HEALTHCARE REGULATORY ROUND-UP #82

2025 Medicare Hospital Outpatient Prospective Payment System Final Rule

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Introductions

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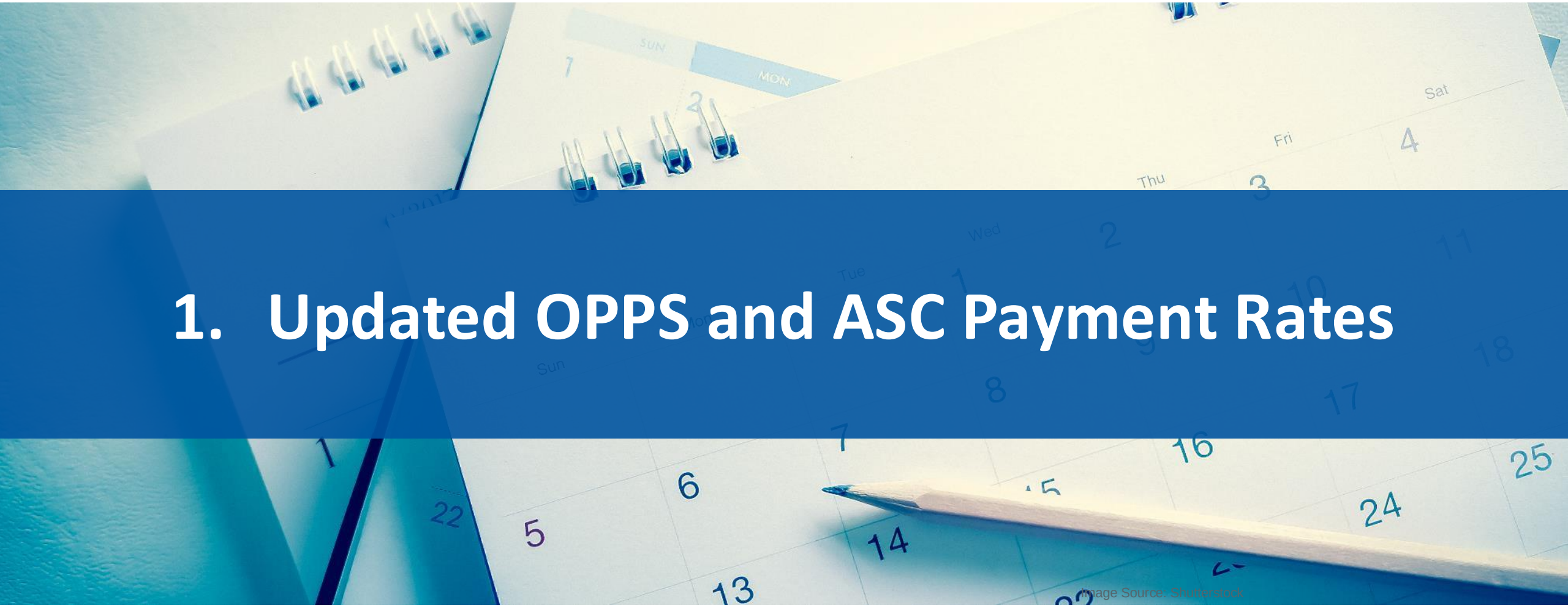
Today's Agenda

1. Updated OPPS and ASC Payment Rates
2. Other Payment-Related Provisions
3. Quality Program-Related Provisions
4. Maternal Health Conditions of Participation
5. Medicare Patient Status Appeals Final Rule

1. Updated OPPS and ASC Payment Rates



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OPPS and ASC Payment Rate Updates

- 2.9% OPPS payment rate increase over 2024
  - Based on market basket of 3.4% less 0.5% statutorily required productivity adjustment
  - 0.3% increase over proposed rate
  - Final conversion factor = $89.169 (currently $87.382)
    - Overall update inclusive of budget neutrality adjustment, cap on wage index reductions, and other similar adjustments
    - Rate reduced to $87.439 if did not meet outpatient quality reporting requirements in 2023 (2.0 percentage point reduction)
  - Rates based on CY 2023 claims data and primarily CY 2022 cost data (most recent data available)
- 2.9% ASC payment rate increase over 2024
  - ASCs paid 60% of OPPS rate
  - 2.0 percentage point reduction if did not meet ASC quality reporting requirements in 2023

2. Other Payment-Related Provisions

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Changes To Inpatient-Only List

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Final Status Indicator
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Add to the IPO list	C
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary)	Add to the IPO list	C
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Add to the IPO list	C
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)	Remove from the IPO list	N

Intensive Outpatient/Partial Hospitalization Services

CY 2025 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$112.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$170.37
5853	Partial Hospitalization (3 services per day) for CMHCs	$112.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$170.37
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$272.46
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$413.50
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$272.46
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$413.50

Final rates payments use CY 2023 claims data

Diagnostic Radiopharmaceuticals

- Separate payment for diagnostic radiopharmaceuticals with per day costs > $630 (subject to recalculation annually)
- For nuclear medicine APCs –
  - Cost of diagnostic radiopharmaceuticals removed from calculation of APC
  - Now paid based on mean unit cost derived from hospital claims data
  - Diagnostic radiopharmaceuticals with per day cost below threshold continue to be packaged into applicable APC

Non-Opioid Treatment for Post-Surgical Pain Relief

- Required under Consolidated Appropriations Act, 2023
  - Limits add-on to ≤ 18% of OPPS payment for service/group of services for which the pain relief furnished
  - Program runs from CY 2025-2027
  - Applies to treatments in both hospital outpatient and ASC setting
- 6 drugs and 5 devices/therapies qualify for separate payment in 2025
  - Qualifying drugs - FDA-approved indications to reduce post-operative pain or produce post-surgical analgesia
  - Qualifying medical devices - demonstrable evidence of reduction in opioid usage when used in post-operative setting
- New status indicators
  - K1: Non-opioid drugs and biologicals for post-surgical pain relief
  - H1: Non-opioid medical devices for post-surgical pain relief

3. Quality Program-Related Provisions

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Outpatient, ASC, & REH Quality Reporting Programs

- Commitment to Health Equity Measure
  - Mandatory reporting in CY 2025 (2027 payment determination)
  - Attestation across five domains (equity as strategic priority, data collection, data analysis, quality improvement, leadership engagement)
- Screening for Social Drivers of Health Measure
  - Voluntary reporting in CY 2025, mandatory in CY 2026 (2028 payment determination)
  - Number of adult patients receiving care at HOPD*, REH, or ASC screened at time of service for HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, & interpersonal safety) using self-selected tool (update for those previously screened)
- Screen Positive Rate for SDOHs Measures
  - Voluntary reporting in CY 2025, mandatory in CY 2026 (2028 payment determination)
  - Number of adult patients receiving care at HOPD*, REH, or ASC screened at time of service for all 5 HRSNs who screened positive for specified HRSN(s)

*Yes, that includes physician practices operated as HOPDs

Other Quality Reporting Program Changes

- OQR Program
  - Add Patient Understanding of Key Information Related to Recovery After a Facility-Based Procedure or Surgery (voluntary in 2025, mandatory in 2026)
  - Remote MRI Lumbar Spine for Low Back Pain in CY 2025
  - Remote Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery in CY 2025
  - Require EHR technology be certified to all eCQMs available to report in OQR Program
  - Report on Care Compare Median Time from ED Arrival to ED Departure (Psychiatric/Mental Health Patients)
- ASCQR Program
  - RFI on changes to data reporting requirements relating to case volumes
- REHQR Program
  - Extend reporting period for Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery from 1 to 2 years
  - Commence data submission on first day of quarter following REH conversion

4. Maternal Health Conditions of Participation

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U.S. Maternal Health Crisis

- In 2022, 22 maternal deaths per 100,000 live births
  - Other industrialized countries < 9 deaths per 100,000 live births
  - Significant variation among states (highest rate 4x greater than lowest rate)
- More than 80% of maternal deaths preventable
- 25% occur at delivery or within 6 days following end of pregnancy
- Maternal morbidity for minority women is 2 to 4 times higher than White women
- Women in rural communities ~60% more likely to die before, during, or following birth than those in urban communities

Hospital and CAH Conditions of Participation

1. New CoPs establishing baseline standards for obstetrical services
   - Similar to CoPs for other optional services
   - New CoPs "do not dictate standards of care or otherwise require hospitals to offer any specific type of care to patients."
2. Update to QAPI CoPs to include OB-related activities
3. Update to hospital discharge planning CoP to include transfer protocols
4. Update to emergency services CoPs to include protocols, provisions, & training

With exception of update to emergency services CoPs, requirements only apply to hospitals/CAHs providing OB services outside emergency department

Phased-In Effective Dates

- July 1, 2025
  - Emergency services readiness
  - Hospital transfer protocols
- January 1, 2026
  - Baseline standards for OB services (except OB staff training requirements)
- January 1, 2027
  - OB staff training requirements
  - QAPI program for OB services

Update to Emergency Services CoPs (07/01/2025)

- Maintain protocols consistent with (1) complexity and scope of services offered, and (2) nationally recognized evidence-based guidelines for care of patients with emergency conditions
  - Including, but not limited to, OB emergencies, complications, and immediate post-delivery care
  - Facility must “be able to articulate their standards and source(s) and to demonstrate that their standards are based on evidence and nationally recognized sources”
- Maintain adequate provisions readily available to treat emergencies
  - Including equipment, supplies, drugs, blood & blood products, and biologicals commonly used in life-saving procedures
  - Call-in system for each patient in each emergency services treatment area (clarifications in future sub-regulatory guidance
- Train applicable staff annually on protocols and provisions
  - Governing body must identify and document staff to be trained
  - Must be informed by QAPI program findings
  - Must document successful completion of training in staff personnel records
  - Must be able to demonstrate staff knowledge on training topics

Update to Hospital Discharge Planning CoP (07/01/2025)

- Maintain written P&Ps for transferring patients (not just OB patients) to appropriate level of care promptly and without delay to meet specific patient's needs
  - Including transfers from ED to inpatient admission, transfers between inpatient units within hospital, and inpatient transfers to different hospital
- Provide annual training to relevant staff regarding P&Ps for patient transfers
- CMS encourages hospitals to –
  - Develop P&Ps on acceptance of transfers
  - Develop collaborative relationships to facilitate regional continuum of care
  - Foster relationships with birthing facilities

New CoPs - Obstetrical Services

1. Organization and staffing (01/01/2026)
   - OB services must be integrated with other departments
   - OB facilities must be supervised by experienced MD/DO, NPP, or RN
   - OB privileges must be delineated for all practitioners based on competencies
2. Delivery of services (01/01/2026)
   - Provisions and protocols for OB emergencies, complications, post-delivery care, other health/safety events consistent with nationally recognized and evidence-based guidelines
   - At a minimum, call-in system, cardiac monitor, and fetal doppler or monitor must be readily available (vs. present in every room)

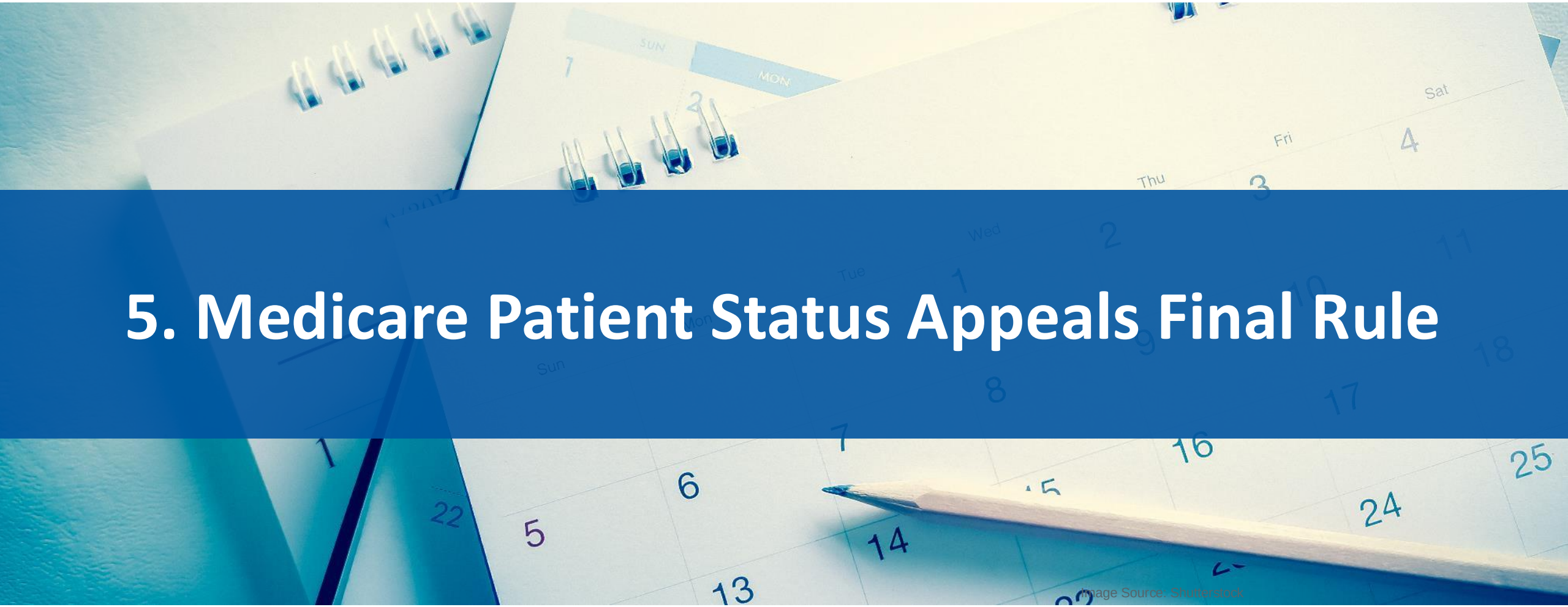
New CoPs - Obstetrical Services

3. Staff training (01/01/2027)
   - Governing body must identify and document which staff must complete initial and biannual training on evidence-based best practices/protocols + QAPI program-identified needs
     - Governing body may delegate task but retains responsibility
     - Initial training as part of new staff orientation
     - Hospital/CAH must “be able to articulate their standards and the source(s) to demonstrate that their staff training requirements are based on evidence-based best practices.”
     - Use findings from QAPI program to inform staff training needs
   - Hospital/CAH must document successful completion of training in staff personnel records
   - Hospital/CAH must be able to demonstrate staff knowledge on training topics

Update to QAPI CoPs (01/01/2027)

- OB leadership must engage in QAPI to assess and improve health outcomes & disparities among OB patients
  - Analyze data and quality indicators by diverse subpopulations among OB patients
  - Measure, analyze, and track health equity data, measures, and quality indicators on patient outcomes and disparities in processes of care, services and operations, and outcomes among OB patients
  - Analyze and prioritize identified outcomes and disparities, develop and implement actions to improve outcomes and disparities, and track performance to ensure improvements are sustained
  - Actively performing at least one measurable OB-focused PI project each year (same PIP over multiple years)
  - Include process for incorporating state/local Maternal Mortality Review Committee data and recommendations into QAPI program
- CMS to publish sub-regulatory guidance on how surveyors will assess compliance

5. Medicare Patient Status Appeals Final Rule



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Applicability

- Traditional Medicare beneficiaries only (not Medicare Advantage)
- Beneficiaries initially admitted as inpatients but then reclassified to outpatient observation *but not enrolled in Part B at time of stay*
- Beneficiaries staying at hospital for 3 or more consecutive days with less than 3 days as inpatient, but at least 1 inpatient day
  - Unless 30+ days have passed between discharge from hospital and SNF admission
- New processes in response to court order in *Alexander v. Azar* (D. Conn.)
  - Class action lawsuit originally filed in 2011

Patient Notice

- Hospital must provide new Medicare Changes of Status Notification (MCSN) to patients while they are still in the hospital
  - Informs patient of status change, effect on Medicare coverage, and appeal rights
    - Those without Part B coverage may be charged full cost of stay
  - Must be provided as soon as possible after status change, but no later than 4 hours prior to discharge
  - Form available at *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10868* (multiple languages provided)

Prospective Appeals

- Expedited appeals
  - Filed prior to release from hospital following status change (inpatient to outpatient observation)
    - Patient does not have to remain in hospital during appeal
  - Conducted by BFCC-QIO following telephone or written request
    - Decisions to be completed and notification made within one calendar day of request
    - Unfavorable decision: beneficiary could be responsible for Part B coinsurance and deductible for covered services and full cost of non-covered services
- Standard appeals
  - Allowed for patients who do not file expedited appeal
  - Similar process as expedited appeals but does not follow expedited timeframes

Retrospective Appeals

- Permitted for status changes back to January 1, 2009
- Follows current appeals process (MAC, QIC, ALJ, Medicare Appeals Council, federal court)
- Beneficiaries have 365 calendar days from rule implementation to file appeal
  - Providers will have 120 days to submit records in response to contractor request
  - Providers will not be penalized if unable to locate records (record retention requirements)
  - Providers have 365 days to submit Part A claim following ruling in patient's favor
    - Must first refund Part B payments before billing Part A
    - MAC will recoup any Part B payments hospital received even if hospital does not bill Part A
    - Billing instructions under development/new condition codes and remark codes expected

Effective Date for Appeals

- CMS has not yet announced effective dates
  - Per CMS report to federal district court –
    - Retrospective appeals process should be operational by January 1, 2025
    - Prospective appeals process should be operational by February 15, 2025

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