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POLSINELLI REIMBURSEMENT TEAM NEWSLETTER

CMS Greenlights Teletherapy and Signals Support for Future Telehealth Services

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The end of 2021 brings positive indications of the continued acceptance of telehealth as an important clinical care approach post public health emergency ("PHE"). The Centers for Medicare and Medicaid Services ("CMS"), like other payors, overhauled its approach to telehealth services in response to the COVID-19 PHE. In the CY 2022 Physician Fee Schedule Final Rule ("Final Rule") just published this November, CMS recognized telehealth's surge in popularity during the PHE and responded by announcing two further regulatory changes to promote wider use of telehealth: (1) an extended timeline for Medicare reimbursement for current telehealth services, and (2) relaxed criteria for diagnosing, evaluating, and treating mental health disorders via telehealth. Such changes signal CMS' appreciation for telehealth and an openness to continue revisiting its reimbursement criteria. Limits a patient's financial responsibility for OON emergency services, most non-emergency services furnished by OON providers at in-network ("INN") hospitals, and OON air ambulance services to the amount for which the patient would be responsible had those services been furnished by INN providers (i.e., INN cost-sharing amounts); and

Extended Reimbursement Timeframe

First, CMS extended the reimbursement timeframe for all telehealth services temporarily authorized for Medicare reimbursement during the PHE on a Category 3 basis ("Telehealth Services"). In the Final Rule, CMS announced that providers may continue to be reimbursed for such services until the end of the 2023 calendar year.[ii] This extended timeline will allow providers to continue to provide Telehealth Services, while developing clinical evidence to support their permanent addition to the CMS Telehealth List.

Relaxed Criteria for Mental Health Disorders

Second, CMS significantly relaxed its reimbursement criteria for telehealth services furnished "for purposes of diagnosis, evaluation, or treatment of a mental health disorder." Historically, Medicare paid for such services, like all on the CMS Telehealth List, only if: (1) a qualified practitioner furnished the services; (2) the practitioner was located at qualified distant site (e.g. certain facility types); (3) the patient presented at a qualifying originating site (e.g. a rural area in a provider's office or facility); and (4) the parties used technology that permitted two-way, real-time interactive communications complying with state and federal privacy laws.[iii]

[i] 86 Fed. Reg. 64996 (Nov. 19, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf.
[ii] 86 Fed. Reg. 65055 (Nov. 19, 2021).
[iii] See 42 C.F.R. §410.78(b).

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The Final Rule, however, authorizes Medicare payment for telehealth services furnished "for purposes of diagnosis, evaluation or treatment of a mental health disorder" on a permanent basis (even after the PHE ends) under the following relaxed criteria:[iv]

- First, a patient's home may now serve as a qualifying originating site for telehealth encounters for the diagnosis, evaluation or treatment of a mental health disorder, provided that such services are preceded and followed by an in-person visit. Specifically, the practitioner furnishing the telehealth services must: (i) have also furnished an item or service in-person to the patient (i.e., without use of telehealth) within 6 months before the first time the provider furnished telehealth services to the patient; and (ii) furnish in-person services to such patient every 12 months after a telehealth service.[vi] However, the "same practitioner" may include either (i) the practitioner rendering the telehealth service; or (ii) a practitioner in the same specialty and same group as such practitioner.[vii] Consequently, CMS is allowing telehealth practitioners to rely on others in their group to provide in-person services to meet this requirement.
- Second, for the evaluation and treatment of mental health disorders, CMS waived the geographic restrictions for patient's homes.[viii] Now, a patient's home may serve as an originating site for such services even if not in a qualifying rural zip code.
- Third, for the evaluation and treatment of mental health disorders, CMS is permanently allowing audio-only visits when: (1) the patient's home serves as the originating site for the encounter, and (2) the telehealth provider has audio-visual technical capabilities for the encounter, but the patient either is not capable of or does not consent to a video encounter.[ix] For services other than behavioral health counseling services, CMS is still requiring providers to use two-way, audio-visual communications technology.[x]

Collectively, these changes are likely to significantly broaden access to behavioral health care for Medicare beneficiaries and provide a runway for providers to develop clinical arguments for other services to be reimbursed as telehealth services. Finally, the Final Rule suggests CMS's greater acceptance of the importance of telehealth in promoting accessible care, which may signal to providers that the telehealth revolution is here to stay.

[iv] Telehealth services must meet the conditions in 42 C.F.R. 414.65 and 410.78, as well as state requirements, to lawfully seek Medicare reimbursement.

[v] A patient's "home" may include their residence, a temporary residence (e.g. hotel, shelter), or a nearby location where the patient goes for privacy or other reasons.

[vi] 86 Fed. Reg. 65058 (Nov. 19, 2021).

[vii] 86 Fed. Reg. 65058 (Nov. 19, 2021).

[iii] 86 Fed. Reg. 65057 (Nov. 19, 2021) (CMS noted a patient's home does not need have to be located in a qualifying location provided by 41 C.F.R. §410.78(b)(4) (i.e. a rural health professional shortage area)).

[ix] 86 Fed. Reg. 65057 (Nov. 19, 2021).

[x] CMS justified limiting phone-only consultations to mental health services primarily involving verbal conversation between the patient and provider by noting that visualization of the patient is less necessary for such services, but important for others.

The No Surprises Act: A Final Checklist for 2022

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The No Surprises Act ("NSA") passed in the final days of 2020 as part of the Consolidated Appropriates Act, 2021 to create a federal solution to the problem of "surprise billing." Most provisions of the NSA took effect on January 1, 2022. In this article, we provide a final "checklist" for providers and facilities to take inventory of their NSA compliance and operational measures as we dive into the new year.[ii]

- No Surprises Act Disclosures. Certain providers[iii] and facilities[iv] must notify patients of their rights under the NSA on a public website, and by providing to patients in a one-page written document, disclosures that include: (1) the requirements and prohibitions applicable to the provider or facility under the NSA and its implementing regulations; (2) information regarding any state balance billing laws;[v] and (3) information about how to contact state and federal agencies if the patient believes the provider or facility has violated the NSA.[vi]
- Implement the Notice and Consent Process. The NSA does not apply to some out-of-network services when the patient is given notice and consents to the out of network care. Providers should develop systems to identify those encounters eligible for the notice and consent process and implement a procedure for giving notice and obtaining consent.[vii]
- Prepare to Engage in the Independent Dispute Resolution ("IDR") Process for Reimbursement Disputes. Health plans and issuers must reimburse providers and facilities directly for out-of-network services subject to the NSA at an undefined amount the NSA calls the "initial payment." This "initial payment" must be made within 30 days after claim submission. The provider or facility may accept that amount as payment in full or dispute the amount through a statutory IDR process. The IDR process begins within a 30-day open negotiation period.[viii] The open negotiation period is followed by submission of the dispute to a third-party arbiter when the parties cannot settle.[ix] If the dispute is submitted to an arbiter, the parties must submit a final offer and the arbiter must select one of the two offers submitted as the prevailing award.
- Understand What Factors Are Considered at the IDR Process. When a dispute involves providers (excluding air ambulance providers)[x] or facilities, the arbiter of the IDR process must consider seven general factors in reimbursement disputes involving providers and facilities: (1) median in-network rates (as calculated by the plan or issuer); (2) the provider's training and experience, quality, and outcomes; (3) the market share of either party; (4) patient acuity or complexity of the service; (5) in the case of a hospital, its teaching status, case mix, and scope of services; (6) good faith efforts (or lack thereof) of either party to agree to a network contract and any contracted rates during the prior four years; and (7) any additional information submitted, so long as it is credible and reliable and does not relate to the provider's billed charges, UCR charges, or governmental reimbursement rates.
- Understand the Burden of Proof at the IDR Process. The Departments[xi] imposed a mandatory presumption through regulation that the health plan or issuer's median contracted rate is the appropriate reimbursement rate. This presumption may be rebutted only by "credible" and "relevant" information that the median contracted rate is "materially different" than the appropriate rate.
- Implement Good Faith Estimates for Uninsured (or Self-Pay) Patients. At the time of scheduling or upon request, providers and facilities must inquire about the patient's health insurance status or whether the patient wants to submit a claim to their health plan or issuer for the care sought. If the patient is uninsured (or self-pay), the provider or facility must give a good faith estimate of expected charges for services reasonably expected to be provided, including services that may be furnished by other providers or facilities.[xii]
- Prepare to Engage in Reimbursement Disputes for Uninsured (or Self-Pay) Patients. An uninsured or self-pay patient may institute a patient-provider dispute resolution process when the provider's final bill is $400 or greater than the original good faith estimate (discussed above). In this dispute process, the provider or facility must demonstrate that the difference between the amount billed and the good faith estimate is based on unforeseen circumstances not anticipated when the estimate was provided.
- Take Note of Uncertainty in Washington Over Existing NSA Rules. Industry associations and lawmakers have publicly denounced the presumption that the health plan or issuer's median contracted rate should be presumed an appropriate level of reimbursement via letters[xiii] to the Departments and lawsuits[xiv] against the federal government. It is unclear whether regulators will amend the regulations in response, but this uncertainty is worth the industry's continued attention.

[i] Surprise billing sometimes occurs when patients unintentionally receive emergency or non-emergency services from providers who do not participate in their health plan's network. Patients often bear the financial burden of such out-of-network 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. We summarized many of the NSA's key features in our Reimbursement and Payor Dispute Update published in February, 2021. But generally speaking, the NSA does four major things: (1) prohibits balance billing and limits a patient's financial responsibility for certain out-of-network 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 out-of-network care and resolve reimbursement disputes under a statutory independent dispute resolution ("IDR") process; (3) creates protections for uninsured and self-pay patients and a patient-provider dispute resolution process; and (4) imposes additional transparency requirements. Congress delegated many important aspects of the NSA to federal agencies in rulemaking that occurred throughout 2021.

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[ii] This checklist is intended to be a high-level summary of the NSA's requirements and does not account for all nuances in the law. For more information and questions related to the NSA or its implementing regulations, please contact the authors.

[iii] Excluding air ambulance providers.

[iv] Including hospitals and independent free-standing emergency departments.

[v] The NSA defers to existing state surprise billing laws in certain situations. Any comprehensive state surprise billing law will likely apply instead of the NSA in the context of a fully-insured plan and state-regulated insurance product (and sometimes self-funded ERISA plans if the particular state allows such plans to "opt-in" to state law) if the state law meets the NSA's so-called "floor requirements" by: (1) prohibiting balance billing like the NSA; (2) limiting patient cost-sharing to INN amounts; and (3) setting forth either a process to resolve disputes over OON reimbursement, like arbitration, or a mathematical formula for determining the total OON reimbursement rate for the item or service in question.

[vi] CMS has released a model disclosure that, if used by providers and facilities, will be deemed as good faith compliance with the NSA's disclosure requirements.

[vii] CMS has released form notice and consent documents that must be used.

[viii] CMS has released a form "Open Negotiation Notice" that must be used to initiate this process.

[ix] CMS has released a form "Notice of IDR Initiation" that must be provided to the opposing party and to CMS using the new Federal IDR portal.

[x] The factors considered at the IDR process involving an air ambulance provider are slightly different: (1) median contracted rates; (2) the air ambulance providers' training and experience, quality, and outcomes; (3) patient acuity and complexity of service; (4) air ambulance vehicle type, including the vehicle's clinical capabilities; (5) population density of the pick-up location; (6) good faith efforts (or lack thereof) of either party to agree to a network contract, and any contracted rates during the prior four years; and (7) any additional information submitted, so long as it is credible and reliable and does not relate to the provider's billed charges, UCR charges, or governmental reimbursement rates.

[xi] The NSA made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); ERISA, which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. Congress delegated rulemaking to these Departments, along with the Office of Personnel Management ("OPM") (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act). These Departments have issued two primary sets of interim final rules in 2021 implementing portions of the NSA: Requirements Related to Surprise Billing; Part I ("Part 1 IFR"), and Requirements Related to Surprise Billing; Part II ("Part 2 IFR"), which were published in the Federal Register on July 13, 2021, and October 7, 2021, respectively. We summarized key takeaways of the Part 1 IFR in our Reimbursement and Payor Dispute Update published in October, 2021.

[xii] CMS has released model good faith estimate documents that, if used by providers and facilities, will be deemed as good faith compliance with the NSA's good faith estimate requirements for uninsured (or self-pay) patients. The NSA has a parallel good faith estimate requirement for patients with commercial health plans / insurance, but that requirement has been delayed. See FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021, Implementation Part 49 (Aug. 20, 2021).

[xiii] On October 4, 2021, the House Committee on Ways and Means wrote a bipartisan letter to the Departments voicing in no uncertain terms that the presumption in favor of the median contracted rate contradicted Congressional intent. On November 5, 2021, nearly one-third of the House raised the same issue in a letter to the Departments signed by a bipartisan group of 152 lawmakers. Additionally, on December 6, 2021, Senator Mike Braun (R-IN) requested CMS and HHS reconsider the required presumption, arguing that this rule "creates a de-facto benchmark."

[xiv] On December 9, 2021, the American Health Association ("AMA"), American Hospital Association ("AHA"), and other industry players sued the federal government in the federal district court for the District of Columbia seeking declaratory and injunctive relief, alleging that the Departments acted outside of their statutory authority by issuing certain provisions of the IFRs. See American Hospital Association, AHA, AMA and others file lawsuit over No Surprises Act rule that jeopardizes access to care (Dec. 9, 2021), Specifically, the AMA and AHA assert that the IDR process, as written by the regulators, would unfairly benefit plans and insurers because of the IFRs' mandatory presumption that the median contracted rate is the appropriate rate to determine the final award. The AMA and AHA allege this requirement contradicts Congressional intent and express statutory language calling for the arbiter at the IDR process to consider all seven enumerated factors. Accordingly, the associations ask the Court to block the pertinent IFR provisions. A few weeks prior, the Texas Medical Association and Association of Air Medical Services filed similar lawsuits against the federal government in the district courts for East District of Texas and the District of Columbia, respectively. See Texas Medical Association, TMA Sues Feds Over Unfair Rule for Surprise Billing Law; AAMS, AAMS Sues Federal Government Over Rules Favoring Insurers.

Medicare IPPS Highlights

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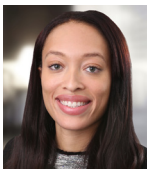

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The CMS IPPS for FY 2022 covers the usual topics, including a 2.5 percent increase in the standardized amount for general acute care hospitals. Some other highlights include:

1. **Graduate Medical Education**

IRIS Reporting. Under the FY 2022 IPPS Final Rule, for cost reporting periods beginning on or after October 1, 2021, hospitals' GME (weighted and unweighted) and IME FTE counts listed in IRIS data must match the total GME and IME FTE counts reported on Worksheets E-4 and E, Part A of the filed Medicare cost report. Providers must also use the new Extensible Markup Language (XML)-based IRIS file format, which is designed for consistency with FTE reporting on the cost report.

To address concerns raised in response to the FY 2022 proposed rule, for cost reporting periods before October 1, 2022, hospital cost reports will not be rejected if the IRIS and cost report FTE counts do not match. Additionally, to address potential rounding errors, CMS will also establish a tolerance threshold for variances between the cost report and IRIS data. CMS will also release a list of software vendors that have been validated to meet the new IRIS XML specifications.

CCA/New Residency Slots. Separate from the IPPS Final Rule, CMS published a final rule with comment period on Dec. 27, 2021 to implement sections of the Consolidated Appropriations Act of 2021 (CAA) that provide for 1,000 new residency positions to be distributed to qualifying hospitals from 2023-2027. The CCA also allows qualifying hospitals to establish new FTE caps and per-resident amounts. Comments on the GME final rule are due February 25, 2022. The GME final rule:

- Creates 1,000 new Medicare-funded residency positions with up to 200 new positions per fiscal year to be distributed beginning in FY 2023. Hospitals are prioritized based on HPSA scores and four prioritization categories defined by statute, and they may receive up to 5 FTEs per year depending on the length of the specific residency program. Applications for each FY are due by March 31 of the prior year and the online application system is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.
- Incentivizes the creation of new rural training track (RTT) programs, and the addition of additional RTTs to existing urban core programs of the same specialty, by giving both hospitals a rural track FTE limitation or, for existing programs, by adjusting such limitation. CMS will also provide additional FTE resident slots to any ACGME-accredited program in any specialty where the residents spend more than 50 percent of the entire residency program in a rural area. And during the five-year cap growth window for RTTs, FTE residents participating in the RTT will not be included in the hospital's 3-year rolling average calculation (or the cap on the IME IRB ratio on Medicare cost reports) during the cost reporting periods prior to the beginning of the applicable hospitals' cost reporting period that coincides with or follows the start of the sixth program year of each rural track.
- Allows hospitals that established a very low or $0 PRA that meet certain criteria to establish new PRA if the hospital trains residents in a cost reporting period beginning on or after Dec. 27, 2020 and before Dec. 26, 2026. And similarly allows hospitals that have very low FTE resident caps and meet certain criteria to have their cap "adjusted" if the hospital begins training FTE residents in a new residency program in a cost reporting period beginning on or after Dec. 27, 2020 and before Dec. 26, 2026.

2. **COVID-19 Add-On Payments**

In response to the COVID-19 PHE, CMS established the COVID-19 Treatments Add-on Payment ("NCTAP") for eligible discharges during the PHE. As CMS anticipates inpatient cases of COVID-19 beyond the end of the PHE, the NCTAP was extended through the end of the fiscal year in which the PHE ends. As part of the NCTAP, CMS provides enhanced payments for eligible inpatient cases that involve the use of certain new products authorized or approved to treat COVID-19 (i.e., therapeutics). Hospitals are generally reimbursed a fixed payment amount for the services they provide during an inpatient stay, even if their costs exceed that amount. Under current rules, hospitals may qualify for an additional "outlier payment," but only when their costs for a particular patient exceed a certain threshold. The NCTAP allows hospitals to qualify for additional payments when they treat patients with certain new products approved or authorized to treat COVID-19. A hospitalization qualifies for NCTAP if (1) a technology is used that has FDA approval or an EUA with an indication for the treatment of COVID-19; (2) the hospitalization is eligible for the 20% increase in MS-DRG payment per the CARES Act, including the hospital documenting a positive COVID-19 laboratory test; and (3) the cost of the hospitalization exceeds the MS-DRG payment. The enhanced payment will be equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the cost of a COVID-19 stay beyond the operating Medicare payment (including the 20 percent add-on payment under section 3710 of the CARES Act) for eligible cases.

CMS also did not finalize the proposal to discontinue the NCTAP on October 1, 2021, for a product that is approved for new technology add-on payments beginning in FY 2022. Instead, hospitals will be eligible to receive both NCTAP and traditional new technology add-on payments for patient stays that qualify. As with the NCTAP, this provision will apply "through the end of the fiscal year in which the PHE ends, with the new technology add-on payment reducing the total amount of the NCTAP." Additionally, the final rule has added authorization of additional

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payments for diagnostics and therapies to treat COVID-19 during the time of the current PHE.

3. **Quality Report for COVID-19 Vaccinations**

   In the FY 2022 IPPS final rule, CMS added a new measure to the Hospital Inpatient Quality Reporting (IQR) Program that will require hospitals to report the percentage of health care personnel (HCP) who have received a vaccination course against COVID-19. CMS believes it is important to incentivize and track healthcare provider vaccination in acute care facilities to protect healthcare workers, patients, and caregivers. The numerator of this measure is the cumulative number of healthcare personnel eligible to work in the healthcare facility for at least one day during the submission period and who received a completed vaccination course against COVID-19 since the date the vaccine was first available or on a repeated interval if revaccination is recommended.

   The denominator of the measure is the number of healthcare personnel eligible to work in the healthcare facility for at least one day during the submission period, excluding persons with contraindications to the COVID-19 vaccination as described by the CDC. The first reporting period spanned October 1, 2021 through December 31, 2021 and will be applicable for payments in FY 2023. Then, for CY 2022 and subsequent years, CMS is proposing data collection for a full year of data.

4. **DSH**

   CMS chose not to finalize its proposal to modify the Medicaid fraction of the DSH formula to limit the Medicaid days to patients eligible for inpatient hospital services under an approved State plan or under a Section 1115 waiver, where Section 1115 days would count only if the patient received inpatient hospital insurance coverage on those days. CMS plans to continue to review this limiting proposal.

5. **Bad Debt**

   CMS finalized a proposal to require state Medicaid agencies to enroll providers so that the Medicare patient cost-sharing amounts can be determined. This is necessary for providers desiring to claim Medicare bad debt to comply with Medicare's "must bill" policy to Medicaid for dually-eligible patients to attempt to collect from Medicaid before seeking Medicare bad debt reimbursement.

Provider-Payor Contracting: Increasing State Legislative Efforts Focused on Provider Contracting Practices and Restrictive Provisions

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States are setting their sights on health care provider contracting practices with payors. Specifically, state legislatures are increasingly seeking to prohibit health care providers from willfully entering into contracts that contain restrictive covenants and funding agencies to investigate these prohibited contracting practices. This emerging trend is usually tacked on to larger legislative bills aimed at transactions in health care or in setting standards related to cost, quality, and market competitiveness. Therefore, health care providers should take notice and understand this growing trend and how it may affect negotiation approaches and terms that can be included in agreements with payors.

Historically, states have generally prohibited certain unfair trade practices. But now, states are moving to introduce and enact legislation that would prohibit health providers, including facilities and physicians, from engaging in certain negotiation practices or entering into contracts containing terms that restrict insurers. For example, Nevada SB 329, effective October 1, 2021, bars contract provisions that restrain the ability of insurers to contract with other unaffiliated providers of health care, including health facilities, that are not parties to the contracts or conditionally requires third parties to contract with affiliated health care providers.[1]

Nevada's new law defines a violation to occur when a health care provider willfully enters into, willfully offers to enter into, or willfully solicits a contract with a third party insurer that directly or indirectly does one or more of the following: (a) restricts a third party insurer from offering incentives to a covered person to use specific health care providers or otherwise steers covered persons to a specific health care provider; (b) restricts a third party insurer from assigning health care providers into tiers to encourage the use of certain health care providers; (c) requires a third party insurer to place all health care providers affiliated with a business entity in the same tier; (d) requires a third party insurer to contract with a business entity affiliated with a health care provider as a condition of contracting with the provider; or (e) prohibits a third party insurer from contracting with a health care provider that is not a party to the contract, or penalizes a third party for entering into such a contract. For this law, a health care provider is defined to include physicians or other health care practitioners licensed in Nevada, hospitals, ambulatory surgery centers, skilled nursing facilities, residential group facilities, laboratories and institutions providing health care services. Contracts containing these restrictions will be deemed void and severed from the agreements, and providers cannot execute new contracts, amendments, or renewals that contain restrictive covenants of this nature. A provider who violates or conspires to violate the law is guilty of a misdemeanor offense[2] and would be subject to a civil penalty.[3]

California also recently sought unsuccessfully to pass similar payor contracting restrictions. If passed, AB 1132, the Health Care Consolidation and Contracting Fairness Act of 2021, would have prohibited providers from contracting with health plans or health insurers that either (a) restricted the plans or insurers from steering enrollees to other

[1] N.R.S.§ 598A.060.
[2] N.R.S.§ 598A.160; N.R.S.§§ 598A.180 – 598A.210.
[3] N.R.S.§ 598A.170.

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providers or facilities; or (b) required the plans or insurers to contract with other affiliated providers or facilities. Additionally, the bill would have prohibited contractual restrictions on affiliates of health plans or insurers from offering rates lower than the amounts providers or facilities accepted from contracting health plans or insurers. Despite failing to pass, these themes are expected to be re-introduced in future bills.

California and Nevada are not alone in these legislative efforts. They join other states, including Connecticut, Washington, Massachusetts, Virginia, Washington, New York, New Jersey, and Indiana, which are actively seeking ways to address increasing health care costs as well as market competitiveness. We anticipate this trend will continue at the state level. Therefore, healthcare providers are encouraged to consult with counsel before employing related negotiation strategies or embarking on payor contracts in which restrictive covenants may be contemplated.

Summary of OPPS/ASC Final Rule

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The Calendar Year (CY) 2022 Medicare Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems Final Rule (Final Rule) was published on November 16, 2021. In the Final Rule, the Centers for Medicare & Medicaid Services (CMS) significantly increased penalties for non-compliance with price transparency rules, reinstated the Inpatient Only list, and implemented several additional policies that signal its ongoing efforts to navigate the 2021 change in administration and the COVID-19 Public Health Emergency. Below are key takeaways. The full Final Rule is available here.

1. **Hospital Price Transparency**

   CMS' Hospital Price Transparency Final Rule, which became effective January 1, 2021, requires hospitals to annually publish a list of all standard charges for all items and services (Charge Lists). To address hospitals' sub-optimal compliance, the Final Rule made certain modifications to the Hospital Price Transparency Final Rule.

   Chiefly, beginning January 1, 2022, CMS increased the penalty amounts for non-compliance, calculated based on hospitals' bed counts: $300 per day for hospitals with 30 or fewer beds; and $10 per bed, per day for hospitals with a bed count greater than 30. Annually, the minimum total penalty amount would be $109,500 per hospital, and the maximum total penalty amount would be $2,007,500 per hospital.

   Additionally, the Final Rule required hospitals' Charge Lists be accessible to automated searches and direct downloads. Finally, the Final Rule provides that federally owned or operated hospitals, not treating the general public, will be deemed to be in compliance with the Hospital Price Transparency Rule, as these hospitals' charges are already publicized to their patients in advance.

2. **Reinstatement of the Inpatient Only List**

   CMS historically restricted payment for certain services in an outpatient setting, deeming that services on its Inpatient Only (IPO) list required an inpatient level of care. In 2021, CMS initiated a major change for hospitals through a gradual elimination of the IPO list. The Final Rule, in an abrupt reverse course, reinstated the IPO list for all but a select number of services. Explaining its reinstatement, CMS noted stakeholder pushback on several fronts, including patient safety and accuracy of OPPS rate setting for services removed from the IPO list.

   In connection with reinstatement of the IPO list, CMS amended the IPO list regulation at 42 CFR § 419.22(n) to remove references to elimination of the IPO list. CMS also codified its longstanding criteria for determining whether a service should be removed from the IPO list in a new regulation at 42 CFR § 419.23.

   Finally, CMS finalized its proposal that for a period of two years, procedures removed from the IPO list will be exempt from two-midnight rule medical review activities such as site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals, and Recovery Audit Contractor (RAC) referrals.

3. **ASC Covered Procedures List**

   The Proposed Rule reinstated the ASC Covered Procedures List (CPL) criteria that had been in effect in CY 2020. The reinstated criteria follow the safety standards specified in 42 C.F.R. § 416.166, which exclude from reimbursement surgical procedures that may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC. Under thesecriteria, the 2022 OPPS Proposed Rule (Proposed Rule) proposed the removal of 258 procedures from the CPL. Based on commenters' feedback, the Final Rule ultimately removed 255 procedures from the CPL. The Final Rule also installed a nomination process for adding services to the CPL, by which stakeholders may nominate a procedure to be added to the CPL in the subsequent rulemaking cycle. Subregulatory guidance on the nomination process is anticipated to be released in early 2022.

4. **Additional Key Takeaways**

   OPPS and ASC Rate Updates. For CY 2022, CMS increased OPPS and ASC payment rates by 2% for hospitals and ASCs that meet applicable quality reporting requirements. Failure to meet quality reporting requirements will result in a 2% rate reduction. Due to the variability of CY 2020 data caused by COVID-19, CMS used CY 2019 claims data to set these rates.

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Temporary COVID-19 Measures. In the Proposed Rule, CMS sought comment on whether to permanently adopt certain flexibilities currently in place due to COVID-19. CMS focused on COVID-19 flexibility regarding 1) mental health services furnished by hospital staff remotely to patients in their homes; 2) direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation by audio-virtual communication technology; and 3) payment for COVID-19 specimen collection in hospital outpatient departments. Although CMS did not permanently adopt these flexibilities as part of the Final Rule, CMS noted that it intends to continue considering comments as part of future rulemaking.

Continuation of Site-Neutral Policy for Clinic Visits. CMS will continue its site neutral policy of paying for clinic visits provided at off-campus hospital outpatient departments at 40% of the OPPS rate. This policy has been a topic of significant industry pushback and litigation since implementation in 2019. In 2019, hospital plaintiffs successfully challenged this policy at the federal district court level. However, in 2020 the US Court of Appeals upheld CMS's authority to implement site neutrality, and in June 2021, the U.S. Supreme Court declined to hear the case. Given this outcome, CMS's site neutral policy is likely here to stay.

Quality Reporting Programs. CMS finalized updates to quality reporting measures under the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program, including the addition of COVID-19 Vaccination of Health Care Personnel Among Healthcare Personnel as a reporting measure.

Radiation Oncology Alternative Payment Model. CMS implemented its Radiation Oncology Alternative Payment Model (RO Model) effective January 1, 2022. The RO Model was initially slated for January 1, 2021 but was delayed due to COVID-19.

The Coming Storm: Coordination of Benefits for Medicaid Providers

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The Families First Coronavirus Response Act (FFCRA), passed in response to the COVID-19 pandemic, offered states the option to expand Medicaid eligibility for coverage of COVID-19 testing and treatment.[1] FFCRA also increased federal financial participation for state Medicaid programs by 6.2% – on the condition that states must maintain beneficiaries' Medicaid enrollment status until the end of the month following the end of the COVID-19 public health emergency (PHE).[2] Every state in America took advantage of this additional federal money for Medicaid. As a result of the FFCRA's new eligibility requirements and enhanced funding, there has been a dramatic increase in Medicaid enrollment – more than 12 million individuals joined the Medicaid rolls between February 2020 and June 2021.[3] This increase was driven by the twin economic forces of the COVID-19 pandemic and rapid increases in unemployment and loss of employer-based health insurance.

While employment has not entirely recovered to pre-pandemic numbers, unemployment is declining. From a health care coverage perspective, this means that many newly employed workers are now eligible for employer-based health care coverage or have the means to purchase separate health insurance coverage through a state or national exchange.[4] Under traditional eligibility rules, individuals with new employer-based health insurance would be removed from Medicaid enrollment as their other sources of coverage become effective (or as they cease to meet Medicaid income eligibility standards). FFCRA, however, requires Medicaid programs to maintain enrollment for these individuals until the PHE is over.[5] With Omicron continuing to surge across the country, it's unclear when the PHE might end, but it has been extended eight times since the initial declaration in March of 2020. The current declaration was effective January 16, 2022 and extends for 90 days

[1] Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 209 (March 18, 2020), https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf.
[2] Id. at § 6008; see also 42 U.S.C. § 1396d; COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, Continuous Coverage, Question 1 (updated as of Jan. 6, 2021), https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf.
[3] See Bradley Carallo, Analysis of Recent National Trends in Medicaid and CHIP Enrollment (Jan. 10, 2022), https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/#footnote-543920-1.
[4] Unemployment rate declined by 0.3 percentage point to 3.9 percent in December 2021, and the number of unemployed persons decreased by 483,000 to 6.3 million. Throughout 2021, these rates dropped by 2.8 percentage points and 4.5 million, respectively. This means that unemployment rates are nearly back to pre-pandemic levels—the unemployment rate in February 2020 was 3.5 percent. Press Release, Bureau of Labor Statistics, The Employment Situation – December 2021 (Jan. 7, 2022), https://www.bls.gov/news.release/pdf/empsit.pdf.
[5] Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6008, 134 Stat. 209 (March 18, 2020), https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf; see also 42 U.S.C. § 1396d.

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or cessation of the PHE. Consequently, Medicaid enrollment will likely extend at least through the end of April 2022.

These unique circumstances – expanded Medicaid enrollment, expanded employment, and regulatory limits on disenrollment from Medicaid create a difficult situation for health care providers, and a need to focus on coordination of benefits. One Medicaid rule that hasn't changed during the PHE is that Medicaid is generally the payer of last resort.[6] Medicaid-participating providers are required to submit claims for health care services to other insurance or third parties that have an obligation to pay for those services before billing Medicaid. If providers (or the Medicaid program itself) discover alternative sources of coverage after the fact, the Medicaid payment will generally be recouped, and the provider must look to the primary insurance coverage for payment.[7]

Because patients are not always reliable sources of information regarding their existing health insurance coverage, and because patients may well be eligible both for Medicaid coverage and new employer coverage, the risk to providers of billing Medicaid in error has and will continue to increase over the coming months. Erroneous submission of claims to Medicaid where another party has primary responsibility risks recoupment from the Medicaid program, coverage and benefit confusion between primary payers and Medicaid coverage, and potential timely filing issues for health care providers. Given these risks, providers should take extra steps to ensure that they obtain full and complete information from patients to promote compliance with Medicaid third party liability rules.

Medicaid is the payor of last resort, and providers should follow that rule when submitting claims. To prepare for the inevitable audits and demands for repayment, Medicaid providers should focus on maintaining good eligibility and coverage records for patients and train billing personnel on proper coordination of benefits so claims will be billed and paid properly the first time.

[6] See 42 C.F.R. Part 433; Medicaid and Chip Payment Access Commission, Third Party Liability (last visited Jan. 24, 2022) https://www.macpac.gov/subtopic/third-party-liability/.
[7] See, e.g., Colo. Dep't of Health Care Policy & Financing, General Provider Information Manual (Nov. 24 2021) https://hcpf.colorado.gov/gen-info-manual#revlog.

U.S. Supreme Court Hears Rare 340B Drug Pricing Program Matter with Significant Reimbursement Implications

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At the end of November, the United States Supreme Court took a rare step and heard oral arguments involving a 340B Drug Pricing Program matter in American Hospital Association v. Becerra. During oral arguments, the Supreme Court justices questioned whether CMS had acted within its authority to implement sweeping Medicare reimbursement cuts for certain separately reimbursable 340B drugs back in 2018 that continue today. With potentially billions of dollars in reimbursement on the line, this case is going to be a big one that Covered Entities (CEs) should be watching closely. If the Supreme Court sides with American Hospital Association (AHA), CEs stand to benefit tremendously.

Along with potentially billions of dollars, the stakes are high because as Justice Breyer pointed out, the decision will have "implications well beyond this case." The case invokes an older legal doctrine, Chevron, which gives agencies, such as CMS, the authority to make decisions when statutes are not clear. If the Supreme Court decides to apply Chevron and rule in favor of HHS, CMS could conceivably gain more power to maintain the reimbursement cuts and have paved the way for even more 340B reimbursement cuts in the future. On the other hand, the Supreme Court could decide to rule in favor of 340B hospitals and reverse the 340B reimbursement cuts. If that happens, CEs will have to determine if further individual action will be needed to pursue prior 340B underpayments, or if CMS will increase payments on a go-forward basis as a remedy.

Although the Supreme Court has until the end of its term in June to issue its opinion on the case, we anticipate a decision will be published no later than early spring at this time.

What Covered Entities Can Do Next

1. **Take Advantage of Opportunities to Provide Feedback to CMS on 2020 Actual Acquisition Cost (AAC) Survey Results**

   CEs should be wary of what CMS will do with the 2020 AAC survey results if the Supreme Court rules in favor AHA. As the attorney for HHS pointed out during oral arguments: 340B hospitals won't "want the result of the survey because the survey is going to lead to lower rates for them, lower rates even than they have now under HHS's guidelines." Given this insight to survey results, CEs must push back on CMS when given the opportunity to ensure that lower reimbursement rates are not implemented. CEs can provide feedback by submitting comment on CMS's use of existing AAC survey data or the use of a

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new survey 340B. As HHS highlighted, very few hospitals responded, so CEs should continue to seek counsel regarding resisting the survey on numerous grounds.

2. **Expect CMS to Push Back on Issuing a New Survey**

   Justice Kagan repeatedly stated during oral arguments, if CMS has AAC survey data, they can do one thing (i.e., use the AAC data to set new payment rates), but if they do not have survey data, then they can do another thing (i.e., pay at ASP+6%). HHS pushed back on this notion and also followed up with stating it has the survey data based on the 2020 340B Drug Acquisition Cost Survey it issued to 340B hospitals. However, AHA argued that the 2020 340B Drug Acquisition Cost Survey issued by CMS is not a valid statistical representation of 340B hospitals and thus, the results should not be considered to influence reimbursement rates. Rather, a survey issued to all hospitals is the appropriate survey representation.

   If HHS loses the case and the Supreme Court says that CMS must follow the procedures outlined in the statute, then the question becomes whether the 2020 survey of 340B hospitals was representative enough to use the results. If the survey is deemed insufficient, or if CMS opts to reissue a survey to avoid additional judicial scrutiny, hospitals should carefully consider all options and plan to consider submitting comments to CMS.

3. **Plan to Appeal**

   If AHA prevails and the Supreme Court strikes down the reimbursement cuts, CEs can begin to develop a strategy to seek underpayments. CEs can also analyze financial impact of 2018-current Medicare reimbursement reductions regarding separately payable 340B drugs to calculate aggregate underpayment. CEs should start assessing avenues to appeal for additional reimbursement dating back to 2018. If the Supreme Court agrees with AHA and rules that CMS did not have the authority to implement the reimbursement cuts in 2018, it's possible that CEs will be entitled to additional reimbursement that has been withheld. CEs can analyze financial impact of 2018-current Medicare reimbursement reductions regarding separately payable 340B drugs to calculate aggregate underpayment.

Medicare Physician Fee Schedule

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The Federal Register published the Calendar Year 2022 Medicare Physician Fee Schedule final rule on November 19, 2021. 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. Following is a brief discussion of key elements in the MPFS final rule for 2022.

- Conversion Factor. Each year, the MPFS updates the Conversion Factor (the amount that is multiplied by the service's relative value units to determine the baseline price of the service). The update generally takes into account any changes to RVUs established for services and any services added to or deleted from the MPFS. Because CMS is required to make MPFS payments budget-neutral year over year, the Conversion Factor update is frequently negative. That was the case this year, as the conversion factor announced in the MPFS Final Rule was $33.59 – a decrease of $1.30 from CY2021. However, Congress subsequently enacted legislation to mitigate the negative adjustment, and consequently, CMS announced on December 15, 2021 that the CY 2022 Conversion Factor would be $34.6062, a reduction of approximately $0.29 from the CY2021 rate.
- Evaluation and Management Codes. CMS made several changes to payment policy for certain evaluation and management services.
  - Split/Shared Services. Split/shared services occur when a physician and a non-physician practitioner both provide portions of the same service to a patient in a facility setting. Unlike "incident to" services in the office setting, split/shared services historically were required to involve a face-to-face interaction with the patient from both the physician and the NPP to allow billing under the physician's billing number and payment at the physician rate. CMS has established a new methodology by stating that only the practitioner who performs the "substantive portion" of the visit, which is defined in 2022 as the history, the physical examination, the medical decision-making, or at least one-half of the total time spent with the patient (except for critical care codes, which may only be determined by time). For CY2023, the "substantive portion" will be determined solely by time. This change is likely to mean that many split/shared services that were previously billed under the physician's number will now be billed under the NPP's number and paid at 85% of the full fee schedule rate.
- Critical Care Services. CMS refined its longstanding policies regarding critical care services.
  - CMS established that critical care services may be provided concurrently by more than one provider representing more than one specialty when medically necessary.
  - Critical care services may be furnished as split/shared visits.

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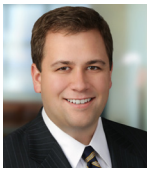
  - Critical care services may also be provided on the same day as other E/M visits, if the other E/M visit is provided before the need for critical care arose and that the services were not duplicative. In this situation, practitioners must report a -25 modifier with the critical care service.
  - Critical care services may also be paid separately in addition to surgical services if the critical services are above and beyond and unrelated to the specific surgical procedure.
- Teaching Physician Services. Teaching physicians have historically been able to bill for off/outpatient E/M visits in which a resident participates based either on time or on medical decision-making if the teaching physician is present for the key or critical portion of the service. CMS clarified that when using time to select the appropriate code, only the teaching physician's time may be counted. Under the so-called "primary care exception," which allows teaching physicians in certain primary care centers to bill for residents' primary care services even when the physician is not present, the teaching physician must bill based on medical decision-making and may not bill based on time.

- Telehealth Services.
  - Certain services that were added to the telehealth list for the COVID-19 public health emergency (PHE) will remain on the list until December 31, 2023.
  - As required under the Consolidated Appropriations Act, 2021 (CAA), CMS will pay for telehealth services provided for the diagnosis, evaluation or treatment of a mental health disorder where the patient's home is the "originating site" for purposes of telehealth billing.
  - CMS also amended its definition of "interactive telecommunications system" to include audio-only technology for mental health disorders where the practitioner has both audio and video capability but the patient either lacks video capability or declines to use video capability. A new modifier will be required for audio-only services.
  - Substance use disorders will be included in mental health services for purposes of the telehealth services described above.
- Therapy Services. CMS has completed its implementation of payment at 85% of fee schedule for therapy services provided by physical therapy assistants and occupational therapy assistants under the supervision of a physical therapist or occupational therapist, respectively.
- Billing for Physician Assistant Services. CMS implemented the requirements of Section 403 of the CAA authorizing direct payment to physician assistants for their services. Previously, payment could only be made to the employer of a physician assistant for services provided by that physician assistant.
- Vaccine Administration.
  - CMS will reimburse $30 per dose for administration of the influenza, pneumococcal and hepatitis B vaccines.
  - CMS will maintain the current rate of $40 per dose for administration of COVID-19 vaccines through the end of the calendar year in which the current PHE ends.
  - CMS will pay an additional $35.50 for home administration of COVID-19 vaccines through the end of the calendar year in which the current PHE ends.
  - CMS will pay $450 for COVID-19 monoclonal antibodies in a health care setting, and $750 in the home setting, through the end of the calendar year in which the PHE ends. Thereafter, monoclonal antibodies will be paid according to existing payment policy for biologicals.
- Medicare Shared Savings Program.
  - CMS extended the transition to e-reporting of clinical quality measures by extending the availability of the CMS web portal through performance year (PY) 2024.
  - CMS also delayed the increase in the quality performance standard that ACOs must meet to be eligible to share in savings until PY 2024.
  - CMS eased the repayment mechanism requirements for ACOs that have accepted performance-based risk to facilitate more ACOs entering into two-sided risk.
  - CMS reduced some of the paperwork requirements related to applications to participate in the Shared Savings Program.
  - Finally, CMS revised the definition of primary care services to be used for beneficiary assignment beginning with PY 2022.
- Other changes.
  - The Final Rule includes clarifying regulations related to practitioners that may provide medical nutrition therapy (MNT) services.
  - CMS implemented Section 122 of the CAA to reduce the coinsurance obligation for beneficiaries whose colorectal screenings become diagnostic services (for example, when a polyp must be removed).
  - RHCs and FQHCs may now provide mental health services by telehealth.
  - CMS implemented the requirements of Section 130 of the CAA to increase the per-visit payment limit for RHCs.
  - CMS finalized the limited circumstances under which it would waive the requirement for prescribers to use e-prescribing for controlled substances.
  - CMS finalized rules expanding coverage of outpatient pulmonary rehabilitation services for patients who were hospitalized with COVID-19.

CMS Innovation Center Releases New Strategic Priorities in 2021 to Set Course for Second Decade of Operations



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The Center for Medicare and Medicaid Innovation ("CMMI") was established as part of the Affordable Care Act and gives the Secretary broad discretion to develop and implement payment models with the goal of achieving higher quality in the delivery of high value services at a lower cost to the Medicare and Medicaid programs. CMMI is responsible for administering many popular programs, including the Bundled Payments for Care Improvement Advanced, ESRD Treatment Choices Model, the Oncology Care Model, Expanded Home Health Value Based Purchasing Model, Million Hearts, and other value-based demonstration programs.

Through the years, CMS has made attempts to implement reforms to Part B drug payments through CMMI. This year, CMMI chose not to implement the Most Favored Nation Model Interim Final Rule (MFN Model) after several delays. The MFN Model was aimed at lowering the amount Medicare Part B pays for 50 high-cost drugs to the lowest price that drug manufacturers receive in similar countries. On December 27, 2021, CMMI announced it rescinded the MFN Model as it "explore[s] all options to incorporate value into payments for Medicare Part B drugs, improve access to evidence-based care, and reduce drug spending for consumers and throughout the health care system." No new Part B drug payment models have been proposed to replace the MFN Model.

Despite the ongoing implementation of demonstration models, perhaps the most notable development for CMMI in 2021 was its release of a new strategic plan entitled the Innovation Center Strategy Refresh ("Strategic Plan"). The Strategic Plan is intended to guide CMMI's health care payment and delivery model development and design priorities over the next decade. According to CMMI's proposed timeline, the first three to six months of this plan's implementation would be dedicated to stakeholder engagement.

Although CMMI's overarching goal continues to be expansion of successful models that reduce program costs and improve quality and outcomes for Medicare and Medicaid beneficiaries, the Strategic Plan establishes the following objectives for CMMI:

1. *Increase the number of Medicare and Medicaid beneficiaries in value-based care models by 2030.* CMMI has a goal that all Medicare Part A and Part B enrollees and the vast majority of Medicaid enrollees will participate in care relationships with accountability for quality and total cost of care by 2030.
2. *Advance Health Equity.* Embed health equity in all models through mandatory reporting of demographic and social determinants of health data as appropriate. Ensure participation of historically underserved populations and safety net providers in new models.
3. *Support Care Innovations.* Support innovation by strengthening patient engagement and including patient experience measures and patient-reported outcome measures in performance measurement.
4. *Improve Access by Addressing Affordability.* Facilitate approaches to address price and affordability of care with the goal of reducing the number of individuals who forgo care due to cost by 2030.
5. *Partner to Achieve System Transformation.* Pursuing more collaborative and ongoing partnerships with a broader group of stakeholders to improve quality, achieve equitable outcomes and reduce health care costs, and, where possible, create multi-payer alignment in all new models available by 2030.

The Strategic Plan notes that achieving the five objectives outlined above will require changes in stakeholder outreach, data transparency, and defining model success. CMMI plans to expand opportunities for stakeholder input from patients and patient advocates as part of its new strategy and to determine barriers to participation by nonparticipants. CMMI also recognizes the need for broader data sharing regarding its models and is piloting efforts through the Virtual Research Data Center so that researchers will be able to link model claims data with model participants for analysis.

Finally, CMMI plans to assess model success by evaluating new endpoints that include: (a) beneficiary impacts, such as patient experience, population level metrics, quality of care transitions, access to care across various settings, coordination across providers, and cost; (b) provider impacts, such as care transformation, impact on administrative burden, level of alignment on models across payers, sustainability of participation in models, and access to actionable data; and (c) market impacts, such as level of consolidation, new linkages or relationships between providers, spread of model elements to other payers, scalability of model to other regions or payors, and generalizability of impacts to other populations. These new assessment points will provide additional information to help craft new models and also assist other payors in moving to value-based care models.

2021 Year in Review: Three Things in the Reimbursement Space That You May Have Missed

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While health care providers continued focusing on fighting COVID-19 in 2021, Medicare reimbursement changes marched on. Three of the more significant changes providers should know about are urine drug testing, CMS' 2022 Physician Fee Schedule final rule, and Medicare Part A coverage for observation v. inpatient services, all of which have put providers on notice for future changes in these areas.

OIG Sees Lack of Clarity in Medicare Contactors' Urine Drug Testing Guidance

On June 8, 2021, the Department of Health and Human Services – Office of Inspector General ("OIG") published a report, "Opportunities Exist for CMS and its Medicare Contractors to Strengthen Program Safeguards to Prevent and Detect Improper Payments for Drug Testing Services." In it, OIG assessed the Medicare contractors' program safeguards for ensuring that Medicare claims for drug testing services for beneficiaries with substance use disorders ("SUD") comply with Medicare requirements.

OIG identified three weaknesses in the Medicare contractors' established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. Specifically, OIG found the contractors did not have: (1) clear and consistent requirements or guidance for laboratories to use when determining the number of drug classes to bill for definitive drug testing services; (2) procedures for identifying or limiting the frequency of drug testing services (e.g., the number of drug tests performed per year) for each beneficiary across all Medicare jurisdictions; and (3) consistent requirements in their Local Coverage Determinations ("LCDs") or any procedures for identifying claims for direct-to-definitive drug testing. OIG concluded these weaknesses occurred because CMS did not issue a National Coverage Determination ("NCD") to provide uniform requirements for drug testing services or instruct the Medicare contractors to develop LCDs with more consistent requirements. Given these findings, OIG is concerned Medicare contractors cannot ensure that laboratories' claims for drug testing services comply with Medicare requirements, and therefore, laboratories may receive improper payments, and beneficiaries with SUD may receive medically unnecessary drug testing services.

OIG recommended that CMS contractors: (1) take the necessary steps to determine whether clinical evidence exists to support a single, specific reasonable and necessary standard for drug testing services, and if such evidence exists, establish an NCD or develop LCDs with more consistent requirements for drug testing services; (2) clearly indicate in LCDs, Local Coverage Articles, or other instructions how laboratories should determine the number of drug classes for billing definitive drug testing services; (3) implement a system edit or procedure to identify and limit the frequency of drug testing services per beneficiary across all Medicare jurisdictions; (4) determine whether a post payment medical review is necessary for laboratories that have been paid for excessive definitive drug tests in a one-week period for the same beneficiary; and (5) consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test. CMS disagreed with OIG's first three recommendations and has not yet implemented any policy aligned with these recommendations.

The lack of clear guidance from CMS on this topic, and OIG's recommendation that CMS clarify existing guidance or develop new guidance for providers, can be a useful argument for providers when challenging an overpayment determination (and any subsequent appeal decision) based on the failure to follow CMS guidelines for SUD urine drug testing.

CMS' 2022 Medicare Physician Fee Schedule Final Rule Makes Several Notable Policy Changes for Medicare Payments

In accordance with the 2021 Consolidated Appropriations Act, the CMS Calendar Year 2022 Physician Fee Schedule final rule ("Final Rule") will allow access for patients in any geographic location, including their homes, to telehealth services for diagnosis, evaluation, and treatment of mental health disorders, including substance use disorders. Providers are now allowed to be reimbursed by Medicare for these telehealth visits when provided by Rural Health Clinics ("RHCs") and Federally Qualified Health Centers ("FQHCs") via interactive telecommunications technology, including audio-only telephone calls. Further, the Final Rule will allow payment to eligible practitioners when they provide certain mental and behavioral health services to patients via audio-only telephone calls from their homes when certain conditions are met (i.e., there must be an in-person, non-telehealth service with the physician or practitioner within six months prior to the initial telehealth service and at least once every twelve months thereafter, though exceptions may apply). Notably, these services include counseling and therapy services provided through Opioid Treatment Programs, which will be particularly beneficial patients in areas with poor broadband infrastructure.

CMS also made numerous refinements to its current policies for split or shared E/M visits, critical care services, and services furnished by teaching physicians involving residents. (For full details, see 42 C.F.R. § 415.140.) Highlights include: (1) allowing split or shared E/M visits to be reported for both new and

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established patients and initial and subsequent visits as well as prolonged services; (2) requiring a modifier on an E/M claim to identify these services; (3) establishing that the CPT Codebook listing of bundled services are not separately payable; (4) allowing critical care services, when medically necessary, to be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, which can be furnished as split or shared visits; and (5) clarifying that when time is used to select the office/outpatient E/M visit level, only the time spent by the teaching physician in qualifying activities, including time that the teaching physician was present with the resident performing those activities, can be included for purposes of visit level selection. (Under the primary care exception, time cannot be used to select visit level.)

Providers should collaborate with their Medicare billing and compliance departments to ensure that they are including the necessary information when submitting claims for these services to ensure that they will be fully reimbursed as allowed by Medicare. Moreover, to the extent a provider qualifies as either a RHC or FQHC, the provider should develop or strengthen programs focused on delivering mental and behavioral health to patients via telehealth under the Final Rule, as these services are now reimbursable in limited circumstances.

Alexander v. Azar: Federal District Court Decision Requires the Secretary to Establish an Appeals Procedure for a Modified Class of Medicare Beneficiaries

When an elderly patient enters the hospital, a physician decides whether to admit that patient under "inpatient" or "observation" status, and Medicare Part A coverage is only available for the former. When a physician decides to admit a patient as an inpatient, that decision is then subject to mandatory utilization review, a requirement established by Medicare statute and regulations for all participating hospitals. Through utilization review, a hospital's Utilization Review Committee ("URC") evaluates a physician's inpatient-admission order for compliance with CMS rules and can reclassify patients from inpatient to observation status. Patients do not participate in the classification process and, until recently, lacked the ability to challenge either a physician's or URC's admission-status decision.

In 2011, a nationwide class of Medicare beneficiaries sued the Secretary of Department of Health and Human Services in *Alexander v. Azar*. The Plaintiffs alleged that the Secretary deprived them of their property interest in Medicare benefits by failing to establish a procedural process for appealing status-changing decisions. In a Memorandum of Decision issued on March 24, 2020, a federal district court ordered, inter alia, that beneficiaries had a protected property interest in Medicare Part A coverage, and that the beneficiaries whose statuses were changed by the hospital's URC from inpatient to observation were denied due process of law. Specifically, the Court found that URC determinations constitute state action because CMS plays a substantial role in shaping the criteria used by hospital URC to evaluate and change patient status (i.e., CMS requires hospitals to implement a utilization review plan, CMS contractors conduct post-payment reviews of a hospital's inpatient claims, contractors educate hospitals on the proper application of CMS' inpatient criteria, and hospitals are subject to audit by HHS-OIG for compliance with CMS criteria). As such, the Court ordered the Secretary to establish a procedure to permit all members of the modified class (as defined in the Memorandum), including those Medicare beneficiaries whose statuses were reclassified from inpatient to observation, to appeal the denial of their Part A coverage. The government appealed the District Court's judgment on May 22, 2020, and subsequently requested for a stay of the decision. On July 16, 2021, the Second Circuit Court of Appeals granted a temporary stay.

It is unclear when CMS will establish a formal appeals procedure. Nevertheless, hospital providers and Utilization Review Committees should carefully review this Court's definition for the modified class of patients. The legitimacy of any future appeal will likely be reviewed on a case by-case basis depending on whether the appellant is entitled to relief under *Alexander's* class definition.

Medicare Advantage Review

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Every year, the Centers for Medicare & Medicaid Services (CMS) make adjustments to the Medicare Advantage (MA) program during its annual rulemaking process. While not as significant as the COVID-19 pandemic driven changes of 2020, there were some notable changes to the program seen in 2021 –through rulemaking, potential legislation, and operations. In this article, we briefly summarize what we view as the most significant developments in the Medicare Advantage program in 2021.

Accurate Diagnosis Codes and Supporting Documentation

CMS uses diagnosis codes submitted by MA plans and Medicare FFS claims to calculate risk scores for payments. Historically, MA plans submitted diagnoses via CMS' Risk Adjustment Processing System (RAPS). Recently, however, CMS has relied on a combination of encounter data, which contains diagnosis codes, submitted by MA plans and from RAPS. Beginning in 2022, CMS will rely entirely on MA encounter data and fee-for-service claims to calculate risk scores. While proper documentation has always been important, MA's increased reliance and focus on encounter data to support MA plan risk scoring and payment further emphasizes how critical it is for Providers to ensure their records fully support recorded diagnosis codes.

Enrollment in Medicare Advantage program plans continues to grow. In 2020, MA plans provided coverage for 40% of all Medicare beneficiaries. The growth, and resulting increase in annual cost to CMS, led the Office of Inspector General for the Department of Health and Human Services to label the MA program an "important priority" for fraud investigations. Several court cases highlighted the government's stance that providers who receive payments from MA plans may face False Claims Act liability. The cases involved allegations that MA plans submitted falsely inflated risk adjustment data to CMS, resulting in higher capitation payments to the plans. Providers may face False Claims Act and other liability for submitting false or unsupported diagnosis codes that result in inflated risk adjustment payments to MA plans.

Build Back Better Act and Medicare Expansion

The Build Back Better Act includes provisions that would expand the scope of coverage provided to Medicare beneficiaries. Currently, traditional Medicare does not cover hearing benefits, with a few exceptions. However, many MA plans offer hearing benefits, including hearing aids, as a supplemental benefit. If enacted, the expansion will require MA plans to offer hearing care as a primary or "basic" benefit. This change would likely result in MA plans renegotiating contracts with hearing providers.

The bill has passed the House of Representatives but has stalled in the Senate. Sen. Joe Manchin III (D-W.Va) has expressed concerns over the bill's expansion of Medicare (among other concerns) and seems to be a key figure in deciding the bill's future. In the evenly divided Senate, the threat of a dissenting vote could lead to changes in the bill that would result in an updated version being sent back to the House or cause the bill to die altogether.

Offshoring

The COVID-19 pandemic, and its impact on the provision of in-person health care, prompted many providers to shift portions of their operations so that they could be conducted remotely, including, for example, billing, collections, and even clinical care delivered via telehealth. In some cases, these remote operations were shifted overseas. The result was a massive expansion of provider operations that are potentially subject to MA offshoring expectations. Offshoring occurs when a service for which the MA plan is responsible is performed outside of the United States or one the United States territories and involves beneficiary protected health information. MA plans are required to report to CMS offshoring arrangements, including those entered into by the MA plans' downstream providers, that involve protected health information. To obtain information needed for reporting to CMS, MA plans contractually require providers to notify or obtain the consent of the MA plan prior to any offshoring. Though MA offshoring rules have been around for some time, MA plans are now taking a much closer look at provider offshoring in response to the COVID-19 pandemic. Before offshoring operations, providers servicing MA beneficiaries should carefully consider their obligations under their contracts with MA plans to notify and/or obtain the consent of MA plans prior to offshoring.

End of Year SNF PPS Final Rule

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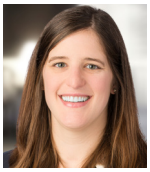

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It is no secret the last eighteen months have changed the way skilled nursing facilities ("SNFs") operate and it appears many of those changes will be permanent, with the potential for more changes on the horizon.

Many proposed changes and comments in the SNF PPS Final Rule for FY 2022 are COVID-driven, with the most prominent change being the addition of new quality reporting measures. Beginning in FY 2023, to avoid penalties associated with the CMS Quality Reporting Program (" SNFs will be required to report two new quality measures: the amount of COVID-19 vaccination coverage among healthcare personnel and the prevalence of healthcare-associated infections ("HAI"). SNFs failing to meet the reporting requirements for any QRP metric may have a 2% reduction in their annual update. While the HAI measure does not explicitly measure COVID infection rates, CMS's stated purpose in adding these quality measures is based on data supporting that facilities with higher HAI rates are more likely to have COVID outbreaks, overall higher number of COVID-19 cases, and they are more likely to have issues in future pandemics.

COVID also found its way into the Final Rule in CMS's consideration of the overall Patient- Driven Payment Model (PDPM) budget. CMS noted that it saw a roughly 5% increase in spending under PDPM; a deviation from the intent that PDPM remain budget-neutral compared to the old RUG-IV system. However, CMS acknowledged that this significant increase may have been skewed due to the higher-acuity case mixes SNFs saw during the COVID pandemic. Instead of taking immediate action to attempt to reset the budget, CMS agreed with commenters to hold the discussion until next year.

Meanwhile, the Final Rule increased SNF payments by 1.2% after accounting for the 0.8% forecast error adjustment and a 0.7% productivity adjustment.

Other notable updates in the SNF PPS Final Rule include:

- **QRP Transfer of Health information to the Patient-Post-Acute Care Measure:** CMS updated the denominators used in the measure to exclude residents discharged home to the care of a home health service or hospice for the FY 2023 reporting period.
- **Measure Suppression and Special Scoring for the SNF Value-Based Purchasing (VBP) Program:** As a result of pandemic-related readmission rates, CMS will suppress the 30-day All-Cause Readmission Measure for FY 2022. All SNFs will receive a performance score of zero regardless of performance.
- **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. However, CMS declined to implement any changes due to COVID-19.
- **Wage Index Updates and Core-Based Statistical Area Designation:** CMS adopted the most recent OMB Core-Based Statistical Area delineations, though the OMB 18-04 updates adopted last year will remain unchanged.

Looking beyond the final rule, we anticipate PDPM creeping into state Medicaid programs nationwide. As state regulatory and legislative bodies are reflecting on the impact COVID had on the long-term care industry, many discussions are leaning towards reforms that tie quality to reimbursement and adopting a PDPM model is a popular solution. We anticipate this will be a common and debated topic throughout the next year.

2022 Hospice/Home Health Update

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HHA/Hospice Rule Updates Intro

CMS updated rules related to home health and hospice, improving home health care for older adults and people with disabilities by finalizing the expansion of a system that pays for value rather than volume, updating payment rules and rates, and incorporating into regulation several Medicare provider enrollment policies, among other actions.

Home Health Value-Based Purchasing (HHVBP)

CMS finalized a nationwide expansion of the successful Home Health Value-Based Purchasing (HHVBP) model, after the success of HHVBP in the nine original Model States where the approach was piloted. The Model tested whether payment incentives rewarding improved quality of care would result in better value and higher quality of care. The program achieved a 4.6% improvement in quality scores as well as an average annual savings of $141 million to Medicare. Thus, CMS is expanding the HHVBP to all 50 states. CY 2022 will be a pre-implementation year and CY 2023 will be the first performance year of the expanded HHVBP model.

Medicare Home Health Prospective Payment System (PPS)

The final rule updates the Medicare Home Health Prospective Payment System (HH PPS) rates and wage index for CY 2022. CMS estimates that Medicare payments to HHAs in CY 2022 will increase in the aggregate by 3.2% or $570 million.

CMS has also finalized the recalibration of the patient-driven groupings model (PDGM) case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the CY 2021 low utilization payment adjustment (LUPA) thresholds for CY 2022 to more accurately pay for the types of patients HHAs are serving.

Home Infusion Therapy Services Payment Rates

CMS is updating the home infusion therapy services payment rates for CY 2022, 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 5.1%.

Home Health Quality Reporting Program Updates

The new rule improves the Home Health Quality Reporting Program by instituting a claims-based measure that addresses concerns surrounding attribution and is more strongly associated with positive patient outcomes, and removing a measure that is no longer improving performance.

Home Health Conditions of Participation

CMS makes permanent the changes to the Home Health Conditions of Participation (CoP) that were implemented during the COVID-19 public health emergency, including blanket waivers related to home health aide supervision and the use of telecommunications in conducting assessment visits. CMS expects that in most instances, HHAs would conduct 14-day supervisor assessments during an on-site, in-person visit, and the HHA would use interactive telecommunications systems only for unplanned occurrences.

Survey and Enforcement Requirements for Hospice Programs

CMS finalized provisions to support transparency, oversight, and enforcement of health and safety requirement for hospice programs. CMS enhanced the hospice program survey process by requiring multidisciplinary survey teams, prohibiting surveyor conflicts of interest, and expanding surveyor training options. The provisions also require state survey agencies facilitate a hospice program complaint hotline, and broaden enforcement options to include remedies in addition to termination of participation in Medicare for noncompliant hospice programs.

Enrollment

CMS finalized some provider enrollment changes applying to a broad variety of providers beyond home health or hospice agencies. Namely, CMS finalized existing effective date policies to apply to additional providers, added grounds for rejection or return of enrollment applications that are presently in the Program Integrity Manual but were not previously in the regulations, and finalized changes to rules related to deactivation of Medicare enrollments, including specifying that a provider or supplier may not receive payment for services while deactivated.

Specific to home health agencies, CMS finalized changes related to the requirements related to home health agency capitalization and the proof required to show such capitalization. CMS also finalized a change to the 36 month rule exception regarding home health agencies that have submitted two consecutive years of full cost reports, clarifying which cost reports apply (2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later).

End Stage Renal Disease (ESRD) Final Rule

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The CY 2022 End Stage Renal Disease ("ESRD") final rule, available here, focused on outlining a 2.5 percent increase in payments for freestanding ESRD facilities. CMS published its final updates and modifications to the ESRD Quality Incentive Program ("QIP") and the ESRD Treatment Choices ("ETC") innovation model. CMS continued encouragement towards home dialysis and acknowledged the impact of the COVID-19 Public Health Emergency ("PHE") on quality measures.

Payment Updates

The final CY 2022 ESRD Prospective Payment System ("PPS") base rate will be $257.90, up from $253.13 in CY 2021. CMS predicts that the updates will increase the total payments to all ESRD facilities by 2.5% compared with the previous year. The AKI base rate will also be updated to the same amount.

CMS also approved a Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies ("TPNIES") for the Tablo® System, a hemodialysis machine authorized for home use. ESRD facilities can receive an add-on payment for the next two yearsThe add-on, designed to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies, will last for two years.

CY 2022 will also bring adjustments to outlier payments – additional payments for ESRD facilities that treat beneficiaries with unusually high resource requirements. CMS updated the outlier services Medicare Allowable Payment (per treatment) and the outlier services fixed-dollar loss ("FDL") amounts based on 2020 claims data in order to get closer to their policy goal of having outlier payments make up 1% of total ESRD payments. CMS will continue to look at potential modifications to the outlier calculation or policy to address concerns that the 1% target has not been met.

ESRD QIP

Because of the COVID-19 public health emergency, CMS has chosen to suppress a number of ESRD Quality Incentive Program ("QIP") measures, including hospitalization and readmission measures. Under CMS's finalized policies, no facility will receive a payment reduction for PY 2022, and the performance standards for PY 2024 will be calculated using CY 2019 data.

ESRD Treatment Choices Model

The ESRD Treatment Choices Model ("ETC"), which began January 1, 2021, saw some updates for the coming years. The ETC is designed to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, including by directly addressing health equity and social determinants of health. ESRD facilities and Managing Clinicians who are selected are required to participate in the model.

In the CY 2022 rule, CMS included some ETC payment adjustments, as well as two changes to further address health and socioeconomic disparities. As part of the payment adjustments, providers may see upward or downward performance-based adjustments on dialysis and dialysis-related claims between July 1, 2022 and June 30, 2027. To address disparities, CMS added a Health Equity Incentive, through which providers may earn points by demonstrating significant improvement in the home dialysis rate or transplant rate among their dual-eligible attributed beneficiaries or Low Income Subsidy ("LIS") recipients. CMS will also stratify achievement benchmarks by the proportion of beneficiaries who are dual-eligible for Medicare and Medicaid or are LIS recipients in order to not penalize providers with high proportions of those populations.

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Contact Sinead McGuire, smcguire@polsinelli.com, for more information about any upcoming Polsinelli Health Care events.

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