HEALTHCARE REGULATORY ROUND-UP #70

Spring 2024 Weather Report: It's Raining Rules!

May 8, 2024

Introductions

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Today's Agenda

1. FY 2025 Hospital Inpatient PPS and Long-Term Care Hospital PPS Proposed Rule
2. FY 2025 Inpatient Rehabilitation Facility PPS Proposed Rule
3. FY 2025 Skilled Nursing Facility PPS Proposed Rule
4. FY 2025 Inpatient Psychiatric Facility PPS Proposed Rule
5. FY 2025 Hospice Payment Rate Update Proposed Rule
6. Minimum Staffing Standards for Long-Term Care Facilities & Medicaid Institutional Payment Transparency Reporting Final Rule
7. Ensuring Access to Medicaid Services Final Rule
8. Medicaid and CHIP Managed Care Access, Finance, and Quality Final Rule
9. Federal Trade Commission Non-Compete Clause Final Rule
10. Department of Labor Overtime Pay Final Rule
11. Health Resources & Services Administration 340b Administrative Dispute Resolution Final Rule
12. Office of Civil Rights Non-Discrimination in Health Programs and Activities Final Rule

That’s Not All

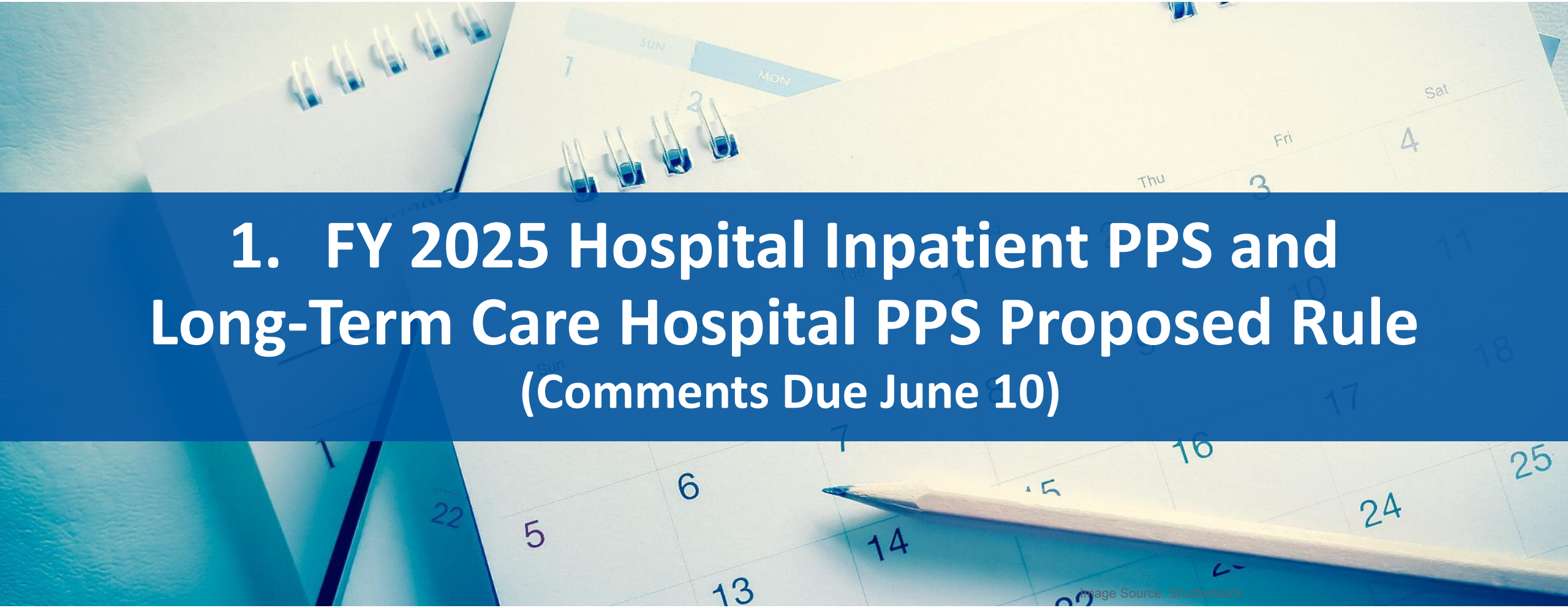
- HHS Office of Civil Rights HIPAA Privacy Rule to Support Reproductive Health Care Privacy (April 22)
- Federal Trade Commission Health Breach Notification Final Rule (April 26)

These rules will be addressed in PYA’s June 19 HIPAA Update Webinar

- Medicaid Disproportionate Share Hospital Third-Party Payer Final Rule (Feb. 23)
- Streamlining the Medicaid, CHIP, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes Final Rule (March 27)
- Clarifying the Eligibility of DACA Recipients and Certain Other Noncitizens for a Qualified Health Plan through an Exchange, Advance Payments of the Premium Tax Credit, Cost-Sharing Reductions, and a Basic Health Program (May 3)

Why *So Many* Rules?

- Proposed federal fiscal year Medicare payment rules (IPPS, Hospice, SNF, IPF, IRF)
  - Proposed calendar year Medicare payment rules published in June/July (OPPS, MPFS, Home Health, ESRD)
- Congressional Review Act
  - Empowers Congress to overrule new federal regulations by means of disapproval resolution
  - Must act within 60 legislative days of publication
  - In 2017, newly elected GOP Congress used CRA to strike down 15 Obama-era rules going back to May 2016 (due to shortened legislative session)
  - Biden Administration also has published new rules on fair housing, Title IX, gun safety, vehicle emission standards, energy efficiency standards, drinking water standards. . . .



1. FY 2025 Hospital Inpatient PPS and Long-Term Care Hospital PPS Proposed Rule

(Comments Due June 10)

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Proposed IPPS Payment Update

- Payment increase of ~2.6% over FY 2024 (assumes meaningful user of EHR + submitted quality data in 2023)
  - Based on market basket update of 3.0%, less 0.4 percentage points productivity adjustment
    - Standardized rate increased to $6,666.10 (currently $ 6,497.77)
    - Labor share for hospitals with wage index > 1.0 = 67.6% (no change)
- Capital rate increased to $516.61 (currently $503.83)
- Outlier threshold increased to $49,237 (currently $42,750)

Proposed IPPS Payment Update

TABLE 1A.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2025

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,506.29	$2,159.81	$4,407.47	$2,112.45	$4,473.35	$2,144.02	$4,374.53	$2,096.66

TABLE 1B.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2025

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,132.98	$2,533.12	$4,042.35	$2,477.57	$4,102.77	$2,514.60	$4,012.14	$2,459.05

MS-DRG Classifications and Relative Weights

- Use single year data to set weights
  - FY 2023 MedPAR claims and FY 2022 cost report data
- Modify list of MS-DRGs subject to post-acute care transfer policy
  - Add 5 MS-DRGs, delete 2
- Update list of reimbursable MS-DRGs
  - 10 new DRGs, re-title 6, delete 3

Z Codes - Housing Instability/Inadequacy

- Change severity level designation from non-complication or comorbidity (Non-CC) to complication or comorbidity (CC)
    - Based on claims data analysis of impact on resource use (i.e., more costly to care for these patients than previously believed)

ICD-10-CM Code[a]	Description[b]
Z59.10	Inadequate housing, unspecified
Z59.11	Inadequate housing environmental temperature
Z59.12	Inadequate housing utilities
Z59.19	Other inadequate housing
Z59.811	Housing instability, housed, with risk of homelessness
Z59.812	Housing instability, housed, homelessness in past 12 months
Z59.819	Housing instability, housed unspecified

New Technology Add-On Payments (NTAP)

- Continue coverage for 24 technologies still considered ‘new’
  - Discontinue coverage for 7 no longer considered ‘new’
  - Assessed 26 applications
- Change from April 1 to October 1 cut-off to determine 2-3-year newness period
- Increase NTAP percentage from 65% to 75% of estimated costs of new technology for gene therapy for treatment of sickle cell disease
  - FY 2025 through end of ‘new’ period

Medicare DSH and UCC

- Apply current Medicare DSH formula
  - 25% of “empirically justified” payments (based on original statutory formula)
    - ~$3.49B for FY 2025
  - 75% separate funding pool updated to reflect percent of uninsured
    - Distributed based on proportion of total uncompensated care provided
      - Uses three-year average of most recent fiscal years for which audited cost report data are available
    - ~$6.50B for FY 2025
- Results in DSH and UCC payment increase of ~$560 million over FY 2024

Wage Index Policies

- Maintain low wage index hospital policy (hospitals with wage index < 25th percentile)
  - Increases wage index to half the difference between otherwise applicable hospital-specific wage index value and 25th percentile for all hospitals
  - Policy applied in budget-neutral manner by adjusting standardized amounts (winners and losers)
- Impact of CBSA changes
  - CMS believes current 5% cap on year-to-year decreases adequately mitigates any negative financial impacts

Transforming Episode Accountability Model

- Mandatory 5-year episodic payment model beginning January 2026
- Includes 5 common but costly procedures
  - Coronary artery bypass graft (MS-DRGs 231-236)
  - Lower extremity joint replacement (MS-DRGs 469-470, 521-522 and HCPCS codes 27447, 27130, 27702)
  - Major bowel procedures (MS-DRGs 329-331)
  - Surgical hip/femur fracture treatment (MS-DRGs 480-482)
  - Spinal fusion (MS-DRGs 453-455, 459-460,471-473 and HCPCS codes 22551, 22554, 22612, 22630, 22633)
- 25% of CBSAs (excluding Maryland) to be selected for participation

TEAM Payment Methodology

- Track 1: PY 1 only
  - Upside-only risk and quality adjustments
    - 10% stop-gain with quality adjustment limited at 10%
- Track 2: PYs 2-5 for safety net hospitals, rural hospitals, MDHs, SCHs, EACHs
  - Two-sided risk with quality adjustments
    - 10% stop-gain and stop-loss with quality adjustment limited at 10% for positive reconciliation and 15% for negative reconciliation
- Track 3: PYs 2-5 for all participants
  - Two-sided risk with quality adjustments
    - 20% stop-gain and stop-loss with quality adjustment limit of 10%

TEAM Quality Measures

1. Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and EHR Data (all episodes)
2. CMS Patient Safety and Adverse Events Composite (all episodes)
3. Hospital-Level Total Hip and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (LEJR episodes only)

LTCH PPS Proposed Payment Update

- Increase in standard payment of ~ 2.8% over FY 2024
  - Based on market basket update of 3.2%, less 0.4 percentage points for productivity adjustment and less 1.3 percentage points for outliers and other adjustments
  - Update reduced by 2.0 percentage points if fail to submit quality data under LTCH QRP
- Labor-related share = 72.8% (currently 68.5%)
- Cost outlier threshold = $90,921 (currently $59,873)
  - Required to ensure projected outlier payment = 7.975% of projected payments

LTCH PPS Payment Update

TABLE 1E.— PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2025

	Full Update (2.8 Percent)	Reduced Update* (0.8 Percent)
Standard Federal Rate	$49,262.80	$48,304.38

* For LTCHs that fail to submit quality reporting data for FY 2025 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Hospital and CAH Conditions of Participation

- Update to infection prevention and control and antibiotic stewardship program CoP to require weekly electronic reporting to CDC on respiratory illnesses (COVID-19, influenza, RSV) (with additional requirements during PHE)
  - Confirmed infection among hospitalized patients
  - Bed census and capacity
  - Limited patient demographics
- Effective 10/01/2024

Inpatient Quality Reporting (IQR) Program

- 7 new measures
  - Falls with injury eCQM (CY 2026)
  - Post-operative respiratory failure eCQM (CY 2026)
  - 30-day risk-standardized death rate among surgical inpatients with complications (failure-to-rescue) claims-based measure (7/1/2023 – 6/30/2025 reporting period)
    - Replacing death among surgical inpatients with serious treatable complications measure
  - Patient safety structural measure (CY 2025)
  - Age-friendly hospital structural measure (CY 2025)
  - Catheter-associated urinary tract infection standardized infection ratio stratified for oncology locations measure (CY 2026)
  - Central line-associated bloodstream infection standardized infection ratio stratified for oncology locations measure (CY 2026)

Promoting Interoperability (PI) Program

- Create two measures from current Antimicrobial Use and Resistance Surveillance measure
  - Antimicrobial Use Surveillance
  - Antimicrobial Resistance Surveillance
- Two new eCQM measures available for hospitals and CAHs to select related to hospital harm
- Modify Global Malnutrition Composite Score eCQM
- Modify eCQM reporting by implementing progressive increase in the number of eCQMs hospitals and CAHs required to report

Paying for Value

- Hospital Readmission Reduction Program (HRRP): No proposed changes to methodology for calculating readmission rates, imposing penalties
- Hospital Value-Based Purchasing (HVP): Proposed revisions to HCAHPS survey
  - Would be applicable to patients discharged on or after January 1, 2025
  - Three new sub-measures
    - Care coordination
    - Restfulness of the hospital environment
    - Information about symptoms
- Hospital-Acquired Conditions (HAC) Penalty: No proposed changes

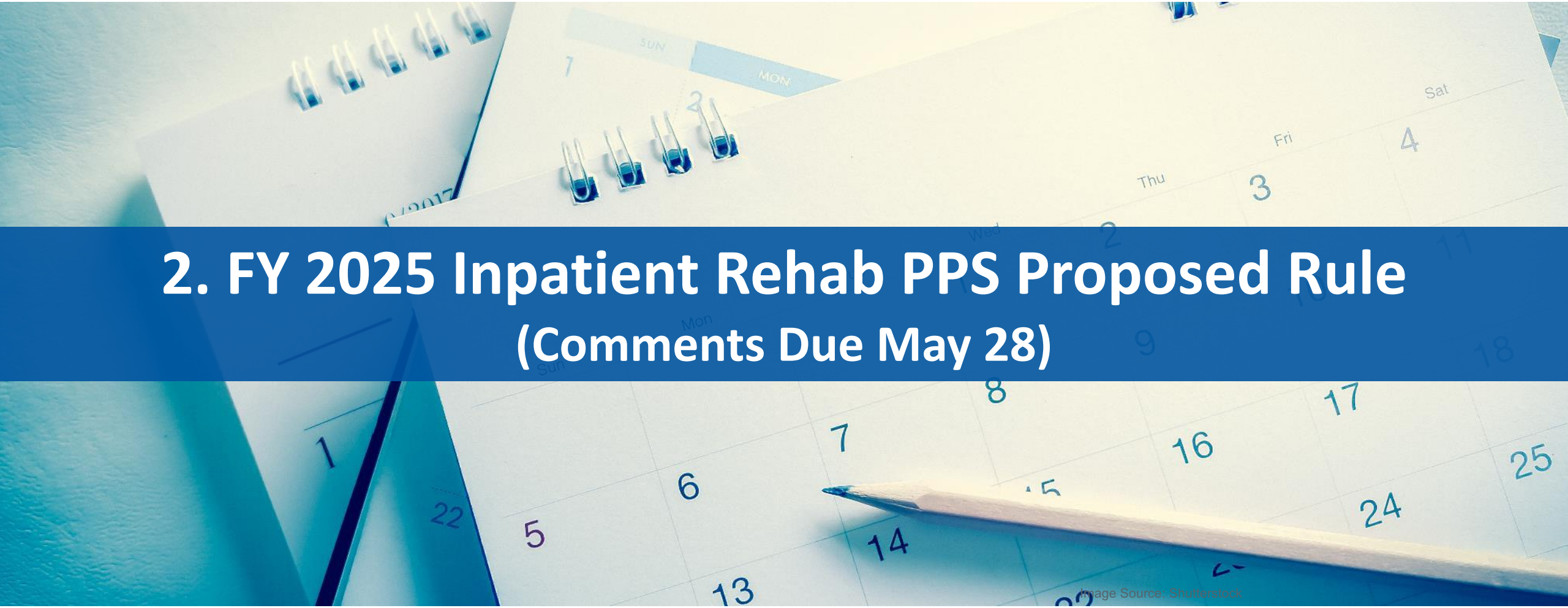
Buffer Stock of Essential Medicines

- Intended to address resiliency of medical supply chains
- Proposes separate IPPS payment to small, independent hospitals to cover cost of maintaining voluntary six-month buffer stock
  - Small = 100 or fewer beds
  - Independent = not part of a chain organization

Requests for Information

- How quality reporting can better address unplanned visits (inpatient or outpatient) after discharge
- Impact of Medicare maternity care payment on other payers
- Obstetrical services standards for hospitals, CAHs, and REHs

2. FY 2025 Inpatient Rehab PPS Proposed Rule
(Comments Due May 28)



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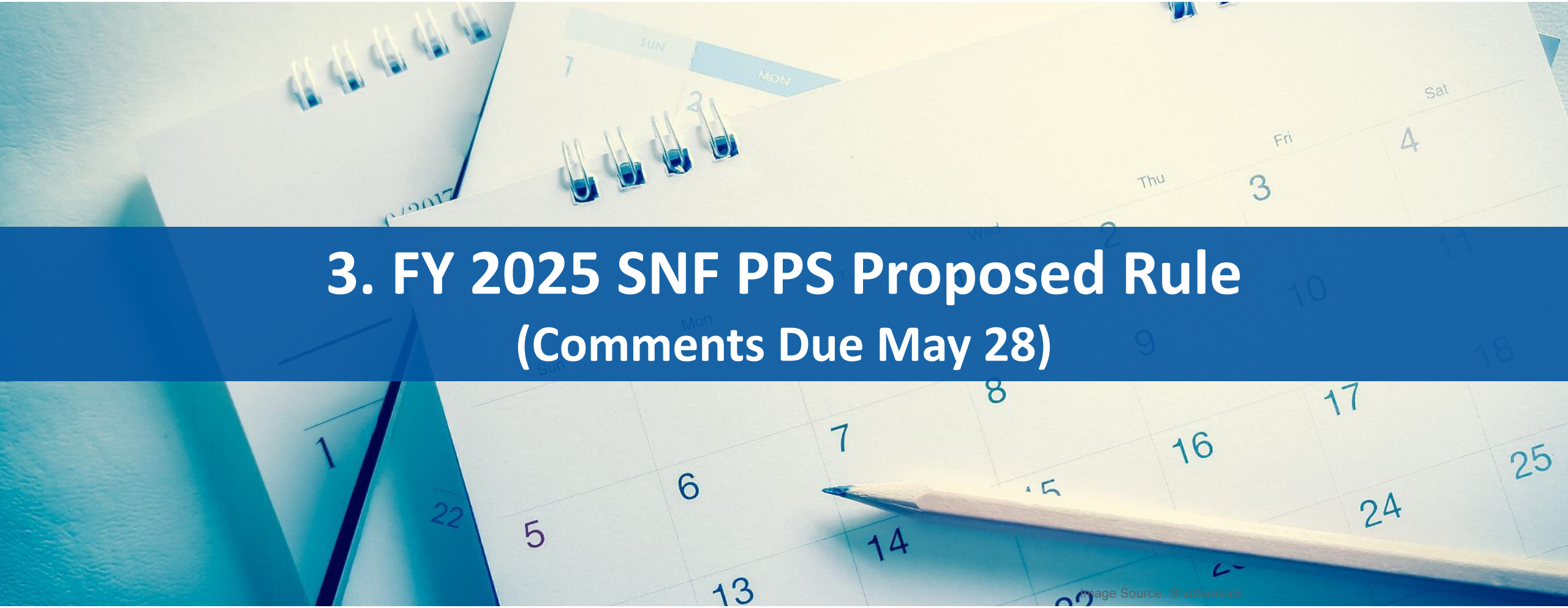
IRF PPS Proposed Payment Update

- Increase in payments of ~2.8% over FY 2024
  - Based on market basket update of 3.2%, less 0.4 percentage point productivity adjustment
    - Standard payment conversion factor = $18,872 (currently $18,541)
    - Outlier threshold = $12,158 (currently $10,423)
      - Outliers would equal 3% of total payments
- Wage index
  - Labor-related share increased from 74.1% to 74.2%
- Impact of new CBSAs on rural add-on (14.9%)
  - Most wage index decreases mitigated by permanent 5% percent cap on negative wage index change
  - Proposes to phase out rural adjustment for IRFs that transition from rural to urban over 3 years

Other Issues

- IRF QRP - no changes to quality measures
- IRF patient assessment instrument changes
  - Removal of admission class beginning October 1, 2026
  - Addition of new SDOH categories for FY 2028
    - Living situation, food, utilities
  - Modify transportation to collect at admission only, address look-back period, and simplify response options for the patient
- RFI - Star rating system IRFs on Care Compare
  - Would allow consumers to identify differences in quality
  - What measures should be incorporated?

3. FY 2025 SNF PPS Proposed Rule
(Comments Due May 28)



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SNF PPS Proposed Payment Update

- Increase in payments of ~4.1% over FY 2024
  - Based on market basket update of 2.8%, less 0.4 percentage point productivity adjustment, ***plus*** 1.7 percentage points related market basket forecast error
  - Updates market basket base year from 2018 to 2022
- Additional technical changes to the PDPM ICD-10 code mapping to improve payment and coding accuracy
  - Used to assign patients into clinical categories
  - RFI on potential updates to non-therapy ancillary component of PDPM

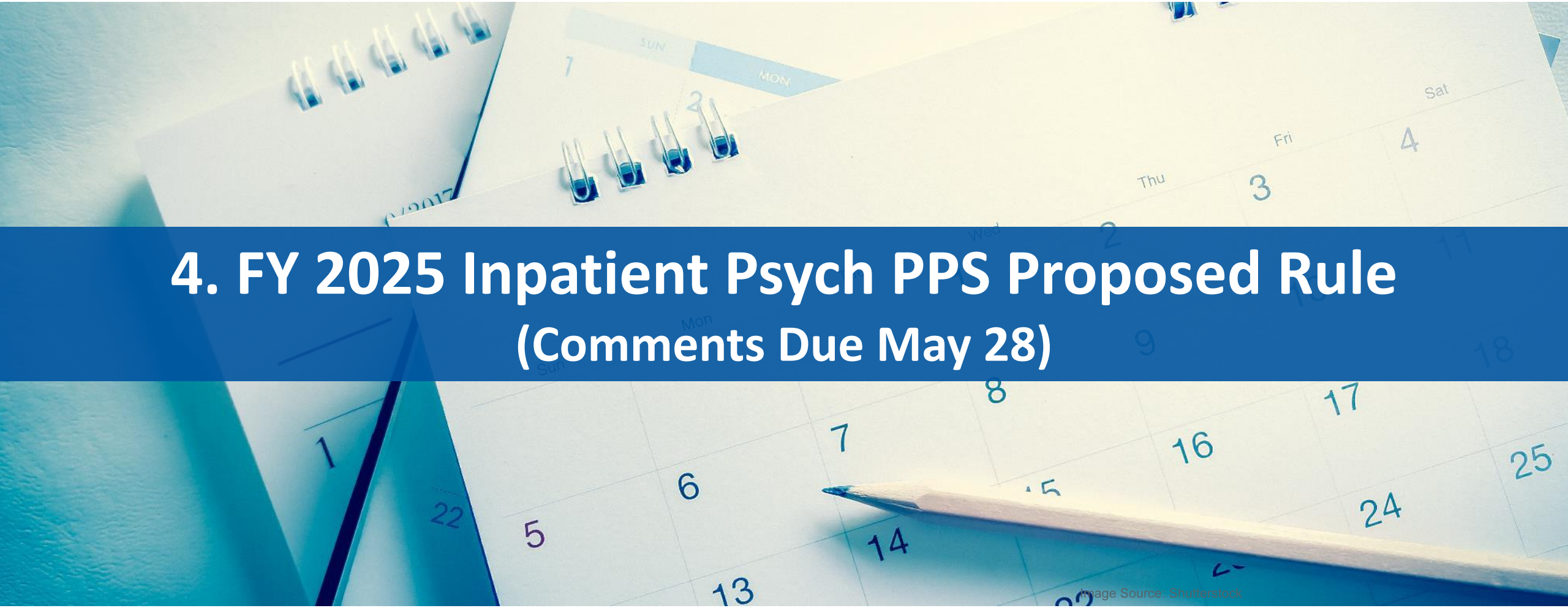
SNF QRP Updates

- Modify patient assessment instrument to include SDOH
  - Effective for admissions beginning October 1, 2025
  - Measures collected:
    - Living situation: housing instability
    - Food: running out without ability to buy more
    - Utilities: power turned off in home
  - Would also simplify transportation question and revise look-back period
- Require SNFs to participate in data validation process effective for FY 2027 SNF QRP

Other Proposals

- SNF Value-Based Purchasing Program
  - Focused on operational updates to revise regulatory language
    - Addresses measure selection, retention, and removal
- CMS nursing home enforcement authority
  - Allow CMS to impose CMPs on nursing homes with quality/safety deficiencies
    - Currently limited to non-compliance
  - Increase CMPs per instance **and** per day
    - Currently allows penalties per day **or** per instance basis, not both

4. FY 2025 Inpatient Psych PPS Proposed Rule
(Comments Due May 28)



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IPF PPS Proposed Payment Update

- Increase in payments of ~2.6% over FY 2024
  - Based on market basket update of 3.1%, less 0.2 percentage point productivity adjustment, ***less*** 0.1 percentage point related to change in outlier threshold
    - Federal per diem base rate = $874.93 (currently $895.63)
    - ECT per treatment rate = $660.30 (currently $385.58)
    - Outlier threshold increased to $35,590 (currently $33,470)
  - Wage index
    - Labor-related share increased from 78.7% to 78.8%
  - Impact of new CBSAs on rural add-on
    - Allows 3-year phase-in from rural to urban status

IPF QRP/Standardized PAI

- New quality measure - 30-day all-cause risk standardized ED visit following IPF discharge
  - Report in CY 2025 for payment adjustment in FY 2027
- Change from annual to quarterly patient-level data reporting
  - If finalized, Q1 2025 to be reported by November 15, 2025
- Standardized IPF patient assessment instrument
  - Requirement of CAA, 2023
  - Effective for admissions and discharges beginning in FY 2028
  - Request input on development of IRF-PAI, included data elements, and potential administrative burden

Other Issues

- Clarifies eligibility criteria for filing all-inclusive cost report effective October 1, 2024
  - Limited to providers without charge structure such as (e.g., government-owned facilities, IHS hospitals)
  - Disallows conversion to system where provider operates under all-inclusive rate
- Solicits comments on revision to IPF PPS facility adjustments required by CAA, 2023
  - How to differentiate between facilities with higher costs
    - Low-income subsidy/uncompensated care similar DSH adjustment
    - Rural status
    - Teaching status

5. FY 2025 Hospice Payment Rate Update Proposed Rule (Comments Due May 28)

Image Source: Shutterstock

Hospice Proposed Payment Update

- Increase in payments of ~2.6% over FY 2024
  - Based on 3.0% market basket increase less 0.4 percentage point productivity adjustment
- Providers not meeting Hospice QRP requirements will see 4.0 percentage point reduction in payment update
  - Results in negative adjustment for 2025 (-1.4%)
- Annual payments (aggregate cap) per patient capped at $34,364.85 (currently $33,494.01)
- Requests comments on implementation of separate payment mechanism to account for high-intensity palliative care services (e.g., chemotherapy, radiation)

Hospice QRP Updates

- Add 2 measures to determine # of patients with pain were assessed within 2 days
  - Timely Reassessment of Pain Impact
  - Timely Reassessment of Non-Pain Symptom Impact
- Adopt hospice outcomes & patient evaluation (HOPE) patient level data collection tool for FY 2025
  - Allow for collection of information at multiple points during the patient stay
    - Provides for sociodemographic data, additional diagnoses, symptom impact assessment, imminent death factors
  - Replaces Hospice Item Set (used at admission/discharge only)
- Revisions to Hospice CAHPS survey
- RFI on incorporating SDOH

6. Minimum Staffing Standards for Long-Term Care Facilities & Medicaid Institutional Payment Transparency Reporting Final Rule

Image Source: Shutterstock

Enhanced Facility Assessment Requirements

- LTC facilities now required to conduct and review annually facility-wide assessment to determine resources needed to care for residents during regular operations and emergencies
- Additional requirements effective August 8, 2024:
  - Use evidence-based methods when care planning for residents, including those with behavioral health needs
  - Use facility assessment to assess each resident's specific needs and adjust as necessary based on any significant changes in resident population;
  - Include member of governing body + medical director as active participants in assessment process
  - Include input from leadership, management, nursing staff, other staff
  - Include input from residents and family members
  - Develop staffing plan to maximize staff recruitment and retention

Minimum Staffing Requirements

- RN physically present + available to provide direct patient care 24/7
  - 05/10/2026 for urban facilities, 05/10/2027 for rural facilities
- Minimum # of hours of nursing care per resident day (HPRD)
  - 3.48 HPRD irrespective of staff type
    - Compliance by 05/10/2026 for urban facilities, 05/10/2027 for rural facilities
  - 0.55 HPRD from RN, 2.45 HPRD from nurse aide (LPN, LVN, CNA)
    - Compliance by 05/10/2027 for urban facilities, by 05/10/2029 for rural facilities
  - Hardship exemption
    - May apply if located in workforce unavailability area (≥20% below nat'l average provider-to-population ratio for nursing workforce or ≥20 miles from another LTC facility) + demonstrate financial commitment to staffing (total annual amount spent on direct care staff) and good faith efforts to hire
    - Not eligible if (1) failed to submit required Payroll Based Journal data, (2) designated as special focus facility, or (3) cited for widespread insufficient staffing with resident harm or immediate jeopardy with respect to insufficient staffing
    - If granted, facility must provide specified notice to residents and general public

7. Ensuring Access to Medicaid Services Final Rule

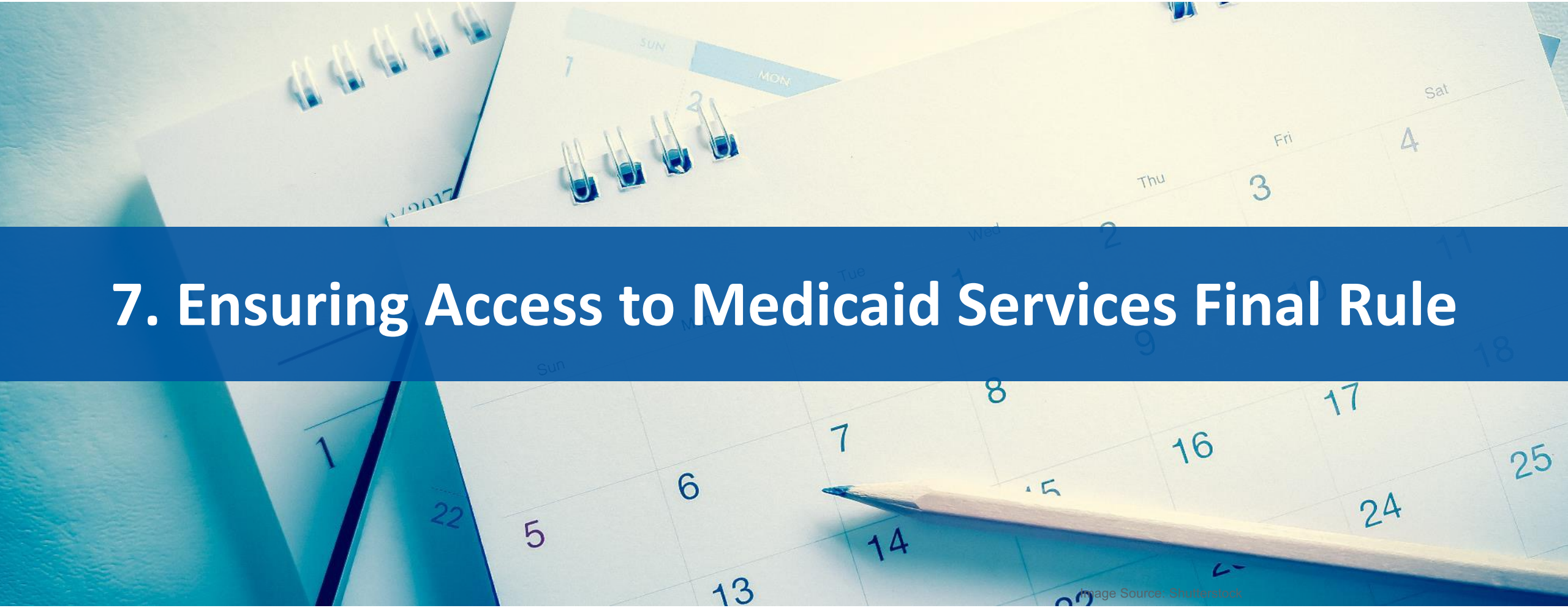

Image Source: Shutterstock

Medicaid Access Rule

- State Medicaid agency requirements - Home and Community Based Services (HCBS)
  - Implement HCBS payment adequacy standards requiring providers spend ≥80% of reimbursement for homemaker, home health aide, and personal care services on employee compensation
  - Publish average hourly rate paid for personal care, home health aide, homemaker. and habilitation services
  - Report on waiting lists in section 1915(c) waiver programs + service delivery timeliness for personal care, homemaker, home health aide, and habilitation services
  - Ensure person-centered service plan is reviewed and revised ≥ every 12 months for at least 90% of individuals continuously enrolled in state's HCBS programs
  - Report on standardized HCBS quality measures
  - Establish a grievance process for fee-for-service HCBS beneficiaries to submit complaints
- State Medicaid agency requirements - Transparency
  - Publish all FFS Medicaid fee schedule payment rates on publicly available website (replacing access monitoring review plan requirements) and compare those payment rates for primary care, OB/GYN care, and outpatient mental health and substance use disorder services to Medicare rates
  - Meet specified performance and reporting requirements for investigation and action related to critical incidents, including maintenance of electronic incident management system
  - Transition existing Medical Care Advisory Committees (MCACs) to dual framework consisting of Medicaid Advisory Committee (MEC) and Beneficiary Advisory Council (BAC)

8. Medicaid and CHIP Managed Care Access, Finance, and Quality Final Rule

Image Source: Shutterstock

Medicaid Managed Care Rule

1. Network Adequacy
   - Establish appointment wait time standards - 15 business days for routine primary care and OB/GYN; 10 business days for outpatient mental health and substance use disorder services
   - Arrange annual secret shopper surveys to validate MCO compliance with wait time standards and accuracy of provider directories
   - Conduct an annual enrollee experience survey for each MCO
   - Complete annual payment analysis comparing MCOs' rates to Medicare payment rates
   - Implement a remedy plan for any MCO not meeting required access standards
2. Medicare & CHIP Quality Rating System (MAC QRS)
   - Establishes measures and methodology for standardized reporting
3. Medical Loss Ratios
   - Standardizes criteria for calculating MLRs and reporting requirements

Medicaid Managed Care Rule

4. State-directed payments (SDPs)
    - Limits provider payment levels for SDPs for inpatient and outpatient hospital services, nursing facility services, and the professional services at AMCs to average commercial rate
    - Requires SDP comply with all federal requirements for financing non-Federal share (hold harmless arrangements in connection with healthcare-related tax programs)
        - Notice of enforcement discretion through 01/01/2028 to avoid program disruption
    - Adopts other program integrity standards for SDPs
5. In lieu of services and settings (ILOS)
    - SMA may permit MCO to offer services or settings that substitute for standard Medicaid benefits, if substitute is medically appropriate and cost-effective
    - Imposes safeguards to ensure appropriate use of ILOS

9. FTC Non-Compete Clause Final Rule

Effective September 4, 2024

Image Source: Shutterstock

Unenforceability of Non-Compete Clauses

- Non-compete clause = prohibition on or penalty for work after employment ends (e.g., liquidated damages, forfeiture of severance, buyout clauses)
- For workers other than senior executives, unfair method of competition to enter into or attempt to enter into non-compete clause; to enforce or attempt to enforce non-compete clause; or to represent that worker is subject to noncompete clause
  - Worker = employee, independent contractor, extern, intern, volunteer, apprentice, sole proprietor
- For senior executives, prohibition does not apply to non-competes entered into *prior to* effective date
  - Senior executive = authority to make policy decision (not just advise/exert influence) + annual compensation of at least $151,164
  - FTC believes most physicians will not qualify (even medical directors, practice group leaders)
  - Contract renewals?

Exceptions

- Does not extend to non-competes relating to sale of business
  - Can agree to non-compete individually, but not on behalf of other workers
- May still prohibit current worker from working for competitor at same time
- Confidentiality provisions, prohibitions on misuse of trade secrets, etc., still enforceable
- Applies only to entities organized to carry on business for its own profit or those of its members (scope of FTC Act)
  - For-profit entities within non-profit organizations?
  - Non-profit organizations behaving like for-profit entities?
    - “Merely claiming tax-exempt status in tax filings is not dispositive.”
  - Entities that are part of/sponsored by state or local governments (state action doctrine)?

Notice Requirements

- Final Rule eliminates Proposed Rule's requirement that employers rescind (i.e., legally modify) existing non-competes
- Employer must provide clear and conspicuous notice to worker by effective date that worker's non-compete clause no longer in effect/ enforceable
- Form and method of notice
  - Must include worker's name
  - Hand-delivered, mailed to last known personal street address, sent by e-mail (work e-mail or last known personal e-mail), or sent by text message to worker's mobile number

A new rule enforced by the Federal Trade Commission makes it unlawful for us to enforce a non-compete clause. As of [DATE EMPLOYER CHOOSES BUT NO LATER THAN EFFECTIVE DATE OF THE FINAL RULE], [EMPLOYER NAME] will not enforce any non-compete clause against you. This means that as of [DATE EMPLOYER CHOOSES BUT NO LATER THAN EFFECTIVE DATE OF THE FINAL RULE]:

- You may seek or accept a job with any company or any person—even if they compete with [EMPLOYER NAME].
- You may run your own business—even if it competes with [EMPLOYER NAME].
- You may compete with [EMPLOYER NAME] following your employment with [EMPLOYER NAME].

The FTC's new rule does not affect any other terms or conditions of your employment. For more information about the rule, visit [*link to final rule landing page*]. Complete and accurate translations of the notice in certain languages other than English, including Spanish, Chinese, Arabic, Vietnamese, Tagalog, and Korean, are available at [URL on FTC's website].

Litigation

- Chamber of Commerce, other entities seeking injunctive relief
  - Delay effective date
  - Vacate rule in its entirety
- Major Questions Doctrine
  - Agency must have clear Congressional authorization to decide major policy issues
  - Different results in different jurisdictions?
- When should employer send required notice? Reference pending litigation?

10. DOL Overtime Pay Final Rule

Image Source: Shutterstock

Changes to Overtime Pay Qualifications

- Employers must pay at least minimum wage for each hour employee works and 1.5 times regular pay for any hours worked over 40 hours in a work week
- Employee exempt from overtime requirement if –
  - Paid minimum annual salary + satisfy “duties test” for “white-collar” exemptions
  - Highly compensated worker who primarily performs office/non-manual work + regularly performs at least one exempt duty
- Final Rule increases minimum annual salary and highly compensated worker thresholds
  - Current – $35,568 / $107,432 (in place since 2020)
  - As of July 1, 2024 - $43,888 / $132,964 (using methodology from 2019 overtime rule)
  - As of January 1, 2025 - $58,656 / $151,164 (using new methodology)
  - Adjusted every 3 years thereafter

Preparing for Changes

- Identify universe of exempt employees with salaries between current and future thresholds
  - Increase salaries or convert to non-exempt roles?
- Revise employee compensation budgets to reflect increased salary/overtime expense
- Plan for rollout of reclassification decisions
  - Train newly non-exempt employees on timekeeping requirements, rules against off-the-clock work
  - Manage employee relations issues, i.e., formerly exempt employees being required to “punch a clock.”
- Monitor legal challenges to new methodology (January 1, 2025, increase)

11. HRSA 340B Administrative Dispute Resolution Final Rule

Effective June 18, 2024

Image Source: Shutterstock

Overhaul of 340B ADR Process

- Replaces trial-like process created by 2020 final rule with 340B ADR Panel to act on claims filed by covered entities and manufacturers
  - Covered entity claims that manufacturer overcharged for covered outpatient drug or limited covered entity's ability to purchase drugs at or below 340B ceiling price
  - Manufacturer claims that covered entity violated prohibition on duplicate discounts or resale/transfer of drugs to non-patient
- Specifies procedures for filing and responding to claim, submitting supporting evidence
  - HRSA Office of Pharmacy Affairs to provide additional guidance prior to effective date
- Details 304B ADR Panel decision and reconsideration processes

12. OCR Non-Discrimination in Health Programs and Activities Final Rule

Image Source: Shutterstock

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
- Implementing regulations published in 2016 superseded by 2020 final rule which is now superseded by 2024 final rule
  - Proposed rule published in July 2022; OCR received over 85,000 comments
  - New rule effective on July 5
- Applies to Medicare/Medicaid participating providers, Medicare Advantage plans, Medicare Part D plans, state Medicaid agencies, Medicaid managed care plans, qualified health plans (non-exclusive list)

Key Provisions

- Designate Section 1557 Coordinator (if 15 or more employees)
- Implement policies and procedures
  - Including language access procedures for LEP patients, beneficiaries, enrollees, and applicants and LEP companions and reasonable modification procedures for individuals with disabilities
  - Including civil rights grievance procedures (if 15 or more employees)
- Provide employee training on policies and procedures
- Comply with notice requirements
  - Notice of Non-Discrimination
  - Notice of Availability of Language Assistance Services and Auxiliary Aids

Notice resources: https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html

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
- May rely on applicable Federal protections for religious freedom and conscience regarding specific contexts, procedures, or health care services
  - Formal process to obtain assurances of such protections
  - Replaces blanket abortion and religious freedom exemptions for health care providers
- Extends non-discrimination requirements to telehealth services and patient care decision support tools (artificial intelligence)
  - Make reasonable efforts to identify tools that employ input variables/factors measuring race, color, national origin, sex, age, or disability and make reasonable efforts to mitigate risk of discrimination

Implementation Timeline

Section 1557 Requirement and Provision	Date by which covered entities must comply
§ 92.7 Section 1557 Coordinator	Within 120 days of effective date.
§ 92.8 Policies and Procedures	Within one year of effective date.
§ 92.9 Training	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than 300 days of effective date.
§ 92.10 Notice of Nondiscrimination	Within 120 days of effective date.
§ 92.11 Notice of Availability of Language Assistance Services and Auxiliary Aids and Services	Within one year of effective date.
§ 92.207(b)(1)-(5) Nondiscrimination in health insurance coverage and other health-related coverage (benefit design changes)	For health insurance coverage or other health-related coverage that was not subject to this part as of the date of publication of this rule, by the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.207(b)(6) Nondiscrimination in health insurance coverage and other health-related coverage (benefit design changes)	By the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.210(b), (c) Use of patient care decision support tools	Within 300 days of effective date.

Source: https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html

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