Summary of CMS' Proposed 2022 Outpatient Prospective Payment (OPPS) Rule

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Yesterday, CMS posted the agency's proposed 2020 Outpatient rule, formally titled, the "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; and, Request for Information on Rural Emergency Hospitals" proposed rule. The rule's press release is here, the fact sheet is here and the 863-page proposed rule is here. Comments are due 60 days after appearing in the Federal Register, or roughly September 19th.

Here is a summary of the proposed rule's major provisions.

OPPS and ASC Payment Update Rates

CMS is proposing to update OPPS payment rates for hospitals that meet applicable quality reporting requirements by a net 2.3 percent. In the 2019 OPPS/ASC final rule with comment period, CMS finalized its proposal to apply the hospital market basket update to ASC payment system rates for an interim period of five years (2019 through 2023). Using the proposed hospital market basket, CMS is updating the ASC rates for 2022 by 2.3 percent. The proposed update applies to ASCs meeting relevant quality reporting requirements.

Health Equity

CMS is seeking input on ways to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable. This includes soliciting comments on potential collection of data and analysis and reporting of quality measure results by a variety of demographic data points including, but not limited to, race, Medicare/Medicaid dual eligible status, disability status, LGBTQ+, and socioeconomic status.

Hospital Price Transparency

CMS is proposing to increase the penalty for hospitals that do not comply with the hospital price transparency final rule. CMS is proposing to set a minimum civil monetary penalty of $300/day that would apply to smaller hospitals with a bed count of 30 or fewer and apply a penalty of $10/bed/day for hospitals with a bed count greater than 30, not to exceed a maximum daily dollar amount of $5,500. For a full calendar year of noncompliance, the minimum total penalty amount would be $109,500 per hospital and the maximum total penalty amount would be $2,007,500 per hospital.

CMS is also seeking comment on alternative or additional criteria that could be used to scale a Civil Monetary Penalty (CMP) such as: hospital revenue; the nature, scope, severity, and duration of noncompliance; and, the hospital's reason for noncompliance. CMS is proposing to update the list of activities that present barriers to access to the machine-readable file, specifically to require that the machine-readable file is accessible to automated searches and direct downloads. CMS is clarifying that an online price estimator tool must provide a cost estimate to an individual that takes the individual's insurance information into account and that the estimate reflects the amount the hospital anticipates will be paid by the individual for the shoppable service absent unusual or unforeseeable circumstances. Finally, CMS is seeking public input on a variety of issues it may consider in future rulemaking including, these include: considerations for 'best practice' online price estimator tools; improving expectations related to 'plain language' descriptions of shoppable services; methods to identify and highlight exemplar hospitals; and, improving standardization of the machine-readable files.

The Inpatient Only (IPO) List

In 2021 CMS finalized a policy to eliminate the IPO list over a three-year period, removing 298 services from the IPO list in the first elimination phase. CMS is now proposing for 2022 to halt the elimination of the IPO list. Specifically, CMS proposes to add the 298 services removed from the IPO list in 2021 back to the IPO list beginning in 2022. CMS is also proposing to codify the longstanding criteria for removal of procedures from the IPO list to make clear in regulatory text how it will evaluate future procedures for removal. CMS is also soliciting comments on several policy modifications including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintaining the IPO list but continuing to systematically scale the list back so that inpatient only designations are consistent with current standards of practice. Regarding CMS' decision to exempt procedures removed from the IPO list from medical review activities related to the two-midnight policy, for 2022 CMS is proposing to return to the exemption period previously in effect such that all services paid for under the OPPS are subject to medical review.

Site Neutral Payments

CMS will continue its policy of site neutral payments for clinic visits furnished in excepted off-campus provider-based departments.

OPPS Payment for Drugs Acquired Through the 340B Program

Beginning January 1, 2018, Medicare adopted a policy to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. For 2022, CMS is proposing to maintain the payment rate of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. Under this proposal, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals would continue to be excepted from this policy.

Payment for Non-Opioids Under the 2018 SUPPORT Act

The law requires the Secretary review payments under the OPPS and ASC for opioids and evidence-based non-opioid alternatives for pain management to ensure there are not financial incentives to use opioids instead of non-opioid alternatives. For CY 2022, CMS is proposing to modify its current policy to provide for separate or modified payment for non-opioid pain

management drugs and biologicals that function as supplies in the ASC setting when those products meet certain criteria, as determined by CMS. CMS proposes that beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply in the ASC setting would be eligible for separate payment when it is FDA approved and indicated for pain management or as an analgesic and with a per day cost above the OPPS/ASC drug packaging threshold. CMS is soliciting comment on establishing an application process, through which an external party could submit an application for separate payment for a non-opioid pain management drug or biological that functions as a surgical supply. CMS is also soliciting comment on several additional criteria that could be implemented through future rulemaking, such as the presence of peer-reviewed literature that demonstrates a clinically significant decrease in opioid use for the surgical procedure and post-operative period.

RFI: Rural Emergency Hospital (REH) Provider Type

Section 125 of the Consolidated Appropriations Act of 2021 (CAA) established a new provider type called Rural Emergency Hospitals (REHs) effective January 1, 2023. REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital with less than 50 beds, and that do not provide acute care inpatient services with the exception of skilled nursing facility services furnished in a distinct part unit. REHs will be required to furnish emergency department services and observation care and may provide other outpatient medical and health services as specified by the Secretary. The proposed rule includes a Request for Information (RFI) to seek public input on a broad range of issues that should be taken into account in establishing this new provider type. For example, CMS is interested in feedback on the health and safety standards, payment policies, and quality measures for REHs. CMS also intends to host other opportunities for public engagement as it considers policies related to establishing the REH provider type, including open door forums and listening sessions.

Outpatient and ASC Quality Reporting Programs

CMS is seeking input on ideas to revise the Hospital Outpatient Quality Reporting and ASC Quality Riteporting programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients.

Under the Hospital OQR program, CMS is seeking comment on future potential additional stratification of quality measure results by race, Medicare/Medicaid dual eligible status, disability status, LGBTQ+, and socioeconomic status. The agency is also seeking input on potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for facility-level disparity reporting until more accurate forms of self-identified demographic information are available. CMS is also seeking comment on the possible collection of a minimum set of demographic data elements by facilities at the time of admission, and using electronic data definitions to permit nationwide, interoperable health information exchange, for the purposes of incorporating into measure specifications and other data collection efforts relating to quality. More specifically, CMS is proposing to: adopt three new measures, including the COVID-19 Vaccination of Health Care Personnel (NQF #0431); make the reporting of two voluntary or suspended measures mandatory; remove two measures; and, update the validation policies of the Hospital OQR Program to reduce provider burden and improve processes. In addition, CMS is soliciting comments on potential future measure adoptions.

Under the ASCQR program, CMS is seeking comment on: ways to address the unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and the relatively smaller proportion of patients with social risk factors; the utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs; and, ways social risk factors influence the access to care, quality of care and outcomes for ASC patients in general or for specific ASC services. More specifically, CMS is proposing to adopt one new measure, the COVID-19 Vaccination of Health Care Personnel (NQF #0431); and make the reporting of six voluntary or suspended measures mandatory. CMS is requesting comment on quality measures for pain management procedures performed in this setting.

CMS is also seeking digital quality measurement-related comments, for example, standardizing data required for quality measures for collection via Fast Healthcare Interoperability Resources (FHIR®)-based Application Programming Interfaces (APIs); leveraging technological opportunities to facilitate digital quality measurement; better supporting data aggregation; and, developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

Concerning the Hospital Inpatient Quality Reporting (IQR) Program and the Medicare Promoting Interoperability Program, CMS is considering future reporting on the Safe Use of Opioids eCQM, therefore, the agency seeks comments on the appropriateness of maintaining this previously finalized policy or instead proposing in future rulemaking to allow hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs. CMS also seeks any other information or considerations commenters may have to inform future measure updates to the Safe Use of Opioids eCQM.

Radiation Oncology (RO) Demonstration

The CMMI RO demonstration, delayed twice due largely due to the PHE, is anticipated to go live January 1, 2022. CMS is proposing to:

- field the demo from January 1, 2022 to December 31, 2026
- change the baseline period from 2016-2018 to 2017-2019
- lower the discounts to 3.5 percent (Professional Component) and 4.5 percent (Technical Component)
- remove brachytherapy from the list of included modalities under the demo so that it would still be paid FFS rates
- remove liver cancer from the RO demo
- revise the cancer inclusion criteria
- in cases where a beneficiary switches from traditional Medicare to Medicare Advantage during an episode before treatment is complete, CMS would consider this an incomplete episode and radiation therapy services would be paid the traditional Medicare rate instead of being paid under the RO model rate
- adopt an extreme and uncontrollable circumstances policy that would provide flexibility to reduce administrative burden of model participation, including reporting requirements, and/or adjust the payment methodology as necessary when extreme and uncontrollable circumstances exist

- exclude hospital outpatient departments participating in the Community Transformation track of the CHART Model from participation in the RO demo. For the CHART ACO Transformation track, CMS would follow the same policy for overlap between the RO demo and the MSSP ACOs
- exclude only hospital outpatient departments that are participating in the Pennsylvania Rural Health Model (PARHM) rather than those that are eligible to participate in PARHM

The proposed also includes clarifications to help address questions from stakeholders and future RO participants related to the interaction between the RO Model and the Quality Payment Program (QPP)

Use of 2019 Claims Data for CY 2022 OPPS and ASC Rate Setting

CMS believes that the 2020 data are not the best overall approximation of expected outpatient hospital services in 2022. CMS believes 2019 data are a better approximation of expected costs for CY 2022 hospital outpatient services for rate setting purposes. As a result, CMS is proposing to use CY 2019 data to set CY 2022 OPPS and ASC payment system rates.

Soliciting Comments on Temporary PHE Policies

CMS is seeking comment on the extent to which stakeholders utilized PHE regulatory flexibilities as well as whether stakeholders believe there are certain policies that should be made permanent to the extent possible. Specifically, CMS is seeking comment on:

- the extent to which hospitals have been billing for mental health services furnished to beneficiaries in their homes through communication technology during the PHE, and whether continued demand for such care is anticipated
- whether there are any changes CMS should make to account for shifting practice patterns that rely on communication technology to provide mental health services to beneficiaries in their homes
- the degree to which providers relied on the flexibility to allow the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services to include virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or practitioner
- whether CMS should keep HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source) active beyond the conclusion of the PHE and whether CMS should extend or make permanent the OPPS payment associated with specimen collection for COVID-19 tests after the PHE ends.

For additional information, or if you have any questions, please contact David Introcaso, Ph.D., at david.introcaso@shcare.net or via 202.907.7426.