Reimbursement and Payor Dispute Update

Special Edition – Year End Regulatory Review

POLSINELLI REIMBURSEMENT TEAM NEWSLETTER

The Centers for Medicare & Medicaid Services Issues New Inpatient Prospective Payment System Final Rule

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On September 3, 2020, the Centers for Medicare & Medicaid Services (CMS) issued the fiscal year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital Prospective Payment System (LTCH PPS) Final Rule (Final Rule) (available here). The Final Rule was effective October 1, 2020. The following is a summary of the Final Rule's most impactful provisions.

Prospective Payment Systems Rates Update

Generally, CMS reimburses acute care hospitals for inpatient stays under the IPPS, and LTCHs for inpatient stays under the LTCH PPS. Both payment systems set forth base payment rates based on the patient's diagnosis and severity of illness. The IPPS is updated annually based on changes in the prices of goods and services in treating Medicare patients; the LTCH PPS is typically updated annually according to the price of delivering LTCH-specific goods and services.

As set forth in the Final Rule, IPPS payment rates are expected to increase by approximately 2.9% in FY 2021 relative to FY 2020 for acute care hospitals that participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users. CMS estimates that, the applicable percentage increase to the IPPS rates should result in an estimated $3.5 billion increase in FY 2021 payments.

LTCH PPS payment rates are expected to increase by 2.3%. CMS estimates that overall LTCH payments will decrease by $40 million in FY 2021 due to the end of the statutory transition period for site neutral payment rate cases.

Disproportionate Share Hospital (DSH) Payments

CMS estimates that Medicare DSH payments for Uncompensated Care (UC) will decrease by approximately $400 million since FY 2020. The Final Rule outlines three factors used to determine UC payments. Specifically, the

CONTINUED ON PAGE 2

CONTINUED FROM PAGE 1

Table of Contents

DSH hospital's proportion of uncompensated care is determined as the product of:

- 75% of the amount of DSH payments that hospitals would receive pursuant to the DSH payment methodology that existed prior to FY 2014, or $11.378 billion.
- 1 minus the percent change in the percent of individuals who are uninsured between 2013 and the most recent year for which data is available.
- A hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage. CMS will continue to use Medicare cost report data accounted by Worksheet S-10 data from FY 2017 to calculate Factor 3 in FY 2021.

Cost Reporting of MA Median Negotiated Reimbursement

The CY 2020 OPPS price transparency rule required hospitals to post standard charges by January 21, 2021, and now the FY 2021 IPPS Final Rule imposes additional price transparency requirements. Under the final rule, hospitals must calculate and report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organization payers, by MS-DRG, beginning with cost reporting periods ending on or after January 1, 2021.

Graduate Medical Education

CMS is amending the Medicare policy regarding closing teaching hospitals and closing residency programs. Regulations will now include a broad definition of "displaced resident," which no longer requires the resident to be physically present at the hospital training on the day prior to or the day of hospital or program closure. The new definition is designed to allow residents more flexibility in finding alternative programs.

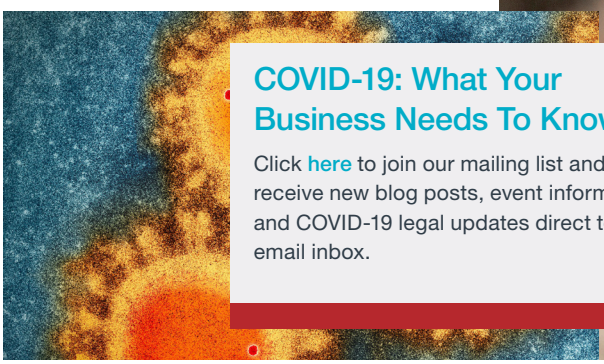
New and Updated MS-DRGs

CMS has introduced a new MS-DRG for Chimeric Antigen Receptor (CAR) T-cell immunotherapy, which includes two procedure codes. CMS also has deleted and replaced a number of MS-DRGs for major head and neck procedures, with the new incorporating severity level splits.

In addition, some existing MS-DRGs have been reassigned, including bone marrow procedures being reclassified from surgical to medical.

New Technology Add-on Payments

With the Final Rule, 24 technologies will be eligible to receive add-on payments, and CMS estimates spending on new technology add-ons will increase nearly 120% over FY 2020.



COVID-19: What Your Business Needs To Know

Click here to join our mailing list and receive new blog posts, event information and COVID-19 legal updates direct to your email inbox.

Three Things Happened in 2020 in the World of Reimbursement Disputes That You Need to Know About

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While most of the health care was focused on COVID-19, reimbursement disputes in three long-standing areas of contention, the Medicare Secondary Payor Act, so called "cross-plan offsetting" and statistical sampling by government contractors, came to a head in landmark decisions by courts and heavy criticism by government watchdogs.

Court Confirms Avenue for Providers to Recover Under Medicare Secondary Payer Act

A September 4, 2020, decision from the Eleventh Circuit has major implications for health care providers seeking reimbursement from primary commercial payers on claims involving patients who also have Medicare coverage. In *MSP Recovery Claims, Series LLC v. ACE Am. Ins. Co.*, 974 F.3d 1305, 1314-15 (11th Cir. 2020), the Court deferred to the Department of Health and Human Services' interpretation of the private right of action under the Medicare Secondary Payer Act, which extends the right to sue to "*any* downstream actor that has 'actually suffered an injury because *it provided* or paid for care from its own coffers and was harmed by a primary plan's failure to provide reimbursement[.]'" (emphasis added).

This decision means that health care providers might obtain double recovery from private insurers who improperly underpay or deny claims for health care services rendered to Medicare enrollees. While providers are thrilled about the additional opportunity for recovery, insurance groups are concerned the decision will cause turmoil in the Medicare Advantage system and primary payer market, increasing the odds it will be appealed to the Supreme Court.

Cross Plan Offsetting Is Not so Easy for Some Plans to Pull Off

On July 14, 2020, self-insured ERISA health plans — AT&T, PetSmart and CenturyLink — with a handful of their members filed a direct class action lawsuit against UnitedHealth Group (UHC) in United States District Court, District of Minnesota, to close a circle left open by that court in *Peterson v. UnitedHealth Group, Inc.*, that cross-plan offsetting may breach a fiduciary duty under the Employee Retirement Income Security Act of 1974 (ERISA). *See Scott, et al v. UnitedHealth Group, Inc.*, Civ. No. 20-1570.

Offsets are an aggressive form of recoupment that health plans utilize to reduce or withhold payments to healthcare providers without following the strict ERISA notice and disclosure requirements tied to plans' adverse benefit determinations. A plan engages in cross-plan offsetting when it recoups alleged overpayments to a health care provider by one plan by either withholding or reducing payments from another plan for later services provided to a different patient by that same provider.

Even though the plans granted UHC as the administrator of the plans broad discretion to interpret and administer the plans, the court held UHC could not engage in cross-plan offsetting as such practice was not allowed in the plan documents. The court did not go so far as to say such a practice constituted a breach of the UHC's fiduciary duty, but it did state "[c]ross-plan offsetting is in tension with this fiduciary duty because it arguably amounts to failing to pay a benefit owed to a beneficiary under one plan in order to recover money for the benefit of another plan."

After the *Peterson* ruling, health plans were encouraged to quickly revise their plan documents to allow for cross-plan offsetting. Meanwhile, the named plaintiffs in *Scott*, *et al* which include major, national self-funded plans, sought from the *Peterson* court a blanket prohibition of the practice by plan administrators that some argue is inevitable as the role of the plan administrator's primary purpose is to provide benefits while acting in the best interest of *each* plan it administers.

On November 20, 2020, UHC filed its *Motion to Dismiss Plaintiffs' Amended Complaint* which rests primarily on the argument that the plaintiffs lack Article III standing because they failed to (1) *allege* a concrete, particularized injury; and (2) *demonstrate* a concrete, particularized injury other than the risk of balance billing liability or that future injury was imminent. Oral arguments are set to be heard January 1, 2021.

Providers in markets heavy in the self-insured business should pay special attention to this case as a ruling in the favor of the plaintiffs would mark the beginning of the end of a reimbursement strategy that allows health plans to circumvent their ERISA obligations in the denial of healthcare benefits.

OIG Slams Statistical Sampling Practices by CMS Contractors

In a new report issued on August 25, 2020, the HHS Office of Inspector General (OIG)

CONTINUED ON PAGE 4

CONTINUED FROM PAGE 3

evaluated the review process for statistical extrapolation during the first two levels of appeal by Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs). The report is available here. As providers are well aware, extrapolation involves high financial stakes for providers as overpayment amounts can go from thousands of dollars to millions with the application of extrapolation. If statistical sampling and overpayment estimation methodology are found to be invalid on appeal, the provider may be liable for the actual overpayment identified in the sample but not the extrapolated amount.

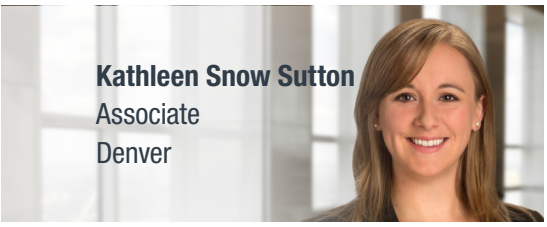
The report acknowledged what providers have long argued, i.e., that the MAC and QIC were inconsistent in evaluation the extrapolation of overpayments, and the report specifically targeted simulation. The simulation test was associated with at least $42 million in extrapolated overpayments that were overturned in fiscal years 2017 and 2018. OIG noted there was no guidance in this area from the Centers for Medicare & Medicaid Services (CMS) regarding simulation and thus it was unclear whether these extrapolations were valid. Additionally, CMS has provided limited guidance to QICs and MACs regarding the extrapolation process which has resulted in them using differing procedures for extrapolation. OIG stressed this limited guidance and oversight was not enough ensure these reviews were performed consistently.

OIG concluded its report with several recommendations for CMS. OIG recommended that CMS should provide additional guidance to Medicare contractors to ensure reasonable consistency in the procedures used to review extrapolated overpayments. Further, OIG suggested that CMS try to identify and resolve discrepancies in the procedures used by contractors to review extrapolations during the appeals process.

Providers looking to appeal audits or overpayment demands involving statistical extrapolations, should consult with a statistician or other professionals familiar the extrapolation process.

For more information on these cases or OIG report, contact the authors listed above.

Calendar Year 2021 Outpatient Prospective Payment System Final Rule: What You Need to Know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The Centers for Medicare and Medicaid Services (CMS) published the Outpatient Prospective Payment System (OPPS) final rule for calendar year 2021 (Final Rule) earlier this month (available here). The Final Rule[1] signals CMS' continued focus on expanding access to procedures in lower-cost care settings, while also making meaningful policy shifts on isolated issues like supervision and physician-owned hospitals. The Final Rule will be published in the Federal Register on December 29, 2020. The following is a summary of what you need to know.

Elimination of the Inpatient Only List

Recognizing advances in surgical care and its longstanding policy to defer to the judgment of treating physicians, CMS finalized its proposal to eliminate the Inpatient Only List (IPO list). The IPO list had previously restricted OPPS payment for certain services that CMS had deemed to require inpatient care because of the nature of the procedure, the recovery time, or the patient's condition. With its removal, CMS will allow physicians to use their clinical knowledge and judgment in conjunction with the beneficiary's specific needs to determine whether a procedure may be performed appropriately in a hospital outpatient setting. There will be a three-year transition for removing procedures from the IPO list and enabling them to be paid under the OPPS beginning in 2021, and the list will be eliminated in its entirety by 2024. In 2021, more than 260 musculoskeletal-related services and 16 HOP Panel-recommended services and related anesthesia codes will be removed from the IPO list. This transition and elimination of the IPO list will be reflected in 42 C.F.R. § 419.22(n).

The elimination of the IPO list also has downstream effects on CMS' medical review policies. Historically, procedures on the IPO list have been exempt from the CMS Two-Midnight Rule policy, a medical review standard for other types of inpatient stays that measures the appropriateness of the admission by whether the practitioner expected the patient to stay in the hospital for more than two midnights. IPO procedures, by definition, required an inpatient stay and were not subject to review.

With the Final Rule, procedures removed from the IPO list are now subject to the

[1] The Final Rule also addresses reimbursement reductions within the 340B Program, a topic addressed in a separate article in this newsletter.

CONTINUED ON PAGE 5

CONTINUED FROM PAGE 4

Two-Midnight Rule. But to allow providers time to adjust to this change, CMS will exempt these procedures from certain medical review activities, including site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) referrals to Recovery Audit Contractors (RACs), and RAC reviews for patient status.

Procedures that are removed from the IPO list beginning on January 1, 2021 will be exempt from these medical review activities until the procedures are more commonly performed in an outpatient setting (i.e., the procedure is performed in an outpatient setting more than 50% of the time). CMS will review claims data to determine when a procedure is more commonly performed in an outpatient setting. Thus, for each procedure removed from the IPO list on or after January 1, 2021, the exemption will continue until terminated in future rulemaking.

Supervision of Hospital Outpatient Therapeutic Services

In 2020, CMS implemented a policy to change the generally applicable required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision. However, some services, including non-surgical extended duration therapeutic services (NSEDTS) and pulmonary, cardiac, and intensive cardiac rehabilitation services (Rehab Services)—continued to be subject to more stringent supervision requirements. As part of its response to the COVID-19 public health emergency, CMS adopted a temporary policy of reducing the minimum level of default supervision for certain services:

- For NSEDTS, CMS reduced the supervision requirement from direct supervision to general supervision, no longer requiring direct supervision for the initiation of the service.
- For Rehab Services, CMS permitted supervision through audio-visual real-time communications technology where indicated to reduce exposure for the beneficiary or provider.

In the Final Rule, CMS made the change permanent for NSEDTS to align the supervision requirement for such services with the general supervision requirement that applies to most outpatient hospital services. However, CMS did *not* make the changes to the Rehab Services supervision requirements permanent, contrary to its position in the proposed rule.

After reviewing the comments, CMS has concluded that it needs more time to study the appropriateness of direct supervision through virtual presence for Rehab Services. Therefore, allowing supervision of Rehab Services via audio-visual communication will not be a permanent change, but may continue until the end of the year in which the public health emergency ends, or December 31, 2021. After this rule expires, CMS will resume its policy of requiring a supervising practitioner to be immediately available to furnish assistance during a procedure.

During the public health emergency, CMS clarified that the audio-visual supervision rule may be satisfied if the supervising practitioner is immediately available via interactive real-time audio/video communications technology. The supervising practitioner is *not* required to be present for or to observe, via interactive audio/video technology, the performance of the procedure for its entire duration.

Physician-Owned Hospitals

Under existing regulations, physician-owned hospitals must meet either the whole hospital exception or the rural provider exception to the Stark Law. These exceptions generally prohibit the hospital from increasing the aggregate number of operating rooms, procedure rooms, or beds above which the hospital was licensed on March 23, 2010, *unless* CMS grants an exception.

With the Final Rule, CMS made several revisions to the regulations to provide additional flexibility to physician-owned hospitals that qualify as high-Medicaid facilities. Namely:

- High-Medicaid facilities may now request an exception to the prohibition on expansion of facility capacity at any time, provided the facility has not submitted another request for an exception for which CMS has not issued a decision.
- CMS removed the cap on the number of additional operating rooms, procedures, rooms and beds that can be approved under an exception (previously capped at 200% of the previously grandfathered number of rooms and beds).
- CMS will allow expansion of facilities in *off-campus* locations, rather than being limited to the hospital's main campus.

Finally, CMS finalized its proposal to defer to state law when determining the number of beds used to calculate the hospital's baseline number. A bed is included in the baseline if it is considered licensed by the state, regardless of the specific number of beds identified on the physical license issued to the hospital by the state.

Additional Takeaways

Site-Neutral Policy for E/M Visits

The Final Rule continues CMS' implementation of a site-neutral payment policy for evaluation and management (E/M) visits furnished in all off-campus provider-based departments, including those that are excepted under Section 603 of the Bipartisan Budget Act of 2015. Although this policy has been subject to challenge, the D.C. Circuit upheld CMS authority to impose the payment reduction in a July 2020 decision.

Mandatory COVID-19 & Respiratory Illness Reporting

As the country continues to battle COVID-19, CMS has also taken the unconventional step of imposing new COVID-19-related conditions of participation (CoPs) for acute care hospitals and critical access hospitals through the OPPS Final Rule. Specifically, hospitals will be required to report: (1) the hospital's current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the HHS Secretary; and, (2) the hospital's current usage rate for any COVID-19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the HHS Secretary. CMS also finalized new requirements for reporting acute respiratory illness information regarding seasonal flu, flu-like illness, and severe acute respiratory infections.

Providers have even seen an increase in certain payor abuse and over-reach, particularly in the areas of so-called "cram-down" amendments and site of care policies.

Payor Contracting

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Health care providers have been on the front lines of the COVID-19 pandemic throughout the better part of 2020. The struggles of the pandemic gave rise to the hope that payors would be more collaborative in their relationships with providers, particularly in the context of payor contracting. Unfortunately, the opposite has been true. Providers have even seen an increase in certain payor abuse and over-reach, particularly in the areas of so-called "cram-down" amendments and site of care policies. In this article, we briefly summarize these two aggressive payor strategies which accelerated in 2020, and offer several key considerations for providers.

"Cram-Down" Amendments

A "cram-down" amendment occurs when a payor attempts to amend an existing provider contract on essentially a "take-it or leave-it" basis. In these cases, the provider's only recourse is to terminate the entire contract. For example, one national payor announced a policy in late March of this year directing providers to use the new HCPCS or CPT codes when billing for COVID-19 diagnostic testing. While that appears innocent enough, the policy also included language whereby mere submission a claim for reimbursement for COVID-19 diagnostic testing to the payor would constitute the provider's agreement to accept Medicare rates on the claim as payment in full. Many of these "cram-down" amendments took advantage of providers struggling with patient surges and cash-flow issues to secure reimbursement below market rates.

Site of Care Policies

Not all payor abuses this year have been directly related to providers rendering medical services to diagnose and treat COVID-19. Payors have also continued to issue and implement aggressive site of care policies having the net effect of reducing reimbursement for other medical services, and indeed even intruding upon providers' independent medical judgment. For example, several national payors have implemented so-called "imaging policies" setting forth rigid medical necessity criteria for radiologic imaging procedures to be performed in a hospital setting. If an imaging procedure for a particular patient did not satisfy the payor's unilateral medical necessity criteria to be performed in a hospital setting, the payor would deem the procedure not medically necessary. That determination would lead to the payor either denying the claim or redirecting the imaging service to a non-hospital setting such as a freestanding imaging center, where the procedure could be performed at a lower cost to the payor. In other words, the payor was determining whether an outpatient imaging procedure was medically necessary based only on the site of care and not on any clinical measures.

Key Provider Considerations

Although "cram-down" amendments and other aggressive policy changes raise a multitude of considerations for providers, below are several key considerations providers must address if faced with issues similar to the above.

- Identify and reserve any contractual rights to challenge "cram-down" amendments and policy changes.
- Identify any contractual provisions restricting unilateral amendments and policy changes that are not revenue neutral.
- Evaluate whether the amendment or policy change constitutes an expansion of the payor's rights under applicable state or federal law that did not otherwise exist.
- Evaluate whether the contract provides deadlines for retrospective reviews and audits, and consider whether the amendment or policy change conflicts with those provisions.
- Consider contract termination rights and whether terminating the contract to force re-negotiation of "cram-down" amendments and policy changes is a viable negotiation tactic.

Calendar Year 2021 Final Medicare Physician Fee Schedule Sets Path for Professional Services After Covid-19 Public Health Emergency

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The Medicare Physician Fee Schedule Final Rule for CY 2021, issued on December 2, 2020[1] (available here), makes several important modifications to professional reimbursement, including a groundbreaking shift of reimbursement towards physicians providing evaluation and management (E/M) services and a modest expansion of telehealth flexibilities. The full impact of the rule is complex and goes far beyond this summary, but the following highlights some of the significant changes.

Major Reductions to Reimbursement for Many Professionals

Medicare pays physicians and other professionals by multiplying a set conversion factor by a certain number of relative value units (RVU) reflecting the time, effort, and intensity of a particular service. This year, CMS reduced the conversion factor by nearly $4 (from $36.09 to $32.41). As a result, unless CMS specifically increased the RVUs for a particular service, *every physician and other professional* will likely be subject to a cut in reimbursement.

New Opportunities for Primary Care Physicians

On the flipside, CMS increased reimbursement for many services most often provided by primary care physicians. These changes include increased RVUs for many evaluation and management (E/M) codes; increased RVUs for associated services including Transitional Care Management, Initial Preventive Physical Examinations and Subsequent Annual Wellness Visits, and several others; and the addition of new add-on codes for prolonged or particularly complex E/M visits. Conversely, RVUs will be reduced for many specialty physician services, further reducing reimbursement for them to counterbalance these increases for primary care.

CMS also made several changes to align E/M documentation requirements with the recommendations of the American Medical Association Current Procedural Terminology Editorial Panel, in which the level of E/M service is based on the level of medical decision making or the total time spent by the reporting practitioner on the day of the visit.

CMS changes to scope of practice requirements may also help primary care and other physicians get the most value from their practices, by broadening the class of providers who may be reimbursed for a variety of services. CMS will allow a variety of non-physicians to supervise diagnostic tests if within their scope of practice and allowed under state law. Pharmacists will be considered "auxiliary personnel" able to bill incident to physicians or other professionals if within scope of practice and allowed under state law, and if payment for services is not made under Medicare Part D. PTs and OTs are allowed to delegate maintenance therapy services to PTAs/OTAs to the same degree as rehabilitative services.

Expansion of Telehealth Opportunities

CMS adopted sweeping waivers of telehealth coverage rules during the COVID-19 public health emergency (PHE). While expressing an interest in expanding telehealth as much as possible, the agency noted that it lacks statutory authority to maintain many of these flexibilities after the PHE. As a result, while it significantly loosens telehealth requirements, the limited effective period for these changes is likely to be disappointing for many providers. Absent statutory changes, Medicare will not maintain flexibilities allowing reimbursement of providers for telehealth services provided to patients in their homes, in non-rural settings, or using audio-only technology (except for a new G-code covering 11-20 minutes of discussion to determine the necessity of an in-person visit).

CMS also modified its Remote Patient Monitoring (RPM) rules in various ways for the post-PHE period. These changes include allowing verbal consent at the time of providing the RPM; clarifying that RPM may only be provided to established patients using "medical devices" as defined by the FDA that are reliable and valid and that data must be electronically and automatically collected and transmitted; only allowing physicians and professionals who can provide E/M services to bill for RPM (except that "auxiliary personnel" can bill for some services incident to these professionals); clarifying that RPM may be medically necessary for acute as well as chronic conditions; and clarifying the kinds of interactive communication required to bill RPM codes.

CMS also finalized several changes that have been adopted alongside telehealth models during the PHE. First, it finalized the PHE rule allowing certain non-physicians to supervise diagnostic tests within scope of practice and state law requirements. Second, it finalized that "direct supervision" may be provided using real-time, interactive audio and video technology through the later of December 31, 2021, or the year the PHE ends.

[1] https://public-inspection.federalregister.gov/2020-26815.pdf. The final rule is scheduled to be published in the federal register on December 28, 2020.

CONTINUED ON PAGE 8

CONTINUED FROM PAGE 7

Changes to Value-Based Programs

The MPFS also made significant changes to the Quality Payment Program and Medicare Shared Savings Program. In some ways these continue the PHE's flexibility for these programs, including by creating new options for "extreme and uncontrollable circumstance" reweighting during the COVID-19 PHE.

Other relevant changes for the MSSP include the following:

- Allowing renewing and re-entering ACOs to reduce the size of their repayment mechanism under certain circumstances and adopting a new methodology to calculate repayment mechanism amounts going forward.
- Requiring all MSSP ACOs to participate in the "APM Performance Pathway" model under the Quality Payment Program, designed to align MSSP reporting with other quality programs.

Changes to the Quality Payment Program include:

- Delaying introduction of any MIPS Value Pathways (MVPs) into the program for the 2021 performance period.
- Finalizing the APM Performance Pathway (APP), a new reporting framework beginning in 2021, to align with the MVP framework.
- Rebalancing MIPS category weights for the 2021 performance year (which equates to the 2023 payment year) so that, for individuals, groups, and virtual groups, Quality will be worth 40% (5% decrease) of the total score and Cost will be worth 20% (5% increase). For APMs Quality will be worth 50% and Cost will still be worth 0%.
- Reversing CMS's proposal to decrease the performance threshold to 50 points due to the PHE. Therefore, clinicians must score at least 60 points in MIPS to avoid a payment reduction and will receive a positive payment adjustment for scores beyond 60.01 and an additional positive payment adjustment if they score more than 85 points.
- Adding significant detail on the obligations of Qualified Clinical Data Registries and Qualified Registries to perform data audits.

Updates to Rules Affecting Inpatient Rehabilitation Facilities, Home Health Agencies, Hospice, Skilled Nursing Facilities, Relative Value Units, and Evaluation and Management Services

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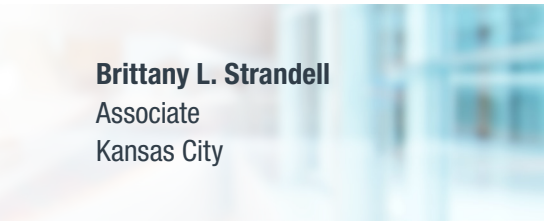

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This article provides the highlights from recent CMS final rules affecting inpatient rehabilitation facilities (IRF), home health agencies (HHAs), hospice facilities, skilled nursing facilities (SNFs) and implementing updates to the Physician Fee Schedule (PFS) affecting relative value units (RVUs) and evaluation and management (E/M) services.

IRF Updates

- 2021 CMS updates to IRF rules provide greater flexibility for clinicians as well as increased payment rates.
- CMS finalized the permanent elimination of the post-admission physician evaluation for Inpatient Rehabilitation Facilities (IRFs). Previously, a physician needed to conduct an evaluation within the first 24 hours of a patient's admission to confirm that his or her condition had not changed since the preadmission screening and that the patient was still an appropriate candidate for IRF admission.
- CMS also finalized rules providing flexibility for IRF physician visits required three times per week. CMS will now allow non-physician practitioners to perform one of the three required visits after the first week of physician visits.
- Lastly, CMS updated the IRF PPS payment rates by 2.4%. An additional 0.4 percent increase to aggregate payments due to updating the outlier threshold to maintain estimated outlier payments at 3.0% of total payments results in an overall update of 2.8% (or $260 million) for FY 2021, relative to payments in FY 2020.

HHA/Hospice Rule Updates

- CMS also updated payment rules related to home health and hospice, and in particular provided HHAs with increased flexibility related to permitted technologies post COVID-19.
- CMS finalized rule updates allowing HHAs to utilize telecommunications technologies in providing care to

CONTINUED ON PAGE 9

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beneficiaries under the home health benefit, so long as the provision of remote patient monitoring or other services furnished via a telecommunications system or audio-only technology are included on the plan of care. CMS requires the use of such technology to be tied to the patient-specific needs as identified in the comprehensive assessment.

- CMS also expands the definition of telecommunications technology, in addition to remote patient monitoring, that HHAs can report as allowable administrative costs on HHA cost reports. The finalized policies will ensure patient access to the latest technology and give HHAs greater certainty that they can continue to use telecommunications technology as part of patient care post COVID-19.
- The rule finalizes statutorily required updates to the home health payment rates for CY 2021. CMS estimates that Medicare payments to HHAs in CY 2021 will increase in the aggregate by 1.9%, or $390 million, based on the finalized policies.
- CMS has also implemented Medicare enrollment policies for qualified home infusion therapy suppliers, updates the CY 2021 home infusion therapy services payment rates using the CY 2021 Physician Fee Schedule amounts, and excludes home infusion therapy services from home health services as required by law.
- Related to hospice, CMS finalized updates regarding geographic delineations used to identify a beneficiary's location to calculate the wage index, a 2.4% payment rate increase, and updated examples of hospice election statements to assist hospices in understanding the content requirements for such statements.

SNF Updates

- The 2021 final rule for SNFs went into effect on October 1, 2020. *See* CMS Fact Sheet.
- This update adjusts the market basket update to 2.2% with a multi-factor productivity (MFP) adjustment of 0% and adopts the revised Office of Management and Budget (OMB) statistical area delineations to identify a provider's status as an urban or a rural facility.
- The final rule includes a five percent cap on wage index decreases from fiscal year 2020 to 2021 and finalizes changes in connection with the SNF Value-Based Purchasing (VBP) Program.
- The update finalizes the changes made to the definition of "performance standards," and adopts a regulation that suppresses from public reporting the data on SNFs that do not meet the threshold for the measure.
- The final rule also updates the 30-day Phase One Review and Correction deadline to the baseline period quality measure quarterly report.

RVU and E/M Rule Updates

- Updates to Medicare payments under the Medicare PFS and other Medicare Part B issues was issued on December 1, 2020. *See* 2021 PFS Final Rule; CMS Fact Sheet. Among the updates include changes to RVU and E/M coding.
- Generally speaking, RVUs are applied to each service for physician work, practice expense, and malpractice. RVUs become payment rates via the application of a conversion factor, and the rates are calculated to include an overall payment update specified by statute.
- The final rule finalizes a conversion factor of $32.41, which represents a decrease of $3.68 compared to the 2020 conversion factor. This decrease comes from the statutory requirement that the PFS must remain budget neutral should revisions to the RVUs that determine physician reimbursement result in changes of more than $20 million. CMS explained that, for 2021, the PFS will experience expenditure changes due to revisions to the RVUs for E/M services.
- Specialties likely to experience decreases are anesthesiology (-8%), cardiac surgery (-8%), interventional radiology (-8%), nuclear medicine (-8%), pathology (-9%), physical/occupational therapy (-9%), radiology (-10%), and thoracic surgery (-8%), among others. *See* 2021 PFS Final Rule at Table 106.
- Specialties likely to experience increases under the 2021 PFS include allergy/immunology (9%), endocrinology (16%), family practice (13%), hematology/oncology (14%), physician assistant (8%), and urology (8%), among others. *See* 2021 PFS Final Rule at Table 106.

The Year in Medicaid

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Like everything else, Medicaid program developments in 2020 were dominated by state and federal responses to the ongoing COVID-19 Public Health Emergency (PHE). But 2020 also saw additional states adopt Medicaid expansion, dynamic policy proposals and retractions, and the anticipation of more change to come as the incoming administration assumes the reins at Health and Human Services.

Consistent with the administration of the Medicaid program as a whole, state responses to the PHE varied widely — with more detail than can be captured here. At a high level, however, states adopted a number of changes in response to the PHE, including:

- **New Enrollment Categories:** 17 states opted to expand coverage for COVID-19 testing and testing related services in one form or another.[1]
- **Eligibility Flexibility:** A number of states adopted flexibility for new beneficiary enrollment, including allowing self-attestation for eligibility, expanding opportunities to verify immigration status, relaxing certain in-state residency standards, and maintaining eligibility and enrollment even under changed circumstances during the PHE.
- **Cost Sharing, Beneficiary Expenses and Authorizations:** A number of states eliminated deductibles, cost sharing obligations, premiums, and other expenses associated with receipt of Medicaid services. Authorization requirements were also relaxed for many services.
- **Telehealth:** Almost every state adopted expanded access to and coverage of telehealth services for Medicaid beneficiaries, sometimes permitting coverage of voice-only services.
- **Additional Federal Funds:** States who accepted federal rules for the PHE response were able to add 6.2% to their non-expansion FMAP, offering some relief for state budgets.

These PHE policy changes were generally designed to improve access to care, preserve status quo for enrolled individuals, and allow for effective state responses to COVID-19. Because each state sets its own rules, however, it is up to providers to look at the new rules in your state to determine what options might be available.

A number of non-COVID policy developments will impact providers not only this year, but for many years to come, including:

- **Increased Emphasis on Value-Based Purchasing.** Consistent with a longstanding Trump Administration policy, CMS released new guidance for State Medicaid Programs outlining promoting value-based purchasing programs in Medicaid.[2] Though the administration is changing soon, there is every reason to believe that the trend towards value-based care in Medicaid will continue.
- **Rescission of Medicaid Fiscal Accountability Rule (MFAR).** By tweet, the CMS Administrator withdrew the final MFAR rule weeks before its effective date. MFAR would have significantly changed the administration and supervision of supplemental payments for Medicaid providers, likely diminishing provider reimbursement and increasing state pressure to cover Medicaid costs.
- **Public Charge Rule and Medicaid Enrollment.** The Trump Administration's public charge rule, which proposed to redefine which public services would be counted against prospective applicants for lawful permanent resident status and certain other immigration determinations, has been the subject of intense litigation across the country.[3] A new administration may modify this policy, but it could be years before we know the true impact of these rules on Medicaid enrollment and other public benefit programs.
- **Enforcement and Government Investigations.** State budgets are under increasing strain, and declining tax revenue arising from the PHE will not help. Medicaid providers will see increased state enforcement efforts to recover funds wherever they can. Medicaid agencies and Medicaid Fraud and Control Units are increasingly using data-driven enforcement tools to screen claims, provider information, and beneficiary eligibility for outlier claims. Examples include specific types of claim (e.g. labs), "impossible" claims (e.g., billing for more than 24 hours in a day), or claims based on easy-to-discern errors, such as billing for deceased patients. Consequently, providers face increased scrutiny and risk of recoupment, payment suspension and investigation.
- **Work Requirements?** In February, the D.C. Circuit invalidated Arkansas' work requirements for Medicaid eligibility and enrollment.[4] While this decision only directly impacted Arkansas and a couple other states, the outcome of this litigation cast doubt over the enforceability of work requirements across the country. Nineteen states currently have work requirement waiver proposals in process or under review. Though the *Gresham* case is headed to the Supreme Court, changes in the White House and at CMS are likely to impact the policy priorities of conditioning Medicaid eligibility on work requirements.

[1] Kaiser Family Foundation, *Medicaid Emergency Authority Tracker: Approved State Actions to Address COVID-19* (as of Dec. 21, 2020) https://www.kff.org/coronavirus-covid-19/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19/.
[2] CMS, State Medicaid Director Letter #20-004, *Re: Value-Based Care Opportunities in Medicaid* (Sept. 15, 2020).
[3] *See* U.S. Citizenship and Immigration Services, *Public Charge Fact Sheet* (Sept. 22, 2020) https://www.uscis.gov/news/public-charge-fact-sheet.
[4] *Gresham v. Azar*, 950 F.3d 93 (D.C. Cir. 2020).

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- **Expansion of Medicaid and Potential Stabilization of the Program.** In 2020, Idaho and Nebraska expanded access to Medicaid for adults up to 138% of FPL. Oklahoma and Missouri also adopted plans to expand Medicaid in the coming years. As of this writing, only twelve states continue to decline Medicaid expansion under the ACA (Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin and Wyoming). While Medicaid expansion continues to inspire political debate in a few state capitols, most states have expanded and moved on.

Though the PHE dominated 2020, there were many other significant policy developments. States will continue to reckon with the PHE, and eventually address the impact of PHE waivers and flexibilities granted to Medicaid providers and beneficiaries while attempting to recover from reduced state revenues. To meet these challenges, expect states to continue to seek new and innovative ways to structure their Medicaid programs, including an increased focus on value-based care and heightened enforcement activity.

Center for Medicare and Medicaid Innovation

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In 2020, CMS's Center for Medicare and Medicaid Innovation (the "Innovation Center") introduced and continued its implementation of numerous payment models designed to improve the quality and value of care to beneficiaries while reducing costs to the Medicare and Medicaid Programs. The focus of the Innovation Center has changed over the years depending on policy priorities, and will likely shift again under the new administration, but, CMS's efforts to test care models that shift payment based on the volume to the value of care in not likely to change.

As with all things in 2020, the Innovation Center was required to adapt its implementation timelines and reform several payment models because of COVID-19 concerns. Despite these conditions, the Innovation Center still introduced several new models, which are at various implementation stages.

Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule

On September 29, 2020 the Innovation Center published the "Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule" which announced two new payment models for Radiation Oncology and End Stage Renal Disease services in Medicare.

- **The Radiation Oncology (RO) Model** is an episodic based payment model that provides bundled payments based on a patient's cancer diagnosis. The RO Model is mandatory for selected participants. RO Model qualifies as an Advanced Alternative Payment Model (APM) and provides prospective bundled payments for clinician and facility services. The RO Model start date has been delayed to July 1, 2021.
- **The ESRD Treatment Choices (ETC) Model** builds on other previously announced innovation models in the kidney care space, such as the **Kidney Care Choices Model**, and the **Transitional Payment for New and Innovative Equipment and Supplies (TPNIES)**. ETC is a mandatory payment model, beginning on January 1, 2021, for select ESRD Facilities and Managing Clinicians (physician or non-physician practitioners furnishing and billing the monthly capitated payment), in order to incentive increasing rates of home dialysis and transplantation. The model will include two payment adjustments for participants:
  - The Home Dialysis Payment Adjustment (HDPA — a positive adjustments on all home dialysis and home-dialysis-related claims for the initial 3 years of the Model.
  - The Performance Payment Adjustment (PPA — an upward or downward adjustment based on the rate of home dialysis, and rate of transplant waitlisting and living donor transplantation.

Primary Care Plus Model

The Primary Care Plus Model is a voluntary payment model in select regions begins operation on January 1, 2021 intended to allow primary care providers the freedom to innovate within their practices by providing additional revenue in exchange for meeting standards relating to quality of care and patient experience with limited downside exposure. Quality of care measures are focused on primary care measures including hemoglobin A1C control, colorectal cancer screening, and advance care planning.

Direct Contracting Model

The Direct Contracting Model is an Advanced APM allowing Direct Contracting Entities (DCEs) to accept financial accountability for the overall cost and quality of care for Medicare beneficiaries. The Direct Contracting Model will provide capitated and partially capitated Medicare FFS payments with the goal of reducing provider burden and increasing beneficiary engagement in their care. A DCE is an ACO-like organization comprised of providers and suppliers which contracts directly with CMS, and assumes two-sided financial risk. The first performance period of the Direct Contracting Model will begin April 1, 2021.

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Community Health Access and Rural Transformation Model

The Community Health Access and Rural Transformation (CHART) Model is a rural health innovation model seeking to transform rural health care delivery and better enable collaboration and alignment among rural providers in order to increase financial stability for rural providers. CMS will assess changes resulting from two tracks:

- **The Community Transformations Track** will provide upfront funding and regulatory flexibility to select Lead Organizations (such as state Medicaid agencies, local/county health departments) that will create and oversee the community's health care redesign strategy. The RFA for this Track should be available early 2021.
- **The ACO Transformation Track** will provide advanced payments for up to 20 rural-focused ACOs as part of joining the Medicare Shared Savings Programs. The Track will also provide certain benefit enhancements and flexibilities such as a waiver of the three-day inpatient stay requirement for SNF stays, expanded telehealth benefits, and a beneficiary incentive programs.

Top Developments in 340B, Drug Pricing and Reimbursement to Watch For in 2021

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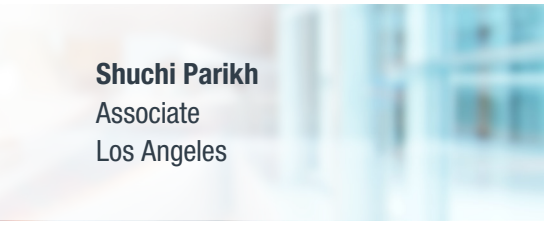

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The final months of 2020 have seen a spate of new activity in the 340B and pharmacy space, with stakeholders, HHS, and courts alike taking action that could have lasting impacts on the industry. Drug pricing remains a top priority as the country prepares for a new incoming administration, although recent successes with a COVID-19 vaccine could thwart meaningful attempts to regulate manufacturers. Below we recap the top five recent legal and policy developments that will continue to impact industry participants well into the new year.

Manufacturer Activity Impacting 340B Contract Pharmacies

Since the summer, a growing list of manufacturers have launched attacks on the 340B contract pharmacy program. Eli Lilly was the first manufacturer to restrict access to 340B pricing for all products in the contract pharmacy setting beginning September 1, 2020[1], with a number of manufacturers quickly following suit. Covered entity groups have challenged the actions in federal court as unlawful under a plain reading of the 340B statute.[2] Some manufacturers, such as Sanofi, have also conditioned the sale of 340B products on the covered entity's provision of contract pharmacy claims data through a "340B ESP" platform. In November, Novartis stopped honoring contract pharmacy arrangements for 340B hospitals outside of a 40-mile radius of the parent facility.

If left unchecked, these manufacturer actions could establish a dangerous precedent under the 340B program. Moreover, covered entities and contract pharmacies continue to face inconsistencies and a lack of clarity regarding implementation of these policies at their facilities. While HHS condemned Eli Lilly for the timing of its restrictions during a global pandemic[3], the agency still has not taken definitive action against these policies.

Final 340B Alternative Dispute Resolution (ADR) Rule

Ten years after the statutorily mandated deadline, HRSA released on December 10, 2020 its long-awaited 340B ADR Final Rule.[4] The rule establishes a binding ADR process to resolve disputes between 340B covered

[1] Limited Distribution Plan Notice for Eli Lilly and Company Products, https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

[2] *See* Complaint, *American Hospital Ass'n v. HHS*, No. 3:20-cv-08806 (N.D. Ca. Dec. 11, 2020), *available at* https://www.aha.org/system/files/media/file/2020/12/associations-hospitals-motion-preliminary-injunction-hhs-action-to-address-340b-contract-pharmacy-issue%20-12-11-20.pdf; Complaint, *Nat'l Ass'n of Community Health Ctrs. V. Azar*, No. 20-cv-3032 (D.D.C. Oct. 21, 2020); Amended Complaint, Ryan White Clinics for 340B Access v. Azar, No. 20-cv-2906 (D.D.C.), *available at* https://www.rwc340b.org/wp-content/uploads/2020/11/FILED-RWC-340B-v.-Azar-Amended-Complaint-Case-No.-20-cv-2906.pdf (Nov. 23, 2020).

[3] Letter from Robert P. Charrow (HHS) to Anat Hakim (Eli Lilly), dated Sept. 21, 2020, available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

[4] 85 Fed. Reg. 80,632 (Dec. 14, 2020).

CONTINUED ON PAGE 13

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entities and manufacturers, such as disputes related to manufacturer overcharges. Manufacturers may also initiate disputes against covered entities related to allegations of diversion or duplicate discounts after conducting an audit of the covered entity. The rule sets forth a three-year lookback period for claims and damages sought must exceed $25,000. Although the final ADR rule will allow covered entities to dispute the recent manufacturer actions detailed above through a formal dispute process, covered entity groups have appealed to HRSA for stronger action against the manufacturers.

Medicare Part B Most Favored Nation Rule

On November 27, 2020, CMS published its Most Favored Nation (MFN) Model Interim Final Rule (IFR) that seeks to lower the amount paid for 50 high-cost Medicare Part B drugs to the lowest price that drug manufacturers receive in similar countries.[5] Beginning January 1, 2021 CMS will phase in the MFN model over four years by setting the drug's price based on a blend of the MFN price and the average sales price. A lawsuit has been filed challenging the validity of the IFR based on arguments that CMS exceeded its authority and failed to follow certain procedural requirements in issuing the rule.[6] The incoming Biden administration may also further scrutinize the rule.

State Regulation of Pharmacy Benefit Managers (PBMs)

Pharmacies obtained a significant victory in the Supreme Court in December in a case upholding a state law regulating PBM reimbursement rates.[7] The Arkansas law at issue requires plans to reimburse pharmacies at or above their acquisition costs and adjust their maximum allowable cost (MAC) lists accordingly. Pharmacies can also decline to dispense a prescription if the PBM's reimbursement will be less than pharmacy's acquisition cost. The Pharmaceutical Care Management Association challenged the law on the grounds that it is pre-empted by ERISA, a federal law that pre-empts any state law that "relates to" an employee benefit plan. In an 8-0 opinion, the Court held that cost regulation of this type is not pre-empted by ERISA as it does not govern a central matter of plan administration. A growing number of states have issued laws regulating the PBM industry in recent years, and the Court's decision could spur additional state regulation of drug reimbursement that is favorable to pharmacies.

Elimination of Anti-Kickback Statute Safe Harbor Protection for Manufacturer Rebates to PBMs

On November 30, 2020, the HHS Office of the Inspector General (OIG) published a final rule that removes protection under the Anti-Kickback Statute (AKS) discount safe harbor for manufacturer rebates on prescription drugs for PBMs under Medicare Part D and Medicaid managed care.[8] The changes are effective January 1, 2022. The Trump administration hopes the rule will incentivize drug manufacturers to lower list prices, although whether this will occur remains to be seen. It is also unclear how the rule will fare following the change of administrations or against potential legal challenges.

The above developments could fundamentally alter the way pharmacies, 340B covered entities, and related stakeholders do business, although the fate of some of the Trump administration's recent drug pricing policies is tenuous. We expect 2021 to continue to bring significant legal activity and policy developments in this space.

[5] 85 Fed. Reg. 76,180, available at https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.

[6] *See* Complaint, *Ass'n of Community Cancer Centers v. Azar* (D. Md. Dec. 4, 2020) (No. 1:20-cv-03531), available at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf.

[7] *Rutledge v. Pharm. Care Mgmt. Ass'n*, No. 18-540 (Dec. 10, 2020).

[8] 85 Fed. Reg. 76,666 (Nov. 30, 2020).

Medicare Advantage

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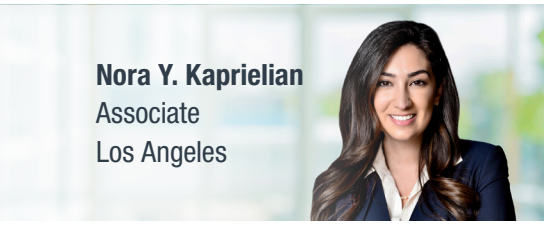

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The Centers for Medicare & Medicaid Services (CMS) makes adjustments to the Medicare Advantage program during its annual rulemaking process. While these annual adjustments are important, they are rarely of the magnitude we have seen in 2020. CMS, likely driven by the pressures of COVID-19 pandemic, appears to have found the motivation to implement some truly significant changes, several of which have the potential to outlast the COVID-19 pandemic. In this article, we briefly summarize what we view as the most significant changes made to the Medicare Advantage program in 2020.

New End-Stage Renal Disease (ESRD) Benefit

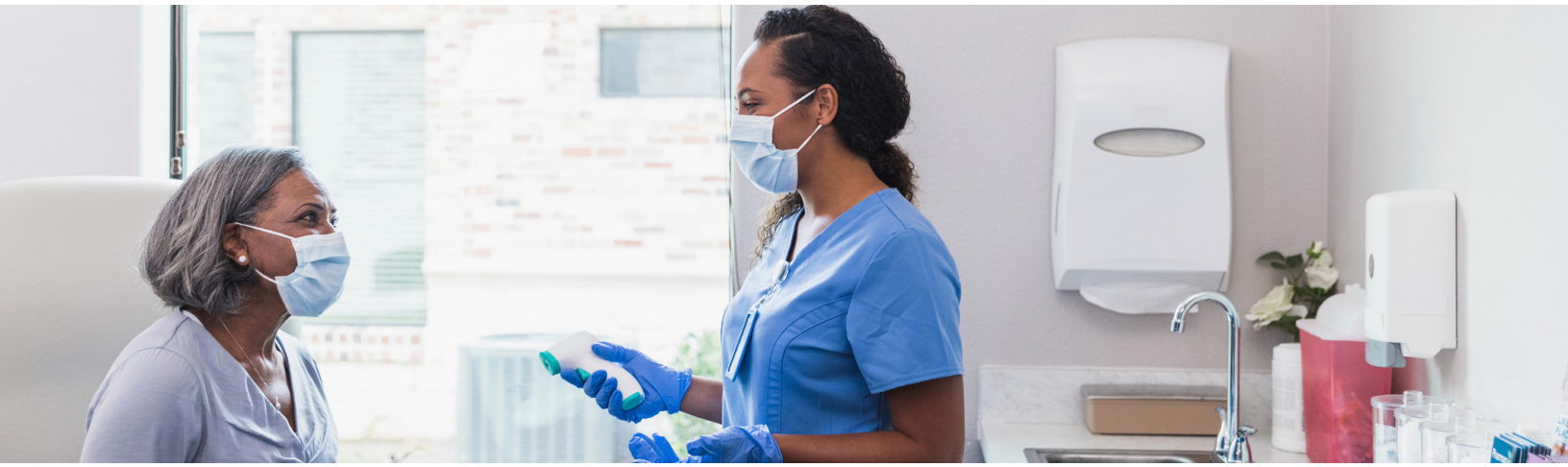
The 21st Century Cures Act amended the Social Security Act to allow beneficiaries with ESRD to enroll in standard MA plans beginning January 1, 2021. Previously, ESRD beneficiaries were ineligible for most MA plans and remained in the Medicare fee for service program. Industry reports estimate that over 400,000 ESRD beneficiaries will be eligible to enroll in MA for the first time. Since ESRD beneficiaries are high-cost patients, providers serving ESRD patients should be prepared to navigate the strict utilization and cost management techniques employed by MA plans.

COVID-19 Developments

The CARES Act, one of the COVID-19 stimulus packages, included $100 billion in funds for hospitals and other health care providers. The first tranche of relief payments — $30 billion — was distributed based on the hospital's proportional share of Medicare fee for service reimbursements in 2019. That means that hospitals in areas with high Medicare Advantage penetration were eligible for less relief funding than they would have been if they were located in an area with low Medicare Advantage penetration. The relief payments were set up as an advance loan on Medicare fee for service payments so there is some logic to it, but that logic is likely to be little comfort to hospitals with a large number of Medicare Advantage payments that struggled financially.

Despite the inequity of the CARES Act relief fund distribution, there was some relief for providers in the flexibilities CMS allowed for MA plans. These flexibilities relaxed customary CMS requirements for MA plans with the goal of increasing the supply of health care services, increasing beneficiary access to health care, and ensuring coverage for COVID-19 related testing and treatment. The flexibilities that might result in additional opportunities for provider reimbursement included:

- Expanded coverage for telehealth benefits (and other mid-year benefit enhancements) even if not included in the MA plan's original bid to CMS.
- Delayed involuntary disenrollment for beneficiaries who are absent from the service area for an extended time due to COVID-19.
- Delayed involuntary disenrollment for beneficiaries who lose "special needs" status and cannot recertify eligibility due to COVID-19.
- Relaxation of prior authorization requirements for Part D drugs used to treat or prevent COVID-19.
- Relaxation of limitations on retail pharmacies delivering Part D drugs via home or mail delivery.
- Prohibition on MA plans charging beneficiary cost sharing (or any other prior authorization or utilization management techniques) for clinical laboratory testing for COVID-19.



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