HEALTHCARE REGULATORY ROUND-UP - Episode #51

2024 Proposed Rules – Part 1

July 12, 2023

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WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Introductions

Martie Ross, JD
mross@pyapc.com

Kathy Reep, MBA
kreep@pyapc.com

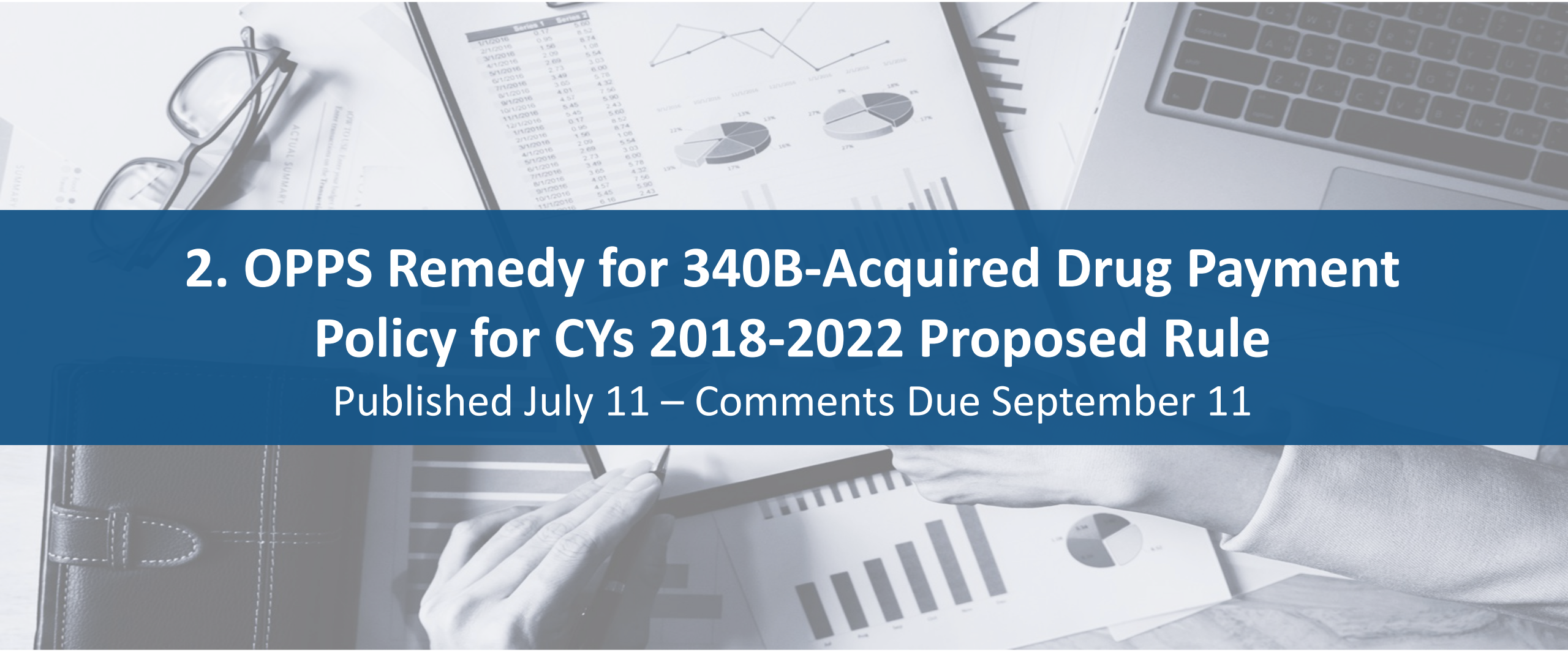
pyapc.com
800.270.9629

Agenda

1. CY 2024 Hospital Outpatient PPS Proposed Rule
2. Remedy for 340B-Acquired Drug Payment Policy for CYs 2018-2022 Proposed Rule
3. CY 2024 Home Health PPS Proposed Rule
4. CY 2024 ESRD PPS Proposed Rule
5. Request for Information - Medical Payment Projects
6. The Latest No Surprises Act FAQs

1. CY 2024 Hospital Outpatient PPS Proposed Rule

Coming Soon



2. OPPS Remedy for 340B-Acquired Drug Payment Policy for CYs 2018-2022 Proposed Rule

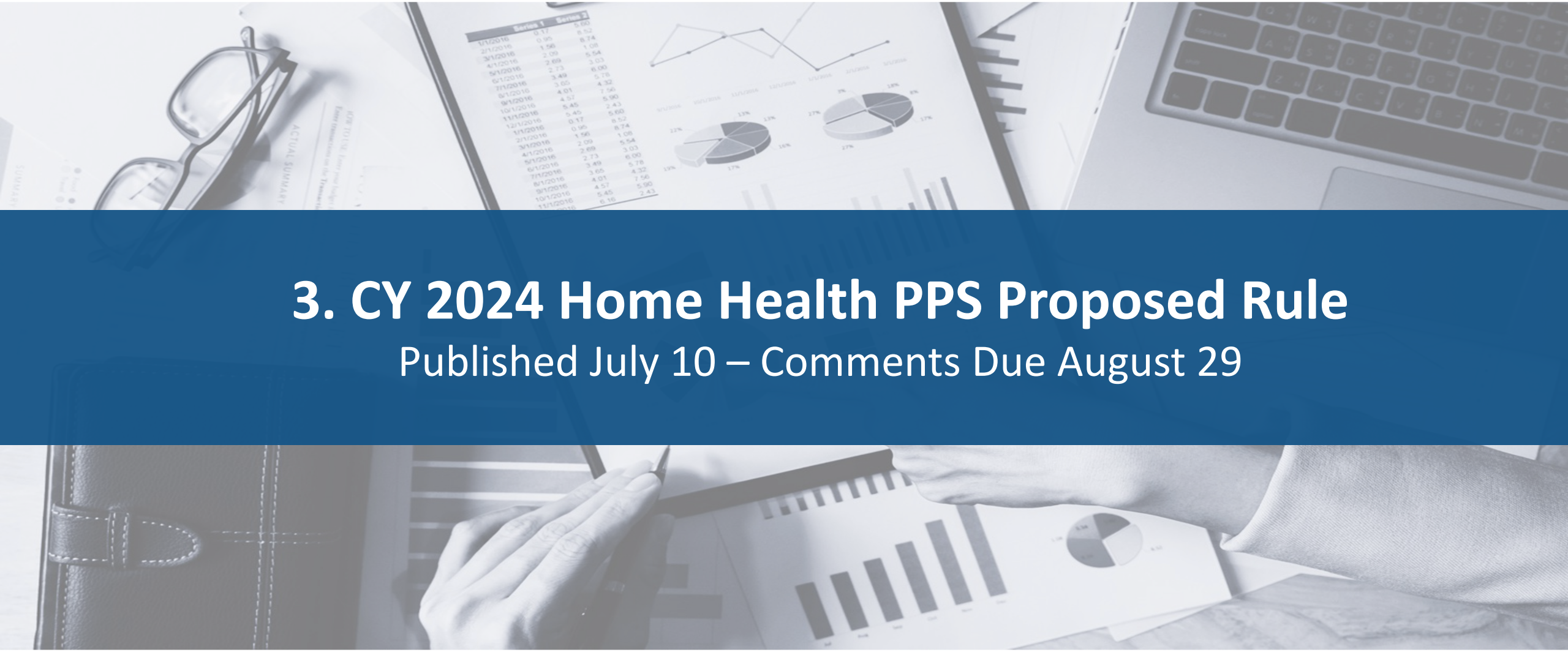
Published July 11 – Comments Due September 11

American Hospital Association vs. Becerra

- In 2018, CMS adjusted OPPS payment rate for 340B acquired drugs from average sales price (ASP) + 6% to ASP minus 22.5% based on estimated acquisition costs
  - Exempted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals
  - CMS re-distributed $1.6B drug savings with 3.19% increase to OPPS conversion factor for non-drug items and services for all OPPS hospitals
- In 2018, AHA filed lawsuit arguing CMS failed to follow statutory rate setting requirements
- In 2022, Supreme Court ruled in AHA's favor; remanded case to District Court to determine remedy
- From 09/27/22 to 12/31/22 and CY 2023, CMS changed payment rate back to ASP +6%
  - CMS also reprocessed claims for 340B drugs back to 01/01/2022
  - Correspondingly, CMS reduced OPPS conversion factor by 3.09% for CY 2023
- In January 2023, District Court gave CMS opportunity to determine proper remedy for reduced payments to 340B hospitals for CY 2018 through CY 2022

CMS' Proposed Remedy

- One-time lump sum payments to ~1,650 340B hospitals based on difference between actual payments received and what hospital would have received without payment adjustment including beneficiary co-payments (~$9 billion total)
  - X = (Y/0.775)*1.06 (Y = total amount hospital received under 340B policy from 01/01/2018 to 09/27/2022)
  - Payments to be made by MACs within 60 days of receiving instructions from CMS – late 2023/early 2024
- To offset additional payments for non-drug items and services (3.19% increase in OPPS conversion factor from 2018 to 2022), adjust OPPS conversion factor by minus 0.5% starting in 2025 and continuing for ~next 16 years

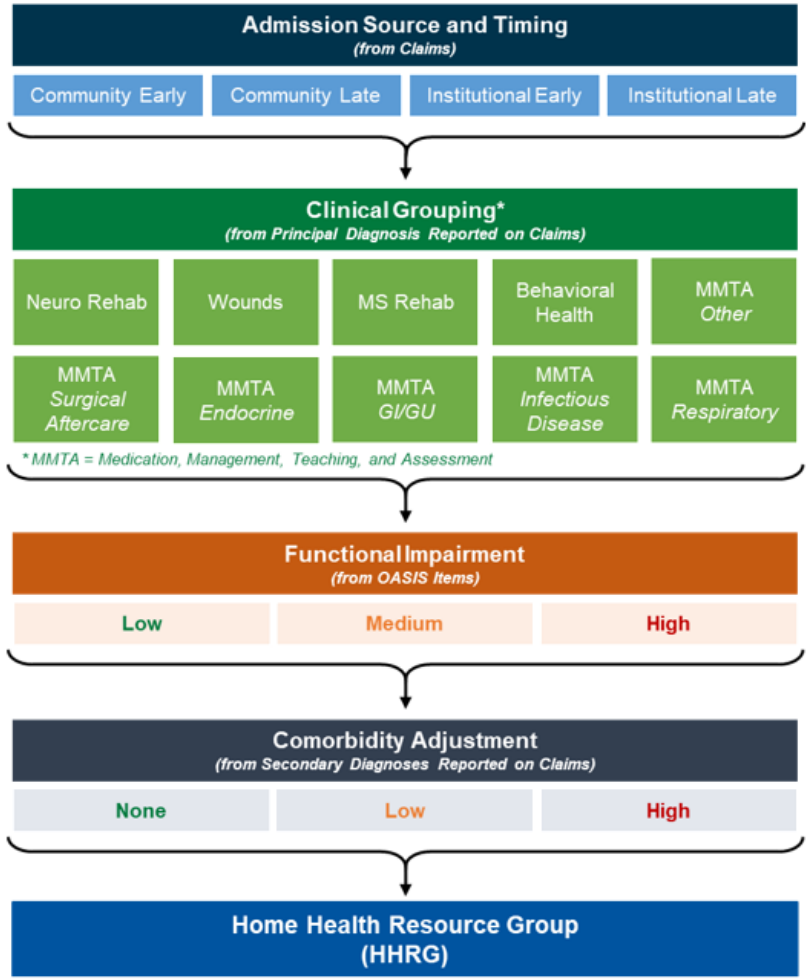


3. CY 2024 Home Health PPS Proposed Rule

Published July 10 – Comments Due August 29

Patient-Driven Groupings Model (PDGM)

- National, standardized 30-day period payment rate
- Agency-specific adjustments
  - Wage Index
  - Quality Reporting Program
  - Value-Based Purchasing Model
- Case-specific adjustments
  - Each 30-day period assigned to one of 432 Home Health Resource Groups based on beneficiary's health conditions and care needs
  - Additional adjustments for low-utilization and partial periods, outliers, rural add-on payment



2024 Base Rate

- 2.2% reduction to base rate ($375 million decrease from 2023)
  - 2.7% market basket increase ($460 million increase)
    - Adopting 2021-based home health market basket, including changes to cost weights and price proxies
    - Decreasing labor-related share from 76.1% to 74.9%
  - 5.1% prospective, permanent behavior assumption adjustment ($870 million decrease)
  - 0.2% increase due to proposed update to fixed-dollar loss ratio ($35 million increase)
- Behavior assumption adjustment
  - Accounts for differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures due to implementation of PDGM and 30-day unit of payment (budget neutrality)
    - Clinical group coding, comorbidity coding, and low utilization payment adjustments
  - Permanent adjustment previously made in 2023, but CMS determined amount insufficient based on more recent claims data
- Pending litigation
  - National Association for Home Care and Hospice filed lawsuit on 07/05/23 challenging 2023 behavior assumption adjustment claiming methodology “arbitrarily and capriciously”

Other Payment-Related Changes

- Recalibrate the PDGM case-mix weights
- Update low utilization payment adjustment thresholds, functional impairment levels, and comorbidity adjustment subgroups
- Establish separate payment for disposable device used in negative pressure wound therapy (per Consolidated Appropriations Act, 2023)
- Establish regulations to implement payment for items and services under two new benefits: lymphedema compression treatment items and home intravenous immune globulin

Home Health Quality Reporting Program

- Two new measures beginning with CY 2025 HH QRP
  - COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
  - Functional Discharge Score
- Removal of three measures
  - Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function
    - Replaced by new Functional Discharge Score
  - Two OASIS items no longer necessary for collection
    - M0110 - Episode Timing
    - M2220 - Therapy Needs items
- Technical changes codifying data submission requirements

Proposed 30-Day Period Payment Rates

TABLE B34: CY 2024 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2023 National Standardized 30-Day Period Payment	Permanent BA Adjustment Factor	Case-Mix Weights Recalibration Budget Neutrality Factor	Wage Index Budget Neutrality Factor	Labor-Related Share Budget Neutrality Factor	CY 2024 HH Payment Update Factor	CY 2024 National, Standardized 30-Day Period Payment
$2,010.69	0.94347	1.0121	1.0015	0.9998	1.027	$1,974.38

TABLE B35: CY 2024 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAs THAT DO NOT SUBMIT THE QUALITY DATA

CY 2023 National Standardized 30-Day Period Payment	Permanent BA Adjustment Factor	Case-Mix Weights Recalibration Budget Neutrality Factor	Wage Index Budget Neutrality Factor	Labor-Related Share Budget Neutrality Factor	CY 2024 HH Payment Update Factor Minus 2 Percentage Points	CY 2024 National, Standardized 30-Day Period Payment
$2,010.69	0.94347	1.0121	1.0015	0.9998	1.007	$1,935.93

Home Health Value-Based Purchasing Model

- Changes effective 01/01/2025
  - Replace Total Normalized Composite Measures (for Self-Care and Mobility) with Discharge Function Score measure
  - Replace OASIS-based Discharge to Community measure with claims-based Discharge to Community-Post Acute Care measure
  - Replace claims-based Acute Care Hospitalization During the First 60 Days of Home Health Use and the Emergency Department Use without Hospitalization During the First 60 Days of Home Health measures with the claims-based the Potentially Preventable Hospitalization measure
  - Change weights of individual measures due to change in total number of measures
  - Update Model baseline year to CY 2023 for all applicable measures
- Reminder - public reporting of HHVBP performance data and payment adjustments to begin in December 2024

DMEPOS Refill Policy

- Require documentation that beneficiary confirmed need for refill within 30-day period prior to end of current supply.
- DMEPOS items cannot be delivered more than 10 calendar days before expected end of current supply.
- CMS seeking comments on ways to balance beneficiary burden with potential risks/burdens of not verifying beneficiary's actual need for recurring supplies

Hospices

- Enrollment provisions
  - Subject hospices to highest level of provider enrollment application screening
  - Expand HHA change in majority ownership provisions in 42 CFR § 424.550(b) to include hospice changes in majority ownership
  - Clarify that definition of “Managing Employee” in 42 CFR § 424.502 includes hospice administrator and medical director
- Hospice Special Focus Program
  - Required by Consolidated Appropriations Act, 2021
  - Proposed methodology and algorithm criteria for SFP (identify hospices providing poor quality or unsafe care) based on Technical Expert Panel and stakeholder recommendations

Request for Information – Home Health Aides

- How to ensure appropriate access to and provision of home health aide services for all beneficiaries receiving home health care
- Barriers and obstacles to recruitment and training
- Ways to ensure that aides are consistently paid wages that are equivalent to other care settings and commensurate with the impact they have on patient care

4. CY 2024 ESRD PPS Proposed Rule

Published June 30 – Comments Due August 25

Payment Changes

- Increase base rate to $269.99 (1.7% increase)
- Update outlier threshold using 2022 claims data
- Low volume payment adjustment (LVPA)
  - Allow facilities to close temporarily and reopen in response to disaster/ emergency and still receive LVPA
  - Allow facilities to maintain LVPA if treatment counts increase due to treating additional patients displaced by disaster/emergency
- Require facilities to report “time on machine” to better measure resource use
- Transitional pediatric ESRD add-on payment adjustment of 30 percent of the per treatment payment amount (2024-2026)
- Additional 3-year payment adjustment for certain new renal dialysis drugs and biological products (in addition to current 2-year Post-Transitional Drug Add-on Payment Adjustment)

ESRD Quality Incentive Program (QIP)

- Changes for PY 2026
  - Add Facility Commitment to Health Equity reporting measure
  - Update COVID-19 Vaccination Coverage Rate Among Healthcare Personnel reporting measure to align with updated CDC measure specifications
  - Convert Clinical Depression Screening and Follow-Up reporting measure to clinical measure
  - Remove Ultrafiltration Rate reporting measure
  - Remove Standardized Fistula Rate clinical measure
- Changes for PY 2027
  - Add Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health reporting measures

5. Request for Information – Medical Payment Products

Published July 12 – Comments Due September 10

Medical Payment Products

- CMS, Consumer Financial Protection Bureau, and Department of Treasury soliciting comments on prevalence, nature, and impact of commercial medical payment products (e.g., medical credit cards and installment loans) and policy solutions to address any negative impacts
    - Significant growth in product usage over last decade
    - Charge interest rates higher than general purpose credit cards
    - Anecdotal evidence of providers promoting medical payment products -
        - To earn incentives from financial institutions
        - To avoid having to provide financial assistance to qualifying patients
        - To avoid assisting patients in securing coverage or referring patients to in-network providers
        - To charge patients higher prices for goods and services
        - To avoid consumer protections laws

Specific Agency Concerns

- Consumer Financial Protection Bureau
  - Providers take advantage of patients' trust in them to act in their best interests
  - Leads to higher out-of-pocket costs for patients
  - Contributes to health care cost inflation
- CMS
  - No Surprises Act
  - Hospital Price Transparency
  - Anti-Kickback Statute
  - How might HHS improve patient understanding of options for covering the cost of medical treatments? At what points in the care process could patients be provided with information about their financial obligations and payment options?
- Department of Treasury
  - Restrictions on extraordinary collection actions by not-for-profit hospitals
  - Hospitals claiming medical payment products provide community benefit or constitute financial assistance

6. New No Surprises Act FAQs

Published July 6

No Surprises Act FAQ Issues 7/7/23

- Included in *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 60*
- Issue of facility fees for services furnished outside of hospital settings
  - Requirement for plans/issuers to make price comparison information on facility fees available to participants and enrollees through internet-base self-service tool and in paper form, upon request
  - Also requires providers and facilities to provide GFEs to self-pay individuals in connection with facility fees

https://www.cms.gov/*cciio*/resources/fact-sheets-and-faqs#Affordable_Care_Act

Our Next Healthcare Regulatory Round-Ups:

- **July 26: Hospital Outpatient PPS Proposed Rule and Overview of Medicare Physician Fee Schedule Proposed Rule**
  (90 minutes, 1.5 CPE Credits)
- **August 2 or 9: Deeper Dive into Medicare Physician Fee Schedule Proposed Rule**
- **August 16: FY 2024 Final Rules**
- **August 30: EMTALA Update**

- **July 20: *PYA Unscripted* – Provider Compensation of the Future**