UnityPoint Health

Outpatient Prospective Payment System (OPPS) Summary - FY 2022

Highlights: On July 19, 2021, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule [CMS-1753-P], which includes proposals to update payment rates and regulations affecting Medicare services furnished in hospital outpatient and ambulatory surgical center settings beginning in CY 2022.

For CY 2022, CMS proposes to increase payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) Payment Systems by a factor of 2.3 percent. In continuation of an existing policy, hospitals and ASCs that fail to meet their respective quality reporting program requirements are subject to a 2.0 percent reduction in the CY 2022 fee schedule increase factor.

CMS estimates, based on the proposed policies that total payments to OPPS and ASC providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization and case-mix) for CY 2022 will be approximately $82.704 billion and $2.5 billion, respectively. This represents an increase of approximately $10.757 billion and a decrease of $20 million, respectively, from CY 2021 payment levels.

Key Takeaways:

- Withdrawing previous plans to eliminate the Inpatient Only list and expand the ASC Covered Procedures List
- Increased penalties for hospitals to drive compliance with the recently established hospital price transparency program
- Continued emphasis on health equity and how to address it in the hospital quality programs
- A request for information about a soon to be established Rural Emergency Hospital designation
- Plans to implement the Radiation Oncology Alternative Payment Model as of January 1, 2022

CMS Resources: Proposed Regulations | CMS Fact Sheet
Comments Due: September 17, 2021

The below content is a topline summary of major provisions in the proposed rule.

Revisions to the Inpatient Only List

Key Takeaway: CMS proposes to halt previous plans to eliminate the inpatient only list.

Historically, CMS has identified services that are safely provided only in an inpatient setting and thus would not paid by Medicare under the OPPS. Services identified as such were designated to the "inpatient only (IPO) list. In the CY 2021 OPPS/ASC Final Rule, CMS announced that it would eliminate the IPO list over the course of three years (85 FR 86084-88). In the first year of the transition, in CY 2021, CMS removed 298 codes from the IPO.

In a somewhat surprising move, CMS is now proposing to stop the phased elimination of the IPO list and to restore the 298 codes back to the IPO beginning in CY 2022. It is rare to see CMS reverse course on a clinical policy so abruptly, but the about-face is most likely a reflection of the change in political leadership that took over this year.

CMS has not at this juncture completely abandoned its longer-term objective to discontinue the IPO list. Instead, CMS is considering alternative approaches, and soliciting feedback on the following questions:

- Whether CMS should continue plans to discontinue the IPO list;
- Whether CMS should maintain the IPO list but modify how it evaluates services for inclusion or exclusion in order to keep pace with technological advances; and
- How eliminating or scaling back the IPO list may impact safety and quality of care for Medicare beneficiaries.

Should procedures be removed from the IPO list, CMS proposes to exempt these procedures for 2 years (rather than indefinitely as finalized in the CY 2021 rulemaking cycle) from the 2-midnight medical review activities.

Transitional Pass-through Payment for Medical Devices

Key Takeaway: To offset the impact of the Public Health Emergency (PHE) on devices currently eligible for transitional pass-through payment, CMS provides an additional year of separate payment for one device whose pass-through payment status is set to expire at the end of CY 2021.

Transitional pass-through payment for devices allows for adequate payment of new innovative technology during the interval in which CMS collects the data necessary to incorporate costs for these devices into the accompanying procedure's payment rate. Devices that meet the requisite qualification criteria are eligible to receive transitional pass-through payment. CMS also has established an alternative pathway for devices approved under the US Food and Drug Administration (FDA) Breakthrough Device Program.

Acknowledging the impact of the PHE on utilization, in the CY 2021 rulemaking cycle, CMS sought feedback from stakeholders on the Agency using its authority to provide separate payment for an undefined period of time after pass-through status ends for these device categories to account for the period of time that device utilization was reduced. In this rule, CMS proposes to exercise its authority to provide an additional four quarters of payment under pass-through for the one device (C1823 Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads) whose transitional payments are set to expire at the end of this calendar year. CMS does not propose to extend the pass-through for the five devices whose transitional payments are set to expire at the end of CY 2022.

CMS does not propose any changes to its qualification criteria for transitional pass-through payments for medical devices. As part of its quarterly review cycle, CMS evaluated eight applications for device pass-through payments and preliminarily approved one device, Shockwave C2 Coronary Intravascular Lithotripsy catheter.

Site Neutral Payments for Clinic Visits at Off-Campus Provider-Based Departments

Key Takeaway: CMS will continue to pay clinic visits provided by off-campus hospital outpatient departments at 40 percent of the OPPS rate.

Beginning in 2019, CMS implemented a policy that reduced OPPS payments for clinic visits described by HCPCS code G0463 and furnished at off-campus provider-based outpatient departments that previously were excepted or grandfathered from site-neutral payment policies. CMS phased in the payment reduction over two years. In 2020, CMS implemented the second portion of the payment reduction, a change that reduced payments for these services to 40 percent of the OPPS rate.

The site-neutral payment policy has been the subject of litigation since it was implemented. In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to implement the change. However, in July 2020, the U.S. Court of Appeals for the District of Columbia Circuit reversed the lower court in favor of CMS, holding that the agency's regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service.

The hospital plaintiffs appealed to the U.S. Supreme Court, but the Court announced in June 2021 that it would not take up the case, leaving the Appeals Court ruling upholding CMS' authority intact.

For CY 2022, CMS proposes to continue the policy of paying the Physician Fee Schedule-equivalent rate of 40 percent of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus provider-based department.

Price Transparency

Key Takeaway: CMS proposes to increase penalties for larger hospitals

As part of the Affordable Care Act (ACA), Congress enacted section 2718(e) of the Public Health Service Act, which requires hospitals to publish the hospital's standard charges for items and services provided and to update this list annually.

In the CY 2020 OPPS Final Rule, CMS revised its policy to require publication of more detailed price information in a machine-readable format, including gross charges, discounted cash prices, payer-specific negotiated charges, minimum and maximum negotiated charges for items and services provided by the hospital and to display charges for the hospital's 300 most shoppable services in a consumer-friendly format. This requirement went into effect on January 1, 2021, despite opposition and legal challenges from hospital associations. Failure to comply is subject to civil monetary penalties (CMP) of up to $300 a day.

On April 13, 2021, a bipartisan group of leaders from the House of Representatives Committee on Energy and Commerce wrote a letter to Secretary Becerra urging HHS to conduct "vigorous oversight" of the implementation of the hospital price transparency rule. The Congressional leaders cited recent analysis indicating that the majority of the nation's largest hospitals are non-compliant with the transparency requirements and urged CMS to revisit its enforcement tools.

CMS is now proposing steps to enhance compliance in 2022 by increasing the amount of the CMP by a scaling factor based on hospital bed count, as specified in the most recently available hospital cost report data submitted to CMS. Larger hospitals would incur a penalty of $10/bed/day, but not to exceed a maximum daily penalty amount of $5,500. The rule would maintain a minimum CMP of $300/day for smaller hospitals (with 30 or fewer beds). Under this proposed approach, for a full calendar year of noncompliance, the total penalty amount would range from a minimum of $109,500 for small hospitals to a maximum total penalty of $2,007,500 for larger hospitals.

Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years

Number of Beds	Penalty Applied per Day	Total Penalty Amount for full Calendar Year of Non-Compliance
30 or less	$300 per hospital	$109,500 per hospital
31 to 550	$310 - $5,500 per hospital (number of beds x $10)	$113,150-$2,007,500 per hospital
> 550	$5,500 per hospital	$2,007,500 per hospital

Source: Table 63 in the CY 2022 OPPS and ASC PS Proposed Rule

CMS is also seeking comment on alternative or additional criteria that could be used to scale CMPs, such as hospital revenue, the nature, scope, severity, and duration of noncompliance, or the hospital's reason for noncompliance.

The agency also seeks to promote compliance by further requiring that the machine-readable files must be accessible without barriers, allowing automated searches and direct file downloads. The agency also clarifies that when a hospital chooses to use an online price estimator as an alternative to presenting their standard charge information, the tool must provide an estimate that takes into account the individual's own circumstances, rather than provides estimated average amounts or ranges for the price of a shoppable service that appear to be generated based on a broad population of patients, including outliers. Finally, the rule asks for comments on how CMS could further ensure compliance, describe more detailed best practices as well as identify those hospitals with exemplar transparency practices.

Prior Authorization Process for Certain Services

Key Takeaway: CMS does not propose to add any new service categories to the list of outpatient procedures requiring prior authorization for CY 2022.

For CY 2020, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. CMS originally applied this process to five categories of services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation) starting on July 1, 2020. As part of the CY 2021 rulemaking cycle, CMS expanded the list of services subject to the prior authorization process to include cervical fusion with disc removal* and implanted spinal neurostimulators effective July 1, 2021.

CMS is not proposing to supplement or otherwise change the list of services subject to prior authorization in this rulemaking.

Prior authorization is likely to continue as a hot topic next year as new leadership at CMS gets settled in.

Rural Emergency Hospital Request for Information (RFI)

Key Takeaway: CMS issues an RFI to obtain feedback from stakeholders as the Agency defines its policies specific to Rural Emergency Hospitals (REHs).

The Consolidated Appropriations Act of 2021 (CAA) created a new type of Medicare hospital called the Rural Emergency Hospital. This classification is designed to help meet the needs of rural communities that cannot adequately support a full-service hospital, but that otherwise would lack emergency services.

The statute is fairly prescriptive regarding what the definition of an REH is and what types of institutions can become an REH. To help inform future rulemaking on REHs, CMS is seeking stakeholder input on an extensive 29-question Request for Information on the following categories:

- Type and Scope of Services Offered (e.g., other additional eligible services, virtual/telehealth services, maternal and opioid services, etc.)
- Health and Safety Standards, Including Licensure and Conditions of Participation (e.g., exceptions for REHs from hospital EDs, different training requirements, etc.)
- Health Equity (e.g., how can REHs respond to social determinants, leadership accountability, etc.)
- Collaboration and Care Coordination (e.g., working with other providers and federal agencies)
- Quality Measurement (e.g., use of existing quality measures, reporting challenges, baseline measurement considerations, incentives, etc.)
- Payment Provisions (e.g., claims or reporting issues for estimated facility payment, utility of existing claims forms, etc.)

Payment for 340B Drugs

Key Takeaway: CMS proposes to maintain payment for 340B drugs furnished to hospital outpatients at Average Sales Price (ASP) minus 22.5 percent.

The 340B program is designed to "stretch scarce federal resources" by allowing providers to purchase certain drugs administered in hospital outpatient departments at a discount from drug manufacturers. Prior to 2018, Medicare reimbursed 340B drugs through the Part B benefit at Average Sales Price (ASP) plus 6 percent. The discounted purchase price combined with the higher reimbursement rate allowed hospitals to realize significant savings on high-cost drugs, which in turn would be used to support uncompensated care costs and other safety net programs.

Beginning in 2018, the agency changed its policy to dramatically reduce the reimbursement rate to ASP minus 22.5 percent. Because OPPS policies must be budget neutral, these cuts have implications for all hospitals. CMS chose to redistribute the savings achieved by the reimbursement reduction among all hospitals, including those that do not participate in the 340B program, thereby dividing hospital interests in this policy change.

Immediately following the policy change, the American Hospital Association (AHA) led a group of plaintiffs challenging this rule in federal district court, where they initially prevailed in arguing that the government lacked the authority to implement these cuts. The government appealed district court decision, and a federal Court of Appeals overturned the district court ruling, siding with the government. The plaintiffs have since petitioned the US Supreme Court to review, and in July 2021, the Supreme Court announced that it would hear the case, now styled AHA, et al. v. Becerra, et al., in its next term. This case will determine whether HHS has the authority to calculate and adjust the 340B reimbursement rate in the manner that it did.

While this litigation proceeds, CMS has proposed to continue reimbursing certain separately payable drugs and biologics purchased under the 340B program at ASP minus 22.5 percent or Wholesale Acquisition Cost

(WAC) minus 22.5 percent for WAC-priced drugs. The agency is also proposing to continue requiring hospitals to use the JG and TB modifiers to identify 340B-purchased drugs.

Ambulatory Surgical Center Covered Procedures List

Key Takeaway: Similar to its position on the IPO list transition, CMS proposes to halt expansion of the ASC Covered Procedures List (CPL).

CMS maintains a list of procedures eligible for reimbursement in the ASC setting. The list, known as the Covered Procedures List or CPL, is reviewed and updated each year per a set of clinical safety criteria. Each year, CMS reviews the ASC CPL to determine if there are services that should be added to or removed from the list. Historically, changes to the list have been driven by stakeholder requests and feedback. In the 2021 rulemaking cycle, CMS finalized a policy to eliminate a subset of the exclusion criteria for adding surgical procedures to the ASC CPL. Pursuant to this change, CMS added 267 surgical and surgical-like procedures to the CPL, giving providers additional flexibility and more responsibility in determining whether a surgical procedure can be safely performed in an ASC setting.

Based on stakeholder feedback and after completing an internal review of the aforementioned procedures, CMS is now proposing to restore the ASC CPL criteria that had been in place prior to 2021, and to remove 258 of the 267 procedures added to the ASC CPL this past year under the revised criteria. A key factor driving this proposed change is the concern that many procedures added as part of last year's rulemaking cycle are only appropriate for healthier Medicare beneficiaries, and that these procedures may pose a significant safety risk and require active medical monitoring and overnight care for a typical Medicare beneficiary when performed in the ASC.

CMS also proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. Under this proposal, members of the public and/or medical specialties would make formal nominations for procedures to be added to the ASC CPL by March 1st for consideration for the upcoming rulemaking cycle. CMS would then evaluate the nominated procedures based on the applicable statutory and regulatory requirements for ASC covered surgical procedures and allow for public comment in the proposed rule. CMS would then finalize which procedures will be added to the ASC CPL, or in some cases CMS may choose to defer making a decision for a nominated procedure to later rulemaking. CMS is seeking public comment on how to prioritize nominations for the ASC CPL if a large volume of procedures are nominated.

Hospital Outpatient Quality Reporting (OQR) Program

Key Takeaway: CMS proposes modifications to existing measures and comments on future adoption of measures for services that transition from an inpatient to outpatient setting.

The Hospital Outpatient Quality Reporting Program (Hospital OQR) is a pay for quality data reporting program for Medicare hospital outpatient departments. Hospitals that fail to meet program requirements are subject to a two percent reduction in OPPS payments.

In this rule, the agency proposed several modifications to the Hospital OQR program related to measure removals, additions, and modifications. The agency is also seeking comments on future measure development. These proposed changes are consistent with other agency priorities related to addressing COVID-19, reducing quality reporting burdens, Meaningful Measures goals and the use of measures with greater applicability.

Measure Removal/ Replacement

CMS is proposing to remove two chart-abstracted measures beginning with CY 2023 reporting period:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP-2)
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)

Beginning in the CY 2023 reporting year, CMS is proposing to replace the above two measures with ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) which the agency describes as a more broadly applicable measure. Additionally, the STEMI measure is an electronic measure versus the OP-2 and OP-3 which are chart abstracted measures which are administratively more burdensome.

Measure Additions

CMS is proposing to add two measures beginning with the CY 2022 reporting period:

- COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)
- Breast Screening Recall Rates

The HCP measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19 and will help the agency to determine whether facilities are taking steps to limit the spread of COVID-19 among their staff, which would put facilities in a better position to serve their local communities during and after the PHE. The Breast Screening measure would fill the gap in women's health and oncology care that was left following the removal of the Mammography Follow Up Rates measure (OP-9) (removal finalized in the 2019 OPPS Final Rule).

Measure Modifications

CMS is proposing the return of two measures previously removed from the program. CMS is proposing modifications to these measures which the agency believes address previous concerns.

- Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures (OP-37-a-e) (voluntary for CY 2023 reporting period and mandatory for CY 2024 reporting period)
- Cataracts: Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery (CY 2023 reporting period)

Transition from Inpatient to Outpatient Setting

As discussed above, CMS is proposing to halt the elimination of the IPO list which was finalized in the CY 2021 OPPS Rule. The Agency acknowledges that there is a trend of procedures transitioning from the inpatient setting to outpatient setting and that there needs to be a means for the agency to measure the quality of these services when they are provided in the outpatient setting. As such, CMS is seeking comments on:

- The potential future adoption of measures generally for procedures that transition from the inpatient to the outpatient setting.
- The future adoption of specific measures for two procedures that have recently transitioned to the outpatient setting (elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)). Currently the volume in the outpatient setting is too low to implement a measure for these procedures but the agency anticipates the volume of these procedures will increase in the future.

Stakeholders should review these proposals to assess if they are responsive to the needs and priorities of hospital outpatient departments in the current environment as the impact of COVID-19 lingers, address

measure gaps with the use of well vetted measures and are appropriately balanced between providing meaningful data and minimizing.

CMS is also proposing similar measure modifications to the ASC Quality Reporting Program.

Key Takeaway: CMS issues RFI on the future of digital quality measures.

The agency previously announced that by 2025 it plans to move fully to digital quality measures for the quality reporting and value-based purchasing programs. This initiative would require significant modifications to individual measures as well as across the board programmatic changes.
Consistent with these efforts, in this rule CMS is issuing an RFI to gather broad public feedback on the planning and implementation of such an endeavor. Any changes to a specific program would be pursued through rulemaking.

CMS is proposing changes in four areas: digital data standards; redesign of quality measures to be self-contained tools; better support around data aggregation; and alignment of measure requirements across CMS and other federal or private sector programs. The agency seeks comments in these areas as well as the definition of digital quality measures; and the use of Fast Healthcare Interoperability Resource standards for current eCQMs.

Potential Future Efforts to Address Health Equity in the Hospital OQR Program

Key Takeaway: Continuing the Discussion on Health Equity, CMS Solicits Feedback on How to Address in Hospital Quality Programs.

As part of the Biden Administration's commitment to advancing health equity and the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, CMS issued RFIs and proposed health equity initiatives in recent rules. In this proposed rule, relying on the Executive Order's definition of "equity," CMS solicits comments on potential future efforts to address equity in the Hospital OQR.

Expansion and Stratification of Disparity Methods Measures

CMS has several existing and proposed strategies to help drive more equitable health outcomes across different care delivery settings. These strategies include the CMS Disparity Methods, which were finalized in the 2018 and 2020 Inpatient Prospective Payment System Rules. The disparity methods are broken down into two main categories: the Within-Hospital Disparity Method (WHDM) and the Across-Hospital Disparity Method (AHDM). The WHDM "promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors," while the AHDM " assesses hospitals' outcome rates for patients with a given risk factor, across facilities, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors."

In this proposed rule, CMS is seeking comment on stratifying performance results by dual eligibility (a proxy for social risk) in the outpatient setting for six priority measures in the Hospital OQR Program:

- MRI Lumbar Spine for Low Back Pain (OP-8)
- Abdomen CT – Use of Contract Material (OP-10)
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13)
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32)
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35)

- Hospital Visits after Hospital Outpatient Surgery (OP-36)

The agency is requesting input on confidentially reporting these measures on Care Compare in the future and seeks input on other potential future measures stratified by dual eligibility status as one means of advancing health equity.

Additional Social Risk Factors

The agency has attempted to improve race and ethnicity data using "indirect estimation," which uses an algorithm to predict the race and ethnicity at the population level for beneficiaries based on a combination of other data sources. The agency has also tried the method of Medicare Bayesian Improved Surname Geocoding, which attempts to use other data points and statistical analysis to estimate the likelihood of belonging to one of six ethnic groups. The agency believes the latter approach runs a relatively low risk of unintentional bias, especially compared to bias that currently exists in administrative data. In the long run, CMS hopes to move to self-reported race and ethnicity data.

CMS is asking for comments on potential benefits and challenges with using indirect estimation to assess facility equity. Specifically, the agency wants information on how facilities currently capture demographic data, such as race, ethnicity, sex, sexual orientation and gender identity, primary language, and disability status. The agency believes that a minimum data set that includes demographic data that is used in quality measures could help better identify disparities. However, CMS solicits comments on challenges associated with the use of such a data set on day of service.

This request for comment is complementary to CMS' proposed policies in the FY 2022 IPPS proposed rule and CY 2022 PFS proposed rule. It illustrates how CMS is seeking to advance equity across inpatient and outpatient settings by improving data collecting practices and building out ways to identify disparities through leveraging existing systems.

Radiation Oncology Alternative Payment Model

Key Takeaway: CMS proceeds with the implementation of the previously delayed Radiation Oncology Alternative Payment Model (RO Model) as of January 1, 2022.

In September 2020, CMS finalized two Innovation Center demonstration models, including the Radiation Oncology (RO) Model and the End Stage Renal Disease Treatment Choice Model. The RO Model is a mandatory nationwide demonstration model encompassing approximately 30 percent of eligible radiation oncology episodes. The model pays a prospective payment on a site neutral basis, and the rate does not vary based on the modality of treatment. CMS had intended to implement the RO Model effective January 1, 2021, but the model was delayed by the pandemic and legislation to January 1, 2022.

There has been significant engagement from stakeholders in the radiation oncology field on the RO Model, with varying levels of support and opposition since the model was proposed back in 2019. CMS is now proposing to proceed with implementation on January 1, 2022, but with a number of proposed changes. Foundational aspects of the RO Model remain intact:

- The model is still mandatory and will run for five years;
- Participation will be based on selected geographic areas, representing approximately 30 percent of eligible episodes;

- The model will use site and modality neutral payment based on a 90-day episode of care for selected modalities; and
- Payment rates will be based on case mix, historical experience and efficiency.

CMS proposes a number of changes to the model including, but not limited to the following:

- Removing brachytherapy as an included modality and liver cancer as an included indication;
- Lowering of the discount factors for professional and technical components from 3.75percent and 4.75 percent to 3.5 percent and 4.5 percent, respectively; and
- The RO Model would qualify as an Advanced APM or MIPS APM in Performance Year 1 (as opposed to Performance Year 2).

Given the level of engagement with CMS by many members of the RO community, stakeholders had expectations for meaningful changes in the model. Considering the relatively moderate design changes, it is unclear how well these proposed changes will be received, particularly by those who are still coping with the effects of the PHE while now preparing for an APM that is effective in less than 6 months.

Temporary Policies to Address the COVID-19 Public Health Emergency

Key Takeaway: CMS is seeking comment on temporary policies and flexibilities implemented to address the COVID-19 PHE.

CMS has (prior to the PHE) generally required that hospital outpatient services be delivered to patients physically present in the hospital outpatient department by clinical staff providing who were also physically present. During the PHE, CMS implemented a number of waivers and flexibilities to mitigate the risks of SARS-CoV-2 spread and accommodate the precautions needed to treat patients suspected of having COVID-19. After roughly a year of hospitals delivering care using these temporary flexibilities, CMS is seeking to understand whether there has been a lasting shift in practice patterns and care delivery. Specifically, CMS seeks comments from stakeholders on three specific flexibilities granted during the PHE:

1. Mental health services furnished remotely by hospital staff to beneficiaries in their homes;
2. Direct supervision by interactive communications technology; and
3. Payment for COVID-19 specimen collection in hospital outpatient departments.

While CMS is not currently proposing to make any of these flexibilities permanent, comments could inform future policies regarding outpatient hospital care. These questions appear to reflect a broader effort to reform Medicare payment policies to create reimbursement options for modernized care delivery that takes advantage of advances in technology.

Removal of non-opioid drugs used for perioperative pain relief from payment packaging policies

Key Takeaway: CMS is considering expanding its policies of separate payment for non-opioid drugs to the HOPD and developing clear criteria for separate payment of these drugs.

Over the past decade, opioid addiction has been recognized as a serious health problem. In 2017 the President established a commission on combating drug addiction and opioid crises, and in 2018 Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) by overwhelming majority in the House and Senate. Based on these directives, CMS has had an interest in reviewing payment policies and minimizing economic incentives to use

opioids rather than non-opioid pain relief, which had resulted in modifications to Medicare's surgical packaging policies.

Reimbursement for surgical care, which may rely on opioids for pain relief, often uses packaging policies so as to not pay additionally for drugs used as supplies during surgery. As a result of packaging policies, CMS was not paying separately for Exparel®, a non-opioid drug for perioperative pain relief. Upon finding decreased utilization of Exparel in the ASC setting, CMS finalized a policy to remove Exparel from packaging policies. However, CMS did not allow such separate payment in the hospital outpatient setting. A second drug, Omidria®, was excluded from packaging policies in the 2021 rule. With this background, CMS is considering two policy changes:

- Expanding the ASC policy of allowing separate payment for non-opioid paid medications used as surgical supplies to the hospital outpatient setting; and
- Developing criteria for eligibility for separate payment under the ASC Payment System, which would require that the drug has FDA approval for pain management or analgesia, and that it meets a cost threshold requirement.

Opioid addiction and deaths have been a major focus of HHS in recent years. The CDC's recent provisional drug overdose mortality data has shown that opioid deaths have risen significantly during the COVID-19 PHE with a 29.4 percent rise in 2020 after a couple of years of essentially flat mortality figures. While the current proposed rule is a response to congressional action in 2018, we may again see stepped-up interest on the part of HHS to address opioid-related mortality.

Conclusion

While this rule proposes many changes, there are two overarching takeaways. First, the Administration continues to be sensitive to the burden of the public health emergency and its lingering effects on healthcare providers, particularly hospitals and ambulatory surgical centers. It continues to solicit feedback and explore ways to create flexibilities during and following the PHE. Second, this rule reflects the change in leadership as it reverses course on a few major policy proposals finalized last year. More changes are likely in future rulemakings as this Administration gains its footing.

This rule is also notable for what is not included. A number of areas that were subject to policy change in recent years, including policies concerning skin substitutes, laboratory date of service rule, and comprehensive APCs, were not revisited in this rulemaking.

For more detailed information on specific provisions, please reach out to:

Cathy Simmons
Executive Director, Government & External Affairs
(319) 361-2336
cathy.simmons@unitypoint.org

Stephanie Collingwood
Government Relations Specialist
(319) 538-8652
stephanie.collingwood2@unitypoint.org