HEALTHCARE REGULATORY ROUND-UP #74

CY 2025 Proposed Rules – Part I

(Plus New/Proposed Rules and Impact of Recent Supreme Court Decisions)

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Introductions

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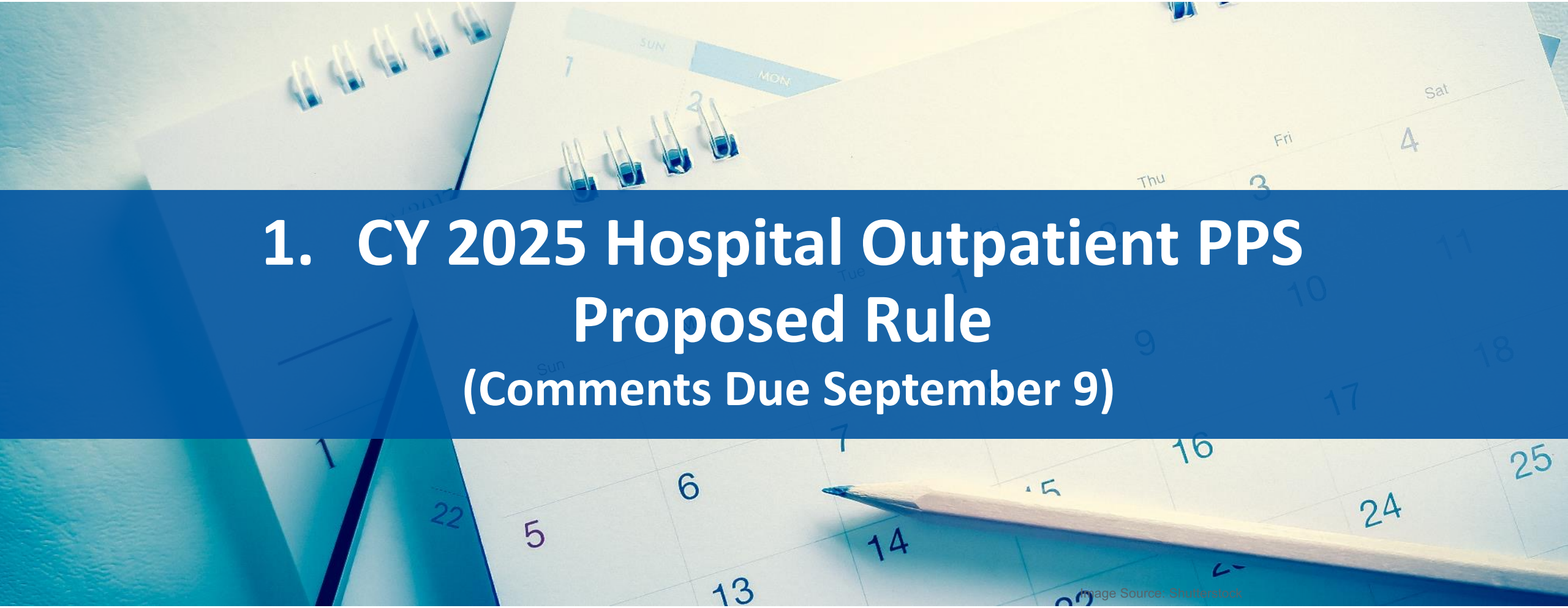
Today's Agenda

1. CY 2025 Hospital Outpatient PPS Proposed Rule
2. CY 2025 ESRD PPS Proposed Rule
3. CY 2025 Home Health PPS Proposed Rule
4. ONC Cures Act Final Rule
5. ONC Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (HTI-2)
6. Consumer Financial Protection Bureau Proposed Rule
7. EMTALA Preemption - Now What?
8. The End of *Chevron* Deference – Now What?
9. Recent Court Decisions Enjoining Final Rules

1. CY 2025 Hospital Outpatient PPS Proposed Rule

(Comments Due September 9)



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Top Ten

1. OPPS and ASC Payment Rate Updates
2. Inpatient Only List
3. Intensive Outpatient and Partial Hospitalization Services
4. Non-Opioid Treatment for Pain Relief
5. Hospital and CAH Conditions of Participation
6. Quality Reporting Programs (Outpatient, ASC, REH)
7. OPPS Payment for Remote Services
8. Formerly Incarcerated Individuals
9. Medicare FFS Prior Authorization
10. Medicaid & CHIP Continuous Eligibility

1. OPPS and ASC Payment Rate Updates

- OPPS payment update for CY 2025 of 2.6% over 2024
  - Proposed market basket of 3.0% less 0.4% statutorily required productivity adjustment
  - Proposed conversion factor = $89.379 (currently $87.382)
    - $87.636 for hospitals that do not satisfy OQR reporting requirements
  - Proposed rates based on CY 2023 claims data and CY 2022 cost data
- ASC payment update for CY 2025 of 2.6% over 2024

2. Inpatient-Only List

CY 2025 CPT Code	CY 2025 Long Descriptor	Action	CY 2025 Proposed 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

3. Intensive Outpatient/Partial Hospitalization Services

- Proposed payments use CY 2023 claims data and cost information from cost reports beginning three fiscal years prior to CY 2025

CY 2025 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$118.69
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$164.84
5853	Partial Hospitalization (3 services per day) for CMHCs	$118.69
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$164.84
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$279.97
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$428.39
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$279.97
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$428.39

4. Non-Opioid Treatment for Pain Relief

- Additional payments on temporary basis
  - Required under Consolidated Appropriations Act, 2023
    - Limits add-on to ≤ 18% of the OPPS payment for service/group of services for which the pain relief is furnished
  - Applies to drugs dispensed in hospital and ASC setting
  - Program would run from CY 2025-2027

TABLE 85: PROPOSED LIST OF QUALIFYING PRODUCTS AND PROPOSED PAYMENT LIMITATION DETERMINATIONS UNDER SECTION 4135 OF THE CAA, 2023

Non-Opioid Drug	HCPCS Code for Primary Procedure	Total Units in CY 2025 data (CY 2023 claims)	Proportion of Top 5	CY 2025 Procedure Payment Rate	18% of the CY 2025 Procedure Payment Rate	Payment Limitation Applied Per Date of Service Volume Weighted Average of 18% of Procedure Payment Rate	Separate Payment Rate (Per Billing Unit)*
Zynrelef (C9088)	27447	9,385	36.25%	$13,048.08	2,348.65	$1,206.16	$0.73
	73560	6,471	24.99%	$86.88	15.64		
	27130	3,831	14.80%	$13,048.08	2,348.65		
	96361	3,256	12.58%	$42.37	7.63		
	86900	2,947	11.38%	$116.11	20.90		
Xaracoll (C9089)	49505	347	47.02%	$3,541.93	637.55	$388.53	$0.85
	88307	106	14.36%	$324.11	58.34		
	88302	99	13.41%	$24.96	4.49		
	88304	95	12.87%	$50.14	9.03		
	49507	91	12.33%	$3,541.93	637.55		
Exparel (C9290)	27447	33,513	24.01%	$13,048.08	2,348.65	$583.29	$1.41
	96361	27,739	19.88%	$42.37	7.63		
	88307	26,224	18.79%	$324.11	58.34		
	86900	26,117	18.71%	$116.11	20.90		
	73560	25,968	18.61%	$86.88	15.64		
Dextenza (J1096)	66984	4,553	46.57%	$2,159.44	388.70	$386.39	$117.01
	68841	4,349	44.48%	$2,114.22	380.56		
	66982	564	5.77%	$2,159.44	388.70		
	66991	174	1.78%	$4,250.50	765.09		
	92499	137	1.40%	$24.96	4.49		
Omidria (J1097)	66984	8,885	79.76%	$2,159.44	388.70	$383.59	$97.12
	66982	1,256	11.28%	$2,159.44	388.70		
	68841	393	3.53%	$2,114.22	380.56		
	92499	370	3.32%	$24.96	4.49		
	66991	235	2.11%	$4,250.50	765.09		
Ketorolac tromethamine Injection (J1885)	96375	659,685	28.34%	$42.37	7.63	$22.82	$0.702
	96361	489,948	21.05%	$42.37	7.63		
	96374	451,076	19.38%	$206.57	37.18		
	96372	395,425	16.99%	$67.47	12.14		
	99284	331,342	14.24%	$381.61	68.69		

*We note the payment rates for drugs and biologicals are subject to our standard quarterly drug pricing updates; therefore, the payment rate is the payment rate available as of April 1, 2024, and may not be the same payment rate available throughout CY 2025.

5. Hospital and CAH Conditions of Participation

1. New CoPs - Obstetrical Services
2. Update to QAPI CoPs to include OB-related activities
3. Update to discharge planning CoP to include transfer protocols (hospitals only)
4. Update to emergency services CoPs to include protocols, provisions, & training

New CoPs - Obstetrical Services

Only applies to hospitals/CAHs offering OB services outside ED

- 5,797 hospitals
- 513 CAHs (~38%)

1. Organization and staffing
   - Facilities must be supervised by experienced RN, NPP, or MD/DO
   - OB privileges must be delineated for all practitioners based on competencies
2. Delivery of service
   - Provisions and protocols consistent with nationally recognized and evidence-based guidelines
   - Each L&D room/suite must have call-in system, cardiac monitor, fetal doppler or monitor
3. Staff training
   - Governing body must identify and document which staff must complete annual training on best practices/protocols + QAPI program-identified needs
   - Hospital must demonstrate staff knowledge on training topics

Update to QAPI CoPs

Only applies to facilities offering OB services outside ED

- 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
  - Conduct at least one measurable OB-focused PI project annually
  - Include process for incorporating state/local Maternal Mortality Review Committee data and recommendations into QAPI program

Update to Discharge Planning CoP

Applies to hospitals only; CAH CoPs include transfer agreements as part of rural health network requirements

- Maintain written P&Ps for transferring patients to appropriate level of care to meet specific patient's needs
- Provide staff training on P&Ps

Update to Emergency Services CoPs

Applies to all hospitals/CAHs, including those without OB programs

- Maintain protocols consistent with nationally recognized evidence-based guidelines for patients with emergency conditions
  - Including, but not limited to, patients with OB emergencies, complications, and immediate post-delivery care
- Maintain adequate provisions readily available to treat emergencies
  - Including equipment, supplies, drugs, blood & blood products, and biologicals commonly used in life-saving procedures
  - Each emergency services treatment area must have call-in system for each patient
- Train staff annually on protocols and provisions
  - Governing body must identify and document staff to be trained
  - Training must be informed by QAPI program findings
  - Must be able to demonstrate staff knowledge on training topics
- RFI on potential REH CoP

6. Outpatient, ASC, & REH Quality Reporting Programs

- Commitment to Health Equity Measure
  - Mandatory reporting in CY 2025
  - 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
  - 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
  - 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

*Yes, that includes physician practices operated as HOPDs

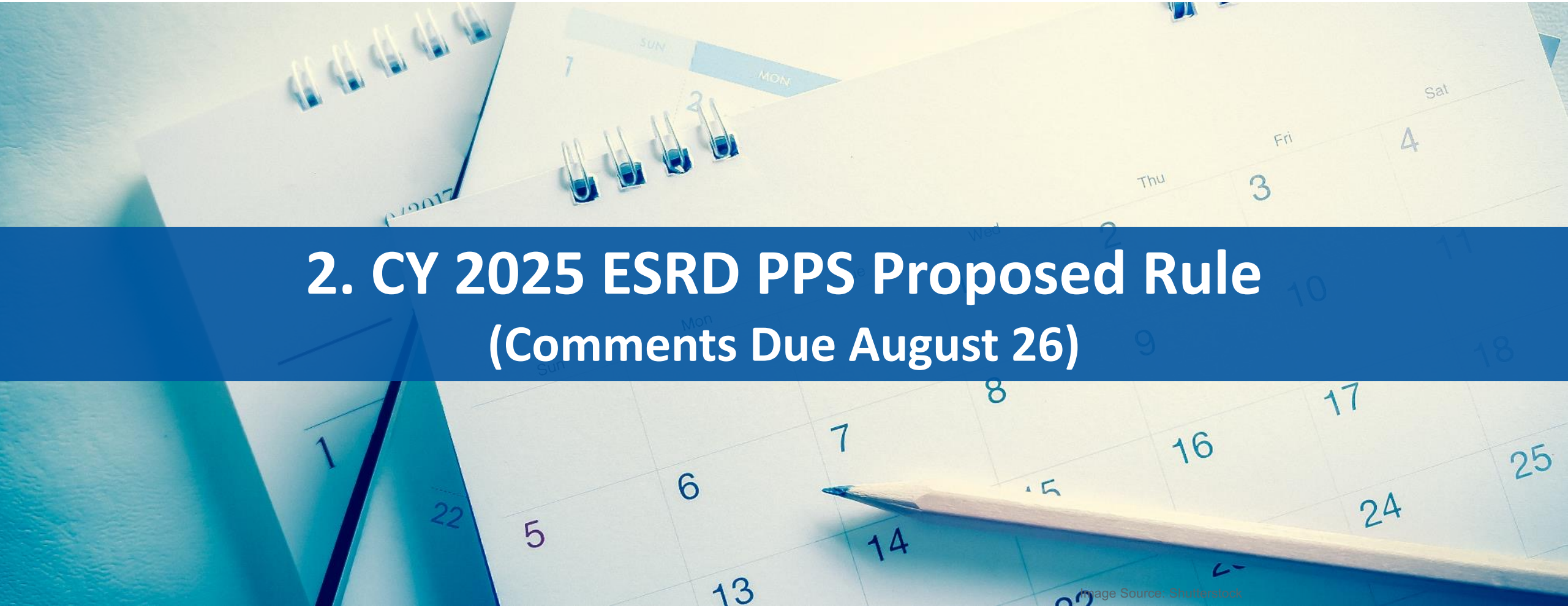
Other Quality Reporting Program Changes

- 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 Outpatint Surgery from 1 to 2 years
  - Commence data submission on first day of quarter following REH conversion

Other Matters

7. OPPS Payment for Remote Services
    - Applies to outpatient therapy, mental health services, diabetes self-management training, and medical nutrition therapy services provided remotely to patients in their homes by hospital staff
        - Align requirements to services furnished via telehealth and billed under the PFS
8. Special Enrollment Period (SEP) for Formerly Incarcerated Individuals
    - Narrows definition of “custody” to exclude individuals on parole, probation, or home detention
    - Ties SEP eligibility to SSA determination that individual no longer incarcerated
9. Medicare FFS Prior Authorizations
    - Moves standard time frame from 10 to 7 days
10. Medicaid & CHIP Continuous Eligibility
    - Requires states to provide full year of continuous eligibility for children under age 19

2. CY 2025 ESRD PPS Proposed Rule
(Comments Due August 26)



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ESRD Payment Rate Update

- Increase base rate from $271.02 to $273.20
  - Approximate overall 2.2% increase over 2024
    - Hospital-based ESRD facilities = +3.9%
    - Freestanding facilities = +2.1%
  - Application of wage index budget-neutrality adjustment factor (0.990228) +1.8 percent increase in productivity-adjusted market basket

ESRD PPS-Specific Wage Index

- Would use data from both the BLS Occupation Employment Wage & Statistics and freestanding ESRD facility cost reports
  - Currently use hospital wage index
- Would also use the revised CBSA delineations

3. CY 2025 Home Health PPS Proposed Rule
(Comments Due August 26)

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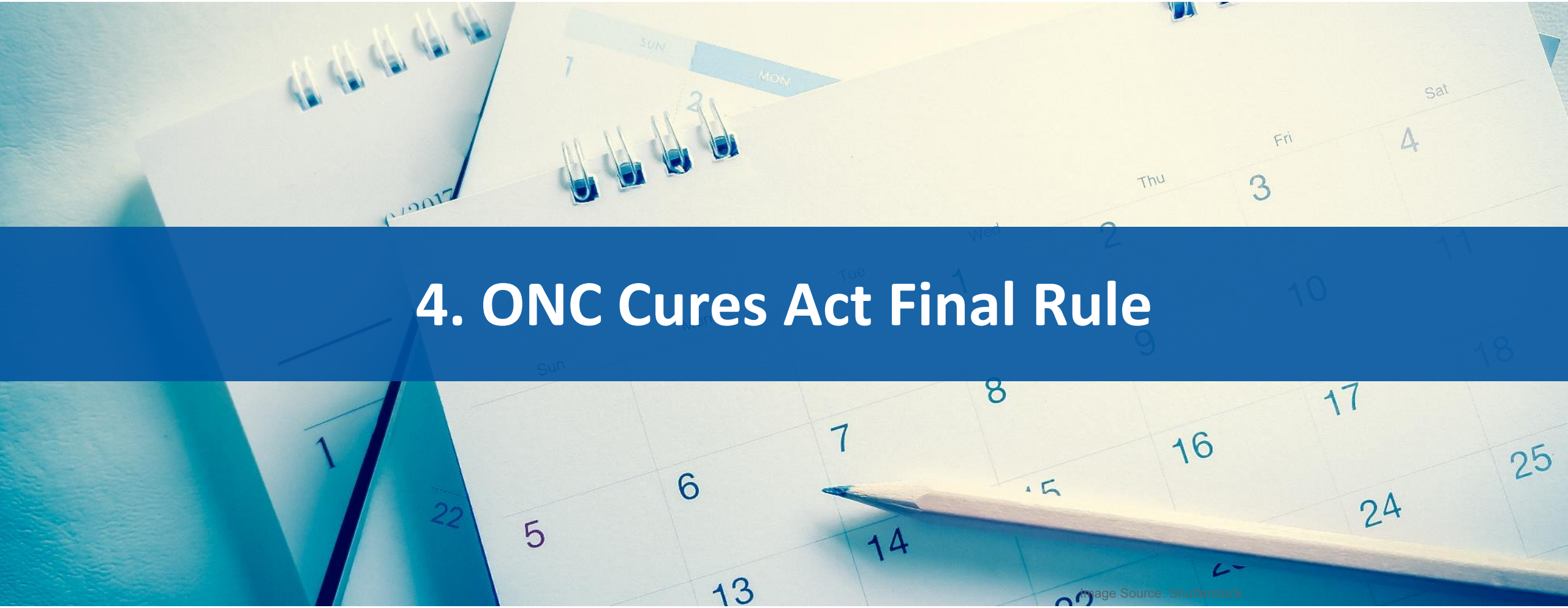
Home Health Payment Rate Update

- Continue to reduce home health payments to address imbalance between payments and costs of providing services
- Reduce rates by ~4%, overall payments by 1.7% ($280 million) compared to CY 2024
  - Market basket increase = 3.0%, less productivity adjustment of negative 0.5% (required by statute)
  - Behavioral adjustment = negative 3.6%
    - Budget neutrality following transition to PDGM
  - Outlier adjustment = negative 0.6%
- National standardized 30-day payment amount = $2,008.12

Other Matters

- Would use new CBSAs for wage index purposes
- Used CY 2023 data to recalibrate weights for the 432 HHRGs
- Additional SDOH assessments added to OASIS data set related to food, living situation, and utilities
- Updates to HHA Conditions of Payment to require patient acceptance service policy
  - Intended to avoid delays and help patients select the most appropriate agency
  - Requires each agency to develop policy applicable to all prospective patients to address capacity, case load, staffing, and case mix based on individual patient's anticipated needs

4. ONC Cures Act Final Rule



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Information Blocking Disincentives

- Final rule published June 24; compounds on promoting interoperability program through prohibition on information blocking
  - Practices that interfere with access, exchange, or use of electronic health information (EHI)
- Finalized disincentives include –
  - Effective 30 days after publication -
    - Hospitals – 75% reduction of annual market basket increase
    - CAHs – reduce payments to 100% of reasonable costs
    - Physicians and other Part B providers – zero score in the MIPS Promoting Interoperability performance category
  - Effective January 2025
    - ACOs – MSSP ineligibility for at least one year
  - Public reporting of information blockers on ONC's website

5. ONC HTI-2 Proposed Rule

(Released July 10)

Image Source: Shutterstock

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule

- Defining two sets of new certification criteria for health IT for public health and health IT for payers under ONC Health IT Certification Program
- Updating technology and standards updates building on HTI-1 Final Rule
- Requiring adoption of US Core Data for Interoperability (USCDI) version 4 by January 1, 2028.
- Adjusting certain exceptions to information blocking regulations to cover additional practices recently identified by regulated community
- Establishing certain Trusted Exchange Framework and Common Agreement™ (TEFCA™) governance rules, including implementation of section 4003 of the 21st Century Cures Act

6. Consumer Financial Protection Bureau Proposed Rule

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Credit Reporting of Medical Debt

- Included in June 18 *Federal* Register (comments due August 12)
  - Proposal to stop the inclusion of medical debt in credit evaluations
  - Applies to reporting agencies –
    - *"… a consumer reporting agency generally would be prohibited from furnishing to a creditor a consumer report containing medical debt information in connection with a credit eligibility determination"*
    - *"… consumers would no longer be unfairly penalized in the credit market for having medical debt"*
- Impact on collection activities
  - Patient motivation to pay
  - Focus on upfront collections
  - Subsequent impact on revenue
  - Rule includes litigation as option for collections

7. EMTALA Preemption: Now What?

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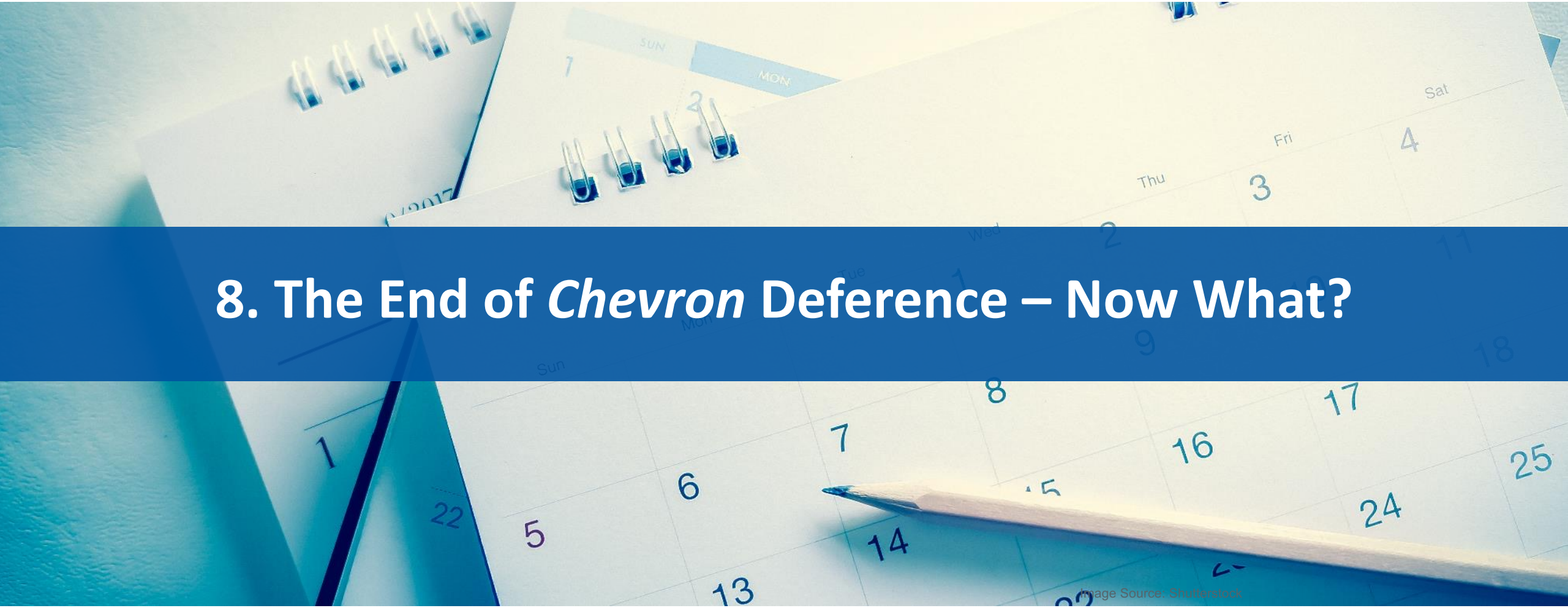
EMTALA Preemption of State Abortion Laws

- On July 11, 2022, CMS published memorandum regarding conflict between state abortion restrictions and EMTALA obligations
  - "If a physician believes that a pregnant patient presenting at an emergency department is experiencing an emergency medical condition as defined by EMTALA, and that abortion is the stabilizing treatment necessary to resolve that condition, the physician must provide that treatment. When a state law prohibits abortion and does not include an exception for the life of the pregnant person — or draws the exception more narrowly than EMTALA's emergency medical condition definition — that state law is preempted."
- On federal government's motion, Idaho district court enjoined enforcement of state's abortion ban to extent it conflicted with EMTALA
  - 9th Circuit Court of Appeals upheld injunction, but Supreme Court in January lifted injunction and agreed to consider the case
- In June, Supreme Court issued order reinstating preliminary injunction without formal explanation; concurring and dissenting opinions reflect differing views
- Biden Administration will continue EMTALA investigations relating to refusal to provide abortion as stabilizing treatment

8. The End of *Chevron* Deference – Now What?



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Chevron Deference

- Since 1984, federal courts applied Chevron deference in 18,000+ cases challenging agency actions
- Is statutory provision on which regulation based ambiguous (i.e., subject to two or more reasonable interpretations)?
  - If no, court must evaluate regulation for compliance with unambiguous statutory language
  - If yes, court must evaluate whether regulation is *permissible* construction, i.e., assume Congress delegated authority to agency to interpret ambiguous statutory provisions
    - If yes, court must uphold regulation, i.e., defer to agency
    - If no, court generally remands to agency to revise regulation per opinion
- Practical challenges
  - Congress directs agency to promulgate implementing regulations (gap-filling)
  - Statute is silent on matter critical to regulatory scheme (e.g., definition of key terms)

End of *Chevron* Deference

- *Loper Bright Enterprises*: Courts, not agencies, are final authority in interpreting statutes
  - "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires. Careful attention to the judgment of the Executive Branch may help inform that inquiry. And when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that they agency acts within it. But courts need not and may not defer to an agency interpretation of the law simply because a statute is ambiguous."
  - "The statute still has a best meaning, necessarily discernible by a court deploying its full interpretive toolkit."
- *Corner Post*: Statute of limitations on challenges to agency rule starts when party suffers injury, not rule's effective date

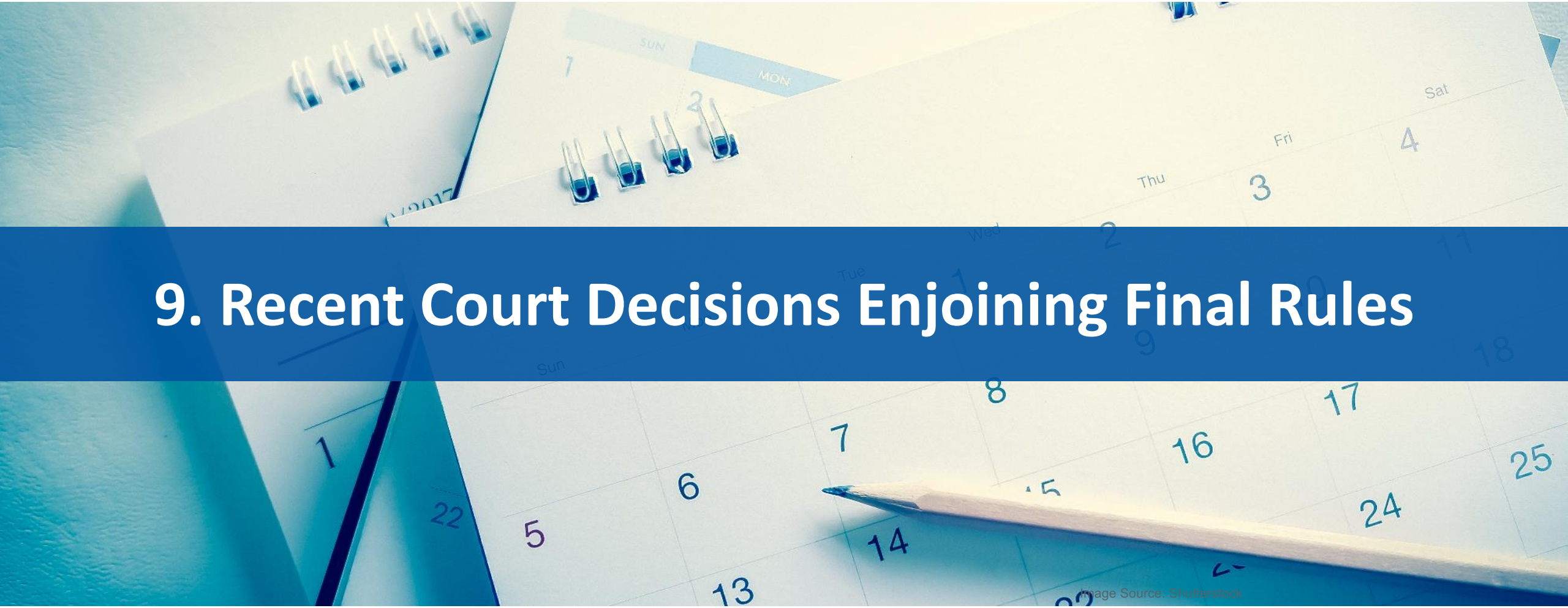
Now What?

- Litigation update
  - Texas Medical Association challenge to No Surprises Act regulations
  - AMCs challenge to GME payment re-calculation
  - American Home Care Association challenge to nursing home minimum staffing requirements
- Coming soon to a courtroom near you…
  - Budget neutrality (HOPD status)
  - Medicare Advantage (e.g., plan audits, risk adjustment, Star ratings, D-SNAP)
  - State challenges to Medicaid rules (e.g., hold harmless, continuous eligibility)
  - Hospital qualification for specific status (CAH, SCH, MDH, LVH)
  - At-home care reimbursement and wages
  - 340B contract pharmacies
  - ACA implementation (e.g., fixed indemnity insurance plans, short-term limited duration health plans)

“Profound Implications”

- More specific statutory language (especially regarding delegation of authority)?
- Longer *Federal Register* notices?
- Agency timidity (e.g., regulation of AI, payments for virtual services)?
- Sibling rivalry/tribalism?
- Reduced access to capital due to market uncertainty?
- Chaos (be careful what you wish for….)

9. Recent Court Decisions Enjoining Final Rules



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Section 1557 Final Rule

- ACA Section 1557 prohibits discrimination based on race, color, national origin, sex, age, or disability in health programs/activities receiving Federal financial assistance
- Key provisions
  - Defines discrimination on the basis of sex to include discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes
  - Permits providers to rely on applicable Federal protections for religious freedom and conscience regarding specific contexts, procedures, or health care services (replacing blanket abortion and religious freedom exemptions)
  - Extends non-discrimination requirements to telehealth services and patient care decision support tools (artificial intelligence)
  - Imposes several administrative requirements on regulated entities

Recent Court Decisions

- Tennessee v. Becerra (S.D. Miss)
  - Nationwide injunction of provisions extending discrimination on the basis of sex to include discrimination on the basis of gender identity
- Texas v. Becerra (E.D. Tex.)
  - Injunction of rule in its entirety in Texas and Montana

Federal Trade Commission Non-Compete Final Rule

- Effective Sept. 4, 2024, worker non-competes unenforceable as unfair method of competition (except pre-existing senior executive non-competes)
- *Ryan LLC v. FTC* (N.D. Tex.) - FTC lacks statutory authority to issue rules defining unfair methods of competition, and FTC's action was arbitrary and capricious
  - However, court declined to grant request for nationwide injunction, as plaintiffs had "offered virtually no briefing (or basis) that would support 'universal' or 'nationwide' injunctive relief."
  - Court intends to issue final opinion by August 30, 2024
- *ATS Tree Services, LLC v. FTC (E.D. PA)* – Court to issue opinion by July 24, 2024
- FTC continues to investigate companies' use of non-competes as unfair trade practice (e.g., U.S. Anesthesia Partners, DaVita, Fresenius)

MA Broker Compensation Rules

- April 2024 Final Rule established fixed per-beneficiary broker/agent compensation and imposed restrictions on data sharing
  - Intended to eliminate adverse incentives and protect beneficiaries from overly-aggressive marketing activities
- *Americans for Beneficiary Choice v. HHS* (N.D. Tex.) - court determined compensation rules were arbitrary and capricious and promulgated without complying with procedural requirements
  - Court ordered universal stay of compensation rules given risk of irreparable harm
  - Upheld restrictions on data sharing

Our Next Healthcare Regulatory Round-Ups

July 31: CY 2025 Medicare Physician Fee Schedule Proposed Rule

August 14: FY 2025 Final Rules

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