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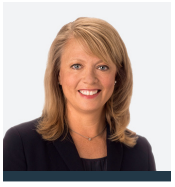
Health Care Reimbursement and Payor Dispute Update

POLSINELLI REIMBURSEMENT TEAM NEWSLETTER

Medicaid Enrollment Overtakes Medicare – But Challenges are Around the Corner



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Continuous Enrollment Ends April 1, 2023

Providers who serve Medicaid beneficiaries will face three significant issues over the next several years as Medicaid policy implemented in response to the COVID-19 Public Health Emergency (PHE) winds down in 2023: elimination of Medicaid coverage for millions of beneficiaries, coordination of benefits risk, and new financial pressures on States to fund Medicaid will increase regulatory scrutiny and financial risk for Medicaid providers.

Recent figures from the Centers for Medicare and Medicaid Services (CMS) show that as of August 2022, the number of individuals enrolled in Medicaid exceeded the number of individuals enrolled in Medicare by more than 25 million. In states that expanded Medicaid with the Affordable Care Act, Medicaid is likely to be one of the largest payors in that state.

During 2020, 2021, and, 2022, Medicaid enrollment grew to historic levels. The Families First Coronavirus Response Act, passed in response to the PHE, increased federal Medicaid funds to states in exchange for continuous enrollment of all Medicaid beneficiaries. Any individual who was enrolled in Medicaid during or after March of 2020 has enjoyed continuous Medicaid enrollment without redetermination of eligibility and potential loss of Medicaid enrollment. When continuous enrollment ends on April 1, 2023, states will again be required to redetermine an individual's eligibility for Medicaid. The Department of Health and Human Services ("HHS") estimates approximately 9.5% of Medicaid enrollees (8.2 million people) will lose eligibility, and another 7.9% (6.8 million people) could lose Medicaid coverage through "administrative churning" (meaning that those individuals are still eligible for Medicaid but will lose coverage due to administrative hurdles, such as difficulty navigating the renewal process).

Risks for Medicaid providers arising from these changes, and advice to manage that risk, is set forth below.

First, continuous enrollment in Medicaid ends for beneficiaries on April 1, 2023. As stated above, in response to the COVID-19 PHE, Congress increased the amount of federal funds available to states to fund the Medicaid program as long as the State's Medicaid program maintained continuous enrollment for beneficiaries until the end of the PHE. However, Congress recently decoupled increased Medicaid funding and continuous eligibility requirements from the end of the PHE. Consequently, while the PHE declaration may be extended, regular redetermination of Medicaid eligibility will resume soon, resulting in the disenrollment of millions of Medicaid beneficiaries who no longer qualify or face enrollment hurdles.

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State Medicaid programs must begin eligibility redeterminations in February, March, or April 2023, and can initiate policies for disenrollment as early as February 1, 2023, with eligibility terminations effective as soon as April 1, 2023. Redeterminations and renewals must be completed by May 31, 2024. Given the extended compliance time for states and anticipated enrollment churn, providers should be especially diligent when verifying Medicaid eligibility. We also recommend a review of and possible revisions to the assignment of benefits and other patient documents in case a state retroactively determines that a patient was not eligible for Medicaid, or that Medicaid was not the primary payor at the time services were rendered.

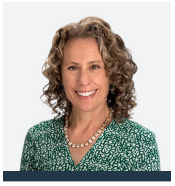
Second, continuous Medicaid enrollment may have resulted in billing mistakes if a Medicaid enrollee obtained new, private health coverage but failed to inform a health care provider during the PHE. Coordination of Benefits rules require Medicaid to be the payor of last resort. We anticipate that State Medicaid Agencies may want to "look back" for claims paid by the Medicaid program when an individual had secured other health insurance coverage through an employer or family member during the PHE. Providers should maintain all insurance documentation in case of future audits or overpayment demands.

In addition to careful insurance verification and documentation, Medicaid providers should consider proactively identifying Coordination of Benefits errors. Timely identification of these errors may permit a provider to affirmatively make Medicaid repayments and receive payment from a patient's new insurance. If providers wait until Medicaid demands repayment for services furnished to a patient who acquired new insurance during the PHE, these repayment demands are likely to be made well past timely filing for any commercial insurance coverage and could result in providers going unpaid for those services.

Finally, Congress is phasing out additional federal funds to states for Medicaid over 2023, renewing pressure on state budgets that could result in provider reimbursement rate cuts. The additional 6.2% of federal funds available since 2020 will only remain through March 2023. Increased federal funds will fall to 5% through June 2023, 2.5% through September 2023, and an additional 1.5% that will expire at the end of December 2023. State policymakers need to be informed about the negative impact of any proposed rate cut on Medicaid providers and beneficiaries at risk of reduced access to care.

Health care providers should reach out to the Polsinelli health care team if they have questions or need assistance planning for the end of the PHE and to avoid or defend Medicaid repayment demands.

Providers Aren't Off the Hook Yet – PRF Audits Have Started



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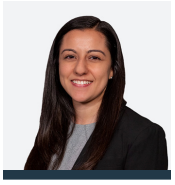

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Providers who have retained and used payments from the Provider Relief Funds (PRF) should begin preparing for an audit if they have not done so already. Throughout 2022, members of Congress have demanded more detailed accounting reports to demonstrate where the COVID funding went and how it was used before allocating additional COVID relief money. In addition to Congress, the New York Times published a few articles throughout the year calling into question whether providers used the funds for the intended purpose and criticized the allocation of funding to providers citing a JAMA Health Forum study. The JAMA Health Forum study concluded the PRF high-impact targeted funding may have disproportionately gone to hospitals that were in a stronger financial situation prior to the pandemic and the funds also were disproportionately distributed to hospitals that had the most cases.[1] With this increased pressure from members of Congress and the media, OIG began auditing providers in the middle of 2022, beginning with nursing homes.

Since the PRF was created, HHS has always indicated that providers who receive and retain payments from the PRF may be audited but did not provide details on when the audits would occur or in what format. Providers now have some idea based on the OIG audits that began in 2022.

Status Current OIG Audits of PRF Payments

OIG is currently auditing nursing homes, and specifically providers who received and retained funding from the Skilled Nursing and/or Nursing Home Infection Control targeted distribution funds during calendar year 2020. OIG's audit sample includes 30 nursing homes that were selected based on the amount of funding received so that the overall sample included providers who received large and small payment amounts from the PRF. To conduct its audit, OIG is requiring providers to complete an initial questionnaire and produce various documentation to substantiate the need for PRFs and how they were maintained and utilized. Further, OIG is interviewing providers regarding their obtaining, maintaining and using PRFs and following up with additional documentation requests pending results from the initial questionnaire and interview. The entire audit process could take over a year to complete. During the audit, OIG is also giving providers the opportunity to offer feedback on HRSA's management and oversight of the PRF as well. At the end of its review, OIG will issue a report—but only to HRSA for review.

Have Providers Increased Their Chances of Being Audited?

Although the OIG has started with nursing homes, other types of providers should be prepared for an audit of its use of PRF funding. As a reminder, HRSA PRF guidance has stated multiple ways providers could increase their chances of being audited, which include, but are not limited to, the following examples:

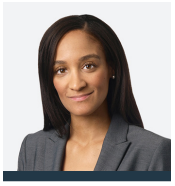
1. Using Option iii (Alternative Method approach) to calculate lost revenue as a use for the PRF payments;
2. Transferring targeted funds to parent entity; and
3. Receiving over $10,000 in either Phase 4 General Distribution or American Rescue Plan Rural Payment funding and reporting a merger or acquisition during the Payment Received Period.

Providers can best prepare for audits by compiling and maintaining documentation in one single stored area that is readily available to produce to the OIG. We recommend providers sort the documentation by years and the applicable requirements published by HRSA at that time as an additional explanation as to the documentation requirements that may be necessary for responses to OIG inquiries. The documentation should clearly be able to demonstrate that the funds were used in accordance with the PRF Terms and Conditions and align with information that was stated in its reports submitted to HRSA.

Polsinelli is available to assist with responding to any audit requests from state or federal agencies and prepare providers to ensure they are compliant to retain the funding.

1 See, JAMA Health Forum, "Association Between COVID-19 Relief Funds and Hospital Characteristics in the US" (Oct. 22, 2021) at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785399?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=102221, accessed Feb. 3, 2023.

Key Takeaways Regarding Telehealth from the 2023 Physician Fee Schedule



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On November 1, 2022, the Centers for Medicare and Medicaid Services ("CMS") issued the 2023 Physician Fee Schedule ("PFS") Final Rule ("2023 Final Rule"), which finalized several key changes, which are summarized below.

Telehealth Flexibilities Extended for 151 Days

The 2023 Final Rule confirmed that Medicare telehealth flexibilities will remain in place for 151 days, or approximately 5 months, following the expiration of the COVID-19 Public Health Emergency ("PHE"). As noted in the 2022 final rule, at the conclusion of the PHE and the subsequent extension period, CMS waivers and interim policies will expire and payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Social Security Act.

Telehealth Telephone E/M Services Discontinued

CMS will discontinue reimbursement for audio-only evaluation and management ("E/M") services, other than for mental health care, following the end of the PHE and the 151-day extension period. Prior to the PHE, Medicare telehealth services required the use of two-way, audio-video telecommunication technology. In early 2020, CMS instituted waivers that allowed for reimbursement of telehealth services furnished using audio-only technology (e.g., telephone), which over the past three years has become particularly prevalent, especially for beneficiaries that lack access to broad-band service or video technology.

In discontinuing the use of audio-only services, CMS highlights that telehealth services, other than mental health services, are required to be analogous to in-person care to serve as a substitute for a face-to-face encounter and as such, two-way, audio-video communications technology is the appropriate standard. Following the end of the PHE and extension period, the only Medicare telehealth services that will be permitted to be furnished using audio-only technology will be the mental health telehealth services.

Telehealth Mental Health Services In-Person Requirements

As noted in prior final rules, CMS implemented certain provisions of the Consolidated Appropriations Act, 2022, including removing telehealth geographic limitations and authorizing the patient's home as a permissible originating site for telehealth services furnished to beneficiaries with a substance use or mental health disorder. Such services require an in-person, non-telehealth visit to be furnished within 6 months prior to the telehealth visit and every 12 months thereafter.

CMS clarifies in the 2023 Final Rule that the initial 6 month in-person visit does not apply to beneficiaries who began receiving mental health telehealth services in their homes during the PHE. If a beneficiary began receiving mental health telehealth services during the PHE or begins receiving mental health telehealth services during the 151-day extension period, the prior 6 month in-person visit requirement will not apply because the individual will be considered an established patient. However, these services will continue to be subject to the requirement that at least one in-person visit be furnished every 12 months.

Virtual Direct Supervision Discontinued

Medicare Part B requires certain types of services (e.g., incident to services, radiation therapy services, diagnostic tests, etc.) to be furnished under the direct supervision of a physician or practitioner, which requires the immediate, in-person and physical, availability of the supervising physician or practitioner, but does not require the physician or practitioner to be present in the room during the service.

CMS temporarily changed the definition of "direct supervision," for certain services during the PHE, to allow the immediate availability of the supervising physician or practitioner through virtual means via real-time audio and video technology. CMS declined to extend or permanently adopt virtual direct supervision and after December 31st of the year in which the PHE ends, the requirement to be immediately available for direct supervision may no longer be met through virtual presence. Importantly, the discontinuation of virtual direct supervisions means that the temporary exception to allow immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners, incident to their professional services, will no longer apply.

General Supervision for Behavioral Health Services Furnished "Incident to"

CMS finalized their proposal to amend "incident to" direct supervision requirements to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner ("NPP"), when these services are provided by auxiliary personnel incident to the services of a physician or NPP. CMS notes that individual practitioners are in the best position to determine whether particular treatments or diagnostic services are behavioral health services. However, generally, behavioral health services include services furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders (e.g., psychotherapy, Screening, Brief Intervention and Referral to Treatment (SBIRT) services, and psychiatric diagnostic evaluations, among others). Auxiliary personnel providing incident to services under general supervision are required to meet all of the applicable requirements to provide such services, including any applicable licensure requirements imposed by the State in which the services are being furnished.

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Remote Therapeutic Monitoring

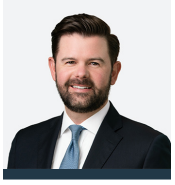
CMS finalized key changes related to remote therapeutic monitoring ("RTM") services. Namely, CMS confirmed that beginning in 2023 all RTM services may be furnished under general supervision. Additionally, CMS opted to not finalize their proposed creation of 4 new HCPCS G-codes (GRTM–1–4). In the 2023 Proposed Rule, CMS discussed creating four new G codes with one pair of codes aimed at increasing patient access to RTM services and the second pair of codes aimed at reducing physician and NPP supervisory burden but based on commentary CMS declined to finalize this proposal.

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

CMS finalized the following changes for FQHCs and RHCs for the 151-day extension period following the end of the PHE:

- Continue payment for telehealth services furnished by FQHCs and RHCs using the methodology established for telehealth services during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the physician fee schedule;
- Delay in-person visit requirements for mental health visits furnished by FQHCs and RHCs;
- Expand the originating site requirements to include any site in the United States where the beneficiary is located, including an individual's home; and
- Extend coverage and payment of telehealth services that are furnished via audio-only communications.

The No Surprises Act in 2022 – Unsettled Issues and All Eyes on Texas Litigation



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The No Surprises Act ("NSA") went into effect on January 1, 2022, which means all individuals with commercial health coverage are protected against "surprise" bills when they receive certain out-of-network ("OON") health care services.[1] However, important unsettled issues remain as to how certain aspects of the NSA should be implemented, many of which are pending in litigation in a federal court in Texas. In this article, we take a look at some of these issues and explore the potential impact the various pieces of NSA litigation might have on OON reimbursement in 2023 and beyond.

Factors Considered During Reimbursement Disputes

The NSA takes patients out of the middle of payment disputes for certain OON services. If a provider wants to challenge the amount an insurer paid, the dispute is resolved in a new independent dispute resolution ("IDR") process administered through CMS where neutrals (known as "IDR entities") decide the appropriate payment amount. Congress set forth multiple factors that IDR entities ***must*** consider when determining appropriate OON rates, like the provider's experience, the patient's acuity, the contracting history between the provider and the insurer, what the insurer typically pays in-network providers for the same service, and other factors. Congress chose not to give any more or less weight to any of these factors. However, in interim final rules[2] issued in July of 2021, IDR entities were instructed to presume that only one of the factors should ultimately dictate the rate: the insurer's "qualifying payment amount" or "QPA" (generally speaking, the median in-network or "INN" rate as unilaterally calculated by the insurer). In other words, the rules imposed a "QPA presumption."

A federal court in Texas ultimately struck down the QPA presumption on a nationwide basis in two cases, one brought by the Texas Medical Association and another by an air ambulance provider, LifeNet. See ***Texas Medical Association, et al. v. U.S. Dept. of Health and Human Serv's, et al.***[3] *("TMA I"); **LifeNet, Inc. v. U.S. Dept. of Health and Human Serv's, et al.***[4] *("LifeNet I").* In short, the court concluded that the federal agencies had rewritten clear statutory terms to "suit [their] own sense of how the statute should operate."

In August of 2022, the agencies went back to the drawing board and released a Final Rule[5] to "make changes" to the IDR process "in light of" the court's ruling in *TMA I* and *LifeNet I*. Under the Final Rule, IDR entities

1 "Surprise" billing sometimes occurs when patients unintentionally receive emergency or non-emergency services from OON providers (i.e., providers who do not participate in the patient's insurance network). Prior to the NSA's enactment, patients often assumed the financial burden for such OON care. While some states have enacted laws addressing this issue in varying ways to protect patients from surprise bills, not all states have. And even those states with existing law on the books are generally unable to regulate many patient encounters, including those encounters with patients who have health coverage under self-funded health benefits plans regulated by the federal Employee Retirement Income Security Act of 1974 ("ERISA"). The NSA addresses this problem on a federal level to "fill the gaps" where states have not enacted (or are unable to enact) laws regulating encounters with patients who have commercial health coverage. Broadly, the NSA does four major things: (1) prohibits balance billing and limits a patient's financial responsibility for certain OON care to the amount for which the patient would be responsible had those services been furnished by in-network providers; (2) requires health plans and issuers to reimburse providers directly for such OON care and resolve reimbursement disputes under a statutory independent dispute resolution process; (3) creates protections for uninsured and self-pay patients and a patient-provider dispute resolution process; and (4) imposes additional transparency requirements.
2 Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021).
3 587 F. Supp. 3d 528 (E.D. Tex. 2022).
4 --- F. Supp. 3d ---, 2022 WL 2959715 (E.D. Tex. Jul. 26, 2022).
5 Requirements Related to Surprise Billing; Part II, 87 Fed. Reg. 52,618 (Aug. 26, 2022).

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were instructed to consider the QPA first, without questioning its credibility, then consider the other statutory factors ***only*** when the QPA does not already "account" for those factors. In other words, the Final Rule imposed a "no double-counting of information rule."

The same plaintiffs from *TMA I* and *LifeNet I* each filed suit a second time, in the same federal court in Texas before the same judge, asserting that the no double-counting of information rule was actually a new QPA presumption. See ***Texas Medical Association, et al. v. U.S. Dept. of Health and Human Serv's, et al.,* 6:22-cv-00372-JDK** (filed Sept. 22, 2022) ("*TMA II*") and ***LifeNet, Inc. v. U.S. Dept. of Health and Human Serv's, et al.,* 6:22-cv-00373-JDK** (filed Sept. 23, 2022) ("*LifeNet II*"). In these cases, the plaintiffs argued that the Final Rule departed from the text and intent of the NSA by inappropriately placing an emphasis on the QPA, just like the "original" QPA presumption in the interim final rules. After the two cases were consolidated, the court issued a ruling on February 6, 2023, and agreed with the plaintiffs a second time.[6] The court concluded that the agencies, when issuing the Final Rule, had "not relinquished their goal of privileging the QPA, tilting arbitrations in favor of insurers, and thereby lowering payments to providers." The court further concluded that the Final Rule improperly restricted IDR entities' discretion by placing an unlawful *de facto* presumption in favor of the QPA. The court explained for a second time that nothing in the NSA instructs the IDR entities to weigh any one factor more heavily than the others.

The court vacated the challenged portions of the Final Rule on a nationwide basis and remanded rulemaking back to the agencies for "further consideration in light of the court's opinion" with the reminder that "[they] may not promulgate a rule that conflicts with the [NSA] or attempt to fill in nonexistent gaps" in the NSA's statutory language. It is currently unknown whether the agencies will appeal this decision. In the meantime, IDR entities must consider all of the statutory factors when determining OON rates without giving a preference to any one factor.

How Insurers Must Calculate Their Median Contracted Rates ("QPAs") for NSA Purposes, When Insurers Must Make Payments to Providers, and Confusion Over How Air Ambulance Claims Must Be Submitted to IDR

While *TMA II* and *LifeNet II* were pending, the same plaintiffs each filed their third lawsuit, in the same federal court in Texas before the same judge, challenging other aspects of the interim final rules.[7] See ***Texas Medical Association, et al. v. U.S. Dept. of Health and Human Serv's, et al.,* 6:22-cv-00450-JDK** (filed Nov. 30, 2022) ("*TMA III*") and ***LifeNet, Inc. et al. v. U.S. Dept. of Health and Human Serv's, et al.,* 6:22-cv-00453** (filed Dec. 1, 2022) ("*LifeNet III*").[8] In these cases, the plaintiffs argue that the interim final rules and other subregulatory NSA guidance violate the text and intent of the NSA in other ways, including:

- **"Ghost Rates" in QPAs.** The NSA requires insurers to calculate the QPA by using the median contracted rate for "the same or similar item or service ***that is provided*** by a provider." However, the interim final rules unlawfully allow insurers to calculate the QPA using contracted rates for services that are not actually ***provided*** by providers with the contracts (i.e., so-called "ghost rates"). For example, an insurer could calculate its QPA for anesthesiology or emergency care using rates that happen to appear in an in-network contract's fee schedule for an office-based primary care doctor, or rates for air ambulance services that for some reason appear in in-network contracts with social workers, optometrists, and psychologists.
- **QPAs Not Calculated by Provider Specialty.** The NSA requires insurers to calculate the QPA using contracted rates from providers in the same or similar specialty. However, the interim final rules unlawfully allow insurers to calculate the QPA using "out-of-specialty" rates if, according to the insurer alone, there is no "material difference" between the rates.
- **QPAs Excluding Important Incentive-Based Payment Adjustments.** The NSA requires insurers to calculate the QPA using contracted rates that represent the "total maximum payment" recognized by the insurer. However, the interim final rules unlawfully require insurers to exclude from their QPA calculations any "risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments," which means the QPA does not include key factors weighing on the true market rate for contracted health care services under typical contract negotiations.
- **QPAs Calculated Using All Contracted Rates Under All Plans of a Third-Party Administrator.** The NSA requires that a health plan calculate its QPA as to all plans "***of such plan sponsor***." However, the interim final rules unlawfully permit self-insured group health plans to calculate QPAs using all of the contracted rates recognized by the plan's third-party administrator.
- **QPAs Calculated Using Rates from Vastly Distinct Geographic Regions.** The NSA requires insurers to calculate the QPA using contracted rates for the same service that are "provided in the geographic region" in which the service at issue was provided. However, in some situations, the interim final rules unlawfully require insurers to calculate the QPA using contracted rates from enormous geographic areas, with economically unique markets that are thousands of miles apart, meaning a contracted rate for an air medical transport in Fairbanks, Alaska, for example, could dictate the QPA for an air medical transport in Los Angeles, California.
- **QPAs Exclude Single Case Agreements.** The NSA requires insurers to calculate the QPA using all of the insurer's "contracted rates." However, the interim final rules unlawfully require insurers to exclude rates agreed to in case-specific or single-case contracts, which are incredibly common methods by which providers and insurers negotiate specific rates.
- **No Meaningful Disclosure About How QPAs Are Calculated.** The NSA requires the agencies to issue rules establishing the information insurers "shall share" with providers regarding their QPA calculation. However, the interim final rules unlawfully require the disclosure of only barebones information that are insufficient and do not serve any meaningful purpose.

6 2023 WL 1781801 (E.D. Tex. Feb. 6, 2023).

7 Most of the rules challenged in these third lawsuits were those found in the interim final rules published in July of 2021. See **Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,872 (July 13, 2021)**.

8 Polsinelli represents two of the plaintiffs in LifeNet III, and we make no comments regarding the case or its potential outcome beyond the information contained in the public record.

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- **Deadline for Insurers to Make Payments to Providers.** The NSA requires an insurer to make an "initial payment" on claims for services subject to the NSA within 30 calendar days after the provider "transmits" its "bill" to the insurer. However, the interim final rules unlawfully changed this deadline by stating that the initial payment is due 30 calendar days after "the date the [insurer] receives the information necessary to decide a claim for payment for the services," with no mechanisms to avoid "abuse and gaming" by insurers to delay payment.
- **Air Ambulance Claims at IDR.** The NSA allows a single dispute over the amount of payment for a single air ambulance transport to be resolved in a single IDR process. However, the agencies' subregulatory guidance issued in August 2022 departed from this directive and instructed IDR entities to separate a payment dispute for a single air ambulance transport into two different IDR process—only because a single air ambulance transport necessarily involves two different billing codes (a base code and a mileagecode).

TMA III and *LifeNet III* have been consolidated and the parties are engaged in briefing on motions for summary judgment. It's likely that a decision will be rendered sometime in 2023.

IDR Administrative Fees and Provider Claim Batching

On December 23, 2022, CMS announced, without any forewarning or an opportunity for affected parties to comment, that the nonrefundable administrative fee that each party to an IDR process must pay (win or lose) would be increased in 2023 by 600%, from $50 to $350. Congress gave the agencies the authority to set the IDR administrative fees through rulemaking and instructed them to associate the fees to "the amount of expenditures estimated to be made by [CMS] for such year in carrying out the IDR process." Under this authority, CMS essentially explained that a fee increase was necessary in 2023 to cover the administrative costs related to conducting IDR eligibility reviews and the significantly greater number of IDRs submitted in 2022 than the agencies predicted,[9] resulting in a serious backlog of IDR cases.

On January 30, 2023, the Texas Medical Association filed its fourth lawsuit, in the same federal court in Texas before the same judge, challenging the administrative fee increase and the correlated rules regarding claim batching at the IDR process. See ***Texas Medical Association, et al. v. U.S. Dept. of Health and Human Serv's, et al.,*** 6:23-cv-00059 (filed Jan. 30, 2023) ("*TMA IV*"). This fourth case argues that the fee increase "not only will make the process significantly more expensive for all IDR participants but will make it cost-prohibitive for many providers to access IDR at all." The suit also argues that the interim final rules' unnecessarily restrictive limitations on claim batching at IDR are to blame, at least in part, for the high volume of IDRs submitted in 2022, and are themselves unlawful because they permit multiple claims to be batched in a single IDR process only when, among other things, the services in dispute involve the ***exact same service code*** (HCPCS, CPT, or DRG), as opposed to involving the "treatment of a similar condition" as specified in the NSA's text.

Stakeholders should watch these cases closely, as they are geared to have a large impact on OON reimbursement under the NSA. For more information and questions related to the NSA, please contact the author.

9 The agencies had estimated that just over 22,000 IDR claims would be submitted each year. See ***Supporting Statement For Paperwork Reduction Act 1995: Independent Dispute Resolution Process***. In fact, between April and September of 2022 alone, almost nearly 100,000 claims had been submitted to IDR. See **Initial Report on the Independent Dispute Resolution (IDR) Process April 15–September 30, 2022**.

340B 2022 Year-End Review: What Covered Entities Should Do in 2023 to Maximize 340B Savings

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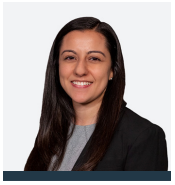

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2022 proved extremely volatile for the 340B Program. Looking forward to 2023, covered entities should be strategizing and acting, where they can, to recoup and preserve 340B savings. We've summarized 4 significant 340B topics for covered entities and provided suggestions on seeking and preserving 340B savings.

1. OPPS Challenges and Opportunities

In a victory for 340B hospitals this past summer, the United States Supreme Court ruled that CMS exceeded its authority when implementing its discriminatory reimbursement policy of ASP minus 22.5% on Part B drugs and biologicals for 340B hospitals. SCOTUS did not discuss the issue of remedies for the years that the unlawful reimbursement policy applied, and it also did not address Medicare Advantage (MA) underpayments resulting from CMS's unlawful policy, among other matters. The case has since been remanded to the United States District Court for the District of Columbia where the Court ruled in the fall that CMS must revert to its old reimbursement policy of ASP plus 6% for remainder of 2022, even though CMS announced in its proposed rule that it intends to revert to ASP plus 6% for CY 2023.

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Right now, 340B hospitals should be acting to seek adjustments to their Part B 340B drug claims with dates of service pre-9/28/2022, while preparing a comprehensive dispute strategy to seek MA plan underpayments for 340B drugs. Depending on the type of 340B hospital, MA plan contract terms, and local MA plan penetration, there may be avenues to recover substantial MA plan underpayments. This includes both in-network and out-of-network MA claims. Our 340B Drug Pricing Program and Managed Care & Payor Disputes groups have teamed up to represent health systems in their pursuit of Medicare and MA plan underpayments.

2. Manufacturers Continue to Increase Profits through Contract Pharmacy Restriction Policies

There are currently 18 manufacturers who have implemented a contract pharmacy restriction policy with most of the manufacturers applying an unlawful condition of requiring covered entities to submit claims data through 340B ESP to restore access to 340B pricing. There is ongoing litigation in multiple circuits dealing with these policy restrictions. All oral arguments were heard in the Fall of 2022, so stakeholders are anxiously awaiting the resulting opinions.

As this saga continues, covered entities should be documenting damages accruing due to the manufacturer policies, logging disputes with the manufacturers and HRSA, and considering pursuit of claims through HRSA's Administrative Dispute Resolution ("ADR") process. As with all matters where damages accrue over extended periods of time, covered entities should not take the administrative process for granted as failure to act could significantly reduce recovery down the road. Building a few processes and acting on those processes now could preserve a covered entity's right to substantial recovery in the long-term. Covered entities should be aware that HRSA's ADR process does include a statute of limitations period of 3 years from the date of the alleged 340B program violation. Be advised that several of the original manufacturer restriction policies will soon approach the 3 year period.

3. HRSA Administrative Dispute Resolution Proposed Rule

In late November, HRSA issued its highly anticipated refreshed ADR proposed rule. Near the close of 2021, HRSA indicated its intent to publish a new ADR proposed rule as soon as January 2022, but covered entities waited almost the entire year for the new processes to be proposed. The proposed rule states that the providers who have already submitted claims under the old ADR process will automatically be transferred to the new ADR process. In addition to comments on the new ADR process generally, HRSA is seeking comments on the following topics:

- Minimum threshold amount, if any, to file an ADR claim
- Whether ADR should be limited to certain types of claims
- Automatically suspend ADR claims that involve issues pending in federal courts

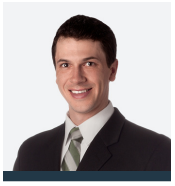
Covered entities should be watching this development closely as the ADR process is the only clear and formal path to air 340B grievances with manufacturers. Covered entities should comment on any of the specific requested topics or on the ADR processes generally in order to maintain an optimal path to resolve 340B program disputes.

4. The *Genesis* Case Calls into Question the Patient Definition

Many covered entities are looking forward to the outcome of the ongoing *Genesis* case because many believe that the case could expand the patient definition if the Court strikes down HRSA's current definition. In that scenario, it's possible that the 340B statutory language would control unless HRSA or Congress take action to develop a new patient definition. Currently, the 340B statute only makes one reference to the word "patient" which may explain covered entity optimism that *Genesis* could optimize program use while reducing administrative and compliance burdens. The statute reads: "With respect to any covered outpatient drug that is subject to an agreement under [340B], a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B).

Fortunately, covered entities do not have to wait for the Court to issue an opinion in *Genesis* to implement models that make use of the 340B program under their current policies regarding patients that qualify for 340B. Polsinelli has assisted many providers with navigating federal and state laws when implementing new models that utilize the current patient definition. We've assisted hospitals who utilize telehealth, advance practice pharmacists and others who are empowered by state law to issue prescriptions, and changes to employee benefit plan structures to qualify additional patients as 340B-eligible patients.

CMS Issues Proposed Rule Aimed at Improving the Medicare Advantage Program



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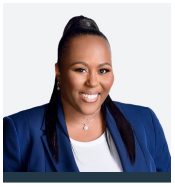

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In July 2022, the Centers for Medicare & Medicaid Services (CMS) solicited information and comments from the public regarding ways in which the Medicare Advantage (MA) program could be improved and strengthened. After reviewing nearly 4,000 comments, CMS responded by introducing a proposed rule on December 14, 2022 that would significantly revise MA rules for Contract Year 2024.[1] Some of the major changes focus on utilization management, plan marketing, and the overpayment rule, which has been the subject of recent litigation. Other key changes focus on increasing beneficiary protections, as well as advancing health equity and access to behavioral health services in the MA space. These changes, among others, collectively make the proposed rule the most impactful policy change that CMS has introduced to the MA program in many years.

The Use of Prior Authorizations and Their Impact on Access to Care

CMS proposes to increase transparency of MA plans' utilization management and prior authorization policies, with several regulatory changes that will address concerns that CMS has received in recent years. Specifically, the proposed changes would impact how and when MA plans develop and use coverage criteria and utilization policies, including how MA plans use prior authorizations that may impact beneficiaries' access to care. CMS proposes the following changes:

1. MA plans' policies on prior authorizations for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards set forth in the rule.
2. Prior authorizations will be valid for the duration of the approved course of treatment and MA plans must provide a minimum 90-day transition period when a plan member, who is currently undergoing treatment, switches to a new MA plan.
3. When making medical necessity determinations, MA plans must follow traditional Medicare coverage statutes and regulations interpreted by CMS, in addition to manuals and other instructions.
4. MA plans cannot deny coverage of an item or service traditionally covered by Medicare, based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. However, if there no applicable criteria in Medicare coverage statutes and regulation, MA plans may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature. But the MA plans must provide CMS, plan members, and providers with a summary of the evidence considered.
5. To ensure prior authorizations are being used appropriately, MA plans must establish utilization management committees to review all policies annually and ensure the policies are consistent with current, traditional Medicare coverage policies.

Addressing Network Adequacy for Behavioral Healthcare Services

In an effort to strengthen system capacity and connect more individuals to behavioral healthcare services in the MA program, CMS proposes some of the following changes: add Clinical Psychology Licensed Clinical Social Workers as a professional type subject to CMS network adequacy review, codify standards for appointment wait times for behavioral health services, clarify that prior authorization may not be imposed for behavioral health services that qualify as emergency services, and require MA plans to establish care coordination programs, including coordination of community, social, and behavioral health services to help move towards parity between behavioral health and physical health services and advance whole-person care.

Disclosure of Certain Marketing Information to Enrollees and Plan Marketing Standards

The proposed rule seeks to strengthen beneficiary protections regarding marketing to ensure beneficiaries are not misled. Some of the proposed changes include notifying enrollees annually, in writing, of the ability to opt-out of phone calls regarding MA and Part D plan business, requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage whenever the enrollee makes an enrollment decision, prohibiting marketing of benefits in a service area where those benefits are not available, requiring third-party marketing organizations to list or mention all of the MA plans or Part D sponsors that they sell, and requiring MA plans and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS.

A New Standard to Identify Overpayments That Aligns With the FCA's Knowledge Standard

The applicability of the current standard of "reasonable diligence" within the "overpayment rule" for MA plans has been the subject of recent litigation.[2] In response, the proposed rule would amend the existing regulations for Medicare Parts A through D, with respect to the standard for an "identified overpayment." The proposed changes would align the regulations with the False Claims Act (FCA) and provide that the terms "knowing" and "knowingly" have the same meaning given those terms under the FCA. As a result, MA plans and Part D sponsors

1 https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
2 See, *UnitedHealthcare Ins. Co., v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022).

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will have identified overpayments when they have actual knowledge of the existence of the overpayments, or when they act in reckless disregard or deliberate ignorance of the overpayments. Importantly, the proposed rule does not resolve existing ambiguity regarding the application of the FCA to providers or pharmacies billing MA plans or Part D sponsors.

Advancing Health Equity in Medicare Advantage

CMS is proposing changes that will address health disparities in the MA program, which could also be essential to more broadly supporting other equity-focused efforts across CMS policies and programs. In an effort to ensure equitable access to MA services, CMS proposes the following changes:

- Clarify the broad application of how MA plans should provide services to certain populations in a "culturally competent" manner, i.e., persons with limited English proficiency; ethnic, cultural, racial, or religious minorities; disabled persons; and persons of diverse sexual orientations and gender identities.
- Require MA plan directories reflect providers' cultural and linguistic capabilities and notate Medications for Opioid Use Disorder-waivered providers.
- Require that MA plans identify plan members with low digital health literacy and offer digital health education to assist them in accessing any medically necessary covered telehealth benefits.
- Require MA plans to incorporate one or more activities into their overall quality improvement program aimed at reducing disparities in health and health care among plan members.

Takeaways and Deadline to Comment

While this proposed rule applies directly to MA plans, many of topics covered have the potential to impact health care providers. MA plans will almost certainly flow down appointment wait time requirements to contracted behavioral health providers, for example. The provider impact on prior authorization requirements is obvious. Health care providers should review the proposed rule and assess whether it presents any financial or operational risk or upside. If the impact in either direction is potentially material, health care providers should consider submitting comments to CMS to consider when finalizing the rule.

Provider-Payor Contracting: Top Five Terms to Focus on in Negotiation or Renewal

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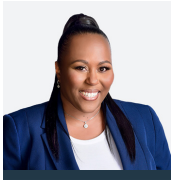

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With the new year, providers and payors may be expending extensive time attempting to agree upon terms for renewals of participation agreements or embarking on new relationships for the coming year. Whether a new or existing relationship, there are key terms of import in any provider – payor agreement warranting attention and protection. These may be driven by a variety of factors including regulatory changes, business changes, revised financial objectives, or the introduction of new benefit products. The following outlines our top five terms of focus for you to consider in your provider-payor relationships and agreements.

1. Products Included

With every arrangement, it is critical to understand the full scope of benefit products and programs included. Large insurers continually add new products and programs, and each contain different operational and/or legal requirements and potentially separate sources of regulation. Common products and programs include HMO, PPO, self-funded ERISA payors, individual/family plans sold on and off the exchanges, Medicaid Managed Care, and Medicare Advantage. Providers should familiarize themselves with the unique requirements of each and ensure their internal processes are sufficient to cover compliance with all products and programs included in an agreement.

2. Amendments and Provider Manual/ Policy Changes

The last several years have revealed consistent attempts by payors to unilaterally modify the terms of agreements – and provider's expectations – through changes made to external provider manuals and payor policies. The impacts of these changes vary but can be significant and material ranging from additional resources necessary to comply with administrative processes to the shifting away of health care services to other providers to decreased reimbursement for contracted services. Changes such as these present an opportunity to negotiate needed changes in your arrangements, but also provide a reminder as to the extent (or limit) of the provider's rights to dispute or challenge such changes. For any new arrangement, providers should seek protections in the form of advance written notice, opportunity to object and negotiate, and potentially a right to terminate the agreement if the change is not agreed upon. Providers should also seek to mitigate past changes implemented that continue to materially impact the provider's operations or reimbursement.

3. Financial Terms & Structure

Compensation methodologies continue to evolve and can differ across different products and programs included within the same agreement. Advanced planning to model different rates and structures is

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important to formulate expectations for the contract's performance and to ensure the negotiated reimbursement is adequate for the services offered by the provider. Further, for providers who are beginning a value-based arrangement – or evolving an existing arrangement to include downside risk – a clear understanding of the mechanics coupled with the necessary administrative support and analytics will be critical to ensuring the arrangement does not result in unnecessary losses for the provider.

4. Term and Termination

The approach for a desired term of an agreement will differ from one provider to another. However, negotiating the appropriate approach for the provider can be the difference between being locked into an unfavorable arrangement or having the freedom to exit when an agreement does not meet expectations or results in losses. Give consideration to the overall length of the arrangement, the time frame in which the arrangement could be terminated without cause, and the operational requirements and timing to facilitate a potential termination.

5. Provider-Specific Objectives

Finally, any agreement or renewal should be approached with an eye toward the future needs of the provider organization. For example, do you anticipate future mergers or acquisitions? Are new locations and facilities being built? If so, advance negotiation of the additions of new facilities or practitioners to an existing agreement may be of high importance. Similarly, if there are future divestitures planned, the ability to assign the agreement to a purchaser may become highly important. Understanding future plans and anticipating the terms needed to effectuate those plans can significantly help ensure future objectives and strategies can be efficiently achieved without unnecessary delays or hurdles.

The success of any arrangement with a payer depends on the preparation and effort put into negotiations. While there are many terms in payer agreements that are significant, placing focus on the five points outlined above will be well spent and put providers on the right path to accomplishing successful arrangements with its payer partners.

Reimbursement Audits and Disputes: What We Learned from 2022 and What to Expect Moving Forward

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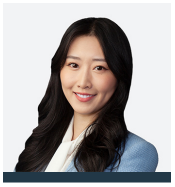

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2022 brought a lot of changes for providers in the audits and reimbursement realm compared with the previous two years, as government contractors appear to have revamped their audit activities following a relative slowdown during 2020 and 2021 due to the COVID-19 pandemic. While we have learned much over the past year, the changes have also shown what we can expect in 2023. This article focuses on three particular areas active in 2022 and what providers can expect in these areas in 2023 – Provider Relief Fund payment scrutiny, updates to the Medicare appeals backlog, and where Uniform Program Integrity Contractors ("UPICs") may turn their attention to next.

American Hospital Association v. Azar: Updates to the Medicare Appeals Backlog

As many providers throughout the United States know, the Office of Medicare Hearings and Appeals ("OMHA"), which oversees appeals relating to Medicare audits and overpayments, has encountered significant delays over the past several years in administering ALJ final hearings. At the end of the first quarter of 2022, OMHA had 52,641 appeals 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.

Unfortunately, this backlog is not new to providers. Previously, in *American Hospital Association v. Azar*, the American Hospital Association with three other regional hospitals and health-care systems sued in May 2014 seeking mandamus to compel the HHS Secretary 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.

While the HHS was unsuccessful in eliminating the backlog by the end of 2022, the U.S. District Court recently acknowledged in an October 26, 2022 Order that HHS had achieved admirable results, and as a result, the court modified its original mandamus order such that HHS is required reduce the prior pending backlog by 98% by the end of the second quarter of FY 2023. The court further 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.

Providers should continue seeing reductions in processing times for their new Medicare appeals, and to the extent they have any longstanding appeals awaiting scheduling for ALJ hearings, providers can expect those to be adjudicated sooner rather than later. Notwithstanding, for those providers seeking an alternative to waiting for an ALJ hearing, OMHA's Settlement Conference Facilitation ("SCF") option is available for requests for hearing filed by November 3, 2017 by Part A or Part B providers or suppliers with: (1) 25 or

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more SCF-eligible appeals pending at OMHA and the Medicare Appeals Council, combined; or (2) Fewer than 25 SCF-eligible appeals pending at OMHA or the Medicare Appeals Council, and at least one appeal has more than $9,000 in billed charges.

UPICs Vow to Increase Scrutiny for Medicaid Providers; OIG Concludes Challenges Remain

A September 2022 report from the HHS OIG found that UPICs conducted substantially more Medicare fee-for-service audits in 2019 compared to that for Medicaid and conducted only minimal activities related to Medicaid managed care, even though most Medicaid enrollees receive services through managed and Medicaid spending exceeded Medicare FFS spending by approximately $147 billion. Specifically, UPICs' Medicaid activities accounted for less than 25 percent of UPICs' program integrity activities Overall, the OIG concluded that UPICs conducted disproportionately fewer Medicaid activities compared to the levels of funding they received from CMS for Medicaid program integrity activities and found wide unexplained disparities in program integrity activities across UPICs, even after adjusting for the size of their respective oversight responsibilities. OIG recommended that the CMS and UPICs implement a plan to increase the UPICs' Medicaid program integrity activities, particularly those related to managed care.

CMS and UPICs have since stated that they have laid a foundation for improvements, including the development of collaborative processes, analytical tools, and new technologies such as the Unified Case Management (UCM) system and Major Case Coordination (MCC) initiative. Every UPIC indicated that the level of Medicaid managed care work has increased since 2019, which they contend is due in part to improved relationships with the States, including more access to managed care data and the States' willingness to allow UPICs to conduct work within Medicaid managed care. While limitations with obtaining state Medicaid data are a hurdle that remains for UPICs, UPICs hope that regular MCC meetings will help them overcome these challenges.

Based on the OIG's report and the UPICs' comments, providers should expect Medicaid audits to increase which means increased time and resources that must be dedicated to implementing and maintaining adequate documentation processes for Medicaid services, responding to medical records requests, and appealing adverse UPIC Medicaid audit findings. Providers should remember that UPICs are only one piece of program integrity network by both the States and Federal government, which also includes State Medicaid program integrity units, Medicaid Fraud Control Units, and Special Investigation Units within Medicaid managed care plans.

Providers Should Be Wary of Increased Audit Activity Across the Board in 2023

Providers should be bracing for increased audit activity by across the board this upcoming year, including heightened scrutiny relating to Medicaid services. Providers should ensure they have adequate policies and procedures in place to review documentation relating to these areas to ensure compliance with applicable rules and guidance and identify any potential issues that may necessitate voluntary refunds and/or improvement in provider practices. Providers should also be prepared for a flurry of activity relating to new or pending Medicare appeals as HHS continues its push to eliminate the appeals backlog by early next year.

Changes in Clinical Research Reimbursement Present New Opportunities and New Risks for Academic Medical Centers

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Tucked inside the omnibus Consolidated Appropriates Act passed by Congress on December 21, 2020 was the Clinical Treatment Act, which included a requirement that beginning January 1, 2022 "routine costs" during "qualifying clinical trials" must be covered for all Medicaid beneficiaries.[1] Intended to increase equitable access and diversity in clinical trial participation, the expansion of clinical research reimbursement for Medicaid beneficiaries creates new opportunities for academic medical centers (AMCs) to expand their research patient population base and trial enrollment, and by doing so increase clinical research related revenue. Yet with this increased opportunity for AMCs to grow their clinical research programs also comes a corresponding increase to the associated risks related to clinical research billing.

At the same time, in April of 2022 the Department of Justice (DOJ) Consumer Protection Branch (CPB) published its first ever recent highlights report, in which it underlined the CPB's recent work and continued prioritization of clinical trial fraud. The CPB report comes on the heels of Deputy Assistant Attorney General Arun G. Rao's remarks on December 9, 2021 highlighting the DOJ's continued prioritization of clinical trial fraud as a key focus for future enforcement actions; noting that the DOJ expects to bring further actions on clinical trial fraud.

As reported by the Centers for Medicare & Medicaid Services (CMS), the latest enrollment figures for Medicaid, Medicaid now includes approximately twenty-million more enrolled beneficiaries than Medicare, with all but eleven states expanding Medicaid access.[2] At the same time, these enrollment numbers are complicated by the fact that during the COVID-19 Public Health Emergency (PHE) the Families First Coronavirus Response Act (FFCRA) included provisions that required states to provide continuous coverage for Medicaid enrollees, meaning that states were prohibited from disenrolling people from coverage until the PHE is over.[3] However, an individual who enrolled in Medicaid at the beginning of the PHE may now be employed with separate insurance coverage. This creates an added layer of complexity for clinical research billing compliance, as Medicaid is always the payor of last resort. As such, if an AMC bills Medicaid for routine costs associated with a clinical trial for a beneficiary that now has separate insurance, any payment received from Medicaid may be at risk. As of the writing of this article, the PHE is slated to end on May 11, 2023, leaving states to quickly develop plans for how they will unwind the Medicaid continuous enrollment requirement and resume routine operations following that date.

The clinical research billing operations for most AMCs rightly follow Medicare rules for determining coverage for items and services provided in connection with a clinical trial. Under the Medicare Clinical Trial Policy (CTP), known commonly as National Coverage Determination (NCD) 310.1, Medicare covers routine costs (defined as items or services that are conventional care, for the administration of the investigational item, or for the detection or prevention of complications) for qualifying clinical trials.[4]

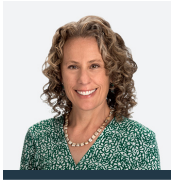
The new Medicaid regulations similarly require coverage of routine costs during qualifying clinical trials but define the terms "routine cost" and "qualifying clinical trial" differently from Medicare. Under the Medicaid definition, routine costs only include items and services that are required for the administration of the investigational item, or for the detection, prevention, or management of complications.[5] Unlike the Medicare definition, the Medicaid definition of routine costs does not include items and services that are considered conventional care. Similarly, the definition of a "qualifying clinical trial" under the Medicaid regulations requires that the study must enroll patients with a "serious or life-threatening disease or condition," contrasted with the broader definition under the CTP that requires only that the study enroll patients with a "diagnosed disease."[6]

The cumulative effect of the differing definitions under Medicaid is that, as written, fewer studies and fewer items and services will qualify for coverage for Medicaid beneficiaries as compared to Medicare beneficiaries. That said, the new Medicaid regulations only set the minimum, and some state legislatures may choose to add greater clinical trial coverage. Due to fact that Medicaid regulations will be enacted individually by each state, there will naturally be a level of variability among states regarding which clinical trials and which items and services will qualify for coverage. As such, AMCs should carefully evaluate new state regulations related to clinical research billing and must now incorporate both Medicare and Medicaid regulations into their clinical research billing operations and policies.

After a period of relative quiet during the COVID-19 pandemic, recent changes to clinical research reimbursement for Medicaid beneficiaries combined with the added complexities associated with the Medicaid continuous enrollment requirements during the PHE and renewed focus from the DOJ and OIG on clinical trial fraud should serve as a stark reminder to all AMCs of the need to reevaluate their clinical research billing policies and procedures, and take proactive steps to address coverage risks. Taken together, these changes represent new opportunities for AMCs to expand their research portfolios and revenue, but also pose new and more complex risks for unintentional research related overpayments.

1 Public Law No: 116-260, Sec. 210.
2 Centers for Medicare & Medicaid Services, Access to Health Coverage (November 29, 2022).
3 Families First Coronavirus Response Act (FFCRA), Pub.L. 116–127.
4 Medicare Clinical Trial Policy (CTP), Pub. L. 100-03, Sec. 310.1.
5 42 U.S.C. § 1396d(gg)(1).
6 Id. at § 1396d(gg)(2).

Select Highlights of FY 2023 Inpatient Prospective Payment (IPPS) Rule



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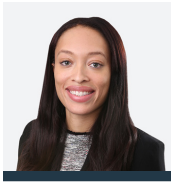

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Conditions of Participation (CoP) Requirements for Hospitals and Critical Access Hospitals (CAHs) Pandemic Reporting

In 2020, CMS adopted a CoP requiring hospitals and CAHs to submit certain data related to COVID-19 (e.g., number of staffed beds, supply information, count of patients with COVID-19, inventory of COVID-19-related therapeutics) and other acute respiratory illnesses (e.g., Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) to the Department of Health and Human Services (HHS). While the CoP was written to expire at the conclusion of the COVID-19 public health emergency (PHE), CMS has decided to extend pandemic reporting obligations and adopted revisions to decrease the number of data categories that hospitals and CAHs are required to report. CMS removed suspected COVID-19 infections among patients and staff as well as several categories relating to COVID-19 and influenza infections among staff. The revisions will apply upon conclusion of the COVID-19 PHE and continue until April 30, 2024, unless the Secretary establishes an earlier ending date.

Hospital-Acquired Conditions (HAC) Reduction Program

Recognizing the continued impact of COVID-19 on hospitals, CMS will not penalize any hospitals under the HAC Reduction Program. For FY 2023, CMS will suppress the CMS PSI 90 measure and the five CDC National Healthcare Safety Network (NHSN) Hospital-Acquired Infection (HAI) measures from the calculation of measure scores and Total HAC Score. CMS will continue to calculate and report CMS PSI 90 measure results through the Compare tool, however. Beginning with the FY 2023 Program Year, CMS also updated the measure specification to the minimum volume threshold for the CMS PSI 90 measure. For the FY 2024 HAC Reduction Program Year, CMS (1) has updated the measures specifications to risk-adjust for COVID-19 diagnosis in the CMS PSI 90 measure, (2) has updated the NHSN CDC HAI data submission requirements for newly opened hospitals, and (3) will suppress CY 2021 CDC NHSN HAI measures data.

Hospital Value-Based Purchasing Metrics

In further recognition of the ongoing impact of COVID-19, for FY 2023, CMS will also suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (NQF #0166), as well as five HAI Outcome Measures: (1) NHSN Catheter-Associated Urinary Tract Infection (NQF #0138), (2) NHSN Central-Line-Associated Bloodstream Infection (NQF #0139), (3) American College of Surgeons- Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (NQF #0753), (4) NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus Bacteremia (NQF #1716), and (5) NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (NQF #1717). CMS will also update the baseline periods for these and other measures for the FY 2025 year. Hospitals will not receive Total Performance Scores (TPSs) this year due to revisions to the scoring and payment methodology for the FY 2023 program year. To account for this, each hospital will be awarded a value-based incentive payment equal to the amount withheld for the fiscal year (two percent).

Hospital Quality Reporting

Aside from the above suppression measures and adjustments, CMS also adopted ten new measures for the Hospital Inpatient Quality Reporting (IQR) Program, including several electronic clinical quality measures (eCQMs). Specifically, CMS added the following new measures: (1) Hospital Commitment to Health Equity, (2) Screening for Social Drivers of Health, (3) Screen Positive Rate for Social Drivers of Health, (4) Cesarean Birth eCQM, (5) Severe Obstetric Complications eCQM, (6) Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e), (7) Global Malnutrition Composite Score eCQM (NQF #3592e), (8) Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559), (9) Medicare Spending Per Beneficiary (MSPB) Hospital measure (NQF #2158), and (10) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550). The measures have various implementation timelines, with reporting periods beginning as early as CY 2023 and payment determination impacts as early as FY 2024.

Hospital Readmissions Reduction Program

CMS made several changes to the Hospital Readmissions Reduction Program, including the resumption of the previously-suppressed Pneumonia Readmission Measure (with an exclusion of patients with a COVID-19 diagnosis) and other technical updates intended to address readmissions for patients with a clinical history of COVID-19.

Graduate Medical Education (GME) Changes

Following the May 2021 D.C. District Court's decision in Milton S. Hershey Medical Center, et al. v. Becerra, CMS is adjusting the FTE cap effective for cost reporting periods beginning on or after October 1, 2001. Specifically, if a hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also

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exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. On the other hand, if the number of weighted FTE residents does not exceed the FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count. This change applies retroactively to all open cost reports, but will not be used as a basis for reopening any cost reports.

Disproportionate Share (DSH)

With respect to the DSH calculation, CMS did not finalize prior proposals related to the treatment of Medicare Advantage days and Section 1115 Waiver days in the Medicaid fraction. CMS likely will address these proposals in future year final rules.

CMS continues to reduce the uncompensated care payments through several mechanisms. First the Factor 1 amount is $10.46 billion, $27 million less than the final Factor 1 for FY 2022. Second, for Factor 2, CMS finalized the nationwide uninsured rate at 9.2%. Third, the overall pool of funds for uncompensated care in 2023 decreased by $300 million from 2022.

Highlights from Outpatient Prospective Payment System/ Ambulatory Surgical Center Final Rule

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In the Calendar Year (CY) 2023 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 3.8% (higher than the 2.7% initially proposed for 2023). Despite these increases, CMS will also apply several adjustments – most notably a 3.09% reduction to non-drug services under the OPPS to maintain budget neutrality under the 340B drug pricing program.

Below we highlight additional policy updates from the Final Rule. The full Final Rule, released on November 1, 2022, is available here.

1. Rural sole community hospital (SCH) clinic visit payment policy

Since 2019, CMS has paid for off-campus hospital outpatient clinic visits (HCPCS code G0463) at a site-neutral rate intended to approximate payment in a freestanding practice. In the Final Rule, CMS finalized its proposal to exempt rural SCHs from this site neutrality policy. In effect, rural SCHs with "excepted" status will be paid at the full OPPS payment rate for clinic visits, rather than the site-neutral rate which is 40% of the OPPS payment rate.

2. Drugs and Devices

Discarded single-dose drugs (JZ modifier)

Pursuant to the Infrastructure Investment and Jobs Act, drug manufacturers refund CMS for discarded amounts from a refundable single-dose container or a single-use package drug. Beginning on January 1, 2023, manufacturers must use the HCPCS modifier "JW" to report the amount of discarded drug or biological. Moreover, beginning on July 1, 2023, manufacturers must use the "JZ" modifier to report cases in which no billing units of such drugs were discarded. Medicare Administrative Contractors will begin claims edits for the JW and JZ modifiers in October 2023.

Pass-through policies for drugs and devices

CMS currently provides transitional pass-through payments for certain new drugs, biologicals, and devices, with the goal of ensuring adequate payment while CMS collects data necessary to include costs under applicable packaged OPPS rates. For CY 2023, CMS received eight applications for device pass-through payments and approved four for transitional pass-through payments beginning January 1, 2023. In the Final Rule, CMS also announced that it will not provide any extension for technologies for which the transitional pass-through period is set to expire on December 31, 2022.

Skin substitutes

CMS will eliminate HCPCS code C1849, which is the code that reports the usage of synthetic skin substitute products. Henceforth, providers will use product-specific HCPCS codes. Furthermore, CMS will retain its methodology for categorizing skin substitutes into high-cost and low-cost groups based on certain thresholds (e.g., geometric mean unit, per-day cost). Finally, citing the broadness of the term "skin substitutes," CMS announced a forthcoming Townhall in early 2023 to discuss future terminology, such as "wound care management" or "wound care management products."

3. Organ procurement and research

Certain hospital services provided to donors whose death is imminent will now be covered as organ acquisition costs, based on a stated effort to "promote organ procurement and enhance quality." Additionally, transplant hospitals and organ procurement organizations will have more flexibility in

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how to account for organ acquisition costs to align with the organization's normal accounting methods.

4. Prior authorizations for facet joint interventions

For services on or after July 1, 2023, hospital outpatient departments must now seek prior authorization for facet joint interventions. The new facet joint interventions service category includes facet joint injections, medial branch blocks, and facet joint nerve destruction.

5. COVID-19 PHE updates

The COVID-19 Public Health Emergency (PHE) ushered in significant flexibilities in coverage and payment for hospital outpatient and ASC services. Over the past two years and most recently in the Final Rule, CMS has permanently adopted some of these flexibilities.

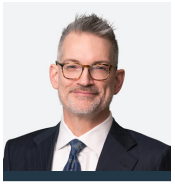
Permanent - Remote behavioral health services. Under the Final Rule, CMS will permanently treat hospital outpatient department remote behavioral health services as covered outpatient services paid under the OPPS. [For additional detail, see the [separate telehealth update] in this Year End Review].

Permanent - Diagnostic test supervision by Non-Physician Practitioners (NPPs). At the PHE onset, CMS implemented flexibilities for the types of practitioners authorized to supervise outpatient diagnostic tests. In the Final Rule, CMS clarified its policy that NPPs (including nurse practitioners and physician assistants) may continue to supervise certain diagnostic tests consistent with their scope of practice and applicable state law. CMS also extended flexibility for virtual supervision of outpatient diagnostic services from the end of the PHE to the end of the calendar year in which the PHE ends.

Permanent - IPPS/OPPS payment adjustments for PPE/N95 Respirators. Recognizing the strain on hospitals from shortages of N95 respirators at the onset of the PHE, beginning for cost reporting periods on or after January 1, 2023, CMS will provide payment adjustments to hospitals under the OPPS and IPPS for additional costs to acquire domestically manufactured, National Institute for Occupational Safety and Health-approved surgical N95 respirators.

Unwind - Although several of the PHE-related flexibilities are now permanent, many flexibilities will end with the PHE. Chief among unwinding considerations for many hospitals will be PHE "Hospital Without Walls" flexibilities. As a PHE response, CMS permitted hospitals to furnish services in temporary expansion sites, including new or re-located provider-based departments. CMS also permitted ASCs to temporarily enroll as hospitals to address hospital capacity needs. The Biden Administration announced recently that the PHE will be continued until May 11, 2023. Providers relying on flexibilities that have not been adopted on a permanent basis should start unwinding with that date in mind. We will publish additional guidance related to the end of the PHE in the coming weeks.

Medicare Physician Fee Schedule / Medicare Shared Savings Program



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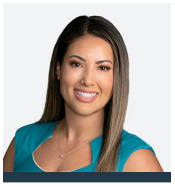

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CMS published the Calendar Year 2023 Medicare Physician Fee Schedule and Medicare Shared Savings Program final rule on November 1, 2022 (87 Fed. Reg. 69404). The MPFS final rule establishes payment and relative value unit assignments for services provided by physicians and other Medicare suppliers. In addition, the MPFS includes payment policies for specific services and specific types of suppliers. The MSSP final rule advances CMS' overall value-based care strategy of growth, alignment, and equity. Below is a brief discussion of key elements in the MPFS and MSSP final rule for 2023.

Evaluation and Management Visits

- CMS adopted in large part the AMA's revised coding and documentation framework for certain E/M visits, including hospital inpatient, hospital observation, emergency department, nursing facility, home or residence services, and cognitive impairment services. These revisions are generally consistent with the changes made in previous years to office and outpatient E/M services, including:
  - New descriptor times (where relevant);
  - Revised interpretive guidelines for levels of medical decision-making;
  - Giving the provider the choice of medical decision-making or time to select the code level for the applicable E/M code (except for certain families like emergency department visits and cognitive impairment assessment, which are not time-based); and
  - Eliminating the use of history and examination to determine code levels (although there is still a requirement of a medically appropriate history and exam).
- As with office and outpatient services, CMS created Medicare-specific codes for prolonged services in the above categories.
- CMS also clarified that, for time-based services, the physician or other practitioner must expend the full amount of time specified.
- Finally, CMS delayed by another year the implementation of fully time-based split/shared services. So, for Calendar Year 23, practitioners will continue to have the choice to bill for a service as "split/shared" if that practitioner provided at least one of the history, the physical examination, or the medical decision-making; or if the practitioner spent more than half of the total time of the visit with the patient. Starting in 2024 (unless the rule is further delayed), the practitioner who spent more than half of the total time must bill the service, regardless of which elements of the service were performed.

Payment for Skin Substitutes

- CMS sought to resolve ambiguities around the use of the term "skin substitutes" to be more inclusive of the broad scope of products (human, animal, synthetic) and their use in wound care as opposed to more traditional skin grafts.
- CMS had proposed to modify the payment structure for these products when used in the physician office setting by changing their classification to incident-to supplies as opposed to the current treatment with HCPS level II codes.
- The CY23 final rule did not make any changes to the existing treatment of or payment for skin substitutes. CMS intends to hold a series of town halls in early 2023 to address both issues and solicit feedback from stakeholders.

Provision to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

- CMS created the AB modifier which audiologists may use to bill the approved diagnostic tests' CPT codes without a physician order once per twelve months per beneficiary. These approved codes will be paid at the standard reimbursement rate per code as opposed to a proposed universal code.

Provisions on Medicare Parts A and B Payment for Dental Services

- The CY23 final rule codifies longstanding fee for service payment policies for medically necessary dental services, including examination and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, performed as part of a comprehensive workup prior to organ transplantation (including hematopoietic stem cell and bone marrow transplantation), prior to cardiac valve replacement or valvuloplasty procedures, and prior to treatment for head and neck cancers.
- CMS is allowing for payment under Medicare Part A and Part B for dental services furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services detailed therein. Dentists may now enroll and bill under Medicare Part B for covered services. CMS clarifies that no payment is made for dental services when an excluded service is the primary procedure involved.

Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and Policies for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests

- CMS is finalizing changes to the data reporting and payment requirements to update the definitions of both the "data collection period" and "data reporting period". CMS has indicated that data

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reporting is required every 3 years beginning January 2023. Finally, for CYs 2023 through 2025, the final rule states that payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

- The CY23 final rule codifies longstanding payment policies for laboratory specimen collection fees. Beginning January 1, 2023, CMS will pay a general specimen collection fee of $8.57 for all specimens collected in one patient encounter. This fee will be increased by $2 ($10.57) for specimen collection from a Medicare beneficiary in a SNF or on behalf of an HHA for all specimens collected in one patient encounter. The regulations will contain guidance on how increases to annual payment amounts shall be calculated.
- To be eligible for a specimen collection fee, the specimen must be: used to perform a clinical diagnostic laboratory test paid under the CLFS regulations; collected by a trained technician from a Medicare beneficiary who is homebound, or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; and of the following type—a blood specimen collected through venipuncture or a urine sample collected by catheterization.
- The Medicare Clinical Laboratory Fee Schedule was also revised to codify existing travel allowance policies. The final rule sets forth the calculations for travel allowances which may be paid on either a flat-rate or a per-mile allowance with both instances including a personnel services expenses component.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

- The final rule expanded CRC screening coverage by reducing the minimum age for CRC screening tests from 50 to 45 years of age for certain Medicare covered CRC screening tests that currently include a minimum age of 50 as a limitation of payment or coverage. As finalized, a screening colonoscopy is available without a minimum age limitation.
- The rule further finalizes coverage of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare-covered non-invasive stool-based positive CRC screening.

Preventive Vaccine Administration Services

- Effective January 1, 2023, CMS finalized an annual update to the payment amount for the administration of Part B preventive vaccines based upon the increase in the Medicare Economic Index. This payment amount may be adjusted to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered.
- In-home administration of the COVID-19 vaccine was extended, unaffected by the May 2023 end of the public health emergency or termination of the emergency use authorization, subject to the aforementioned adjustments.
- CMS also finalized a policy stating that, in the event the EUA declaration continues into CY 2023, CMS will maintain the current payment rates for administration of a COVID–19 monoclonal antibody product used for treatment or for postexposure prophylaxis of COVID–19 with an adjustment based on geographic location, but not the increase to the Medicare Economic Index; after the EUA is terminated, these products will be paid as biological products.

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

- The CY23 final rule provided clarity on several provisions related to nonemergent, scheduled and repetitive ambulance services. CMS maintains that the ambulance provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS, and the ambulance service must meet all program coverage criteria including vehicle and staffing requirements.
- CMS clarified that a signed physician certification statement does not alone demonstrate that transportation by ground ambulance was medically necessary; the statement, and additional documentation from the beneficiary's medical record, may be used to support a claim that transportation by ground ambulance is medically necessary. Any such documentation must provide detailed explanations that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance.
- Finally, the rule clarifies that coverage includes observation or other services rendered by qualified ambulance personnel.

Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment

- CMS issued a final rule stating that managing organizations, defined as an entity that exercises operational or managerial control over, or that directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement, and the officers and directors of a provider/supplier if that provider/supplier is a corporation are now subject to the denial/revocation of Medicare enrollment if convicted of a felony or excluded by the OIG. Relatedly, W-2 employees and contracted parties of the provider/supplier are now also within the scope of the denial and revocation actions. Managing organizations and officers and directors of corporate suppliers/providers are now eligible for reversal of a revocation or denial of enrollment status as outlined in §§ 424.535(e) and 424.530(c).
- CMS expanded the reach of § 424.518's screening regulations to include changes of ownership and the reporting of any new owner regardless of ownership percentage via a change of information. For those provider/supplier types in the high risk category, once enrolled, are subject to high-risk screening if they are submitting change of ownership application or an application to report a new owner. The final rule also modifies those provider/supplier types subject to heightened screening under § 424.518 to include initially enrolling SNFs into the high risk level screening; while revalidating SNFs would be subject to moderate risk-level screening.
- The final rule also adds as a condition of payment for DMEPOS suppliers that the supplier must have been in compliance with all conditions of payment in § 424.57(b) as well as with the enrollment standards listed at § 424.57(c)(1)(ii)(A) at the time the item or service was provided.

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Updates to the Quality Payment Program

- The CY23 rule established a performance threshold of 75 MIPS points for the 2023 performance year (PY). CMS will continue to use the 2017 PY mean final score in establishing the performance threshold. This means providers and groups must reach 75 MIPS points again in 2023 to avoid a negative payment adjustment in the 2025 payment year.
- CMS continues to concentrate on the expansion of MIPS Value Pathways (MVPs), which have been identified as the replacement for traditional MIPS, and subgroup reporting and has finalized a total of 12 MVPs for the 2023 PY.
- There are several quality measure changes, including expansion of the definition of "high priority measure" to include health equity-related quality measures. CMS finalized a total of 198 quality measures for the 2023 performance period.
- CMS also disseminated regulations on subgroup reporting under MIPS and MVPs as applied to multispecialty physician groups including the use of Part B claims data to determine a group's specialty and limitations on a single provider's ability to register for multiple subgroups. Clinicians who choose to participate in a subgroup to report an MVP must register as a subgroup between April 1 and November 30 of the PY.
- The final rule makes MVPs available for reporting beginning with the 2023 PY:
  - 2023, 2024, and 2025 PYs - Individual clinicians, single specialty groups, multispecialty groups, subgroups, and Alternative Payment Model (APM) Entities can report MVPs.
  - 2026 PY and beyond - Individual clinicians, single specialty groups, subgroups, and APM Entities can report MVPs. Multispecialty groups will be required to form subgroups to report MVPs.
- CMS is seeking to encourage participation in APMs through various policies including by making the 8% minimum on the Generally Applicable Nominal Risk standard for Advanced APMs.

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

- The final rule requires certain manufacturers of single-dose container or single-use package drugs to provide a refund when an appropriate amount of such drug is discarded from a multiple-dose vial, package, or bottle due to the clinical circumstances of the patient's treatment. These refund policies are intended to ensure that patients who receive covered drugs do not incur higher costs due to unnecessary waste resulting from inaccurate measuring devices, incorrect dosing instructions, or other miscellaneous circumstances. The policy applies to any manufacturer whose FDA-approved product label includes directions regarding an average dose based on body weight and/or general range dosing instructions applicable across different age groups, gender, or body size.
- Manufacturers who are subject to this policy must submit refunds at least quarterly and must include all relevant information including the NDC Code, name of drug product, number of dose units discarded, total units dispensed and more in order for them to be considered valid. Additionally, these manufacturers must also provide refunds if they exceed their negotiated price in their Average Sales Price (ASP) calculations as well as reimburse pharmacies for drug pricing discrepancies between actual invoices submitted and amounts paid by Medicare Part B. Furthermore, most refunds issued must be paid within sixty days from when the claim was received. The new regulation introduced by CMS is designed to ensure that all patients receive proper coverage for their medications without incurring additional cost due to wastage caused by inaccurate measuring devices and incorrect dosing instructions as well as reimbursement discrepancies between invoices submitted and amounts paid by Medicare Part B.

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

- The final rule expands the regulatory flexibility of Opioid Treatment Programs (OTPs) and allows them to furnish certain OUD treatment services that were previously excluded from coverage. These services include individual counseling, group counseling, pharmacological management, and case management. Additionally, new billing codes have been established in order to make it easier for healthcare providers to bill Medicare appropriately for OUD treatment services. The updated policies also provide more flexibility to determine how much time is spent providing certain services and allow care teams to better coordinate patient care. The changes aim to reduce reimbursement disparities between OTPs and physicians in private practice who render similar types of OUD treatment services. These modifications help ensure that OTPs are able to provide safe, effective, and comprehensive care for those struggling with opioid addiction without facing undue financial hardship.

Opioid Treatment Programs

- This policy change seeks to protect and expand access to care for people with opioid use disorder by preserving vital services offered by opioid treatment programs. The new Methadone Payment Exception will increase the reimbursement rate for methadone treatment provided in an outpatient setting and will allow clinicians to receive payment for opioid use disorder drugs prescribed as part of evidence-based treatment. The Methadone Payment Exception applies only to drugs administered or dispensed in a clinic or onsite pharmacy operated by an opioid treatment program, and providers of these services must be certified as OTPs by the Substance Abuse and Mental Health Services Administration to be eligible for higher payments from CMS. Under this policy, CMS will triple the current payments for methadone products under Part D, including both oral and injectable formulations. Additionally, through this exception, providers are allowed to bill separately for counseling services related to each individual dose of methadone as well as other drug therapy management codes which were previously not allowable under the fee schedule. The Methadone Payment Exception has been implemented without reducing funding from other programs because it is funded through existing resources from Part D. This policy change is expected to reduce financial barriers that limit access to medication-

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assisted treatments while providing support to providers who provide essential services within medically underserved communities affected by the opioid crisis.

Medicare Shared Savings Program

- The updates to the Program are designed to assist Accountable Care Organizations (ACOs) in providing quality care while reducing costs by incentivizing coordination between providers within and across settings. The goal is to improve access to high-value care while investing funds in primary and specialty care services.
- In order to encourage ACOs to transition from a fee-for-service model to value-based purchasing, CMS has established new requirements for ACOs participating in MSSP. These include increasing performance standards for all ACOs, expanding quality measures and financial criteria for shared savings eligibility, creating a stronger emphasis on patient engagement activities, and developing a system of graduated payments based on performance. Additionally, CMS has introduced new program models such as virtual groups and rural provider focused models which provide greater flexibility for smaller practices or those located in rural areas. Beginning January 2024, an option to make advance shared savings payments to certain ACOs, designed to offset the burden of initial costs, becomes available.
- The updates also seek to strengthen ACO accountability by introducing provider enrollment requirements that ensure providers are aware of their participation status as well as their responsibility within an ACO organization. Further, CMS has implemented an enhanced risk assessment process that takes into account not just historical data but also current performance trends when calculating risk levels. Finally, CMS has improved beneficiary access by allowing beneficiaries with any type of coverage to participate in MSSP if they choose; this includes those with commercial insurance plans as well as those enrolled in Medicare Advantage plans.
- In addition to the above changes, CMS has stipulated that ACOs must meet certain thresholds regarding their care delivery system maturity level for subsequent years' participation in MSSP. This means that organizations must continually demonstrate improvements in quality of care provided through additional investments such as staffing or technological advancements before being eligible for shared savings payments.
- All told, these updated requirements present a unique opportunity for ACO organizations with enough resources and dedication to commit towards improving access and quality of care while simultaneously reducing costs. The success of this effort will largely depend on how well providers across settings can coordinate efforts towards providing more efficient patient care experiences while meeting the stringent standards set forth by CMS's updated regulations under MSSP.

CMS Finalizes Rural Emergency Hospital Requirements – But Will Hospitals Make the Jump?

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Many U.S. states, but especially those in the Midwest and South, have experienced rural hospital closures over the past decade, and the COVID-19 pandemic, combined with rising costs, has only exacerbated the problem. In 2020 alone, the nation lost over 650 rural hospital beds across 19 closed facilities.

One recent response to the rural health struggle is the "Rural Emergency Hospital" (REH). At the end of 2020, Congress created this new Medicare provider type, which is available to rural hospitals as of January 1, 2023. The Centers for Medicare & Medicaid Services (CMS) has now finalized its Conditions of Participation (CoPs) and payment methods for REHs. But is this the fix that rural health care providers are looking for?

Background

Under the Consolidated Appropriations Act of 2021, a facility that on December 27, 2020 was a CAH or a rural hospital with 50 beds or fewer will be eligible to enroll as a REH. The law mandates that REHs meet requirements including:

- An annual per patient average of 24 hours or less in the REH;
  - A REH may not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility ("SNF") to furnish post-REH or post-hospital extended care services;
  - Staff training and certification requirements established by regulation;
- Emergency services CoPs applicable to CAHs;
- Hospital emergency department CoPs determined applicable by regulation (the proposed rule largely incorporates CAH CoPs regarding emergency departments);
- A transfer agreement with a level I or level II trauma center.

Proposed Conditions of Participation

Many of the proposed REH CoPs will mirror the current CAH CoPs. For example, the CoPs addressing the hospital governing body, policies, emergency services infection control, discharge planning, medical records, emergency preparedness and physical environment will generally follow the existing CAH CoPs. Some of the proposed CoPs, such as radiology requirements, will align with the existing general acute care hospital CoPs, rather than the CAH CoPs, in order to reflect the REH focus on emergency services.

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The staffing CoPs for REHs will also resemble those for CAHs, although with some additional flexibilities. For instance, a physician, nurse practitioner, clinical nurse specialist or physician assistant will not need to be available to furnish patient care services at all times the REH operates. Instead, such a practitioner with training or experience in emergency care must be on call and immediately available by telephone or radio contact and available on-site within specified timeframes.

Some of the proposed REH requirements will depart from the existing CAH requirements. For example, REHs will provide laboratory services that are consistent with nationally recognized standards of care for emergency services, meaning that REH laboratory services will emphasize immediate availability, will be provided 24 hours per day, and the list of laboratory services provided may be more extensive in a REH. Unlike for CAHs, the REH regulations will include a separate CoP governing pharmaceutical services. Nursing services requirements will also differ for REHs in order to reflect the fact that the REH will not furnish inpatient services.

CMS is also proposing to implement a patients rights' CoP that resembles the current requirement for hospitals – this requirement will newly apply to both REHs and CAHs moving forward.

REHs may establish a distinct-part unit that is a SNF, which must meet the long-term care facility requirements and which CMS notes is a departure from a CAH providing swing-bed services.

In addition to primarily providing emergency services and observation care, CMS is proposing to allow REHs to provide additional medical and health outpatient services if the REH can demonstrate that the service is needed based on an assessment of its community. In that context, CMS is considering whether REHs will be permitted to provide low-risk labor and delivery, outpatient surgical services and behavioral health services. If a REH does provide these additional services, it will need to have a system in place for referral from the REH to different levels of care, as the REH cannot provide inpatient services.

A REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is:

- Licensed in the state as an REH; or
- Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.

Several states have passed laws providing for specific licensing of REHs, including Kansas, Nebraska and South Dakota. The Kansas and Nebraska laws generally mirror the federal legislation, but South Dakota specifies that REHs must be located in a municipality with a population under fifty thousand people that has no acute inpatient services.

Proposed Enrollment and Reimbursement

CMS is proposing a relatively straightforward enrollment process for CAHs and hospitals looking to become REHs. Typically, when a provider seeks to change enrollment types they must terminate and newly enroll as the different type. In this unique circumstance, however, CMS will process a REH conversion as a change of information. Timing seems to be a factor in CMS's approach, as it looks to be able to process applications before January 1, 2023.

By statute, REHs will be reimbursed at 105% of the Medicare Hospital OPPS amount for covered outpatient services and will also receive a monthly facility payment. The 105% rate will apply to all "REH services." CMS is proposing a broad definition of "REH services," which means that any services furnished in an REH that are on the hospital OPPS fee schedule will be reimbursed at 105% (rather than limiting that rate to only specific services). The REH services rate will also extend to off-campus provider-based departments. Services paid on other fee schedules, such as laboratory services, will be reimbursed at their standard fee schedule rate.

CMS spends a notable portion of the proposed rule explaining how it has calculated the monthly facility payment which will go to all enrolled REHs. The bottom line of these calculations is that REHs will receive approximately $ 268,294 per month. The statute requires that REHs maintain detailed information as to how the facility has used this monthly facility payment and must make this information available upon request. For the time being, CMS believes that this requirement can be met using existing cost reporting requirements (which will apply to REHs).

Comments

The proposed REH CoPs are open for comment through August 29th, 2022. CMS appears especially open to comments on additional services including surgical services, rehabilitation services, maternal care, low-risk labor and delivery, behavioral health services and other outpatient services not yet addressed. The proposed patient's rights CoP may also be an area of commenter interest given that it is a new requirement for both REHs and CAHs.

The proposed hospital OPPS rule is open for comment through September 13th, 2022. In addition to comments on enrollment and reimbursement, CMS is also seeking feedback on quality reporting and a new Stark Law exception applicable to REHs.

Appropriations Act 2023 Provides Good News for FQHC/RHC Reimbursement

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On December 29, 2022 the federal Consolidated Appropriations Act of 2023 (CAA) expanded Medicare/Medicaid coverage and extended telehealth COVID-19 flexibilities for federally qualified health centers (FQHC) and rural health centers (RHC).

FQHC/RHCs Continue to be Telehealth Providers

The CARES Act of 2020 recognized FQHCS and RHCs as "distant site providers" during the COVID-19 public health emergency (PHE). The 2023 CAA extended this allowance until December 31, 2024. Payment will continue to be allowed for RHCs and FQHCs for furnishing telehealth services as distant site practitioners (though note that mental health visits can be furnished virtually on a permanent basis) under the payment methodology established for the PHE. This will allow these providers to furnish telehealth services in any geographic area and in any originating site setting, including the beneficiary's home, and allow certain services to be furnished via audio-only telecommunications systems.

New Behavioral Health Providers Authorized for FQHC and RHC Services

The Appropriations Act of 2023 also revised the definition of FQHC and RHC services to allow for expanded mental health services covered by Medicare and Medicaid. The Act recognizes, effective January 1, 2024, for the first time "marriage and family therapist (MFT) services" and "mental health counselor (MHC) services" as covered Medicare Part B services and also expands the definition of FQHC and RHC services to include MHC and MFT services. Importantly, FQHC service benefits under Medicaid is defined by reference to the Medicare statute, therefore MHCs and MFTs will also be included in the Medicaid FQHC benefit.

SNF Payments Still Driven by COVID-19 Quality Initiatives

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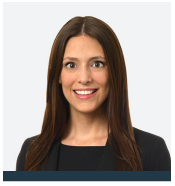

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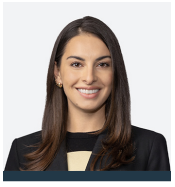

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As expected, many proposed changes and comments in the Skilled Nursing Facility ("SNF") PPS Final Rule for FY 2023 remain driven by COVID-19 quality-based initiatives.

As mentioned last year, value-based payments are a key topic of the adopted changes for this year. CMS finalized several updates for the SNF VBP Program, including a policy to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2023 SNF VBP Program Year for scoring and payment adjustment purposes. More specifically, CMS adopted three quality measures for the SNF VBP expansion. The FY 2026 programs adopted include the healthcare-associated infections (HAI) measure mentioned in last year's newsletter and the Total Nursing Hours per Resident Day Staffing Measure. In FY 2027, the DTC – PAC Measure will begin. We anticipate seeing further emphasis on value- and quality-based reimbursement as regulators and agencies increasingly scrutinize survey performance and staffing requirements.

Following the COVID-19 pandemic, infection control measures in SNFs continue to be a top priority for Healthcare Personnel (HCP). As such, reporting of Influenza Vaccination Coverage among HCP will begin, no later than May 15, 2025, with the FY 2024 SNF QRP. CMS revised the compliance date for the collection of the Transfer of Health (TOH) information to the Provider-PAC Measure, the TOH information to the Patient-Pac Measure, and certain standardized patient assessment data elements on the updated version of the MDS assessment instrument (MDS 3.0 v1.18.11) to October 1, 2023. Beginning with FY 2024, COVID-19 Vaccination Coverage among Healthcare Personnel Measure is added to the SNF QRP and must be submitted through the NHSN.

Other notable updates in the SNF PPS Final Rule include:

- **Permanent Cap on Wage Index Decreases:** There is a permanent 5% cap on annual wage index decreases to smooth the impact of year-to-year changes in SNF payments related to changes in the SNF wage index. This replaces the prior methodology of a 50/50 blended wage index, which is less administratively complex and is intended to provide greater transparency
- **Net Pay Rate Increase:** CMS estimates the aggregate impact will result in a net increase in SNF payments of a 2.7%, or $904 million, for fiscal year 2023.
- **Changes in PDPM ICD-10 Code Mapping:** CMS has made several changes to the ICD-10 code mappings to improve consistency between the ICD-10 code mappings and current ICD-10 guidelines, effective October 1, 2022.
- **Patient Driven Payment Model (PDPM) Parity Adjustment Recalibration:** CMS recalibrated the methodology for the PDPM parity adjustment, including a modified definition of COVID-19 to account for COVID-19 related effects.
- **Director of Food and Nutrition Services:** CMS is revising the qualification requirements for the Director of Food and Nutrition Services, allowing those with two or more years of experience to serve as the Director.
- **Life Safety Code:** CMS is revising Life Safety Code changes in § 483.90(a) to permit older facilities to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment, and people movement requirements.

Highlights from the Final Home Health and Hospice Payment Rule

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CMS updated rules related to home health and hospice payment, including routine updates to payment rates for CY 2023 in accordance with existing statutory and regulatory requirements, changes related to Home Health Value-Based Purchasing, finalization of a methodology to determine the impact of differences of assumed and actual behavior changes on aggregate expenditures, as well as a permanent prospective payment adjustment to the home health 30-day period payment rate to account for any increases or decreases in expenditures. CMS also finalized rules raising hospice payment 3.8 percent.

Home Health Value-Based Purchasing

In 2021, CMS finalized the nationwide expansion of the Home Health Value-Based Purchasing (HHVBP) model, after the success of HHVBP in the nine original Model States where the approach was piloted. For the Expanded HHVBP Model, CMS is finalizing:

- Additional definitions for home health agency (HHA) baseline year and Model baseline year, and removal of the previous definition of baseline year;
- Changes to the HHA baseline year from CY 2019 to CY 2022 for existing HHAs with a Medicare certification date prior to January 1, 2019, and from 2021 to 2022 for HHAs; with a Medicare certification date prior to January 1, 2022 starting in the CY 2023 performance year; and
- Changes to the Model baseline year from CY 2019 to CY 2022 starting in CY 2023.

Medicare Home Health Prospective Payment System (PPS)

- The final rule finalizes routine, statutorily required updates to home health payment rates for CY 2023. CMS estimates that Medicare payments to HHAs in CY 2023 will increase by 0.7%, or $125 million, compared to CY 2022, based on the finalized policies. This increase reflects the effects of the 4.0% home health payment update percentage ($725 million increase), an estimated 3.5% decrease that reflects the effects of the prospective permanent behavioral assumption adjustment of -3.925% ($635 million decrease) that is being phased-in, and an estimated 0.2% increase that reflects the effects of an update to the fixed-dollar loss ratio (FDL) used in determining outlier payments ($35 million increase).
- The rule also finalizes recalibration of the patient-driven groupings model (PDGM) case-mix weights and updates the low utilization payment adjustment (LUPA) thresholds, functional impairment levels, comorbidity adjustment subgroups for CY 2023, and the FDL used for outlier payments. The final rule also implements the reassignment of certain diagnosis codes under the PDGM case-mix groups.
- To achieve the policy goal of increased predictability in home health payments, while aligning with the FY 2023 Inpatient Prospective Payment System final rule and other rules, the rule finalizes a permanent, budget neutral 5% cap on negative wage index changes (regardless of the underlying reason for the decrease) for home health agencies to smooth year-to-year changes in the pre-floor/pre-reclassified hospital wage index.

Home Infusion Therapy Services Payment Rates

- CMS is updating the home infusion therapy services payment rates for CY 2023, in addition to updating the geographic adjustment factor used for wage adjustment. Updating payment rates for home infusion therapy services is expected to increase payments by 8.7%.

Home Health Quality Reporting Program Updates

- CMS is ending the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients. HHAs will be required to submit all-payer OASIS data for purposes of the HH Quality Reporting Program beginning with the CY 2027 program year, with two-quarters of data required for that program year. CMS is finalizing a phase-in period for January 1, 2025 through June 30, 2025, in which failure to submit the data will not result in a penalty.

Hospice Updates

- The FY 2023 hospice payment update percentage is 3.8% (an estimated increase of $825 million in payments from FY 2022). This is a result of the 4.1% market basket percentage increase reduced by a 0.3 percentage point productivity adjustment. As a reminder, hospice agencies that fail to submit their required quality data will incur a 2% payment penalty for FY 2023 and therefore will not enjoy the full percentage increase in the payment update.
- CMS sets the FY 2023 annual hospice cap at $32,486.92, which was derived from increasing the FY 2022 cap amount by the 3.8% payment increase.
- In connection with its annual March 2022 Report to Congress, and December 2022 update, MEDPAC continues to recommend that Congress reduce the aggregate hospice cap by 20% and by wage adjusting the cap. It is widely anticipated that the same recommendations will yet again be included in the March 2023 Report to Congress for implementation in 2024. In MEDPAC's view, the impact of such measures will be primarily focused (roughly 33%) on hospice providers with long lengths of stay, the highest margins and highest live discharge rates, which under their data skews towards freestanding, for-profit, urban hospice agencies (when based on 2019 rebased figures).
- The Hospice Payment Rate Update Final Rule provides an update on the development of a patient assessment instrument, titled Hospice Outcomes and Patient Evaluation (HOPE). This includes an

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update on the beta testing and derivatives that will be achieved during this phase of testing, such as burden estimates and timepoints for collection, as well as additional outreach efforts that will be conducted during and after beta testing and during our planned adoption process.

- While CMS did not release any new quality measures, CMS did discuss potential future quality measures within the Hospice Quality Reporting Program (HQRP) based on HOPE and administrative data, including HOPE-based process measures and hybrid quality measures, which could be based upon multiple sources that include HOPE, claims, and other data sources.
- Similar to home health, CMS is instituting a 5% budget-neutral cap on any decrease to a geographic area's wage index, so that a geographic area's wage index would not be less than 95 % of its wage index calculated in the prior FY regardless of the circumstances causing the decline.

End Stage Renal Disease (ESRD) Final Rule

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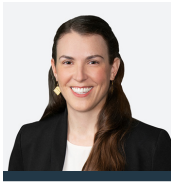

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Summary

The CY 2023 End Stage Renal Disease (ESRD) final rule, available here (https://www.govinfo.gov/content/pkg/FR-2022-11-07/pdf/2022-23778.pdf), includes a 3.1% increase in payments for all ESRD facilities. CMS published an updated definition of oral-only drugs to streamline bundled payment inclusion when appropriate. Final updates and modifications to the ESRD Quality Incentive Program (QIP) and the ESRD Treatment Choices (ETC) model are also included in the rule.

Payment Updates

The final CY 2023 ESRD Prospective Payment System (PPS) base rate will be $265.57, up from $257.90, for dialysis treatments related to both ESRD and Acute Kidney Injury. CMS predicts that the updates will increase the total payments to all ESRD facilities by 3.1% compared to CY 2022. CMS updated the ESRD Bundled (ESRDB) market basket, as it does periodically, to a 2020 base year, which will result in a relative increase in compensation costs and a relative decrease in all other costs, particularly drug costs. The labor share now makes up 55.2% of the ESRDB market basket.

As it does annually, CMS adjusted its outlier policy. CMS used 2021 claims data to update the per treatment Medicare Allowable Payment and the outlier services fixed-dollar loss amounts. Additionally, the adjustments allow CMS to more effectively target the policy goal of having outlier payments make up 1% of total ESRD payments.

No new products were added under the Transitional Add-On Payment Adjustment for New and Innovating Equipment and Supplies (TPNIES) for CY 2023. Three products were under consideration - a monitoring system of peritoneal dialysis, a post-dialysis compression sleeve, and a dialyzer - but they did not meet the eligibility criteria at 42 C.F.R. §413.236(b).

Updated Definition of Oral-Only Drugs

CMS has updated the definition of oral-only drugs at 42 C.F.R. §413.234(a) to mean a drug or biological product with no injectable functional equivalent or other form of administration other than an oral form. CMS intends for this change to clearly define the scope of any new drugs or biological products that could be considered oral-only drugs in the future. This will facilitate incorporations of these renal dialysis services into the ESRD PPS, because any new oral renal dialysis drugs or biological products that fall within existing ESRD PPS functional categories, and have functional equivalents in those categories, would not meet the definition of an oral-only drug. Consequently, those drugs would be included in the ESRD PPS bundle.

ESRD QIP

As in CY 2022, the ESRD QIP data measures were impacted by the COVID-19 public health emergency. The circumstances have significantly affected the validity and reliability of certain measures otherwise used to calculate performance scores. Thus, CMS has paused the use of certain measures to avoid penalizing ESRD facilities based on circumstances caused by the public health emergency. CMS will still provide confidential feedback reports to facilities about their scores under the existing measures so they are made aware of the changes in observed performance rates. CMS will use CY 2019 data to calculate PY performance standards, instead of the CY 2020 data CMS had previously planned to use.

ESRD Treatment Choices Model

The ESRD Treatment Choices (ETC) Model assesses participating providers who manage dialysis patients and assigns positive or negative adjustments based on the home dialysis rate and transplant rate among their beneficiaries. The model's goal is to encourages greater use of home dialysis and kidney transplants, including by directly addressing health equity and social determinants of health. In the CY 2023 rule, CMS finalized refinements to the ETC model, including changing the improvement scoring methodology and the requirements related to patient education services. The rule also discusses CMS's intent to publish participant-level model performance information to the public.

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The Conference will be at London Hotel in Chicago on May 19

2023 Polsinelli Privacy Summit

The Summit will be held at Polsinelli in Chicago on May 11

For additional details on any of the events please contact Ashley Steele at asteele@polsinelli.com

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If you have questions or would like more information, please contact Sinead McGuire at smcguire@polsinelli.com

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