



HEALTHCARE REGULATORY ROUND-UP - Episode #28

Rulings and Rules: The Latest Healthcare News

July 6, 2022

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WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Introductions



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Agenda

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2. Home Health Proposed Rule
3. ESRD Proposed Rule
4. Rural Emergency Hospital and Critical Access Hospital Conditions of Participation Proposed Rule
5. Transparency in Coverage
6. Long-Term Care Facilities
7. Enhancing Oncology Model
8. HHS Request for Information – Primary Care
9. OCR Guidance
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1. Court Decisions

1. American Hospital Association v. Becerra (340b)
2. Becerra v. Empire Health Foundation (hospital DSH payments)
3. Marietta Memorial Hospital Employee Health Benefit Plan v. Davita, Inc. (health plan carve-outs)
4. Dobbs v. Jackson Women’s Health Organization (federal constitutional right to abortion)
5. Ruan v. United States (physician liability for opioid prescribing)
6. West Virginia v. EPA (major-questions doctrine)
7. City of Huntington v. AmerisourceBergen Drug Corporation (drug distributor liability for opioid damages)

1. American Hospital Association vs. Becerra (340b)

- Initial reduction to payments in 2018
 - From ASP + 6% to ASP – 22.5%
 - Applied in budget neutral manner, increasing base rate by 1.38% for all providers
- Decision addresses reduction for 2018 and 2019
- Court focused on failure of CMS to follow statute for setting rates
 - Base reimbursement on hospitals' average drug acquisition costs after doing a survey OR
 - Base reimbursement on ASP charged by manufacturers
- Court sided with AHA/providers
- Question of next steps? Winners and Losers?

2. Becerra vs. Empire Health Foundation (hospital DSH payments)

- Question is determination of Medicare fraction for disproportionate share purposes
 - $\text{DSH Patient Percent} = (\text{Medicare SSI Days} / \text{Total Medicare Days}) + (\text{Medicaid, Non-Medicare Days} / \text{Total Patient Days})$
 - Medicare days = total Medicare inpatient days
 - HHS determined this included patients eligible for Medicare, even if Medicare did not cover all/some of their stay (90-day cap on inpatient hospital services)
- Supreme Court determined the formula used by HHS to calculate DSH payments was interpreted properly in its implementation

3. Marietta Mem. Hosp. Employee Health Benefit Plan vs. Davita, Inc. (health plan carve-outs)



- Under federal statute, employee health plan “may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan”
- Employer plan made all outpatient dialysis providers out-of-network to encourage employees to move to Medicare
- Supreme Court ruled that because plan provided same outpatient dialysis benefits to individuals with and without ESRD it did not violate federal law
 - Otherwise, plans would be required to maintain some minimum level of benefits for outpatient dialysis, which Congress did not intend
- Other carve-outs to limit employer liability? Impact on federal programs?

4. Dobbs vs. Jackson Women's Health Organization (federal constitutional right to abortion)

- Supreme Court overturned Roe v. Wade; right to abortion is not deeply rooted in our history (or integral part of broader right that is so rooted) and thus not constitutionally protected
- States may now regulate abortion to the extent such regulation serves legitimate interests, including “respect for and preservation of prenatal life at all stages of development”
- What's ahead...
 - Application of dormant and trigger laws
 - State constitutional protections
 - New state laws
 - Regulation of travel between states

5. Ruan vs. United States (physician liability for opioid prescribing)

- Controlled Substances Act permits prescription for controlled “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice”
- Apply objective vs. subjective standard to determine practitioner’s criminal liability for prescribing practices
- Supreme Court ruled unanimously that government must prove practitioner had criminal intent in prescribing controlled substances

6. West Virginia vs. EPA (major-questions doctrine)

- Challenge to regulations to curb power plants' carbon emissions issued under Section 7411 of the Clean Air Act that authorizes EPA to determine “best system of emission reduction” for buildings that emit air pollutants
- Supreme Court ruled EPA violated major-questions doctrine, i.e., federal agency cannot make “decisions of vast economic and political significance” absent express Congressional authority
- Future application of major-questions doctrine to healthcare regulations?
 - Challenges to Medicare reimbursement? Price transparency? HIPAA Privacy and Security? Medicaid funding? Stark law regulations? Others?
 - Chilling effect on agencies' regulatory agenda? (e.g., drug manufacturers)

7. City of Huntington v. AmerisourceBergen Drug Corp. (drug distributor liability for opioid harm)



- City and county opted out of settlements to pursue lawsuits against drug distributors for opioid-related damages under state's public nuisance statute
- Following bench trial, federal judge ruled distribution or sale of product does not constitute public nuisance (vs. conduct interfering with public property or resources)
- Impact on future opioid-related litigation and settlements?

2. Home Health Proposed Rule

- Posted June 23; comments due August 16
- Proposed rate reduction of 4.2% for CY2023
 - -\$810 million compared by CY2022
 - Despite 2.9% payment update
 - Permanent -7.69% adjustment to rate to ensure aggregate expenditures under PDGM system are equal to what would have been spent under prior payment system
- Proposes permanent 5% cap on wage index decreases
- Proposes to use CY2021 data to recalibrate PDGM case mix weights
- Proposes data collection on use of telehealth

3. ESRD Proposed Rule

- Posted June 28; comments due August 22
- Proposed rate increase of 3.1% for CY 2023
 - Proposed base rate = \$264.09 (currently \$257.90)
- Proposed labor share of 55.2%
- Proposed permanent 5% cap on wage index decreases
- Would update outlier threshold using 2021 claims data
- ESRD QIP – certain measures will continue to be collected but not scored due to PHE

4. REH/CAH Conditions of Participation (July 13 webinar)

- Posted June 30; comments due August 29
- REHs
 - REH payment provisions and quality reporting requirements addressed in yet-to-be-released OPPS proposed rule
 - Proposes CoPs similar CAH CoPs with minor modifications (e.g., credentialing of telehealth providers)
- CAHs
 - Calculation of distance from other hospital
 - Patient rights – notification of rights; privacy and safety; confidentiality of patient records; use of restraints and seclusion; patient visitation
 - Unified and integrated infection prevention and control and antibiotic stewardship program and quality assessment and performance improvement program for multi-facility system

5. Transparency In Coverage

- Effective July 1, 2022
 - Had been delayed since January 2022
- Posting of machine-readable files by health plan
 - Uses standard data collection format required by CMS (JSON)
 - Disclosure of in-network provider rates and out-of-network allowed amounts
- \$100 per day fine for non-compliance
- 2023: internet-based price comparison tool
 - Would allow consumer to receive estimate of cost-sharing obligation

6. Surveyor Guidance for Long-Term Care Facilities

- Imposes requirements on state surveyors for timely investigations of reported abuse and neglect
- Addresses surveyor use of Payroll Based Journal staffing data to confirm compliance with nurse staffing requirements (pending publication of new minimum staffing regulations)
- Requires facilities to have part-time on-site Infection Preventionist with specialized training to oversee infection prevention and control program
- Urges facilities to limit rooms to single or double occupancy
- Addresses rights of and behavioral health services for individuals with mental health needs and substance use disorders (staff training, use of non-pharmacological interventions)

7. Enhancing Oncology Model

- Announced by CMMI on June 27; applications due September 30
 - RFI and related materials available at <https://innovation.cms.gov/innovation-models/enhancing-oncology-model>
- Voluntary payment model for oncology practices involving episodes of systemic chemotherapy administration to patients with breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer
 - Implement required participant re-design activities (supported with optional Monthly Enhanced Oncology Services payment)
 - Opportunity to earn retrospective performance-based payment (total cost of care below benchmark + quality scores) or owe performance-based recoupment

8. HHS Request for Information – Primary Care



- Published by Office of Assistant Secretary for Health (OASH) on June 27; responses due August 1
- HHS Initiative to Strengthen Primary Health Care
 - “Delineate specific actions that HHS agencies and offices may take ... within the current legislation and funding environment.”
- OASH “seeks information about successful approaches and innovations that improve primary health care payment, delivery models, education, training and well-being, digital health and primary care measurement and research”

9. OCR Guidance

- Use Remote Communication Technologies for Audio-Only Telehealth (June 13)
 - HIPAA compliance for audio-only telehealth once Notice of Enforcement Discretion no longer in effect
- Disclosures of Information Relating to Reproductive Health Care (June 30)
 - Disclosures required by law, for law enforcement purposes, to avert a serious threat to health or safety
- Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet (June 30)
 - Reminder – HIPAA only applies when PHI is created, received, maintained, or transmitted by covered entities and business associates
 - Advice - How to keep data about location/activity on personal devices private

Available at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/index.html>

10. Still Waiting....

- CY2023 Medicare Physician Fee Schedule Proposed Rule
 - Conversion factor, E/M, telehealth, virtual services, MSSP, etc.
- CY2023 Medicare Hospital Outpatient PPS/ASC Proposed Rule
- FY2023 Final Rules (Inpatient Rehab, Inpatient Psych, SNF, Inpatient PPS)
- Notice Regarding Requirements Related to Advanced Explanation of Benefits
- Final Rule - Requirements Related to Surprise Billing, Part 2



Our Next Health Care Regulatory Round-Up:

Rural Emergency Hospital Program/New CAH CoPs

July 13, 2022



2022 Summer CPE Symposium What's Hot in Healthcare



JULY 27 & 28 • 11AM – 3:15PM ET

- Summer 2022 Audit & Assurance Updates
- Medicare Margin & Reimbursement Drivers
 - Single Audits and COVID-19
 - Pricing Transparency: Using the Data
 - Total Costs of IT
 - Stark Law Value-Based Exceptions
- Clinical Trials Program - New or Expanded Service Line





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