Hot Topics in Rural Hospital Regulation and Reimbursement

Maine Hospital Association Webinar
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Introductions

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Following a successful two-decade career as a healthcare transactional and regulatory attorney, Martie now serves as a trusted advisor to providers navigating the ever-expanding maze of healthcare regulations. Her deep and wide understanding of new payment and delivery systems and public payer initiatives is an invaluable resource for providers seeking to strategically position their organizations for the future.

Agenda

1. Trump Administration Health Policy Priorities
2. Swing Beds
3. Telehealth Update
4. RHC Provisions in the 2025 Medicare Physician Fee Schedule Final Rule
5. Maternal Health Conditions of Participation
6. Medicare Advantage
7. Hospital Price Transparency
8. EMTALA Signage
9. CAH Time Share and Leased Space Arrangements
10. Respiratory Disease Reporting Requirements

1. Trump Administration Health Policy Priorities

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House Budget Resolution

- $4.5T in tax cuts
- Instructions to several committees that equal at least $1.5 trillion in cuts to mandatory spending
  - $880B cuts to Energy & Commerce (Medicaid), $230B cuts to Agriculture (SNAP)
  - Committees must submit legislation to House Budget Committee by **March 27**
- Mandate to find another $500 billion in spending reductions without specific committee instructions
- Any shortfall results in corresponding reduction in tax cuts (e.g., if only $1.7B in cuts, tax cuts reduced to $4.2T); any excess results in corresponding increase in tax cuts (e.g., if $2.3B in cuts, tax cuts increased to $4.8T)

Medicaid Funding Cuts

- Reduce or eliminate state-directed payments
  - First Trump administration proposed Medicaid Financial Accountability Regulation (MFAR)
  - Options now on the table: lower threshold from 6% to 5% ($48 billion), to 2.5% ($241 billion), or eliminate completely ($612 billion)
- Place caps on federal spending
  - Set annual maximum amount of federal funds to each state to operate Medicaid ($459 to $742 billion)
  - Set upper limit on federal payments per Medicaid enrollee in each eligibility group ($588 to $893 billion)
- Reduce federal matching rates
  - Standardize 50% match for all administrative services ($69 billion)
  - Remove 50% federal floor for non-ACA eligibility groups ($530 billion)
  - Reduce 90% federal match for ACA eligibility group ($561 billion)
- Expand work requirements
  - Reduce spending by reducing number of eligible beneficiaries (savings to state and federal government

Medicare Provider Payment Cuts

- Site neutral payment reform
  - Pay site-neutral rates for HOPD services routinely performed in physician clinic/ASC ($157 billion)
  - Drug administration services only ($5.6 billion)
  - Imaging services only ($7.6 billion)
- Reduce payments for 340B drugs from current ASP +6%.
  - Reduce payment rates to ASP ($15.4 billion)
  - Reduce payment rates to ASP minus 22.5% ($73.5 billion)
- Reduce/eliminate bad debt coverage from current 65% of allowable bad debt
  - Reduce to 45% ($16.7 billion)
  - Reduce to 25% ($33.2 billion)
  - Eliminate coverage ($54.1 billion)
- Consolidate and reduce Medicare GME payments ($94 and $103 billion)

More Medicare Provider Payment Cuts

- Uncompensated care payment reforms
  - Establish new fund, equitably distribute based on true share of charity care, non-Medicare bad debt ($229 billion)
- Wage index geographic integrity ($15 billion)
- Eliminate inpatient only list ($10 billion)
- Eliminate hospital dual classification ($10 billion)

New Medicare Spending

- Enact H.R. 8246, Second Chance for Rural Hospitals Act ($10 billion new spending)
  - Hospitals that closed between 2014 and 2020 would be eligible for REH status, with certain payment limitations
- Improve senior access to innovation and telehealth ($20 billion new spending)
  - Enact series of bills extending telehealth waivers, hospital-at-home waiver, and Medicare Dependent Hospital and Low Volume Hospital programs; expanding Medicare coverage for certain screening tests and new drug therapies
- Reform Inflation Reduction Act drug policies ($20 billion new spending)
  - Discourage price setting on innovative drugs treating rare patient populations

Cuts To Medicare Advantage Plan Payments

- Modify payments to MA plans for health risk
  - Increase coding intensity risk adjustment from 5.9% to 8% ($159 billion)
  - Increase from 5.9% to 20% ($1.049 trillion)
  - Adjust formula for calculating risk scores ($124 billion)
- Reduce MA benchmarks (currently tied to projected Medicare FFS spending for average beneficiary in same county)
  - Reduce by 10% ($489 billion)

Other Health-Related Cuts and Reforms

- Remote specified categories of non-citizens from eligibility for federal healthcare programs ($35 billion)
- Reduce Exchange subsidies ($102 billion)
- Permit employer defined benefit contributions towards Exchange plans
- Repeal ACA minimum coverage standards

What Happens to Biden Administration Regulations?

- Amend or repeal final rules through notice and comment rulemaking
  - Regulations considered “final” if published in *Federal Register* or released for public inspection even if delayed effective date
  - Likely targets: nursing home staffing levels, HIPAA reproductive rights, Section 1557
  - Exception: Under Congressional Review Act, new Congress can rescind regulations finalized after 8/1/24
- Place moratorium on effective date of final rules not yet in effect
  - Allows new administration time to review
  - Typically not applied to rules required under statute or by judicial decision
- Amend or repeal guidance documents
  - Generally does not require notice and comment rulemaking
- Stop, delay, or withdraw proposed rules
  - Issue moratorium on rules under development
  - Medicare Advantage/Part D proposed rule?
- Exercise enforcement discretion

2. Swing Beds

Image Source: Shutterstock

Site Neutral Payments – Swing Beds

Department of Health and Human Services
Office of Inspector General
Office of Audit Services

December 2024 | A-05-21-00018

Medicare Could Save Billions With Comparable Access for Enrollees if Critical Access Hospital Payments for Swing-Bed Services Were Similar to Those of the Fee-for-Service Prospective Payment System

What OIG Found

- Swing-bed utilization for skilled nursing services at CAHs increased by 2.8 percent from CY 2015 through 2020; meanwhile, the average daily reimbursement amount increased by 16.6 percent over the same period.
- Based on our sample results, we found that 87 of 100 sampled CAHs were within a 35-mile driving distance of an alternative facility that had skilled nursing care available and estimate that 1,128 of the 1,297 CAHs in our sampling frame had an alternative facility within 35 miles that could have provided care during CY 2020.
- Based on our sample results and mathematical calculation, we estimate that Medicare could have saved up to $7.7 billion over a 6-year period if payments made at CAHs were reimbursed using SNF PPS rates.

What OIG Recommends

We recommend that CMS seek a legislative change that will allow it to reimburse CAHs at rates that align with those paid to alternative facilities when it determines that similar care is available at alternative facilities.

CMS did not concur with our recommendation.

https://oig.hhs.gov/documents/audit/10151/A-05-21-00018.pdf

TEAM and Swing Beds

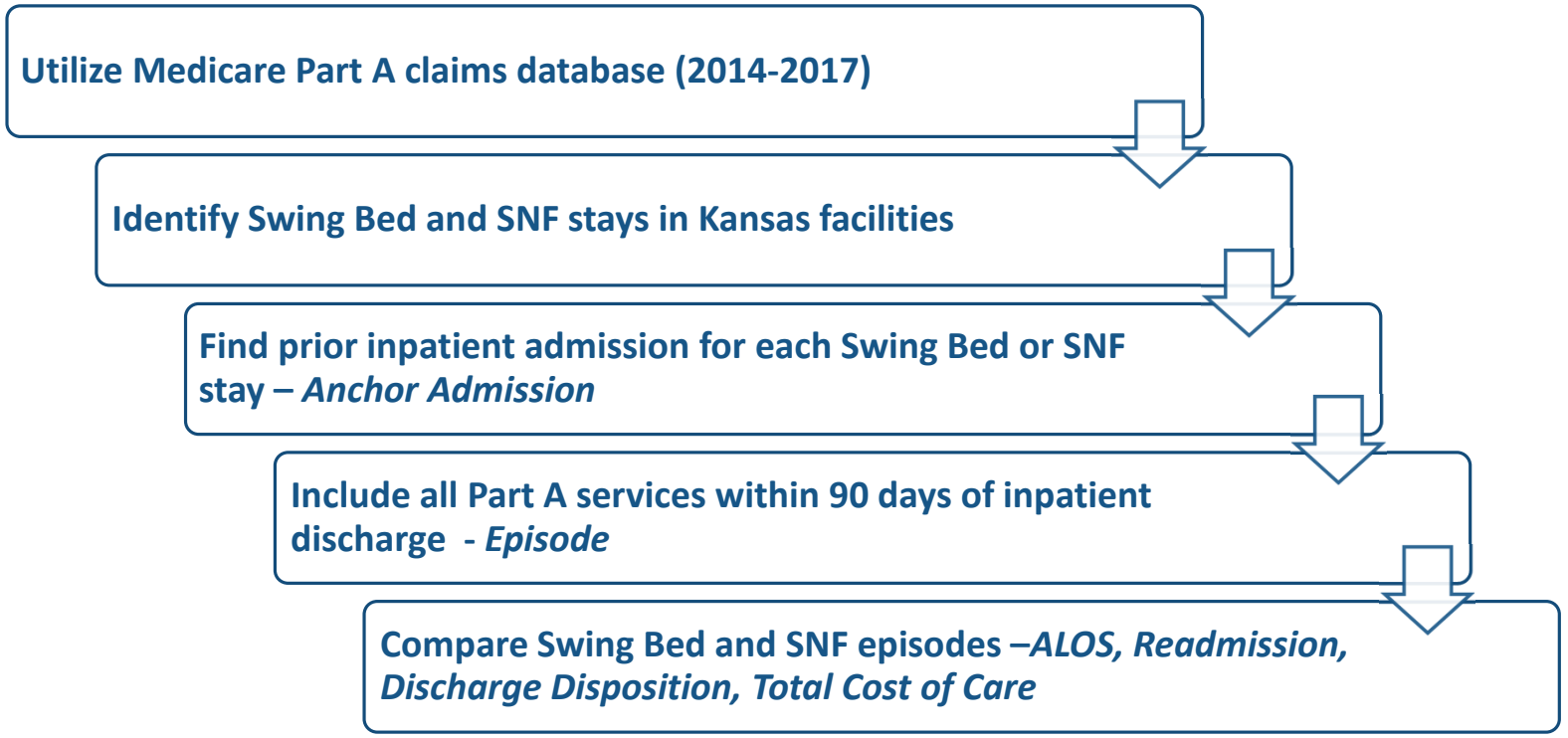
"Since CAH swing beds are exempt from [SNF PPS], they are reimbursed at a higher rate….TEAM participants that have historically utilized CAH swing beds will be in a position to earn significant savings by establishing relationships with traditional SNFs and discharging patients they would otherwise move to CAH swing beds to traditional SNFs."

- 2025 Medicare Inpatient Prospective Payment System Final Rule

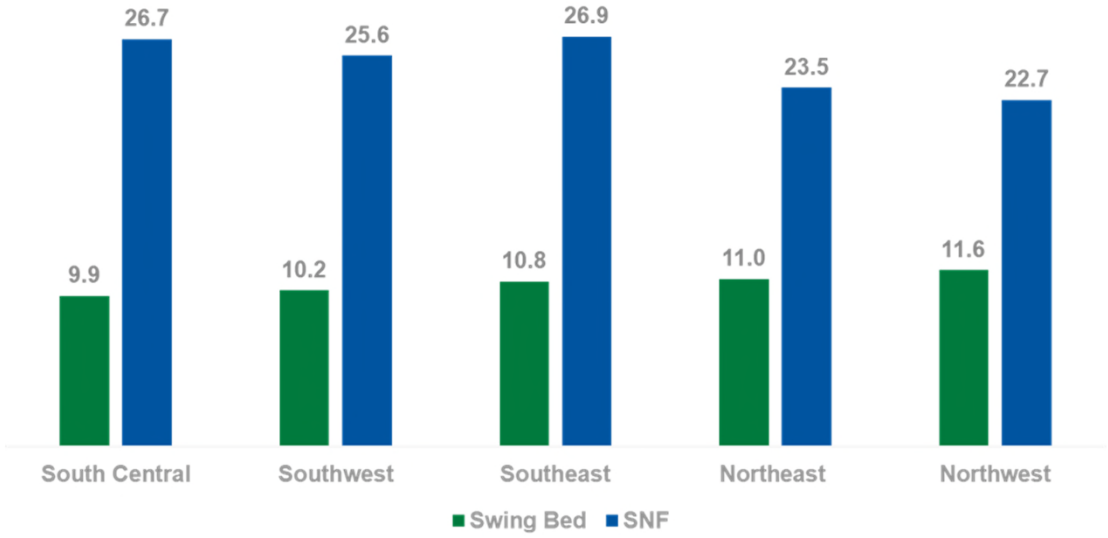
The Truth About Swing Beds

- Swing bed length of stay significantly lower than SNF LOS
- Swing bed patients are significantly less likely to have readmissions
- Total cost of care for post-discharge period for swing bed patients is higher than cost for SNF patients, but not double the cost
- Comparison of swing bed to SNF payments must accurately account for impact on CAH cost allocation

Part A Claims Analysis - Methodology

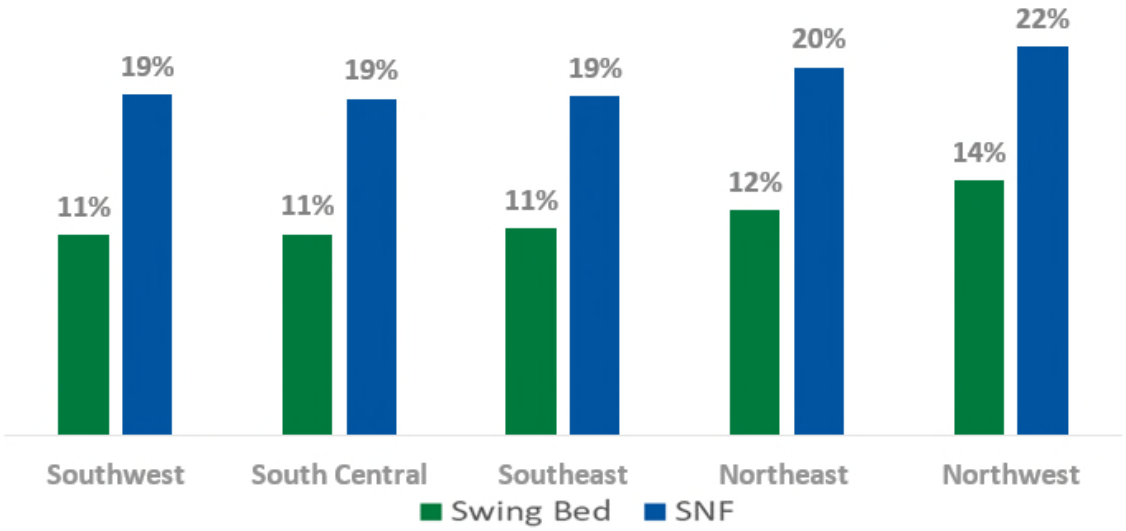


Kansas - ALOS Per Discharge



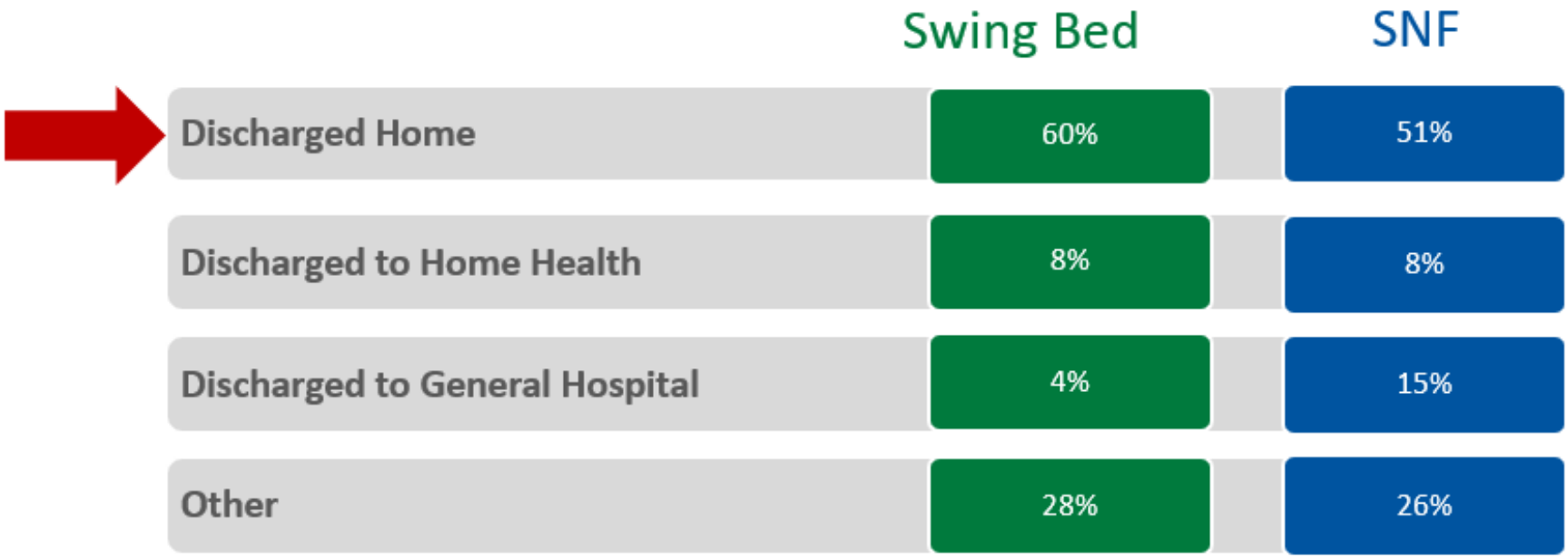
On average, swing beds stays are *~14 days less* than SNF stays

Kansas – Readmission Rate



On average, swing beds have *~7% lower readmission rates* than their SNF peers

Kansas - Discharge Disposition Comparison



Kansas - Total Cost of Care by Admitting Diagnosis

			Average					
IP Admitting DRG	IP Admitting DRG Description	Total Episodes	IP Anchor LOS	Readmission LOS	Swing Bed LOS	Other PAC LOS	Swing Bed Total Cost of Care	SNF Total Cost of Care
470	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W/O MCC	1,723	3.7	0.7	14.9	10.15	$37,030	$25,303
194	SIMPLE PNEUMONIA & PLEURISY W CC	1,597	3.9	2.0	15.9	10.24	$27,689	$21,220
195	SIMPLE PNEUMONIA & PLEURISY W/O CC/MCC	946	3.8	1.5	14.7	11.15	$25,771	$18,901
690	KIDNEY & URINARY TRACT INFECTIONS W/O MCC	898	3.7	1.7	19.5	11.90	$29,132	$22,230
603	CELLULITIS W/O MCC	599	3.7	1.9	18.3	13.78	$31,532	$22,448
481	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W CC	579	4.9	1.0	34.8	15.61	$63,374	$33,142
641	MISC DISORDERS OF NUTRITION,METABOLISM,FLUIDS/ELECTROLYTES W/O MCC	540	3.7	2.1	19.1	12.58	$31,699	$20,634
292	HEART FAILURE & SHOCK W CC	517	4.1	2.2	17.0	12.69	$31,892	$23,471
552	MEDICAL BACK PROBLEMS W/O MCC	444	3.9	2.0	22.6	11.89	$37,285	$25,061
948	SIGNS & SYMPTOMS W/O MCC	437	3.8	2.1	24.3	14.14	$33,020	$24,066

Most significant difference (medical back problems w/o MCC) is less than 50% higher than SNF total cost of care

Additional Costs - Part B Services During SNF Stay

- Patient with severe headache requires CT scan
  - SNF: Excluded service under the SNF PPS consolidated billing requirements = additional Part B expense (not part of $400/day)
  - CAH Swing Bed: Must include on swing bed claim, regardless of reason for service, findings, or if additional services were required (included in $1400/day)

Medicare Post-Acute Care Transfer Policy

- For ~ 270 DRGs, hospital receives per-diem rate (vs. full MS-DRG rate) when patient with LOS < geometric mean is discharged to one of the following:
  - Skilled nursing facilities
  - Inpatient rehab facilities and units
  - Long term care hospitals
  - Psychiatric hospitals and units
  - Children's and cancer hospitals
  - Home with a home health plan of care that begins within 3 days
  - Hospice care
- Does NOT apply to swing bed transfers (Patient Status Discharge Code 61)

3. Telehealth Update

Image Source: Shutterstock

Medicare Telehealth Coverage Waivers

1. Geographic and originating site restrictions for medical telehealth services
   - Patient must be physically present at clinic or facility located in rural area
   - Restrictions no longer apply to tele-behavioral health services (CAA, 2021)
2. Required in-person visit within 6 months of initiating tele-behavioral health services
3. Expanded list of telehealth providers
   - All providers eligible to bill Medicare vs. physicians and non-physician practitioners only
4. RHCs and FQHCs as distant site providers
   - 2025 MPFS Final Rule – 42 CFR 405.2464(g)
5. Audio-only telehealth services
   - 2025 MPFS Final Rule – 42 CFR 410.78(a)(3)

Medicare Telehealth Coverage –American Relief Act, 2025

- Absent Congressional action, existing waivers of Section 1834(m) geographic and originating site limits on Medicare telehealth coverage will expire 03/31/2025
  - 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 04/01/2025, 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

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

RHC Telehealth – Behavioral Health Services

- New coverage created under Consolidated Appropriations Act, 2021
- Qualifies as RHC visit (and thus pays 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)
  - NOTE: If Congress does not extend telehealth flexibilities, telehealth services furnished to patients in their homes will not be reimbursable
- 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

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)

RHC Care Management Services - 2025

- Discontinue use of G0511; bill 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 MPFS non-facility national payment rate
  - Co-payment based on Medicare allowable, not charges
- 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

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 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"

5. 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

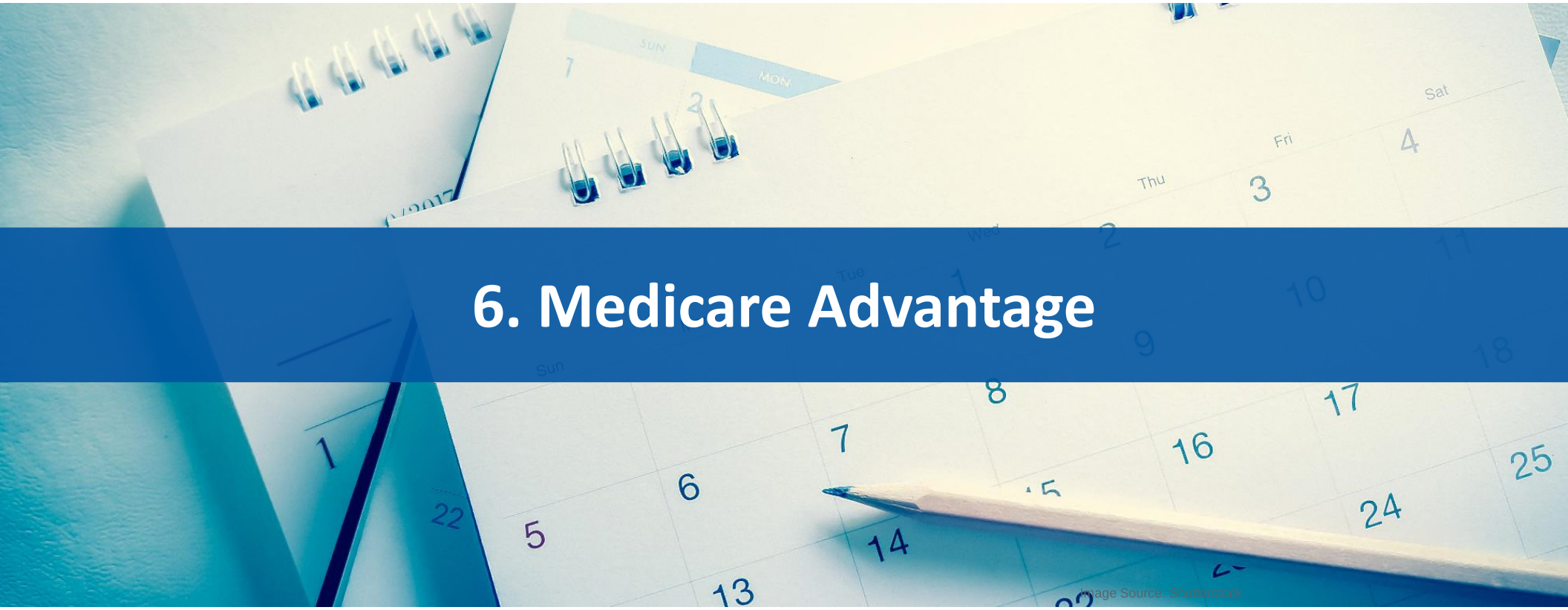
1. Organization and staffing (01/01/2026)
   - OB services must be integrated with other departments
   - OB facilities must be supervised by experienced MD/DO, NPP, or RN
   - OB privileges must be delineated for all practitioners based on competencies
2. Delivery of services (01/01/2026)
   - Provisions 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



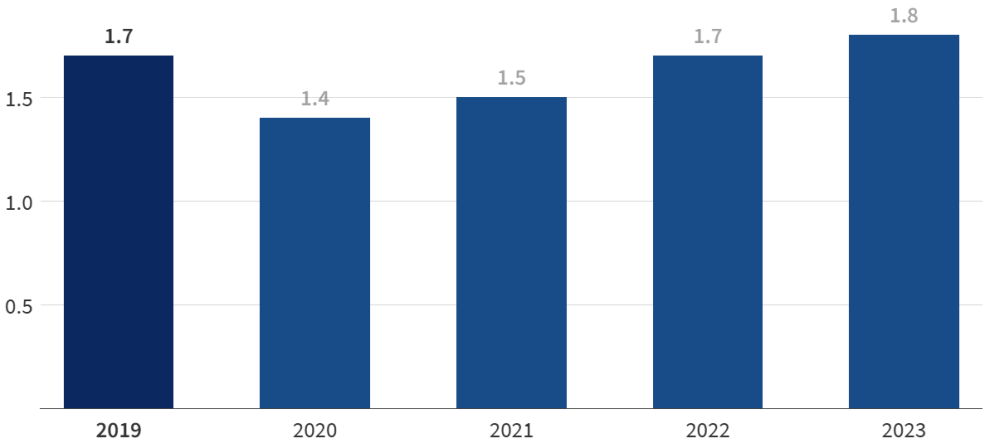
6. Medicare Advantage

Image Source: Shutterstock

MA Prior Authorizations and Denials

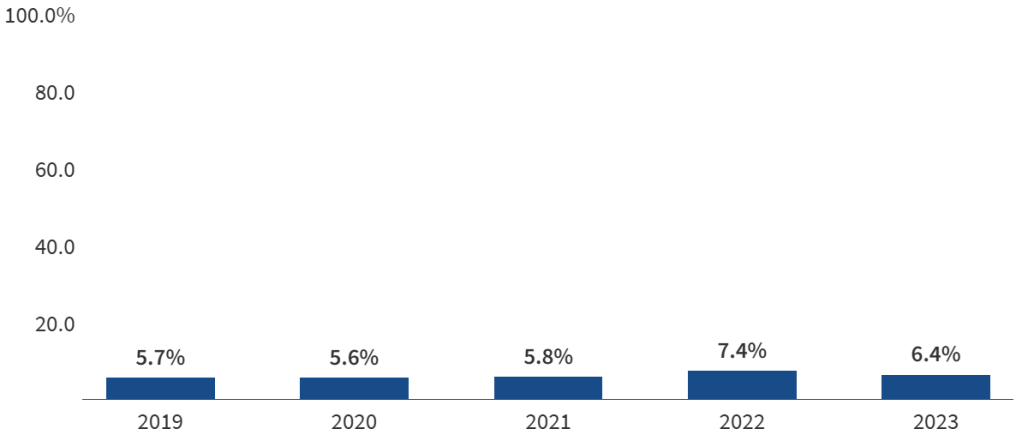
Prior Authorization Determinations per Medicare Advantage Enrollee in 2022 and 2023 Were Similar to Pre-Pandemic Levels

Number of prior authorization requests per enrollee, 2019 - 2023



Medicare Advantage Insurers Denied Fewer than 10% of Prior Authorization Requests in Recent Years

Adverse and partially favorable determinations as a share of all prior authorization determinations, 2019 - 2023



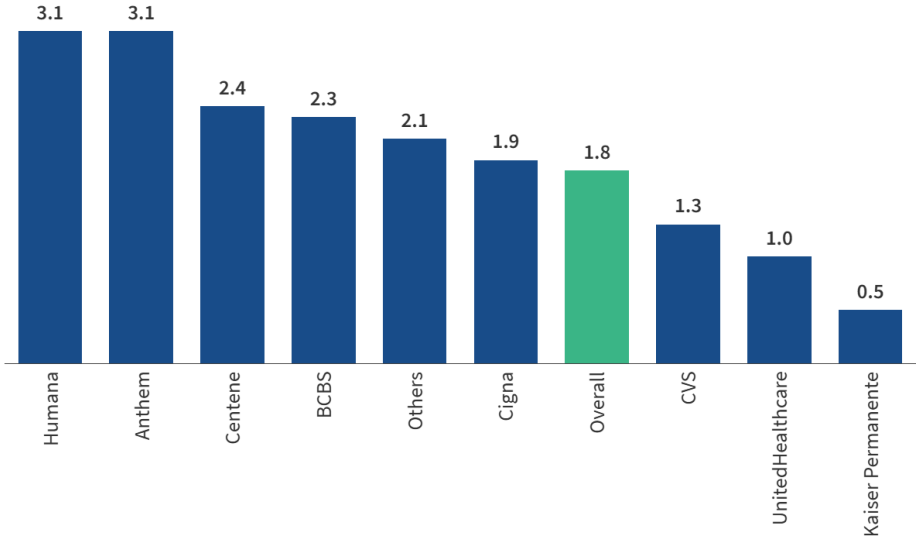
Source: Medicare Limited Data Set, Contract Years 2022 and 2023 Part C & D Reporting Requirements and Public Use File Contract Year 2019 - 2021 Part C & Part D Reporting Requirements

https://www.kff.org/medicare/issue-brief/nearly-50-million-prior-authorization-requests-were-sent-to-medicare-advantage-insurers-in-2023/

MA Prior Authorization – By Payer

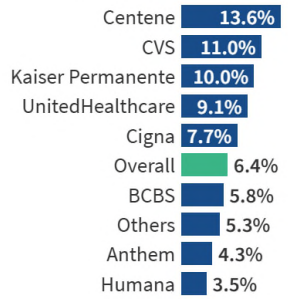
Prior Authorization Determinations Are More Common Among Certain Medicare Advantage Firms

Requests for prior authorization of services per Medicare Advantage enrollee in 2023



Firms Denied Between 4% and 14% of Prior Authorization Requests

Adverse and partially favorable determinations as a share of all prior authorization determinations in 2023



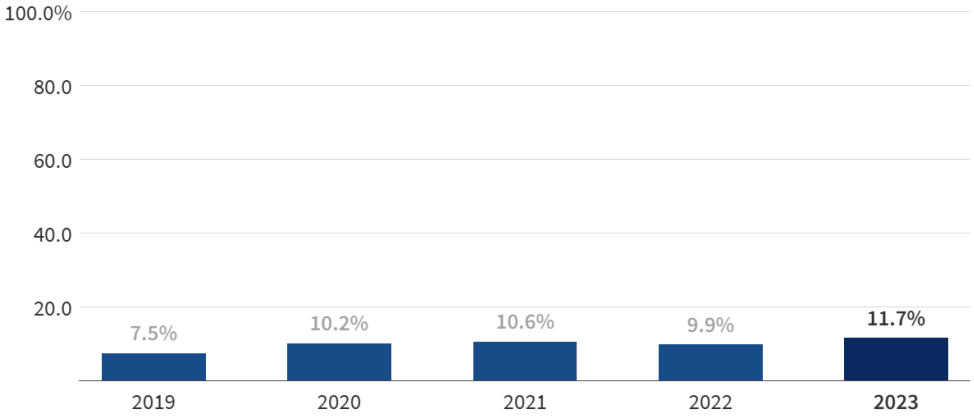
: CMS, "Prior Authorization and Pre-Claim Review Program Stats," September 15, 2023 and "Prior Authorization and Pre-Claim Review Program Stats for Fiscal Year 2023," January 17, 2025.

https://www.kff.org/medicare/issue-brief/nearly-50-million-prior-authorization-requests-were-sent-to-medicare-advantage-insurers-in-2023/

Appeal of Denied Prior Authorization

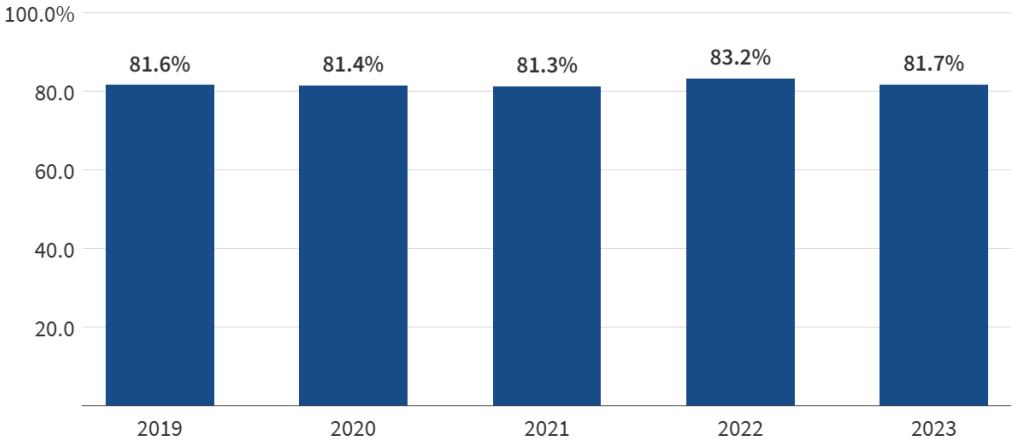
A Slightly Larger Share of Denied Prior Authorization Requests Was Appealed to Medicare Advantage Insurers in 2023 Than in Recent Years

Share of adverse and partially favorable prior authorization determinations that was reconsidered, 2019 - 2023



More Than 80% of Denied Prior Authorization Requests That Were Appealed Were Overturned

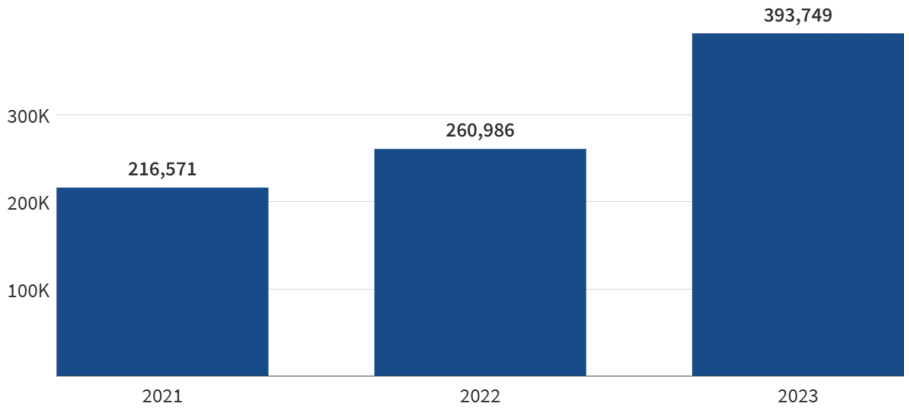
Share of reconsiderations that were fully or partially favorable, 2019 - 2023



Traditional Medicare - Prior Authorization

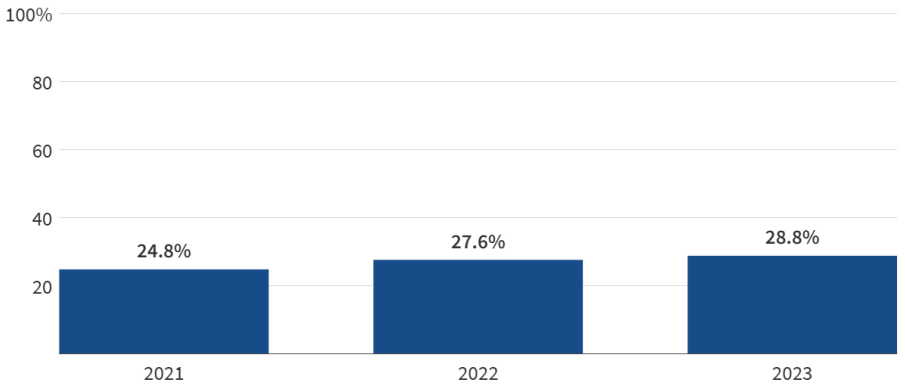
CMS Completed Just Under 400,000 Prior Authorization Reviews for Traditional Medicare in 2023

Reviews completed during the fiscal year



CMS Denied About One-Quarter of Prior Authorization Requests for Traditional Medicare

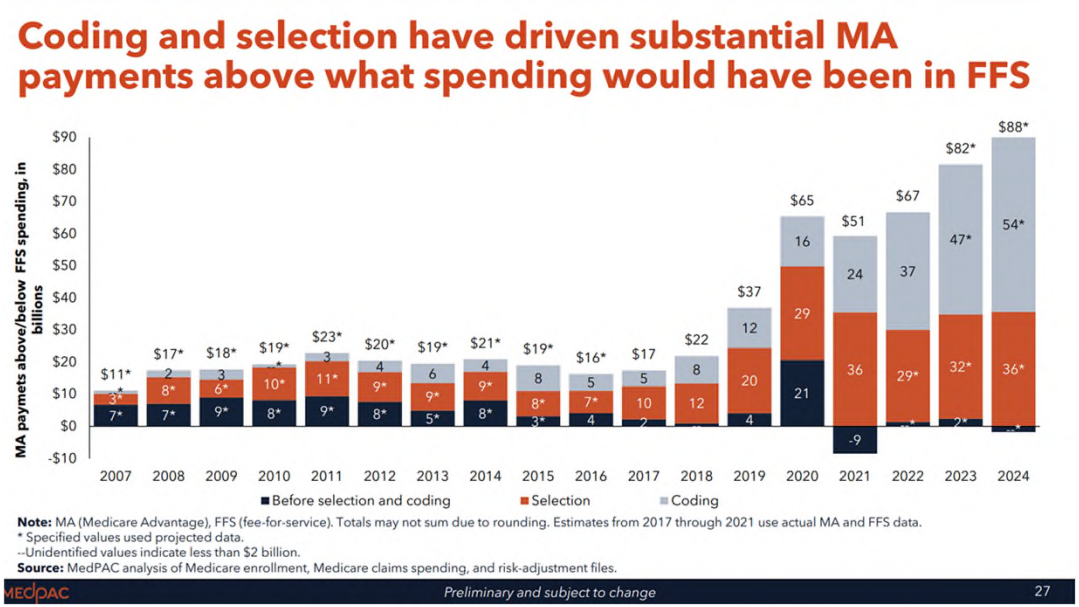
Share of reviews completed that were non-affirmed during the fiscal year



CMS, "Prior Authorization and Pre-Claim Review Program Stats," September 15, 2023 and "Prior Authorization and Pre-Claim Review Program Stats for Fiscal Year 2023," January 17, 2025.

https://www.kff.org/medicare/issue-brief/nearly-50-million-prior-authorization-requests-were-sent-to-medicare-advantage-insurers-in-2023/

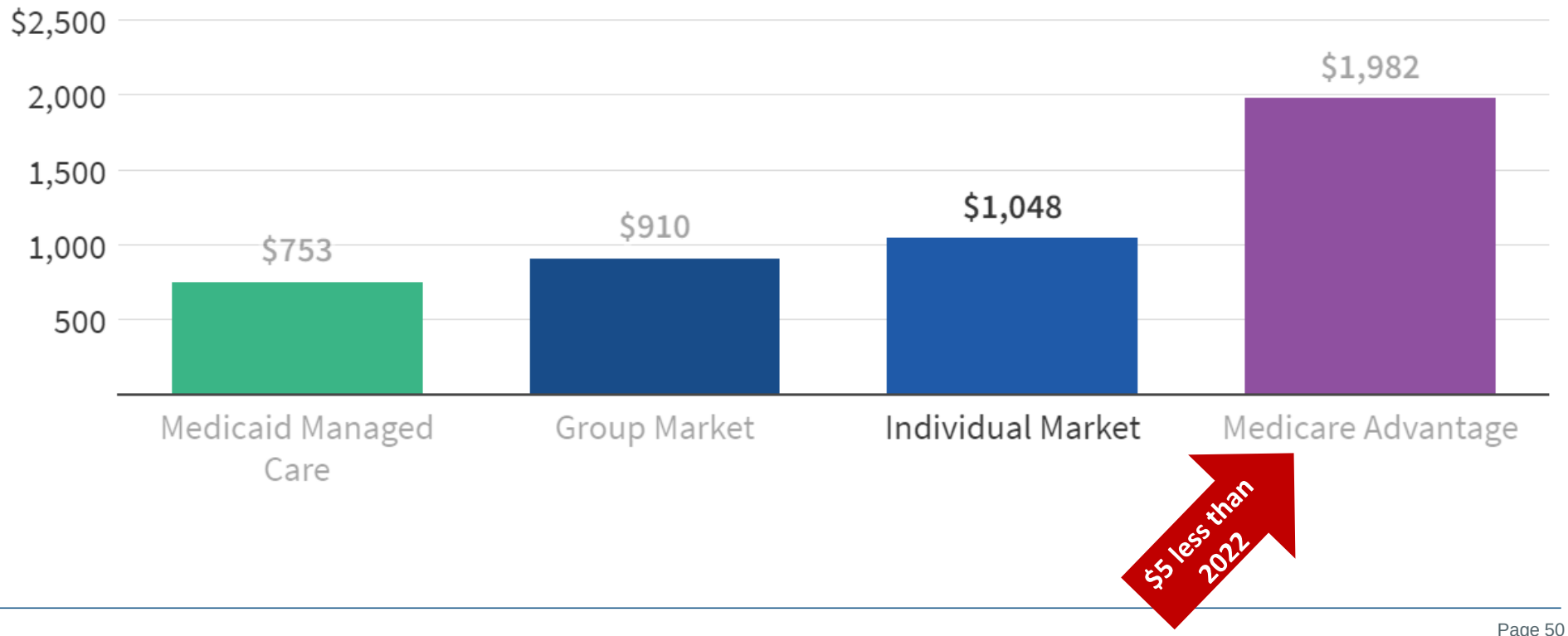
MedPAC 2024 MA Status Report



- Medicare spends approximately **22% more** for MA enrollees than if those same beneficiaries were enrolled in FFS
  - Equivalent to $83B in 2024
  - Some dollars are used for supplemental benefits and better financial protection for MA enrollees
  - Originally, risk-based payment for private plans set at 95% of FFS; averages 122% today

https://www.medpac.gov/wp-content/uploads/2023/10/MedPAC-MA-status-report-Jan-2024.pdf

Gross Margins Per Enrollee, 2023



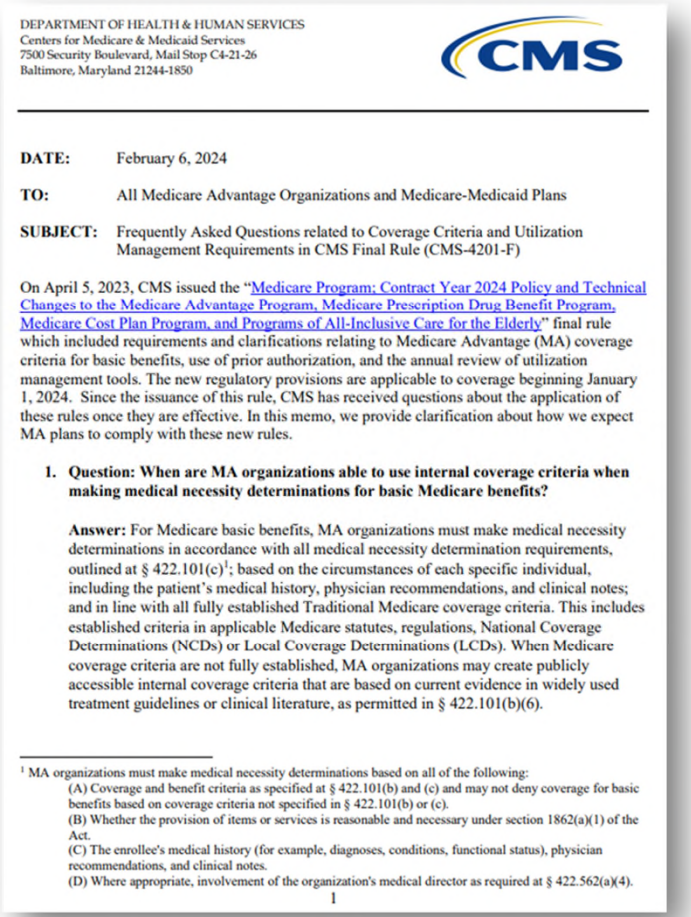
https://www.kff.org/medicare/issue-brief/health-insurer-financial-performance/

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

CMS

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).

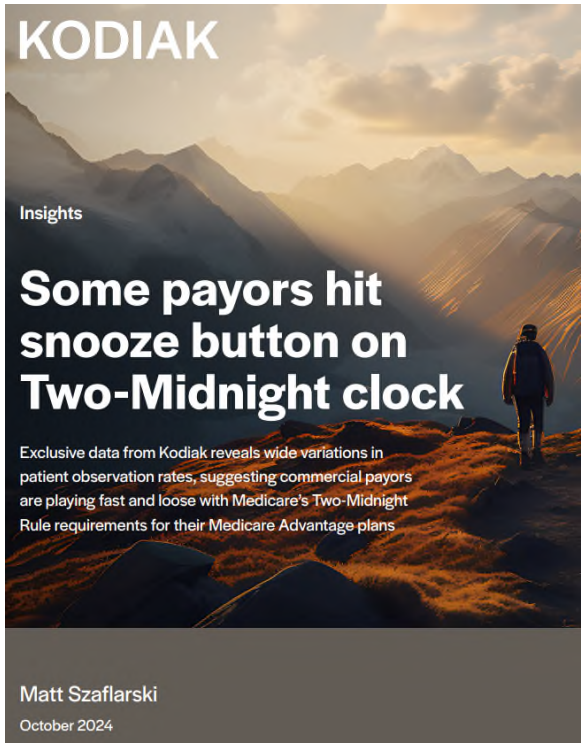
1

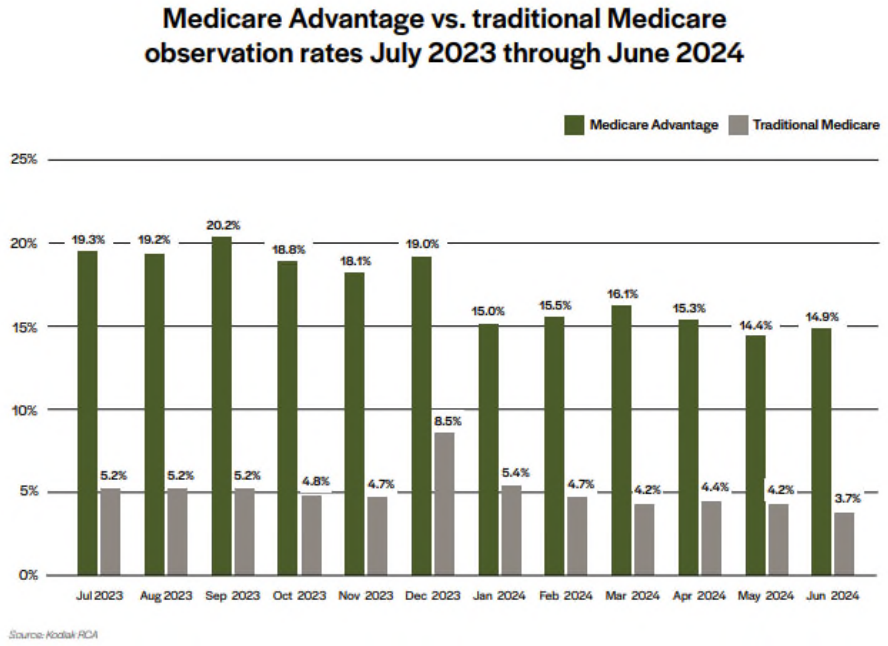
https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf

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

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

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

Coverage for OON Services

1. Ambulance services dispatched through 911 (or local equivalent) if other transport not reasonable
2. Emergency services
   - Apply prudent layperson definition of emergency medical condition (EMC) regardless of final diagnosis
3. Urgently needed services
   - Services required due to unforeseen illness, injury, or condition furnished to enrollee temporarily absent from plan's service area or for whom network provider temporarily unavailable/inaccessible if not reasonable to delay care
4. Post-stabilization care services (services related to EMC provided after enrollee is stabilized to maintain stabilized condition)
   - Administered within 1 hour of request to MA plan for pre-approval of services; administered after unsuccessful attempt to contact MA plan for pre-approval; plan rep and treating physician cannot agree on plan of care and plan physician not available for consultation
5. Renal dialysis services provided while enrollee temporarily outside plan's service area
6. Services for which MA plan denied coverage when such denial overturned on appeal

Payments to OON Providers

- For covered OON services, MA plan (both HMO and PPO) must pay amount provider would have received under traditional Medicare (a/k/a Medicare Rate)
  - Defined in CMS' MA Payment Guide for Out of Network Payments (4/15/2015 Update)
  - Enrollee's liability limited to amount enrollee would have paid if received services from network provider (vs. what traditional Medicare beneficiary would owe); otherwise, plan pays full amount
- For all other services –
  - If HMO plan (~36% of MA beneficiaries), enrollee must pay provider Medicare Rate
  - If PPO or HMO-POS plan (~64%), plan pays Medicare Rate less applicable co-insurance (up to MOOP limit); enrollee pays co-insurance amount; PA requirements apply
- Prompt payment rules
  - Must pay 95% of "clean claims" within 30 days; must pay interest on claims not paid in 30 days
  - Must pay/deny all other claims from non-contracted providers within 60 calendar days from date of request for payment

https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/oonpayments.pdf

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
  - 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

7. 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

New Requirements – January 1, 2025

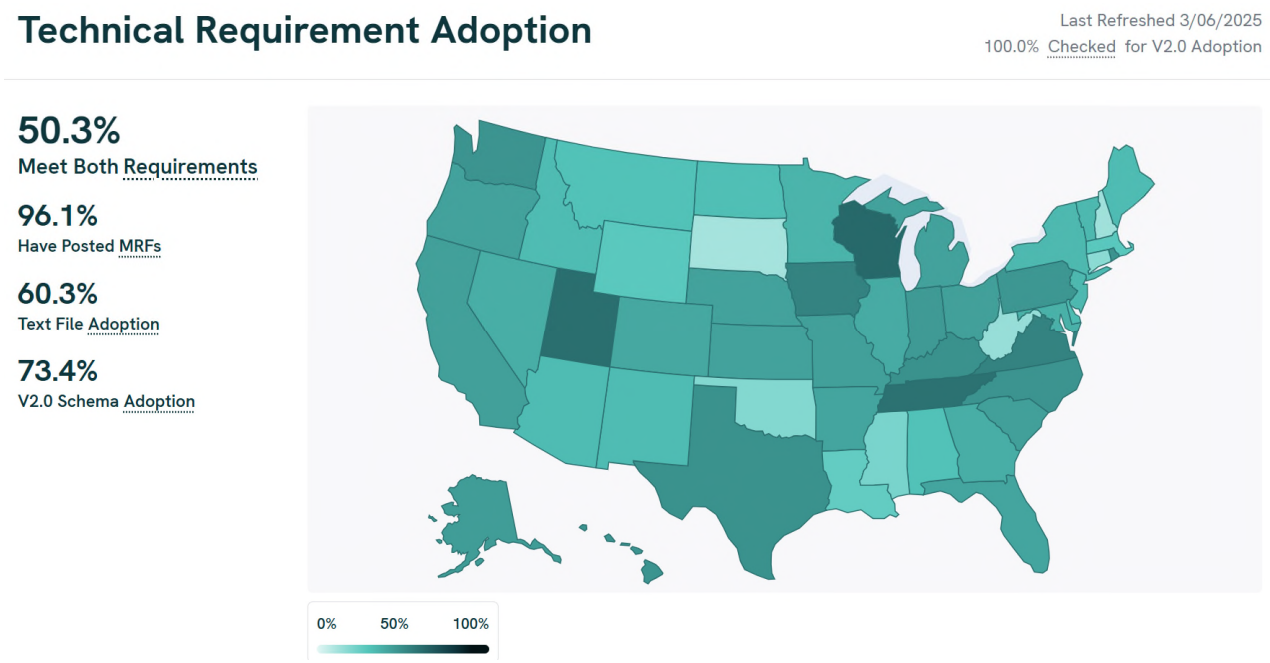
Report “estimated allowed amount” when payer negotiated rate based on algorithm or percentage

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

Current Compliance: Turquoise Health



For Maine, 43% of hospitals meet both requirements

73% have adopted text files and 50% have adopted V2.0 schema

https://turquoise.health/mrf_tracker

LOWERING COSTS FOR AMERICAN FAMILIES: When healthcare prices are hidden, large corporate entities like hospitals and insurance companies benefit at the expense of American patients. Price transparency will lower healthcare prices and help patients and employers get the best deal on healthcare.

DELIVERING ON PROMISES TO PUT AMERICAN PATIENTS FIRST: President Trump is delivering on his promise to once again put American patients first by holding the healthcare industrial complex accountable for delivering transparent prices.

https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-announces-actions-to-make-healthcare-prices-transparent/

8. 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

9. 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

10. 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**

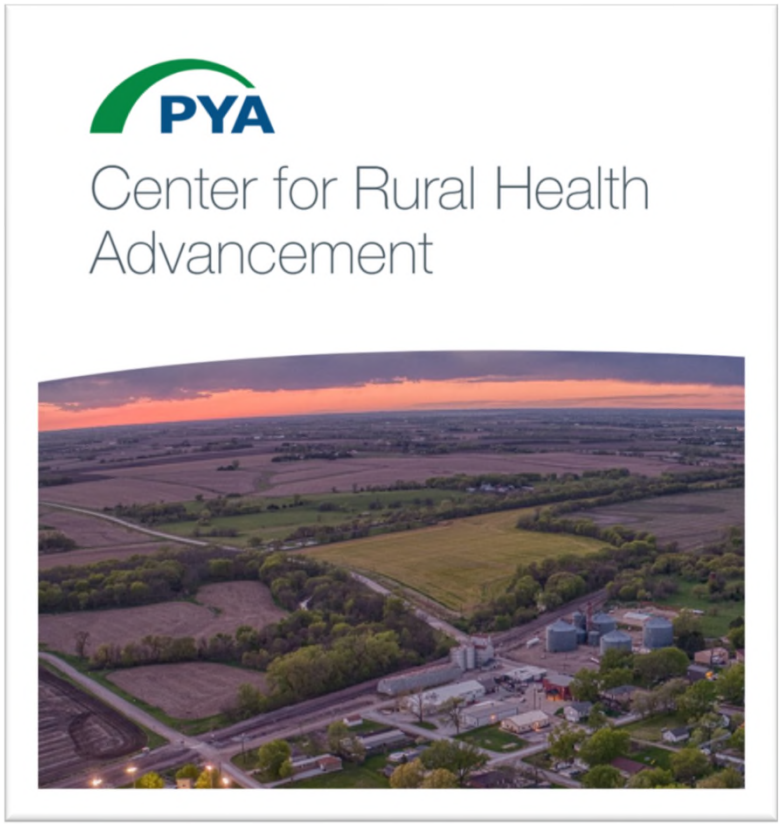
Weekly Reporting

- 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

PYA Healthcare Regulatory Roundup Webinar Series

Twice each month, PYA experts discuss the latest industry developments in our Healthcare Regulatory Roundup webinar series. In addition to straightforward explanations and actionable guidance, attendees can earn continuing professional education units in selected sessions.

- **HCRR #90 -** "Tightening Your Belt: Getting Ready for Site Neutral Payment Reform" | March 5, 2025
- **HCRR #89 -** "Proposed Changes to the HIPAA Security Rule" | February 26, 2025
- **HCRR #88 -** "Chronic Care Management and Remote Patient Monitoring" | February 12, 2025
- **HCRR #87 -** "Building Your Dream TEAM: How to Win at Episodic Payment Models" | January 30, 2025
- **HCRR #86 -** "The American Relief Act, 2025" | January 15, 2025



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.

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