Rural Healthcare Regulatory Roundup

Kathy Reep, PYA
kreep@pyapc.com

Milestones in Rural Health
2023 Small & Rural Hospitals Annual Meeting

IHA 100 Years of Service
Illinois Health and Hospital Association

Agenda

1. End of the COVID-19 Public Health Emergency
2. 2024 Proposed Payment Rules
3. 2024 Medicare Advantage Final Rule
4. Hospital Price Transparency – Enforcement
5. No Surprises Act – Enforcement
6. 340B Program
7. PATIENT Act

1. End of the COVID-19 Public Health Emergency

CMS Expectations on Post-PHE Compliance

State Survey Agency Directors Memorandum (05/01/23)

Acute and Continuing Care (ACC) Provider Flexibilities

CMS is ending the following emergency declaration flexibilities for ACC providers with the conclusion of the COVID-19 PHE. Providers are expected to take immediate steps so that they may return to compliance with the reinstated health and safety requirements as noted below.

For Flexibilities Terminating and Returning to Pre-PHE Requirements upon the Conclusion of the PHE. CMS expects all providers to be in compliance with all applicable requirements after May 11, 2023, unless otherwise noted below.

Hospital Highlights

- Emergency preparedness annual testing requirements
- Facility and equipment inspection, testing, and maintenance
- Quality Assurance and Performance Improvement (QAPI) + Utilization Review CoPs
  - New Interpretive Guidelines (IGs) on hospital QAPI CoPs; CAH IGs coming soon
- Treating patient home as hospital outpatient department (HOPD) for outpatient/OPPS billing
- SNF/swing bed qualifying 3-day hospital stay
- EMTALA – Medical screening exams furnished in dedicated emergency department
- Reduced COVID-19 reporting requirements (through April 2024)
- CAH average 96-hour patient length of stay requirement
  - "The evaluation of the average 96-hour patient length of stay requirements will resume with the CAH's first full cost reporting period after May 11, 2023, which will not include any of the months covered under the COVID-19 PHE blanket waiver"

Medicare Telehealth Coverage – Through 12/31/24

- Continue waiver of geographic and location requirements
- Continue reimbursement for PT, OT, S/L pathologist, and audiologist telehealth services
- Continue reimbursement for audio-only services
  - Audio-only E/M (CPT 99441-43), specified behavioral health & education services
- Continue Federally Qualified Health Center (FQHC)/Rural Health Center (RHC) reimbursement of telehealth services (G2025 - $98.27)
- Delay in-person requirement for initiation of tele-behavioral health services
  - CAA21 permanently eliminated geographic and location requirements for tele-behavioral health services subject to certain requirements + provided coverage FQHC/RHC services
- Continuation of use of telehealth to re-certify eligibility for hospice and required face-to-face encounter for home health

Expired Telehealth Flexibilities

- Discontinue OPPS billing for telehealth services furnished by hospital staff (patient home no longer qualifies as hospital outpatient department (HOPD)
  - E.g. cardiac rehab, partial hospitalization services
  - 2023 OPPS Final Rule created new reimbursement for tele-behavioral health services (HCPCS C7900-C7902)
- Discontinue OPPS billing HCPCS Q3014 for telehealth services furnished to patient at home by physician not present at facility and HCPCS G0463 for same by physician present at facility
- Discontinue use of telehealth for required face-to-face visits for home dialysis patients
- Discontinue use of telehealth for required face-to-face visits for inpatient rehab facility (IRF) patients
- For subsequent inpatient visits, use of telehealth limited to once/3 days (CPT 99231-99233)
- For subsequent SNF visits, use of telehealth limited to once/14 days (CPT 99307-99310)
- For critical care consults, use of telehealth limited to once/day (HCPCS G0508-G0509)

2. 2024 Proposed Payment Rules

FY2024 IPPS Proposed Rule: Payment Rates

- Operating rate increase of 2.8%
  - 3% market basket rate increase (i.e. measure of inflation in costs of goods and services used by hospitals in treating Medicare patients) minus 0.2% multi-factor productivity adjustment
    - Based on FY22 claims data and FY21 cost report data with no COVID-19-related adjustments
    - No plus 0.5% coding and documentation adjustment (FY18 – FY23)
    - Compare to FY23: Proposed Rule = 3.2% increase; Final Rule = 4.3% increase
  - Other adjustments
    - Hospitals ≠ meet Promoting Interoperability Program requirements in FY22 = 0.55% update
    - Hospitals ≠ meet Inpatient Quality Reporting Program requirements in FY22 = 2.05% update
    - Hospitals that met neither program's requirements in FY22 = negative 0.2% update
  - Proposed rule used data from Q3 2022; final rule will likely use data from Q1 2023
  - National standardized amount for FY24 = $6,524.94, a 2.3% increase over FY23 ($6,375.74)
- Capital rate increase from current $483.76 to $505.54
- Increase outlier threshold from $38,859 to $40,732

FY2024 IPPS Proposed Rule: Rural Wage Index Calculation Methodology

- Treat reclassified rural hospitals same as those that are geographically rural for purposes of rural wage index
  - Would include data from hospitals that reclassified from urban to rural in calculating rural wage index
    - In FY23 these hospitals were included in calculating rural floor *but not* rural wage index
  - Would likely increase the wage index of many rural hospitals
- Exclude hospitals with both Sec. 412.103 and MGCRB reclassifications from the calculation of the rural wage index ("dual reclass" hospitals)

FY2024 IPPS Proposed Rule: Z Codes for Homelessness

- For FY24, change severity level designation from non-complication or comorbidity (NonCC) to complication or comorbidity (CC)
  - Based on available data, homelessness results in higher costs; will re-evaluate as additional data becomes available
  - Example – simple pneumonia and pleurisy
    - DRG 195 (NonCC) – 0.6224
    - DRG 194 (CC) – 0.8190
- "[W]e also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of [Z Codes] to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity."

FY2023 IPPS Final Rule: Hospital IQR Measures – Screening for HRSNs

- #1 - Percentage of inpatients age 18+ screened for one or more or the following: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety
  - Use self-selected screening tool (e.g., AHC Health-Related Social Needs Screening Tool)
  - Exclude from denominator (1) patients who opt-out of screening; and (2) patients unable to complete screening during inpatient stay who have no guardian/caregiver able to complete on patient's behalf
- #2 - Separately report positive screening rate for each of 5 domains
- Voluntary Reporting in CY23 Reporting Period; Mandatory Reporting in CY24 Reporting Period/FY26 Payment Determination

2023 MedPAC March Report

- Hospital Proposal: Move DSH and uncompensated care payments/create Medicare Safety-Net Index (MSNI)
  - Add $2B to pool
  - Distribute as add-on payments under IPPS and OPPs
    - Exclude from MA benchmarks
      - Pay directly to providers
- Physician Proposal: Non-budget neutral add-on payment (without cost sharing) for services provided to low-income Medicare beneficiaries
  - 15% primary care
  - 5% all others

Other Proposed Rules

- [placeholder]

3. 2024 Medicare Advantage Final Rule

Key Provisions

1. Prior authorization/utilization management
2. Health equity
3. Behavioral health
4. Plan marketing restrictions

NOTE: CMS ***did not*** finalize proposed changes to regulations governing providers' obligation to report and return Medicare overpayments (replace 'reasonable diligence' with 'knowing' and 'knowingly'); will be subject of later rulemaking

Prior Authorization/Utilization Management

- Based on data from Medicare Advantage (MA) plans representing 87% of enrollment, in 2021 –
  - 35M+ prior authorization (PA) requests were submitted to MA plans on behalf of MA enrollees
  - Volume varied across plans, ranging from 0.3 requests per Kaiser Permanente enrollee to 2.9 requests per Anthem enrollee (average = 1.5 requests per enrollee)
  - 2M+ PA requests were fully or partially denied by MA plans
  - Only 11% of PA denials were appealed
  - 82% of appeals resulted in fully or partially overturning initial PA denial

https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/

Substantive Requirements

- Must comply with national coverage determinations (NCDs), local coverage determinations (LCDs), and general coverage and benefit conditions in traditional Medicare statutes and regulations
  - Including coverage criteria for inpatient, IRF, and SNF admissions and home health (HHA services)
  - Specifically, admissions for surgeries on inpatient only list and admissions meeting two midnight benchmark (but not the two-midnight presumption applied for medical review purposes)
- If (and only if) coverage criteria not fully defined by above, may establish internal coverage criteria
  - Must be based on current evidence in widely used treatment guidelines or clinical literature
  - Must be publicly accessible (including summary of evidence)
  - Plan must demonstrate additional criteria provide clinical benefits highly likely to outweigh any harm, including delayed or decreased access to care

NOTE: Procedural requirements (e.g., turn-around time on PA requests) addressed in separate proposed rule published in December 2022

Health Equity

- Star Rating Health Equity Index
  - Summarizes plan's performance among beneficiaries with specified social risk factors (SRFs) across multiple measures into single score
  - Replaces current reward factor for consistently high performance (biggest driver of Quality Bonus Payments)
  - Initial SRFs = beneficiaries who (1) receive low-income subsidy, (2) are dual eligible and (3) are disabled
  - Initial calculation based on 2024 and 2025 data and applied to 2027 Star Ratings
- Other health equity-related plan requirements
  - Ensure services provided in culturally competent manner to expanded list of populations
  - Include in provider directories providers' cultural and linguistic capabilities (including languages offered by provider or skilled medical interpreter)
  - Identify and offer digital health education to enrollees with low digital health literacy
  - Incorporate activities to reduce disparities in health and health care into overall quality improvement program

Behavioral Health

- For primary care and behavioral health services, plan must ensure wait times do not exceed –
  - Emergency/urgent – immediately
  - Requiring medical attention – 7 business days
  - Routine and preventive care – 30 business days
- Requires plans to demonstrate network adequacy for clinical psychology and clinical social work (time/distance and minimum ratios + telehealth credit)
  - In addition to psychiatry and inpatient psychiatric facility services
- Clarifies 'emergency medical condition' includes both physical and behavioral health conditions
  - No prior authorization; 'medical necessity' based on 'prudent layperson' standard

Plan Marketing Restrictions

- 22 new requirements relating to marketing and enrollment activities
- Based on CMS monitoring activities and complaints received from plans and beneficiaries
- Apply to 2024 plan year and thereafter

We are finalizing several changes to strengthen beneficiary protections and improve MA and Part D marketing. These include notifying enrollees annually, in writing, of the ability to opt out of plan business contacts from their plan; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage; clarifying that the contact is unsolicited unless an appointment at the beneficiary's home was previously scheduled; prohibiting marketing of benefits in a service area where those benefits are not available, unless unavoidable due to use of local or regional media; prohibiting the marketing of savings available based on a comparison of typical expenses borne by uninsured individuals; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they represent in marketing materials; requiring plans and sponsors to have an oversight plan that monitors agent/broker activities and reports non-compliance to CMS; adding SHIPs to the TPMO disclaimer; adding the number of organizations and products a TPMO represents to the TPMO disclaimer; placing limits around the use of the Medicare name, logo, and Medicare card; prohibiting the use of superlatives unless the material provides documentation to support the statement; prohibiting the collection of SOA cards at educational events; prohibiting a marketing event to follow an educational event with 12 hours at the same location; clarifying the requirement to record calls between TPMOs and beneficiaries includes virtual connections such as Zoom and Facetime; limiting the time that a sales agent can call a potential enrollee to no more than 12 months following the date that the enrollee first asked for information; and requiring 48 hours between a Scope of Appointment and an agent meeting with a beneficiary, with exceptions for beneficiary-initiated walk-ins and the end of a valid enrollment period.

4. Hospital Price Transparency

04/26/23 Enforcement Update

- Streamline compliance process
  - CMS will no longer issue warning notice
  - Immediately request hospital submit CAP
- Corrective Action Plan (CAP) completion deadlines
  - Must submit CAP within 45 days of request
  - Compliance required within 90 days of CAP request
    - No longer allows hospital to propose completion date
- Imposition of Civil Monetary Penalties (CMP)
  - Automatically impose CMP if hospital fails to submit CAP within 45 days

Illinois Compliance Data?

5. No Surprises Act – Enforcement

Milestones in Rural Health

Enforcement Activity - Example

- Hospital-based (not employed) anesthesiologist sent bill to patient for balance of claim for emergency service; CMS initiated investigation following patient compliant
- Hospital received request from CMS to provide following information within 10 business days
  - Provide documentation that demonstrates the workflows hospital has in place to catch and prevent violations of NSA's balance billing prohibitions
  - Provide documentation that demonstrates the corrective actions hospital has taken in response to this complaint, including a timeline and nature of improvements to current business practices to eliminate similar complaints in the future
  - Provide documentation that demonstrates the extent of compliance with balance billing prohibitions, including results of impact analysis to determine how many individuals were billed amounts in excess of their in-network cost sharing amount for emergency services

Milestones in Rural Health

6. 340B Program

Waiting …

- Off-site clinics
  - Uncertainty created by HRSA's removal from its website guidance allowing hospitals to prescribe discounted drugs for off-site clinic patients before clinic registered with its 340B Office of Pharmacy Affairs Information System (OPA-IS) and listed on Medicare cost report
- Proposed rule at Office of Management and Budget (OMB) addressing remedy for 340B-acquired drugs purchased in cost years 2018-2022
  - Required under Supreme Court's 2022 decision overturning CMS' payment cuts for 340B hospitals

HR 3290 - Transparency and Oversight of the 340B Drug Discount Program

- Advanced out of House Energy and Commerce Committee on May 24 (29-22)
- Requirements
  - Covered entities required to maintain records regarding use of 340B Program savings which may be audited by HHS
  - DSH covered entities (and potentially others) required to report annually regarding –
    - Number of individuals who received drugs purchased through 340B Program (by payer)
    - Percentage of the number of individuals treated who received drugs purchased through the 340B Program (by payer)
    - Costs incurred at each site, including costs of charity care
    - Costs incurred for treating patients entitled to Medicare Part A benefits or enrolled in Medicare Part B, enrolled in a Medicaid plan (or a waiver of such plan), or who were uninsured, minus the sum of Medicare reimbursements, Medicaid reimbursements and payments by uninsured patients
    - 340B Program savings

7. HR 3561 - Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act

On Its Way To Becoming Law?

- Advanced out of House Energy and Commerce Committee on May 24 (49-0)
- Key provisions
  - Hospital price transparency
  - Health insurer transparency
  - Provider-based status approval
  - Site neutral payments
  - Mandatory reporting of ownership information
  - *Delay Medicaid DSH cuts until FY2026*
  - *Medicare Advantage plan reporting requirements*
  - *Clinical lab price transparency*
  - *Pharmacy benefits managers oversight*
  - *Extension of certain graduate medical education programs*

https://docs.house.gov/meetings/IF/IF00/20230524/116022/BILLS-118-NA-M001159-Amdt-6.pdf

Hospital Price Transparency

- As of 01/01/25 would have to provide list of 300 shoppable services (price estimator tool no longer substitute for such list)
- CMS to publish standard, uniform method and format for reporting (with all rates expressed as dollar amount) hospitals must use by 01/01/25
  - Plain language description with appropriate code (HCPCS, DRG, NCD, etc.)
  - Gross charge (inpatient and outpatient) (chargemaster rate absent discounts)
  - Any payer-specific negotiated charges with name of third-party payer and plan (inpatient and outpatient)
  - De-identified maximum and minimum negotiated charges
  - Discounted cash price (enter gross charge if no cash discount available)

Hospital Price Transparency, Con't

- CMS/OIG to establish process to regularly monitor accuracy of price information
- Increased penalties for non-compliance effective 01/01/24; thereafter, CMS has authority to increase penalties through rulemaking
  - $300/day for hospitals with 30 beds or less
  - $10/day per bed for hospitals with 30+ beds ($5,500/day limit lifted 01/01/24); minimum penalty of at least $5 million for hospital that fails to comply for year or more
- CMS to maintain publicly available list of hospital found to be non-compliant (warning letter, corrective action plan, penalties) + hospitals currently under review
- CMS to submit annual report to Congress on complaints and enforcement activities
- US Government Accountability Office (GAO) to provide report within 1 year on needed improvements and increased CMPs
- CMS to establish requirements to ensure accessibility of pricing information to individuals with limited English proficiency (e.g. interpretation services)

Health Insurer Transparency

- Would impose additional transparency requirements on health plans beyond current Transparency in Coverage rules
- Beginning 01/01/25 and every 3 months thereafter, health plans would make available in manner specified by regulation the following information for each covered item or service
  - In-network rate for each participating provider (identified by NPI)
  - Amount billed by and allowed amount for each non-participating provider (with certain exceptions)
- Health plans would publish instructions written in plain language on how to use publicly reported data

Health Insurer Transparency - Reports

- By 01/01/25, Comptroller General would submit report to Congress regarding health plan compliance, enforcement activities, and opportunities for improvement
- By 01/01/28, Comptroller General would submit report to Congress assessing differences in negotiated rates in private market
  - Rural and urban areas
  - Individual, small group, and large group markets
  - Consolidated and unconsolidated health care provider areas
  - Non-profit and for-profit hospitals
  - Non-profit and for-profit insurers
  - Insurers serving local or regional areas and insurers serving multi-state or national areas

Provider-Based Status Approval

- By 01/01/26, hospital would have to submit provider-based attestation for all off-campus outpatient departments demonstrating compliance with 42 C.F.R. § 413.65
- By 01/01/26, each hospital off-campus outpatient department would have to obtain and bill government payers under separate NPI
  - CMS to establish process for hospitals to obtain these NPIs

Site Neutral Payment Reductions – Drug Administration Services

- Would reduce Medicare payments for drug administration services at all off-campus HOPDs to amount equivalent to what would have been paid "under the applicable payment system"
  - No exception for "grandfathered' off-campus HOPDs (i.e. those opening on/before 11/02/15; mid-build)
- 4-year phase-in period with full implementation by 01/01/28
  - The American Hospital Association estimates these site neutral payments would cost hospitals $3 billion over 10 years
  - Any budget neutrality adjustments would not take into consideration savings generated through site neutral payments

Side Note… MedPAC Site Neutral Payment Proposal

- HHS to annually identify services that can only be provided in hospital outpatient department – exempt from site neutral payment
- Create comprehensive APCs (C-APCs) for emergency, critical care, and trauma visits
- All other services -
  - If hospital outpatient had highest volume, services continue to be paid under OPPS
  - If ambulatory surgery centers (ASCs) had highest volume, hospital and ASC paid at ASC rate
  - If physician office and non-grandfather outpatient departments had highest volume, hospital and ASC paid weighted average of the difference between PFS facility and non-facility rates

Mandatory Reporting of Ownership Information

- Beginning 01/01/25, specified entities would report annually on business structure, mergers, acquisitions, changes in ownership, and other ownership-related matters as determined by CMS
  - "Specified entities" = hospital; physician-owned practices with more than 25 physicians; physician practice owned by hospital, health plan, private equity company, or venture capital firm; ASC; freestanding ED
- Penalty for failure to report
  - Hospitals with 30+ beds: no more than $5 million for each report not provided or report containing false information
  - All other entities: no more than $2 million for each report not provided or report containing false information

Mandatory Reporting of Ownership Information

- Additional required reporting for all hospitals –
  - Debt-to-earnings ratio
  - Average amount of debt incurred by the hospital and the entire specified entity
  - Real estate leases and purchases
- Additional required reporting for non-profit hospitals –
  - Capital gains investments (disaggregated by type of investment)
  - Taxes paid on those gains
- By 01/01/27 HHS to make specified data publicly available

2023 Small & Rural Hospitals Annual Meeting

Milestones in Rural Health

Questions?