Let’s Get Rural!

Managing Regulatory and Reimbursement Challenges

December 5, 2024

Introductions

Martie Ross, JD
mross@pyapc.com

Kathy Reep, MBA
kreep@pyapc.com

Colton Hager
chager@realtytrustgroup.com

PYA

pyapc.com
800.270.9629

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MIPS 101: A Refresher
HCRR #71 | Presented May 22, 2024

Spring 2024 Weather Report: It's Raining Rules!
HCRR #70 | Presented May 8, 2024

Hospital Price Transparency – Are You Ready for July 1?
HCRR #69 | Presented April 24, 2024

Managing Medicare Advantage
HCRR #68 | Presented April 10, 2024

2024 GCPG – Updates, Key Insights, & Recommendations
HCRR #67 | Presented March 20, 2024

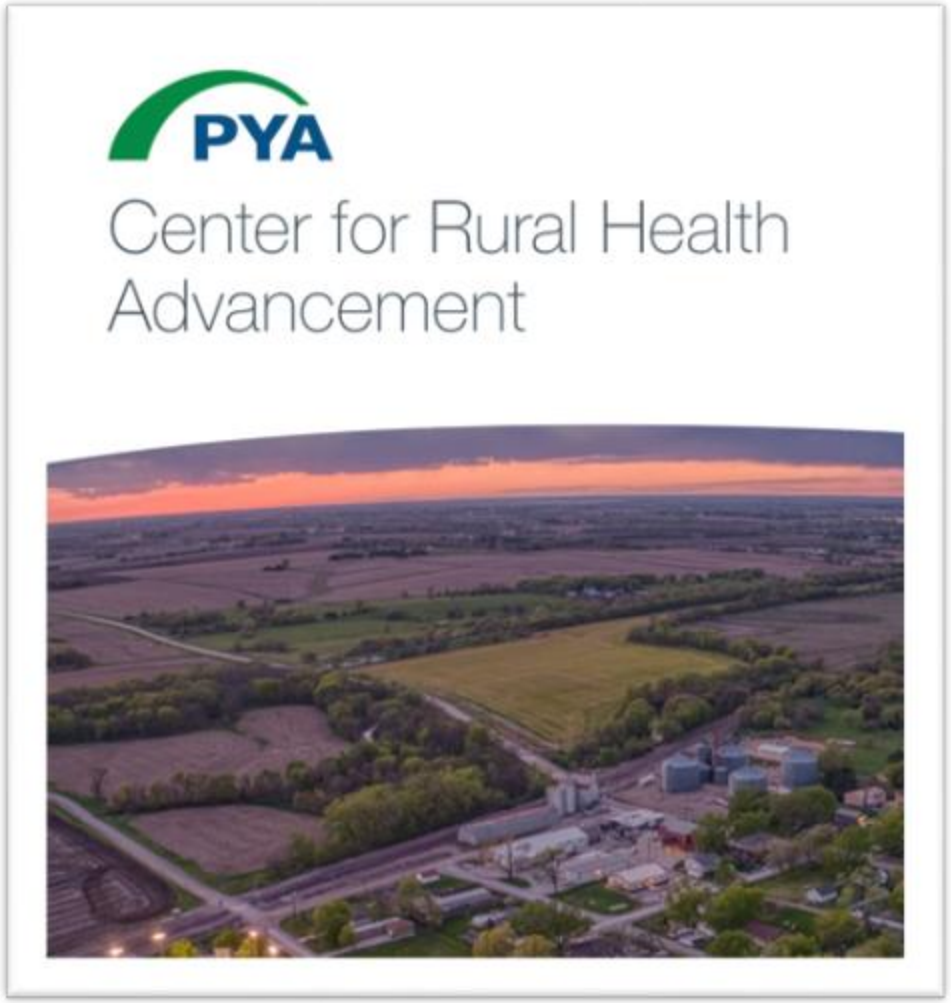
Navigating the Changing Cybersecurity Landscape
HCRR #66 | Presented March 6, 2024

Rural Health Clinic Opportunities
HCRR #65 | Presented February 21, 2024

Billing Medicare for G2211: What You Need to Know Now
HCRR #64 | Presented February 7, 2024

Coming to a Statehouse Near You
HCRR #63 | Presented January 24, 2024

2024 Physician Fee Schedule: MIPS, MSSP, and SDOH
HCRR #62 | Presented January 10, 2024



The PYA Center for Rural Health Advancement helps rural providers transform their operations by delivering a full range of practical, rural-specific solutions focused on the four foundations of long-term sustainability.

Community Engagement – Understanding and prioritizing community needs, aligning with community organizations, building and maintaining trust with local residents, enhancing access to affordable primary care services, maintaining a strong governance and leadership team.

Clinical Excellence – Engaging in service line planning and execution, pursuing collaborative relationships and provider alignment, securing an adequate workforce.

Financial Stability – Gaining access to needed capital, optimizing revenue cycle operations, making purposeful IT investments, positioning for value-based contracting.

Regulatory Compliance – Understanding and implementing new regulatory requirements, ensuring IT security, preparing for and responding to survey findings.

Agenda

1. Telehealth Update
2. Rural Health Clinic Provisions in the 2025 Medicare Physician Fee Schedule Final Rule
3. Rural Emergency Hospital Program Update
4. Hospital Price Transparency
5. EMTALA Signage
6. CAH Time Share and Leased Space Arrangements
7. Respiratory Disease Reporting Requirements
8. Maternal Health Conditions of Participation
9. New Anti-Discrimination Regulations
10. TEAM
11. Changes to HIPAA Privacy Rule
12. Medicare Co-insurance for Critical Access Hospitals
13. Medicare Advantage Coverage Criteria
14. Capital Project Financing
15. Lame Duck Priorities and Possibilities

1. Telehealth Update

Image Source: Shutterstock

Medicare Telehealth Coverage

- Absent Congressional action, existing waivers of Section 1834(m) geographic and originating site limits on Medicare telehealth coverage will expire 12/31/2024
  - Coverage for *medical telehealth services* limited to beneficiaries residing in rural areas physically present at specified facilities at time service provided
  - Coverage for *tele-behavioral health services* not subject to geographic and originating site restrictions per Consolidated Appropriations Act, 2021
    - For services initiated on or after 01/01/2025, must have in-person visit within 6 months of initiating tele-behavioral health services + in-person visit every 12 months (unless waived)

Some Good News

- CMS maintaining expanded list of telehealth services
  - Completing review of ‘provisional’ services
- Audio-only visits covered if –
  - Patient receiving services at home
  - Provider has audio-visual capabilities
  - Patient lacks video access or expresses preference for audio-only
- One-year extension of ‘virtual’ direct supervision
  - Permanent for limited number of services performed by employees
- One-year extension of virtual prescribing of controlled substances
  - No face-to-face encounter prerequisite

POLLING QUESTION #1

2. Rural Health Clinic Provisions in the 2025 Medicare Physician Fee Schedule Final Rule

Image Source: Shutterstock

RHC Telehealth – Behavioral Health Services

- New coverage created under Consolidated Appropriations Act, 2021
- Qualifies as RHC visit (and thus pays PPS rate/AIR) if –
  - Service included on CMS approved list of telehealth services
    - Available at https://www.cms.gov/medicare/medicare-general-information/telehealth/telehealth-code
  - Use audio/visual connection (audio only if patient cannot/does not want to connect visually)
  - Effective **01/01/2026** -
    - In-person mental health service furnished within 6 months prior to furnishing telehealth services (unless services initiated prior to 01/01/2026)
    - In-person, non-telehealth visit furnished at least every 12 months (may be waived; reason documented in medical record)

RHC Telehealth – Medical Services

- Continue current reimbursement methodology through 12/31/25 while evaluating alternatives
  - Service must be included on CMS approved list of telehealth services
  - Not reimbursed AIR; instead, billed under G2025 – reimbursed at $94.96 (regardless of service provided via telehealth)
- May also bill telehealth originating site fee under Q3014 – reimbursed at $29.96 (2024 rate)
  - Patient physically present at RHC facility receiving telehealth from distant site provider

FQHC/RHC Care Management Services – 2024

- Non-face-to-face services billed under G0511 - General Care Management
  - Transitional care management
  - Chronic care management
  - Principal care management
  - General behavioral health integration
  - Chronic pain management
  - Community Health Integration
  - Principal Illness Navigation
  - Principal Illness Navigation – Peer Support
  - Remote Physiological Monitoring
  - Remote Therapeutic Monitoring
- G0511 rate = average of national non-facility payment rate for these services
  - For 2024, $72.90
- Psychiatric Collaborative Care Model (CoCM) billed under G0512 - $146.73 (no more than once/month) (revenue code 0521)

FQHC/RHC Care Management Services - 2025

- Discontinue use of G0511
- FQHC/RHC may bill for following non-face-to-face services under assigned CPT code:
  - Transitional Care Management
  - Chronic Care Management
  - Complex Chronic Care Management
  - Principal Care Management
  - Advanced Primary Care Management
  - Psychiatric Collaborative Care Model
  - General Behavioral Health Integration
  - Chronic Pain Management
  - Community Health Integration
  - Principal Illness Navigation
  - Principal Illness Navigation – Peer Support
  - Remote Physiological Monitoring
  - Remote Therapeutic Monitoring

FQHC/RHC Care Management Services - 2025

- Non-face-to-face services reimbursed at national non-facility payment rate
  - Co-payment based on charges or Medicare allowable?
- 6-month transition period; may continue to bill G0511 through 6/30/2025
  - 2025 reimbursement for G0511 reduced from $72.90 to $54.67
  - All-or-nothing; can't pick and choose when to bill G0511
- Continue to bill CoCM under G0512 ($139.43)

Code	2025 Payment Rate
HCPCS G0511	$54.67
CPT 99490 (CCM, 1st 20 min)	$60.55
CPT 99439 (CCM, each add'l 20 min)	$45.93
CPT 99454 (RPM monthly monitoring)	$47.27

Vaccinations - 2024

- Influenza, Pneumococcal, and COVID-19 Vaccines
  - Vaccines and their administration paid at 100% of reasonable cost through cost report
  - Report charges on cost report Worksheet M-4 (provider-based) or B-1 (independent)
  - Do not report on UB-04
  - Coinsurance waived
- Hepatitis B Vaccine
  - Requires physician order; reimbursement included in PPS/AIR

Vaccinations – After June 30, 2025

- Bill for Part B vaccines (including hepatitis b) and vaccine administration at time of service
  - Includes expanded coverage for hepatitis b – doctor's order no longer required
  - Also bill M0201 for in-home administration
- Due to statutory requirement that RHCs be reimbursed 100% of costs for vaccines and vaccine administration, will reconcile annually as part of cost report
- Additional guidance (including updated cost report instructions) to be released in early 2025

RHC Conditions of Certification/Coverage

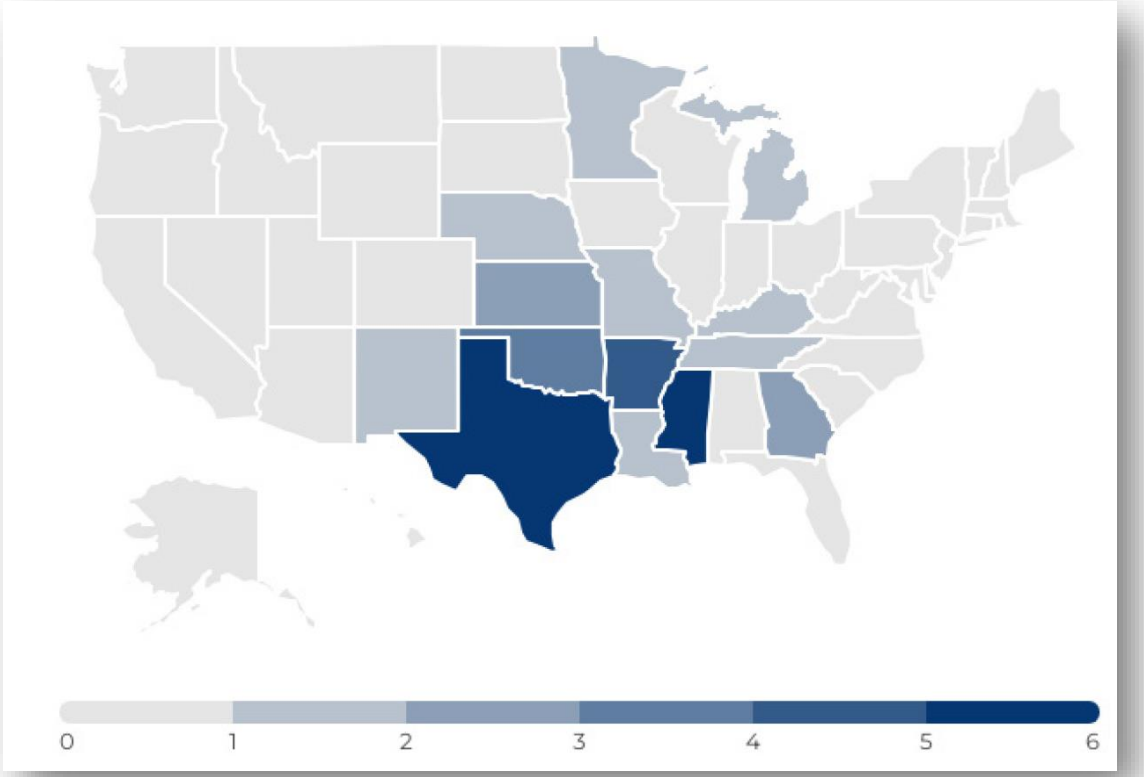
- Eliminate requirement that require >50% of RHC's total hours of operation must involve primary care services
  - Still must provide primary care services, but not at specified level
  - Still cannot be rehabilitation agency or facility primarily for treatment of 'mental diseases'
  - May provide outpatient specialty services within practitioner's scope of practice to meet community needs
- Eliminate RHC productivity standards (specified # of visits per FTE)
- Revise list of required clinical lab services
  - Remove hemoglobin and hematocrit from list of services RHC must provide directly
  - Change "primary culturing for transmittal to certified laboratory" to "collection of patient specimens for transmittal to a certified lab for culturing"

3. Rural Emergency Hospital Update

Image Source: Shutterstock

Completed Conversions

- Predictive modeling identified 68 hospitals that could potentially convert
- By August 2024, 32 hospitals converted to CAHs
  - More PPS than CAHs
  - Discontinuation of Low-Volume Hospital adjustment, Medicare Dependent Hospital program?
- 8 rural hospitals closed in 2023
  - 4 not eligible for REH conversion
- Per National Conference of State Legislatures, 18 states have enacted REH-authorizing legislation



https://bipartisanpolicy.org/report/the-rural-emergency-hospital-model-year-two-progress-report/

Program Challenges

- Statutory limitations
  - Unavailable if hospital closed prior to 2021
  - Loss of swing beds (SNF distinct part unit)
  - Loss of 340B participation
- Reimbursement
  - Medicare Advantage?
    - In network vs. out-of-network emergency services
  - State Medicaid programs?
  - Commercial payers?
- Practical issues
  - Observation bed capacity
  - Transportation to/from inpatient facility
  - Expense reduction/staffing

POLLING QUESTION #2

4. Hospital Price Transparency

Image Source: Shutterstock

Certify Completeness and Accuracy of MRF

Compliance Statement

To the best of its knowledge and belief, this hospital has included all applicable standard charge information in accordance with the requirements of 45 C.F.R. §180.50 and the information encoded in this machine-readable file is true, accurate and complete as of the date indicated in this file.

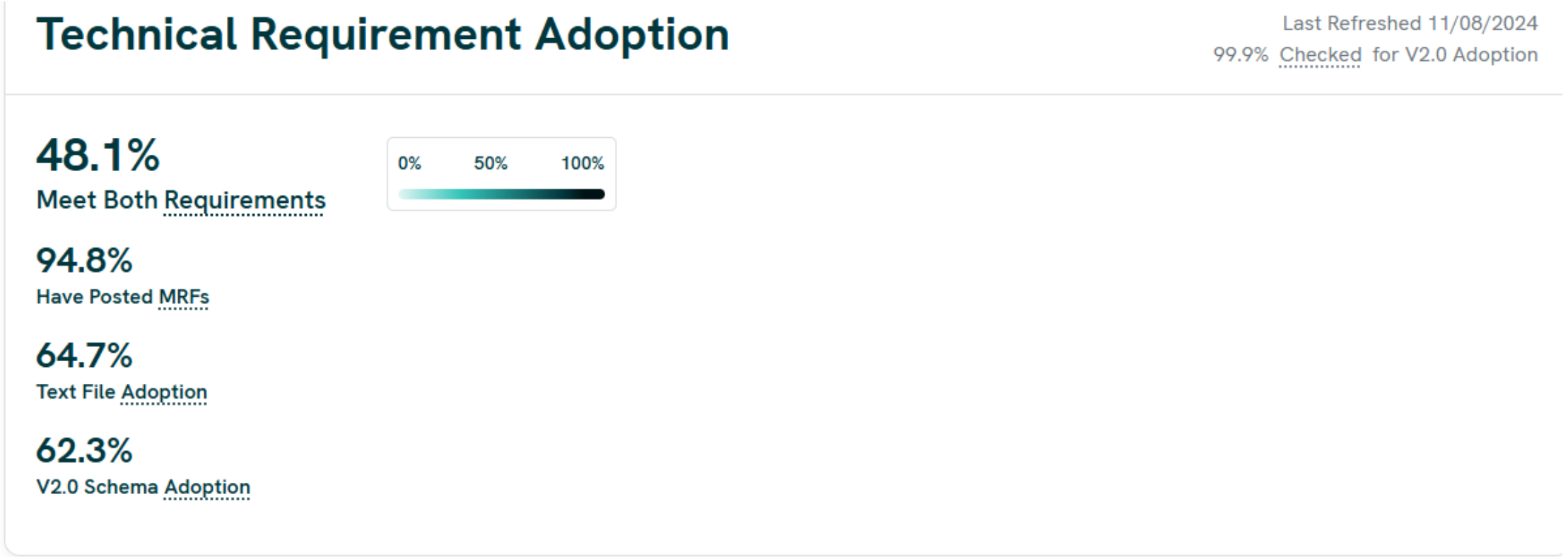
Effective **July 1, 2024**

Hospital enters value of “true” or “false”

TABLE 151A: Implementation Timeline for CMS Template Adoption and Encoding Data Elements

Requirement	Regulation cite	Implementation (Compliance) Date
MRF INFORMATION		
MRF Date	45 CFR 180.50(b)(2)(i)(B)	July 1, 2024
CMS Template Version	45 CFR 180.50(b)(2)(i)(B)	July 1, 2024
HOSPITAL INFORMATION		
Hospital Name	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Location(s)	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Address(es)	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
Hospital Licensure Information	45 CFR 180.50(b)(2)(i)(A)	July 1, 2024
STANDARD CHARGES		
Gross Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
Discounted Cash	45 CFR 180.50(b)(2)(ii)	July 1, 2024
Payer Name	45 CFR 180.50(b)(2)(ii)(A)	July 1, 2024
Plan Name	45 CFR 180.50(b)(2)(ii)(A)	July 1, 2024
Standard Charge Method	45 CFR 180.50(b)(2)(ii)(B)	July 1, 2024
Payer-Specific Negotiated Charge –Dollar Amount	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Payer-Specific Negotiated Charge – Percentage	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Payer-Specific Negotiated Charge – Algorithm	45 CFR 180.50(b)(2)(ii)(C)	July 1, 2024
Estimated Allowed Amount	45 CFR 180.50(b)(2)(ii)(C)	January 1, 2025
De-identified Minimum Negotiated Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
De-identified Maximum Negotiated Charge	45 CFR 180.50(b)(2)(ii)	July 1, 2024
ITEM & SERVICE INFORMATION		
General Description	45 CFR 180.50(b)(2)(iii)(A)	July 1, 2024
Setting	45 CFR 180.50(b)(2)(iii)(B)	July 1, 2024
Drug Unit of Measurement	45 CFR 180.50(b)(2)(iii)(C)	January 1, 2025
Drug Type of Measurement	45 CFR 180.50 (b)(2)(iii)(C)	January 1, 2025
CODING INFORMATION		
Billing/Accounting Code	45 CFR 180.50(b)(2)(iv)(A)	July 1, 2024
Code Type	45 CFR 180.50(b)(2)(iv)(B)	July 1, 2024
Modifiers	45 CFR 180.50(b)(2)(iv)(C)	January 1, 2025

Current Compliance: Turquoise Health



POLLING QUESTION #3

New Requirements – January 1, 2025

Report “estimated allowed amount” when payer negotiated rate based on algorithm or percentage

Estimated allowed amount: Average reimbursement in dollars previously received from payer for specific item or service

Drug unit and type of measurement

Modifiers impacting ‘standard’ charge, including description of modifier and how it impacts standard charge

5. EMTALA Signage

Image Source: Shutterstock

Updated Model Signage

- EMTALA signage must be posted in ED and areas where patients will be examined or treated, or wait to be examined or treated, for emergency medical conditions
  - Regular check-ups?
- CMS released updated model signage on August 13, 2024
  - Replacing “IT’S THE LAW” notice

https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act

6. CAH Time Share and Leased Space Arrangements

Image Source: Shutterstock

November 2024 State Survey Agency Letter

- Time share
  - Arrangement under which another healthcare provider (not hospital or CAH) provides outpatient services at CAH facility using CAH space, staff, supplies for designated time period for CAH and non-CAH patients
  - CAH remains responsible for maintaining and demonstrating compliance with all applicable CoPs at all times
- Leased space
  - Arrangement under which another healthcare provider (not hospital or CAH) leases space without CAH supplying staff and supplies
  - CAH not responsible for CoP compliance with respect to leased space except for requirements relating to CAH's physical structure/environment
- Reminder: all arrangements must comply with applicable fraud and abuse laws

https://www.cms.gov/files/document/qso-25-08-cah.pdf

7. Respiratory Disease Reporting Requirements

Image Source: Shutterstock

Hospital and CAH Conditions of Participation

- 2025 IPPS Final Rule revised Infection Prevention and Control and Antibiotic Stewardship CoPs to require weekly electronic reporting to CDC on respiratory infections (COVID-19, influenza, RSV) (with additional requirements during PHE)
  - Confirmed infection among hospitalized patients
  - Bed census and capacity
  - Limited patient demographics
- Detailed reporting guidance available at https://www.cdc.gov/nhsn/pdfs/pscmanual/HRD-Protocol-Final.pdf
- **Effective November 1, 2024**

Weekly Reporting

- Submit daily data values on weekly basis by 11:59 p.m. PT each Tuesday
  - Include data for each day of previous week, Sunday through Saturday
- Reported as weekly totals
  - New admissions of patients with confirmed respiratory illnesses
  - RSV by age group
- Reported as one-day-a-week snapshots
  - Staffed bed capacity and occupancy
  - Prevalence of hospitalizations
  - ICU patients with respiratory illnesses

8. Maternal Health Conditions of Participation

Image Source: Shutterstock

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 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

9. New Anti-Discrimination Regulations

Image Source: Shutterstock

New Rules Implementing Statutory Provisions

- Section 1557 of the Affordable Care Act
  - Prohibits discrimination based on race, color, national origin, sex, age, or disability in health programs/activities receiving Federal financial assistance
- Section 504 of the Rehabilitation Act
  - Prohibits discrimination based on disability in programs or activities that receive Federal financial assistance

Section 1557 Final Rule - Key Provisions

- Defines discrimination *on the basis of sex* to include discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity*; and sex stereotypes
  - Enforcement of prohibition of discrimination based on gender identity enjoined by federal court order
- Replaces blanket abortion and religious freedom exemptions with new religious freedom and conscience protections exemptions process
- 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

Key Provisions

- Designate Section 1557 Coordinator (if 15 or more employees) by November 2, 2024
- Implement policies and procedures by July 5, 2025
  - 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 by May 1, 2024
- Comply with notice requirements
  - Notice of Non-Discrimination by November 2, 2024
  - Notice of Availability of Language Assistance Services and Auxiliary Aids by May 1, 2025

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

Section 504 Final Rule

- HHS Office of Civil Rights published Final Rule in May 2024 with July 8, 2024, effective date; applies to all Medicare/Medicaid participating providers
- Cannot deny/limit clinically appropriate treatment to individual with disability based on bias/stereotype, belief that individual will be a burden on others, or belief that life of individual with disability has lesser value
- Ensure individuals with disabilities not denied benefits of any program/activity furnished through self-service kiosks
- Ensure web content and mobile apps comply with Web Content Accessibility Guidelines 2.1 levels A and AA (WCAG 2.1 AA) (with specific exceptions)
  - May 11, 2026, for recipients with ≥15 employees and May 10, 2027, for recipients with <15 employees

Section 504 - Medical Diagnostic Equipment

- MDE includes, but is not limited to, medical exam tables, weight scales, dental chairs, radiological diagnostic equipment (e.g., mammography machines)
- All MDE acquired after July 8, 2024, must meet accessibility standards published in 36 CFR Part 1195 (MDE Standards) until scoping requirements satisfied
  - At least 10% of total number of units (but at least 1 unit) of each type of MDE must meet MDE Standards; 20% (but at least 1 unit) for facilities/programs specializing in treatment of conditions affecting mobility subject
  - If use exam tables or weight scales, must acquire at least one accessible unit of each by July 8, 2026
  - Hospitals/large clinics must disperse accessible MDE in manner that is proportionate by departments, clinics, or specialties using MDE
- Ensure staff appropriately trained on use of accessible MDE
- In addition to acquisition requirements, cannot deny services to patient with disability that otherwise would be provided due to lack of accessible MDE
  - E.g., provide services at another location, perform home visit

10. TEAM

Image Source: Shutterstock

Transforming Episode Accountability Model

- Mandatory 5-year episodic payment model beginning 01/01/2026 under which hospital financially accountable for total cost of defined episode of care for traditional Medicare beneficiaries
  - Hospital = Selected PPS hospitals + voluntary participants
  - Episode of care = anchor event (specified inpatient stay/outpatient procedure) + ***30 days*** post-discharge/post-procedure
  - Total cost = all non-exempt Part A & B payments (prorated if service staddles episode)
  - Accountable = owe money if total cost > target price, receive additional payment if total cost < target price

Selected Episodes

1. Coronary artery bypass graft (CABG) (MS-DRGs 231-236)
2. Lower extremity joint replacement (LEJR) (MS-DRGs 469-470, 521-522 and HCPCS codes 27447, 27130, 27702)
3. Major bowel procedures (MS-DRGs 329-331)
4. Surgical hip/femur fracture treatment (SHFFT) (MS-DRGs 480-482)
5. Spinal fusion (MS-DRGs 402, 426-430, 447-448, 450, 471-473 and HCPCS codes 22551, 22554, 22612, 22630, 22633)

Potential Impact of TEAM on CAH Swing Beds

- "Since CAH swing beds are exempt from [SNF PPS], they are reimbursed at a higher rate….TEAM participants that have historically utilized CAH swing beds will be in a position to earn significant savings by establishing relationships with traditional SNFs and discharging patients they would otherwise move to CAH swing beds to traditional SNFs."
- "[W]e note that CAH swing bed allowable charges will be payment standardized as will other Part A and Part B allowable charges in TEAM. CMS has been working closely with the Federal Office of Rural Health Policy to adjust the payment standardization formula for CAH swing beds to reflect resource use that is comparable to that of SNFs. CMS plans to implement this adjusted payment standardization formula for CAH swing beds in the future."

11. Changes to HIPAA Privacy Rule

Image Source: Shutterstock

Key Dates

- January 21, 2021 – Omnibus proposed rule released
- April 17, 2023 – Reproductive health proposed rule released
- April 26, 2024 –Final rule released
- June 25, 2024 – Effective date
- **December 23, 2024 – Compliance date**
- February 16, 2026 – Deadline for updating Notice of Privacy Practices

Purpose-Based Prohibition on Uses/Disclosures

- Prohibits use/disclosure of PHI relating to reproductive health for purpose of -
  - Conducting criminal, civil, or administrative investigation for mere act of seeking, obtaining, providing, or facilitating reproductive healthcare where such care is lawful in circumstances in which provided
  - Imposing criminal, civil, or administrative liability on person for mere act of seeking, obtaining, providing, or facilitating reproductive healthcare where such care is lawful in circumstances in which provided
  - Identifying any person for purpose of conducting such investigation/imposing such liability
- 'Reproductive healthcare' defined broadly
  - Healthcare "that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes"

Lawful Reproductive Healthcare

- If request made to person/entity providing care –
  - Care is lawful under law of state in which care provided in circumstances in which provided
    - Regardless of whether care is lawful in state of patient's residence
  - Care is protected, required, or authorized by Federal law (including U.S. Constitution), regardless of state in which care provided
- If request made to person/entity not providing care, presume care is lawful under circumstances in which provided unless -
  - Have actual knowledge care not lawful under circumstances in which provided
  - Receives information from requester that demonstrates substantial factual basis that care not lawful under circumstances in which provided

Attestation

- Covered entities and business associates must obtain signed attestation that certain requests for PHI potentially related to reproductive health are not for prohibited purposes
  - Health oversight activities
  - Judicial and administrative proceedings (subpoenas, court orders)
  - Law enforcement purposes
  - Disclosures to coroners and medical examiners regarding decedents
- Attestation not required if individual authorizes such use/disclosure
- Model attestation form available at https://www.hhs.gov/sites/default/files/model-attestation.pdf

Legal Challenge

- On September 4, Attorney General of Texas filed lawsuit in federal district court challenging new rule as beyond scope of HIPAA statute
  - Obstructs states' abilities to enforce their own laws
  - Also challenges provision in effect since 2000 limiting when provider can provide PHI in response to government investigation
- Will court enter preliminary injunction prior to effective date? If yes, will it be limited to Texas? Will HHS immediately appeal?

12. Medicare Co-Insurance for CAH Services

Image Source: Shutterstock

Cost Sharing for Outpatient Services at CAHs

- Part of 2025 MedPAC agenda
  - CAH coinsurance = 20% of charges
  - Currently coinsurance > 50% of total payment
  - No cap on coinsurance
- Questions posed to Commissioners
  - Should outpatient coinsurance continue to be set based on charges?
  - If not, is setting coinsurance based on 20% of payment rate a reasonable alternative?
  - Should there be a cap on CAH coinsurance, as in the OPPS?
- MedPAC assumes total payment to CAHs will remain unchanged
  - Reduction in cost sharing results in higher program payments

13. Medicare Advantage Coverage Criteria

Image Source: Shutterstock

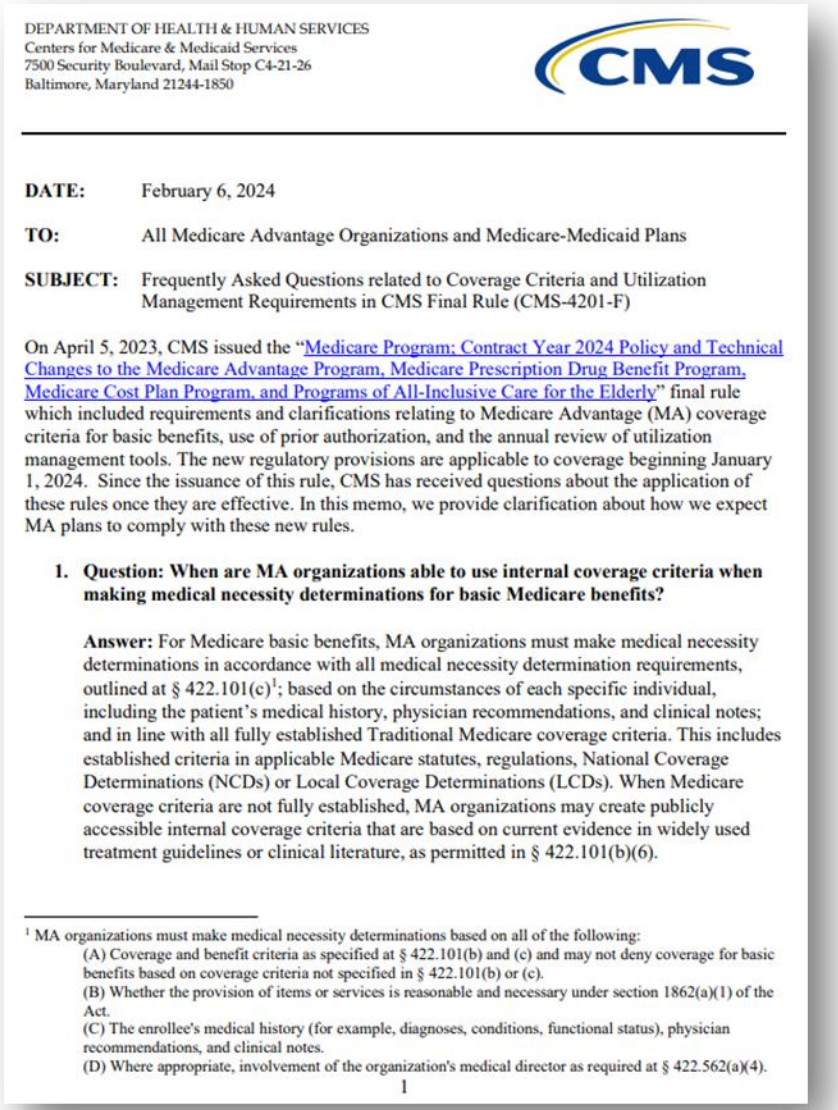
POLLING QUESTION #4

2024 MA & Part D Final Rule (effective 01/01/2024)

1. MA plan must comply with traditional Medicare NCDs, LCDs, and general coverage and benefit conditions
   - Including coverage criteria for inpatient, IRF, and SNF admissions and 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)
2. 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/decreased access to care)

Additional Clarification

February 6, 2024, FAQs on coverage criteria and utilization management requirements



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

DATE: February 6, 2024

TO: All Medicare Advantage Organizations and Medicare-Medicaid Plans

SUBJECT: Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

On April 5, 2023, CMS issued the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule which included requirements and clarifications relating to Medicare Advantage (MA) coverage criteria for basic benefits, use of prior authorization, and the annual review of utilization management tools. The new regulatory provisions are applicable to coverage beginning January 1, 2024. Since the issuance of this rule, CMS has received questions about the application of these rules once they are effective. In this memo, we provide clarification about how we expect MA plans to comply with these new rules.

1. **Question: When are MA organizations able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits?**

   Answer: For Medicare basic benefits, MA organizations must make medical necessity determinations in accordance with all medical necessity determination requirements, outlined at § 422.101(c)[1]; based on the circumstances of each specific individual, including the patient's medical history, physician recommendations, and clinical notes; and in line with all fully established Traditional Medicare coverage criteria. This includes established criteria in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When Medicare coverage criteria are not fully established, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature, as permitted in § 422.101(b)(6).

[1] MA organizations must make medical necessity determinations based on all of the following:
(A) Coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not specified in § 422.101(b) or (c).
(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

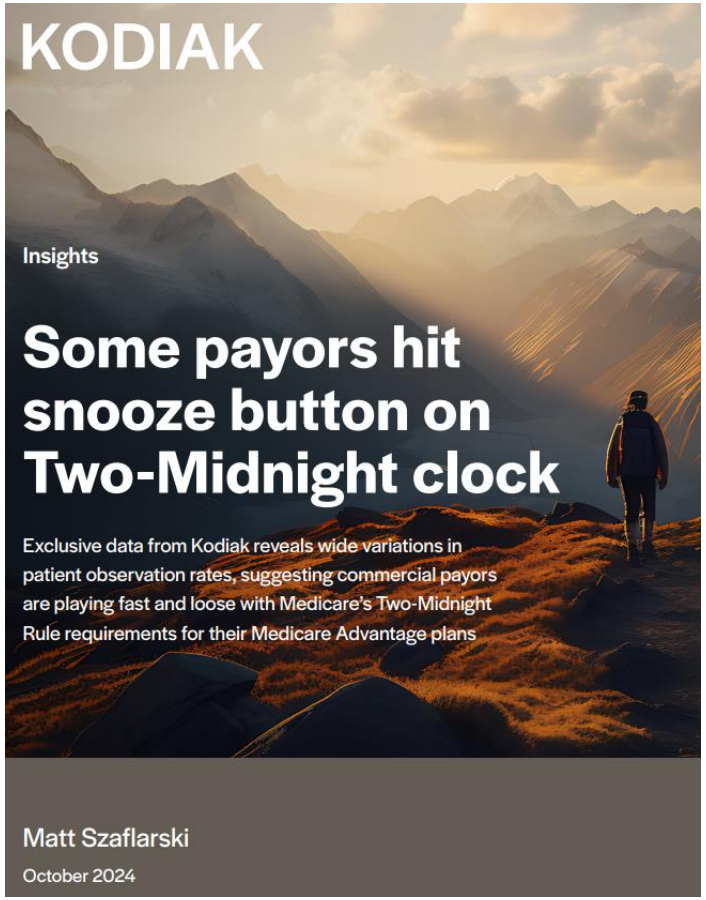
1

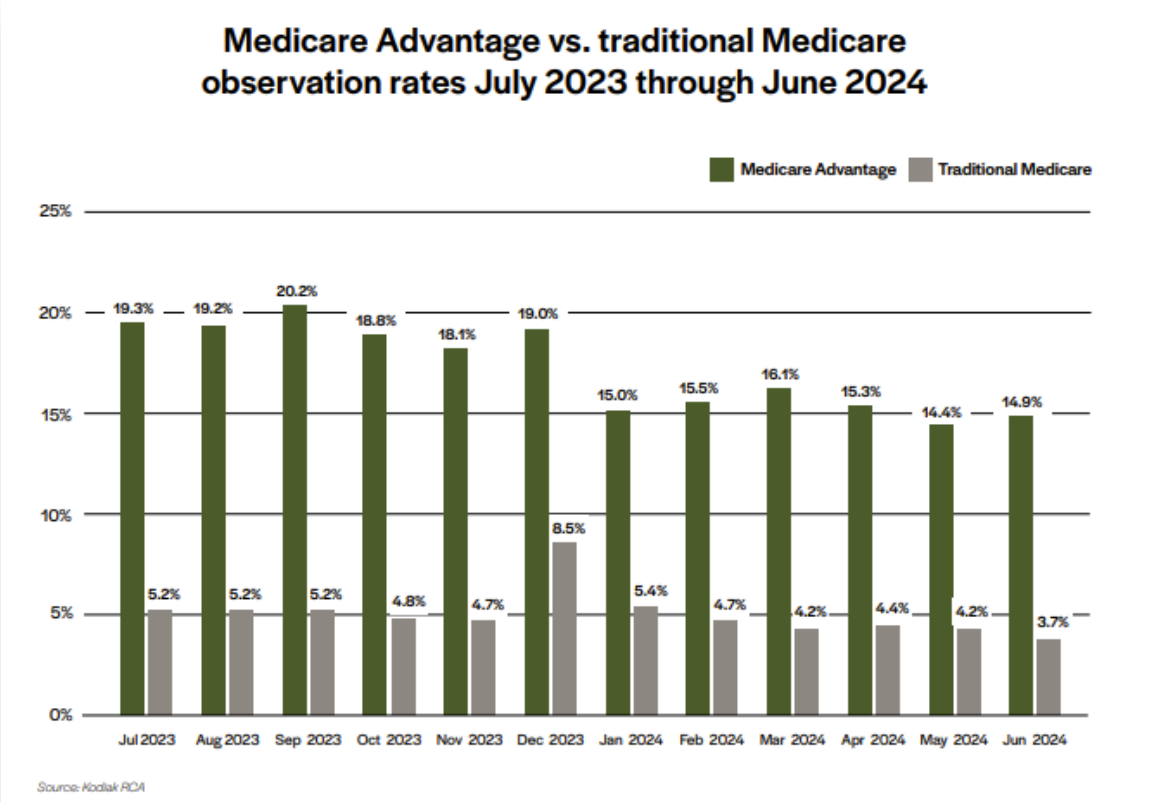
https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf

Two Midnights – Benchmark vs. Presumption

- MA plans must follow two midnights benchmark (42 CFR 412.3(d)(1))
  - Admitting physician expects patient to require hospital care that crosses two-midnights
- MA plans not required to follow two midnights presumption (CMS medical review instruction)
  - Any claim that crosses two midnights following inpatient admission order are presumed appropriate for payment
- MA plan may evaluate whether admitting physician's expectation was *reasonable* based on complex medical factors documented in medical record

Plan Compliance?





https://kodiaksolutions.io/internal/benchmarking_reports/kpi_benchmarking_november_quarterly

Post-Acute Care

- If physician orders post-acute care in specific type of facility (e.g., IRF, SNF, swing bed) and patient meets all applicable coverage criteria, plan cannot deny admission or re-direct care to different setting
  - MA plan may discuss with enrollee treatment options (offer incentives?)
- MA plan bears burden of proving services no longer reasonable and necessary when terminating post-acute care services
  - Such action subject to expedited appeals process

Submitting Provider Complaints to CMS

- CMS recently launched new centralized process for provider complaints against MA plans
  - Provider appeal complaint – plan failed to follow applicable appeals process, e.g., failure to provide notice of appeal rights, failure to act within specified time frames
  - Claims payment dispute - provider's dispute over amount paid by plan for approved service on particular claim, e.g., plan's decision to partially approve, downcode, or bundle services or approve service at lower level of care than service billed
- Provider must submit completed Appeal / Claim Payment Dispute Cover Sheet* for each complaint (i.e., one cover sheet for each beneficiary case) in password-protected file to MedicarePartCDQuestions@cms.hhs.gov and part c part d audit@cms.hhs.gov
  - CMS will not process complaint unless provider previously communicated with plan
- CMS will facilitate plan-provider communication, track and trend types of complaints - but not resolve specific disputes
  - Input complaint into CMS Complaint Tracking Module (Star Rating measure = # of CTM complaints/1000 members)

*https://calhospital.org/wp-content/uploads/2024/08/instructions-for-organizations-representing-providers-to-submit-provider-complaints-related-to-medicare-advantage-organizatio.pdf

January 2024 Prior Authorization Final Rule

- By 1/1/2026, plan must send PA decisions within 72 hours (urgent) and 7 calendar days (standard)
  - For MA plans, current rule is 14 calendar days for standard requests
  - For MA plans, shorter time periods for Part B drugs (24/72 hours) will remain
- By 1/1/2026, plan must furnish provider with written explanation for PA decision
  - For MA plans, current rule requires for post-claim audits
- By 3/31/2026, plan must post PA metrics on website
  - Percent of PA requests approved, denied, approved after appeal
  - Average time between submission and decision
- By 1/1/2027, plans must implement APIs to facilitate electronic PA process
  - Identify items or services requiring PA (excluding drugs)
  - Specify documentation requirements for items and services requiring PA

2026 MA & Part D Proposed Rule

- Prior authorizations
  - Prohibit plans from refusing payment on inpatient admission for which prior authorization was given
  - Tighter standards for internal coverage criteria
  - Requirements regarding enrollee notification of appeal rights
  - Reporting requirements relating to initial coverage decisions and appeals
- Marketing
  - Pre-approval of of ‘generic’ MA advertisements
  - New broker disclosure requirements (including higher cost of supplemental plan if return to traditional Medicare)
- Changes to expenses included in medical loss ratio
- Part D coverage for GLP-1s

14. Capital Project Financing

Challenges Financing Capital Projects

- Common Challenges with Existing Rural Hospital Facilities
  - Aging facilities with increased maintenance and utility costs
  - Non-compliance with current building codes and efficiency standards
  - Inadequate for modern standards of patient care
  - Design no longer aligns with business strategy / care model
- Hospital Replacements & Renovations Require Significant Capital
  - Limited funds available
  - Limited financing options

Potential Funding Solutions for Capital Projects

- Cash / Donations
- Bank Loans (limited lending capacity of local lenders)
- Bond Financing (Potential Increased Public Tax Burden; Not Available based on Credit Profile / Financial Strength of Hospital)
- JV with Larger Systems (potential loss of control)
- HUD Section 242 Hospital Mortgage Insurance Program
- New Markets Tax Credits
- State-specific Programs
- **United States Department of Agriculture (USDA) Community Facilities Program**

USDA Community Facilities – Eligibility

- Eligible Healthcare Projects
  - Hospitals, healthcare clinics, assisted living facilities, rehabilitation centers, and other community-based initiatives
- Eligible Borrowers
  - Public bodies, Community-based non-profit corporations, Federally-recognized Tribes
- Eligible Areas
  - Communities < 20,000 residents according to latest U.S. Census Data
- **Priority System:** Communities <5,500 Population; Median HH Income <80% of State Nonmetro Median HH Income

USDA Community Facilities – Products

- **Low Interest Direct Loan Programs**
  - Excludes Interim / Construction Loans
  - Fixed rate for length of loan
    - 2024 Market Rates: **3.875%** (updates annually on January 1st);
    - Lower of the rates at either Loan Obligation or Permanent Funding (Post-Construction)
  - Loan Term: **Up to 40 years**
  - No Prepayment Penalties
- **Loan Guarantee Program** (USDA Guarantee to commercial financing)
- **Grants** (various sizes based on eligibility)

USDA Community Facilities – Process (1 of 2)

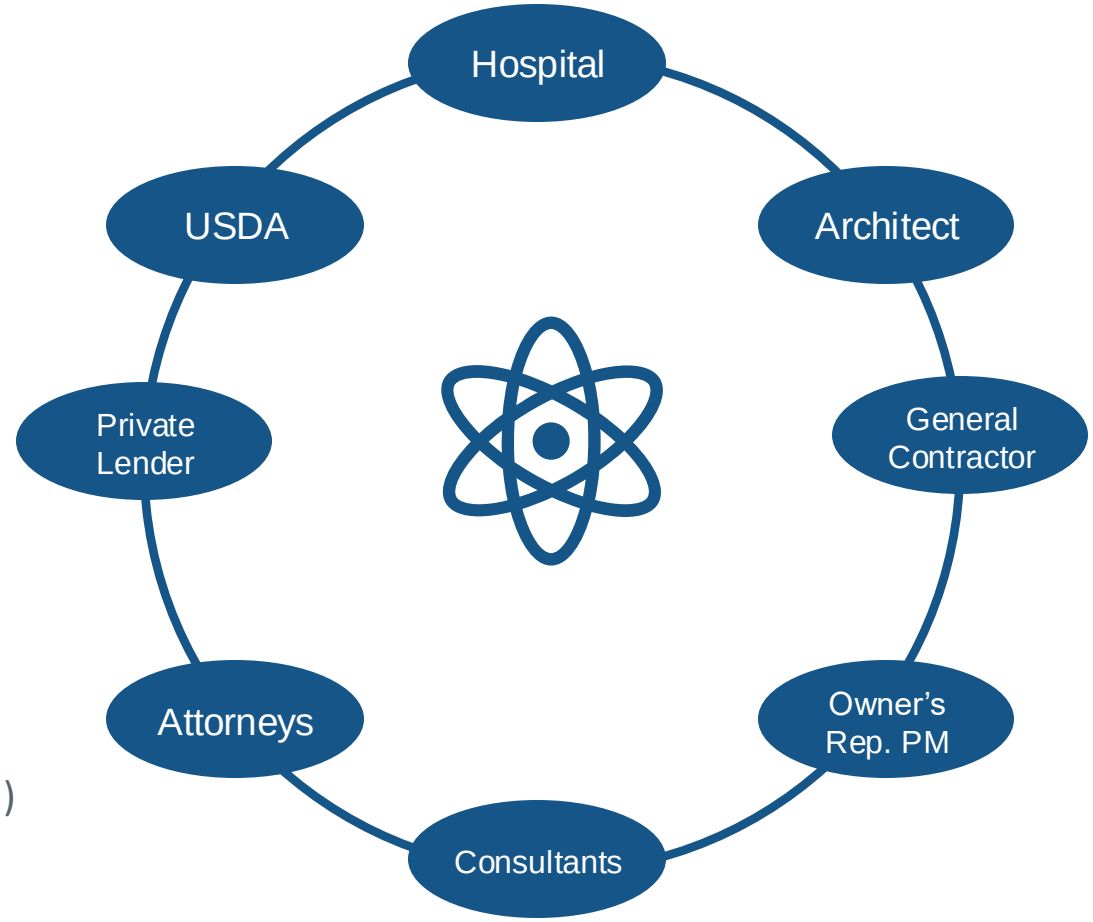
Direct Loan Approval

- Administered by **USDA State Office & Regional Offices** (Local, State, and Federal Approval)
- USDA approval for all aspects of the project (Contracts, GC Selection, Budgets, Design, and Schedule) and continues to monitor project through construction
- Recent ~2020 changes to program led to increased review and project underwriting
- Heavy admin process, up to 3 years from start to loan closing (100s of documents)
  - Identify consultants and project managers w/USDA experience to support hospital leadership
  - Mandatory to have organized file sharing system and follow checklists

USDA Community Facilities – Process (2 of 2)

Direct Loan Approval

- Pre-Application:
  - Project Narratives
  - 3 Denial Letters for Similar-sized Loans
  - Submission of Financial and Org Documents
- Application:
  - Feasibility Study from CPA Firm
  - Preliminary Architectural Report (PAR)
  - USDA Environmental Study
  - Financial Reporting
  - Site Survey
- Loan Approval, Obligation, & Closing:
  - Architect Contract (AIA B133)
  - General Contractor Selection Process & GMP Contract (AIA A133)
  - Final Project Budget, Plans & Specs, and Project Schedule
  - Interim / Construction Financing
  - ***Various USDA Forms and Approvals***



RTG Case Study: DeSoto Regional Health System

Mansfield, LA – Under Construction

- Private, Non-For-Profit, 34-bed Acute Care Hospital
- Former 1950s / 1970s Facilities
- Updated Care Model →
  - 16 Inpatient / Med Surg Beds
  - 9-Bed Emergency Department
  - New RHC, Sleep Lab, & Admin Building
  - New Helipad
- $50M Project
  - $32M USDA Community Facilities Loan (3.5%, 35 yrs)
  - $4M Private Bank Loan (USDA Guaranteed)
  - $14M Hospital Equity

POLLING QUESTION #5

15. Lame Duck Priorities and Possibilities

Image Source: Shutterstock

Lame Duck Priorities

- Funding the federal government beyond December 20
- Telehealth flexibilities
- Physician payment fix
- Extenders for expiring provisions
  - Low Volume Hospital adjustment
  - Medicare Dependent Hospital Program
- Medicaid DHS cuts ($8 billion)
- Medicare PAYGO 4% reduction

Lame Duck Possibilities

- Price transparency
- Site neutral payments
- Medicare Advantage prior authorizations
- Safety from Violence for Healthcare Employees Act
- REH program changes

A national healthcare advisory services firm providing consulting, audit, and tax services