to submit detailed medical records and other relevant documentation. This audit allows the RAC to conduct a thorough review of the provided information to assess the accuracy and legitimacy of the claims. RAC audits have a significant look-back period, extending up to three years from the date a claim was initially paid.

Health care providers who submit claims to Medicare and Medicaid are potential targets for RAC audits. To navigate these audits successfully, providers must ensure they maintain comprehensive documentation of all medical services rendered to patients. This involves not only keeping accurate patient records but also regularly reviewing and auditing these records alongside their own billing processes to preempt any potential discrepancies. Providers should also proactively stay informed about the latest Medicare and Medicaid rules and guidelines, which are subject to frequent changes. Staying informed is crucial to ensuring compliance and to reduce the risk of unfavorable outcomes during RAC audits.

Concluding Thoughts

The government audit trends that appeared in 2023 do not seem likely to disappear in the near future. Therefore, providers should begin proactively preparing for potential audits in these areas by working with their internal compliance teams and legal counsel to help identify potential risks and develop strategies to navigate through audits and overpayment demands relating to the same. Fortunately, affected providers can expect their appeal timelines to be drastically reduced compared to recent years following the end of the Medicare appeals backlog.

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Save the Date

HDC Quarterly Market Update Webinar
January 9

2024 Medical Staff Virtual Conference - Part 1
February 2

Part 7: Round Table – Questions from our clients
February 6

2024 Medical Staff Virtual Conference - Part 2
February 9

2024 Medical Staff Virtual Conference - Part 3
February 23

Reimbursement Summit
February 26-27

2024 Medical Staff Virtual Conference - Part 4
March 1

2024 Medical Staff Virtual Conference - Part 5
March 8

Pharmacy Law Summit
April 16

Healthcare Dealmakers
May 22-23

About Polsinelli's Reimbursement Practice

Polsinelli's Reimbursement Institute was created in an effort to continuously track changes within the industry as well as analyze the implications of those changes more easily and effectively. In providing a single source of news, information and other resources, the Reimbursement Institute is intended to serve as a valuable reference to Polsinelli clients as they navigate the channels of Medicare and Medicaid reimbursement.

Understanding the nuances of Medicare and Medicaid reimbursement is one of the greatest challenges that providers face in today's quickly changing health care world. The reimbursement process can be long and arduous, and can change often, as described in this quote:

> *"There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase."*
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> — Rehab. Ass'n of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir.1994).

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