

Legal and Regulatory Grab Bag - Topics on Everyone's Mind!

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Learning Objectives

- Learn about recent legal and regulatory developments in areas affecting health care finance and operations
- Understand the basic provisions and impacts of such developments
- Receive suggestions and takeaways from each development covered

TAX-EXEMPTION



- Financial Assistance (501r) continues to be in the news
 - Congressional committee hearings –
 - Community benefit commensurate with tax savings
 - Specify types of activities that qualify as a community benefit
 - Revisions to the Form 990 to make community benefits clearer
 - House Democrats –
 - Asked the IRS for new 501(r) regulations and guidance
 - Asked for Revenue Rulings clarifying that hospitals are expected to provide charity care commensurate with financial resources
 - Proposed legislation - Non-Profit Hospital Tax Exemption Transparency Act (H.R. 9080)
 - Required financial assistance threshold

- Executive Compensation

- Senate Committee on Health, Education, Labor & Pensions – Majority Staff Report – “Executive Charity – Major Non-Profit Hospitals Take Advantage of Tax Breaks to Prioritize CEO Pay Over Helping Patients Afford Medical Care”
- Continue to take advantage of the rebuttable presumption of reasonableness (follow Executive Compensation policies)
- Consider levels and amounts of charity care when setting executive compensation

MANAGED CARE CONTRACTING



Financial Impact of Payer Relationships

Hospital Revenues by payer type:

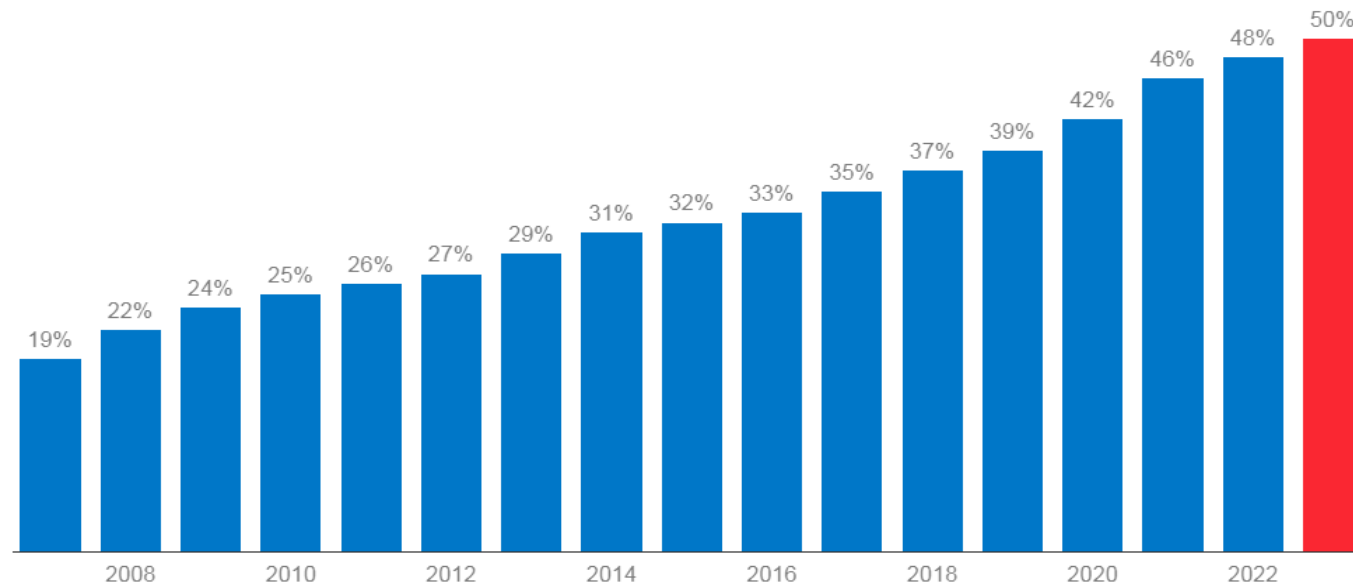
- Private/Self-Pay: \$759 billion (56.5% of total)
- Medicare: \$178 billion (18.9% of total)
- Medicaid: \$141 billion (13.5% of total)

Financial Impact of Payer Relationships (cont.)

Figure 1

Half of All Eligible Medicare Beneficiaries Are Now Enrolled in Private Medicare Advantage Plans

Medicare Advantage Enrollment as a Share of the Medicare Part A and B Population, 2007-2023



NOTE: Includes Medicare Advantage plans: HMOs (including POS), PPOs (local and regional), PFFS, and MSAs. Excludes cost plans, PACE plans, HCPPs, and MMPs. About 59.82 million people are enrolled in Medicare Parts A and B in January 2023.

SOURCE: KFF analysis of CMS Medicare Advantage Enrollment Files, 2007-2023; Medicare Chronic Conditions (CCW) Data Warehouse from 5 percent of beneficiaries, 2007-2017; CCW data from 20 percent of beneficiaries, 2018-2020; and Medicare Enrollment Dashboard 2021-2023. • PNG

Protections in Contracting

- Governing laws
- Every market and every health plan presents unique challenges
- Generally, most health plans provide “template” agreements that are one-sided
- Goal is to negotiate terms to (mostly) get what you want

Managed Care Negotiation Tips

- Definition of “Clean” Claims
- Timely Filing
- Termination
- Automatic Amendment Provisions
- Timeline to Submit Appeals (including levels of appeal)
- Arbitration Clauses
- Mutual Indemnification

Artificial Intelligence





REGULATORY

HHS pushes forward with new requirements for AI transparency, interoperability

By Heather Landi · Dec 13, 2023 1:28pm

Office of the National Coordinator for Health IT (ONC)

Interoperability

Artificial Intelligence

Clinical Decision Support



<https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>

Advances in AI

AI Tools May Detect Heart Valve Disease, Predict Cardiovascular Risk

Two studies to be presented at the AHA's Scientific Sessions show that AI and deep learning may be capable of flagging heart disease and cardiovascular event risk.



How AI Is Changing Medical Imaging to Improve Patient Care

New A.I. Tool Diagnoses Brain Tumors on the Operating Table

A new study describes a method for faster and more precise diagnoses, which can help surgeons decide how aggressively to operate.

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AI Links Sleep and Gut Health to Autism Behaviors

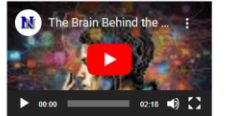
[Autism](#) [Featured](#) [Neuroscience](#) · November 6, 2023

Summary: Researchers utilized AI to uncover a link between sleep and gastrointestinal health, and the challenging behaviors in individuals with profound autism, such as self-injury and aggression.

The study, which offers new insights into predicting these behaviors, found that for 20% of the subjects, GI issues could forecast next-day behavioral challenges with over 80% accuracy. Sleep quality was also a significant factor.

These findings could help caregivers better anticipate and manage these behaviors, enhancing care for those with autism.

Neuroscience Videos



Latest Neuro News

FORBES > INNOVATION > HEALTHCARE

ChatGPT And Depression: Exploring AI's Role In Mental Health Care

William A. Haseltine Contributor

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Nov 3, 2023, 11:49am EDT

AI Use Cases

Efficiency and automation	Data analysis
Improved patient interaction	Telehealth support
ChatGPT for scheduling appointments	AI in medical imaging
Electronic billing	Mental health support

Executive Order on Safe, Secure & Trustworthy Artificial Intelligence



- ✓ Establishes foundational definitions
- ✓ Identifies certain risks
- ✓ Mandates new safety assessments, equity and civil rights guidance and research on AI's impact on the labor market
- ✓ Builds on voluntary commitments the Biden Administration previously secured from leading AI companies
- ✓ Represents the first major binding federal government action re AI

What To Do Now?

- Educate yourself on AI
- How can AI best serve your organization?
- How does AI fit into your existing analytical tools?
- Create risk and legal frameworks that govern the use of AI at your organization

What To Do Now?

- Risk mitigation strategies
- Require vendors to demonstrate how they are safeguarding information when using AI
- Policies and procedures on how to address and implement resources that use AI

Cybersecurity & Information Technology Issues





The image is a screenshot of a news article from CNN. At the top, there is a navigation bar with the CNN logo and various regional links: World, Africa, Americas, Asia, Australia, China, Europe, India, Middle East, and United Kingdom. Below the navigation bar, the article's breadcrumb is "World / Asia". The main headline is "Finance worker pays out \$25 million after video call with deepfake 'chief financial officer'". Below the headline, the author information reads "By Heather Chen and Kathleen Magramo, CNN", followed by "2 minute read · Published 2:31 AM EST, Sun February 4, 2024". There are social media sharing icons for Facebook, X, Email, and a generic link icon. The main image of the article shows a person's hands typing on a laptop keyboard in a dimly lit room with blue lighting.

World / Asia

Finance worker pays out \$25 million after video call with deepfake 'chief financial officer'

By Heather Chen and Kathleen Magramo, CNN
2 minute read · Published 2:31 AM EST, Sun February 4, 2024

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The New York Times

Cyberattack Paralyzes the Largest U.S. Health Care Payment System

The hacking shut down the nation's biggest health care payment system, causing financial chaos that affected a broad spectrum ranging from large hospitals to single-doctor practices.



Cybersecurity

Cyberattack on Change Healthcare brings turmoil to healthcare operations nationwide

April 17 update: UnitedHealth Group says it expects to incur at least \$1 billion in costs this year as a result of the attack.



Nick Hut

Some Good News?

US indicts North Korean hacker accused of helping extort US hospitals

By Sean Lyngaas, CNN

🕒 2 minute read · Published 2:27 PM EDT, Thu July 25, 2024



Ad Tracking



**U.S. Department of
Health and Human Services**

Enhancing the health and well-being of all Americans

Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates

On March 18, 2024, OCR updated this guidance to increase clarity for regulated entities and the public.

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is issuing this Bulletin to highlight the obligations of Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities¹ and business associates² (“regulated entities”) under the HIPAA Privacy, Security, and Breach Notification Rules (“HIPAA Rules”) when using online tracking technologies (“tracking technologies”).³ OCR administers and enforces the HIPAA Rules, including by investigating breach reports and complaints about regulated entities’ noncompliance with the HIPAA Rules. A regulated entity’s failure to comply with the HIPAA Rules may result in a civil money penalty.⁴

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

AHA v. Becerra

OCR Online Tracking Technology Guidance Set Aside by Texas Federal Court



On Thursday, June 20, a Texas federal court judge **ruled** that HHS' Online Tracking Technology Guidance, first released in December of 2022 and **later modified in March 2024** is unlawful. This article covers that guidance and why the court found that HHS issued the online tracking technology guidance beyond the scope of its authority.

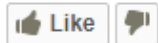
Information Blocking

Healthcare providers face Medicare payment-rate penalties for information blocking under new rule

In an accommodation, the HHS Office of Inspector General says it will not investigate any act of information blocking alleged to have occurred before July 31 of this year.



Nick Hut



July 3, 2024 10:11 am



CHEVRON DECISION



Chevron Background

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc

- Nearly 20,000 judicial opinions
- 2016 last time SCOTUS applied Chevron

Now....

Loper Bright Enterprises v. Raimondo Relentless, Inc. v. dept. of commerce

- June 28, 2024, SCOTUS issued a 6–3 decision striking down Chevron deference

Chevron Impact on Health Care

- Increased litigation
- More detailed rulemaking
- Alternative methods of enforcement (contracts with MCOs, etc.)

Chevron Likely Issues

- Coding reimbursement under the Medicare Act
- Key provisions of CMS's guidance implementing the Medicare Drug Price Negotiation Program established under the Inflation Reduction Act
- Pending rulemaking governing the Medicaid Drug Rebate Program
- Disputes regarding Medicare reimbursement, including the often-litigated issue of disproportionate share (DSH) payments for hospitals
- Recent regulatory changes to the marketing rules for Medicare Advantage and Part D Plans
- Medicare and Medicaid coverage disputes

PROVIDERS

Hackensack Meridian Health cites Chevron's demise in new lawsuit over DSH pay formula

By **Dave Muoio** · Jul 2, 2024 4:00pm

Questions?

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