

Federal Regulatory Update

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2022 SMALL & RURAL HOSPITALS ANNUAL MEETING



Agenda

1. CMS Annual Rulemaking Process
2. Rural Emergency Hospital Program
3. Price Transparency
4. End of the Public Health Emergency

1. CMS Annual Rulemaking Process

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Status Report

- 2023 Proposed Rules for Inpatient Rehab, Inpatient Psych, Hospice, SNF, and IPPS/LTCH published
 - Comment periods now closed
 - Final rules expected in August; effective October 1
- 2023 Proposed Rules for Home Health, ESRD, OPPS/ACS, and Physician Fee Schedule NOT released
 - No later than early July
 - Final rules expected in November; effective January 1

Highlights

- **Rural PPS hospitals**
 - Payment updates (incl. wage index)
 - Uncompensated care payments
 - Quality reporting program
 - Value-based purchasing programs
 - Potential non-renewal of LVH, MDH
- **Rural SNF/Non-CAH swing beds**
 - Payment updates (4.6% reduction)
 - Quality reporting program
 - Value-based purchasing program
 - Request for information – minimum staffing requirements
- **CAHs (including swing beds)**
 - Minor change to infection control CoP
 - More coming
- **RHCs**
 - Addressed in Physician Fee Schedule (including telehealth and virtual services)

Health Equity

- Addressed in every proposed rule
 - Measuring and reporting disparities
 - Adjustments to value-based purchasing programs
- IPPS/LTCH proposed rule
 - New quality reporting measures - commitment to health equity and screening for social risk factors
 - Z-codes and payment adjustments

2. Rural Emergency Hospital Program

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Timeline

- Authorizing legislation requires CMS to commence making payment for Rural Emergency Hospital (REH) services by January 1, 2023
- Still waiting on implementing regulations
 - Proposed rule entitled *Conditions of Participation (CoPs) for REH and Critical Access Hospital (CAH) COP Updates (CMS-3419)* at OMB for approval

Eligibility

- Current CAH or rural PPS hospital with 50 or fewer beds
 - Cannot re-open closed hospital as REH
 - Cannot establish *de novo* REH
 - One-time opportunity for reversion
- Located in state that provides for licensure of outpatient-only hospitals
 - Require legislative/regulatory changes?
- Approved by appropriate state agency as meeting standards established for such licensure

Services

- Must provide emergency department and observation services
 - Cannot exceed annual patient average of 24 hours in facility
- May provide additional hospital outpatient services identified by CMS as REH services
- May include distinct-part unit licensed as SNF to provide post-hospital extended care services
- Maintain status as provider-based rural health clinic

Conditions of Participation

1. Maintain transfer agreement with Level I or Level II trauma center
2. Meet staffing requirements
 - ED must be staffed 24/7
 - Physician, nurse practitioner, clinical nurse specialist, or physician assistant must be available to furnish services at facility 24/7
 - Satisfy staffing requirements and responsibilities specified in 42 CFR 485.631
3. Provide emergency services consistent with 42 CFR 485.618
4. Adhere to EMTALA requirements
5. Meet to-be-developed quality reporting requirements
6. Satisfy other requirements CMS deems necessary
7. Subject to SNF Conditions of Participation (if distinct-part unit)

Payment

- 105% applicable OPPS rate
 - SNF PPS rate for distinct-part SNF services (loss of swing bed cost-based reimbursement)
 - Ambulance fee schedule rate for REH-furnished service (loss of cost-based reimbursement if sole provider within 35 miles of facility)
 - Telehealth originating site
- Additional facility payment (same amount for all REHs)
 - Difference between total amount paid to all CAHs in 2019 and amount that would have been paid under PPS rates divided by total number of CAHs in 2019 (about 1,350)
 - Adjust annually by hospital market basket percentage increase
 - Required reporting on actual use of additional facility payment

Application Process

- Detailed transition plan listing services the facility will -
 - ✓ Modify
 - ✓ Retain
 - ✓ Discontinue
 - ✓ Add
- Description of emergency and observation services applicant will provide
- How applicant intends to use monthly facility payment
- Other information specified by CMS

Evaluating the REH Opportunity

- Board and community education and engagement
- Inpatient/outpatient outmigration analysis
- Opportunities for regional collaboration
- Operational and financial analyses

Modify

- Cost Structure
 - True staffing needs and consideration of severance costs (salaries and benefits)
 - Space planning and modernization addressing revised service offerings
 - Purchased service arrangements for professional and support services
- Service delivery approach
 - Transfer (placement) agreements
 - Necessary practitioners
 - Maximizing scheduling and patient throughput given time limitations
- Organizational Structure
 - Financing structure and bond documents
 - Governance aligned with modified patient care experience and community needs
 - Affiliations and clinical alliances

Retain

- Services
 - Required emergency department and observation services
 - Profitable outpatient services or services that build brand eminence – recapture outmigration
 - Services based on identified community need (e.g., cardiac rehab, substance abuse treatment) even if not “profitable”
- Staffing
 - Professional staff necessary to deliver required, retained, and expanded services
 - Support staff to continue essential services in an efficient manner
- Other
 - Favorable managed care contracts for agreed upon (continuing) patient care services
 - Service arrangements with favorable “buy versus make” analysis
 - Affiliations and clinical alliances necessary for REH operations

Discontinue

- Services
 - Inpatient Nursing services (other than observation)
 - Ancillary services more directly related to inpatient hospitalizations than outpatient care model
 - Less profitable services that don't contribute to brand eminence or required to meet community need
- Practitioners and professional staff
 - Arrangements with practitioners related to discontinued operations
 - Patient care staff related to discontinued operations
 - Support functions that can be out-sourced
- Other
 - Facilities not directly connected to continuing services
 - Contracts related to expansion of any inpatient services

Add

- Services
 - Profitable outpatient services for which there is identified need
 - Alignment with tertiary facility programs (e.g., cancer treatment)
 - Services with potential to build brand eminence
- Practitioners and professional staff
 - Arrangements with practitioners aligned to new service offerings
 - Patient care staff related to new operations
 - Resources necessary to ensure accurate and compliant billing and collection related to new services and payment delivery system
- Other
 - Equipment necessary for new services
 - New clinical alliances to capture more activity related to new service offerings

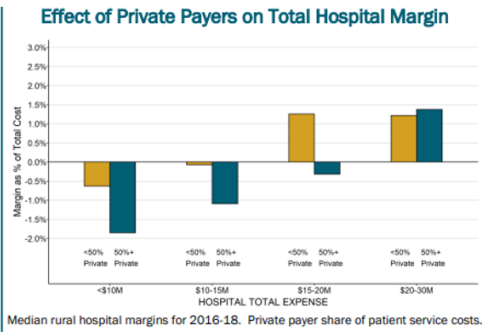
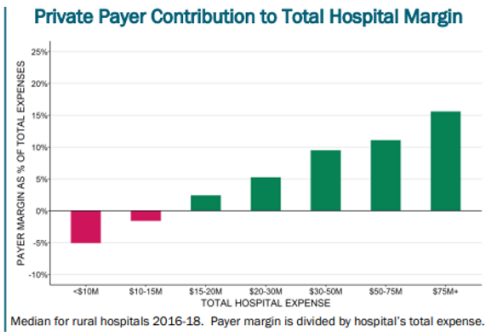
3. Price Transparency

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Posting Charges and Rates

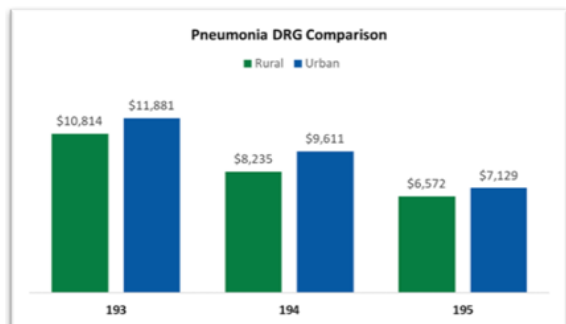
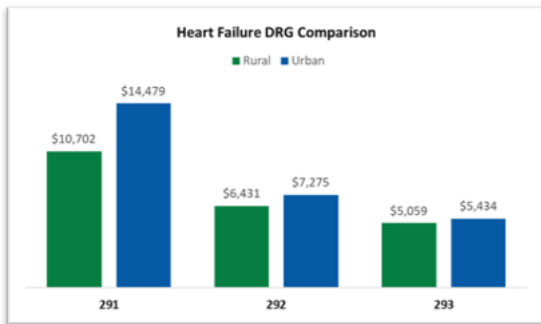
- Effective January 1, 2021, all hospitals (including CAHs) required to post (and update annually) actual charges and all payer-negotiated rates for all services in single machine-readable file
 - Each rate must be clearly presented with name of third-party payer and plan with which it is associated
- Penalties for non-compliance
 - Up to 30 beds: \$300/day up to \$109,500
 - 31 to 550 beds: 10 x number of beds/day

Private Payer – Historical Data

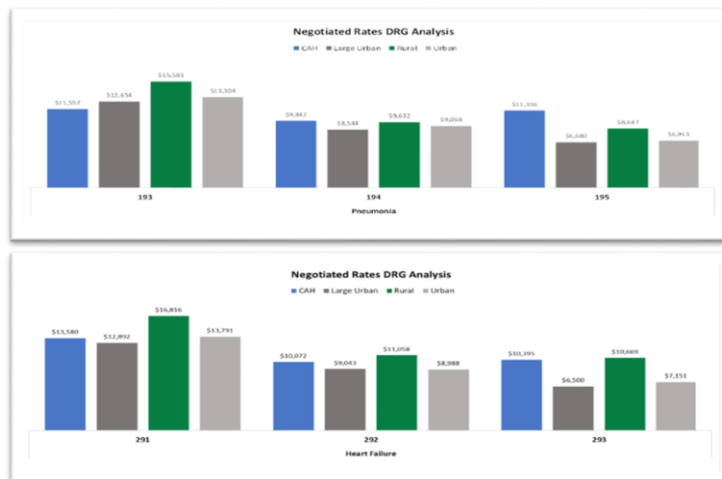


Center for Healthcare Quality and Payment Reform, Saving Rural Hospitals and Sustaining Rural Healthcare (September 2020), available at https://chqpr.org/downloads/Saving_Rural_Hospitals.pdf. Calculations derived from expense and revenue data in hospital cost reports filed with CMS.

Rural vs. Urban (Kansas)



Rural vs. Urban (Illinois)



Health Plan Price Transparency

- By July 1, 2022, health plans must post machine-readable files containing the following sets of costs for items and services
 - In-Network Rate File: rates for all covered items/services between plan and in-network providers
 - Allowed Amount File: allowed amounts for, and billed charges from, out-of-network providers
- By January 1, 2023, health plans must provide internet-based price comparison tool to provide estimate of individual’s cost-sharing responsibility for specific item/service from specific provider

4. End of the Public Health Emergency

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Medicare Telehealth Coverage

1. **Geographic** - Patient must reside in rural area
2. **Location** - Patient must be physically present at healthcare facility when service is provided (facility fee)
3. **Service** – Coverage limited to CMS' list of approved telehealth services (CPT and HCPCS codes)
4. **Provider** – Service must be provided by physician, non-physician practitioner, clinical psychologist, clinical social worker, registered dietician, or nutrition professional
5. **Technology** - Must utilize telecommunications technology with audio *and* video capabilities that permits real-time interactive communication.

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COVID-19 Coverage Expansion

- **CMS Interim Final Rules**

- Suspends certain *service* restrictions for duration of PHE
 - Expands list of covered services
 - Eliminates frequency requirements
 - Permits use of telehealth for required face-to-face visits, direct supervision for incident-to billing, teaching physician presence
- Suspends certain *provider* restrictions for duration of COVID-19 PHE
 - Waives Medicare state licensure requirement (but not state law requirements)
 - Permits therapists and S/L pathologists to provide covered services via telehealth
 - Permits FQHCs and RHCs to bill for telehealth services under HCPCS G2025
 - Permits billing for hospital outpatient department and critical access hospital (Method 1 billing) services furnished via telehealth
- Authorizes payment for certain *audio-only* E/M services (CPT 98966-68, 99441-43)
- Provides reimbursement for telehealth services at higher non-facility rates to compensate practices for telehealth-associated costs

COVID-19 Coverage Expansion

- **Other Agencies' Actions**

- Office of Civil Rights Notice of Enforcement Discretion - Will not impose penalties if, in good faith, use any non-public remote audio/visual communication product
- Office of Inspector General Notice of Enforcement Discretion– Permits waiver of co-insurance
- Drug Enforcement Administration – Use of telehealth for in-person medical evaluation prior to prescribing scheduled II – V controlled substances

Tele-Behavioral Health

- Consolidated Appropriations Act, 2021 – eliminate geographic and location restrictions for diagnosis, evaluation, and treatment of mental health disorder
- Must have in-person, non-telehealth service by practitioner in same practice as billing practitioner within 6 months prior to initial telehealth service + each 12 months thereafter
 - Exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with reason documented in beneficiary's medical record)
- May use audio-only communication technology (vs. audio/video required for other telehealth services) but only if
 - Practitioner has audio/video capability + beneficiary lacks capacity or refuses to use video connection
 - Documented in medical record + include service-level modifier on claim

Telehealth Flexibility Extensions

- For 151 days post-PHE
 - ✓ Continuation of waiver of geographic and location requirements
 - ✓ Continuation of reimbursement for therapist and S/L pathologist telehealth services
 - ✓ Continuation of reimbursement for audio-only services
 - ✓ Continuation of FQHCs and RHCs for telehealth services
 - ✓ Continuation of use of telehealth to recertify eligibility for hospice case
 - ✓ Delay in in-person requirement for initiation of tele-behavioral health services

Waivers and Flexibilities

- Under SSA Section 1135, HHS can modify or waive certain Medicare, Medicaid/CHIP, and HIPAA requirements during a declared PHE to ensure beneficiary access to care
 - Expand capacity
 - Reduce regulatory burden
- Under this authority, HHS has modified or waived nearly 200 federal regulatory requirements during COVID-19 PHE
- Under separate statutory authority, HHS has approved changes to state Medicaid plans; these remain in effect unless state requests termination

Preparing to Unwind

- Capacity
 - Return all facilities to pre-PHE operations (i.e., modifications made for surge capacity and patient quarantine)
- Regulatory burden – return to “old” normal
 - E.g., verbal orders, medical records, nursing plan of care, respiratory care, CRNA supervision, utilization review, QA/PI, advance directives, information sharing during discharge planning



COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS's regional offices.**

Flexibility for Medicare Telehealth Services

- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.
- **Audio-Only Telehealth for Certain Services.** Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

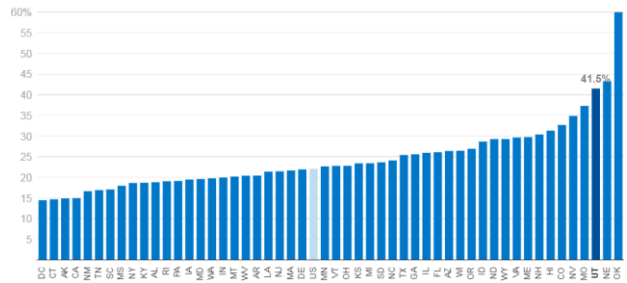
www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

Medicaid Continuous Coverage

- As condition of receiving 6.2% increase in FMAP, states agreed to continuous coverage requirement
 - Cannot disenroll from Medicaid unless individual requests disenrollment, moves out of state, or dies
- Medicaid/CHIP enrollment increased by 13.6 million (19.1%) between 02/20 to 09/21
 - State enrollment growth ranged from 12.6% to 48.7%
 - Illinois = 25.9%

Enrollment From February 2020 To January 2022 Has Increased In Every State.

Cumulative Percent Change In Medicaid/CHIP Enrollment From February 2020 Through January 2022 By State



Renewal and Disenrollment

- Following end of PHE, states have up to 12 months to return to normal eligibility and enrollment operations
 - Initiate renewals for *all* beneficiaries through automated processes, sending renewal notices and requests for information
 - Incentives created by end of FMAP increase
- Anticipate *significant* disruption in Medicaid coverage, despite CMS' guidance encouraging smooth transition to other coverage (e.g., marketplace)
- Anticipate corresponding increase in uncompensated care, disruption in ongoing treatment

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