2024 Health Law Seminar

July 24, 2024

Lathrop GPM

Welcome

Jennifer Reedstrom Bishop, Lathrop GPM

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CLE QR Code

Health Regulatory Update: Year in Review

Jesse Berg, Lathrop GPM

Agenda

- What's happening in enforcement?
  - Statistics, interesting enforcement actions, new (and old) targets, updated compliance guidance
- Health related social needs & social determinants of health
- Behavioral health changes
- Value-based programs
- Survey & certification & accreditation
- 340B developments; provider-based rule; lab developed tests
- Payment transparency
- Provider enrollment
- Various payment updates (Physician Fee Schedule, telehealth, split shared billing)

Enforcement Developments

DOJ's FCA Recovery Statistics for 2023

- Record year for DOJ (recoveries exceeded $2.6 billion)
  - 543 settlements/judgments (**most** in history)
- Self-initiated investigations way up (from 305 to 500)
- Third highest number of new qui tams (712) filed
- Continued emphasis and recoveries related to alleged health care fraud
- +/- $1.8B in health care recoveries
- Recoveries since 1986, when FCA was substantively amended, now total **more than $75 billion**.

	2022	2023	Increase
Settlements	351	543	55%
Recoveries	$2.2B	$2.68B	20%

OIG Numbers

At-a-Glance Highlights for Fiscal Year 2023

Statistic	FY 2023 (10/1/2022-9/30/2023)
Audit Reports Issued	127
Evaluations Issued	42
Expected Audit Recoveries	$283.5 million
Questioned Costs	$51.5 billion
Potential Savings	$47.2 million
New Audit and Evaluation Recommendations	464
Recommendations Implemented by HHS O Divs	493
Expected Investigative Recoveries	$3.16 billion
Criminal Actions	707
Civil Actions	746
Exclusions	2,112

OIG Numbers

- Hotline reported expected recoveries of **$117,939,623** as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (10/1/2022–3/31/2023)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	84,536
Total tips evaluated	36,244
Tips referred for action	21,740
Closed; no basis provided for further action	1,950
Closed; no HHS violation	537
Closed; other administrative reason	12,017

Sources of Tips Referred for Action

Phone	8,117
OIG website	11,645
Letters or faxes	835
Other	1,143

Stark Law / Anti-kickback Statute

- October 2023 settlement with mobile cardiac PET scan provider Cardiac Imaging Inc. and its CEO
  - $75 million + additional amounts based on revenue to be paid by company
  - $10.5 million to be paid by CEO
  - Alleged violations of AKS and Stark Law:
    - Payments to cardiologists for supervising scans of cardiologists' patients exceeded fair market value because cardiologists were not always available or on-site
    - Cardiologists were paid for services not actually provided
    - Company claimed to rely on consultant's FMV analysis that US alleged was premised on fundamental inaccuracies regarding services provided and that consultant withdrew
  - Corporate Integrity Agreement
  - Relator was former billing manager of testing company
  - February 2024 – complaint filed against another co-owner defendant
- https://www.justice.gov/opa/pr/mobile-cardiac-pet-scan-provider-and-founder-pay-85-million-resolve-allegedly-unlawful

Stark Law / Anti-kickback Statute

- Community Health Network entered into $345 million settlement and CIA in December 2023
  - Largest FCA/Stark Law recovery in history
  - *Qui tam* had been filed by CHN's former CFO, who will pursue additional claims in which DOJ did not intervene.
- Settlement resolved allegations that:
  - CHN offered physicians CHN offered physicians substantially higher salaries than in private practice in order to capture their "downstream referrals"
  - Incentive compensation was based on hitting referrals targe
  - Despite use of valuation firms to review compensation plans:
    - CHN provided incorrect information to valuation consultants
    - CHN disregarded opinions that valuation exceeded FMV
- https://www.justice.gov/usao-sdin/pr/community-health-network-agrees-pay-345-million-settle-alleged-false-claims-act

Stark Law / Anti-kickback Statute

- *United States ex rel. Goldsholl v. Covenant Healthcare System, et al.*, No. 12-15422 (E.D. Mich.) – Regional hospital system and 2 physicians paid over $69 million in 3 related settlements to resolve allegations that they shared improper financial relationships with 8 referring physicians and investment groups that failed to satisfy Stark Law/AKS exceptions
- ChristianaCare $42.5 million settlement (December 2023)
  - *Qui tam* filed by former chief compliance officer
  - Allegations that system "provided illegal remuneration to non-employee neonatologists and surgeons in the form of services from ancillary support providers (including nurse practitioners, hospitalists, and physician assistants) to inpatients at ChristianaCare hospitals" in violation of the AKS and Stark Law
  - Services allegedly provided below fair market value or for free
  - Physicians allegedly were able to bill for the services
  - Focused on neonatology, cardiovascular, neuroscience, and ear nose and throat departments
- https://www.justice.gov/usao-de/pr/christianacare-pays-425-million-resolve-health-care-fraud-allegations-0

Private Equity Investors

- Recent remarks from Principal Deputy Asst. AG (Civil Division) Brian Boynton:
  - "Another source of influence on provider behavior that we are increasingly seeing are investors, such as private equity firms or venture capital firms. These entities may influence patient care by providing express direction for how a provider should conduct their business, or more indirectly by providing revenue targets or other indirect benchmarks intended to prioritize reimbursement. . . . [I]f an investor knowingly engages in conduct that causes the submission of false claims, they may subject themselves to liability."
  - "[T]hey can undermine medical judgment, inappropriately influence the doctor/patient relationship, and cause the submission of false claims to federal healthcare programs. In those instances, the department will not hesitate to pursue them for their roles in defrauding the government.
- https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024

Increased Scrutiny Surrounding the OTC COVID-19 Testing Demonstration

- In August 2023, OIG announced a work plan to evaluate the OTC COVID-19 Test Demonstration.
  - The Demonstration ran between April 4, 2022, to the end of the PHE.
  - Eligible providers could distribute up to 8 U.S. FDA-approved or authorized OTC COVID-19 tests per calendar month to each beneficiary.
- CMS set a fixed national payment rate of $12 per OTC COVID-19 test.
- CMS disbursed $1.1 billion for about 101 million OTC COVID-19 tests to 8 million Medicare beneficiaries.
- On April 20, 2023, the DOJ announced criminal charges against 18 defendants across 9 federal districts for involvement in pandemic-related fraud schemes, including the distribution of unsolicited OTC COVID-19 tests.
- CMS took adverse administrative actions against 28 medical providers for their alleged roles in COVID-19 related schemes.

Criminal COVID-19 Fraud Enforcement

- August 2023 DOJ announcement of “a coordinated, nationwide enforcement action to combat COVID-19 fraud”
  - Criminal charges against 371 defendants nationwide
  - Forfeiture of over $231 million
  - Over $836 million in alleged COVID-19 health care-related fraud
  - Launched 2 additional COVID-19 Fraud Enforcement Strike Forces
- https://www.justice.gov/opa/pr/justice-department-announces-results-nationwide-covid-19-fraud-enforcement-action
- In addition to allegations of fraud related to unemployment insurance benefits and SBA loan programs, accusations include alleged:
  - Unnecessary lab tests;
  - Unnecessary over-the-counter COVID-19 tests
  - Improper claims to the Provider Relief Fund
  - Manufacturing and distributing fake vaccination record cards

COVID-19 Settlements

- United Memorial Medical Center - $2 million settlement by medical center
  - Submitted false claims for cost outlier payments, retained overpayments, and double-billed for COVID-19 tests.
  - Submitted claims for COVID-19 tests despite being reimbursed for those services by the State of Texas/City of Houston.

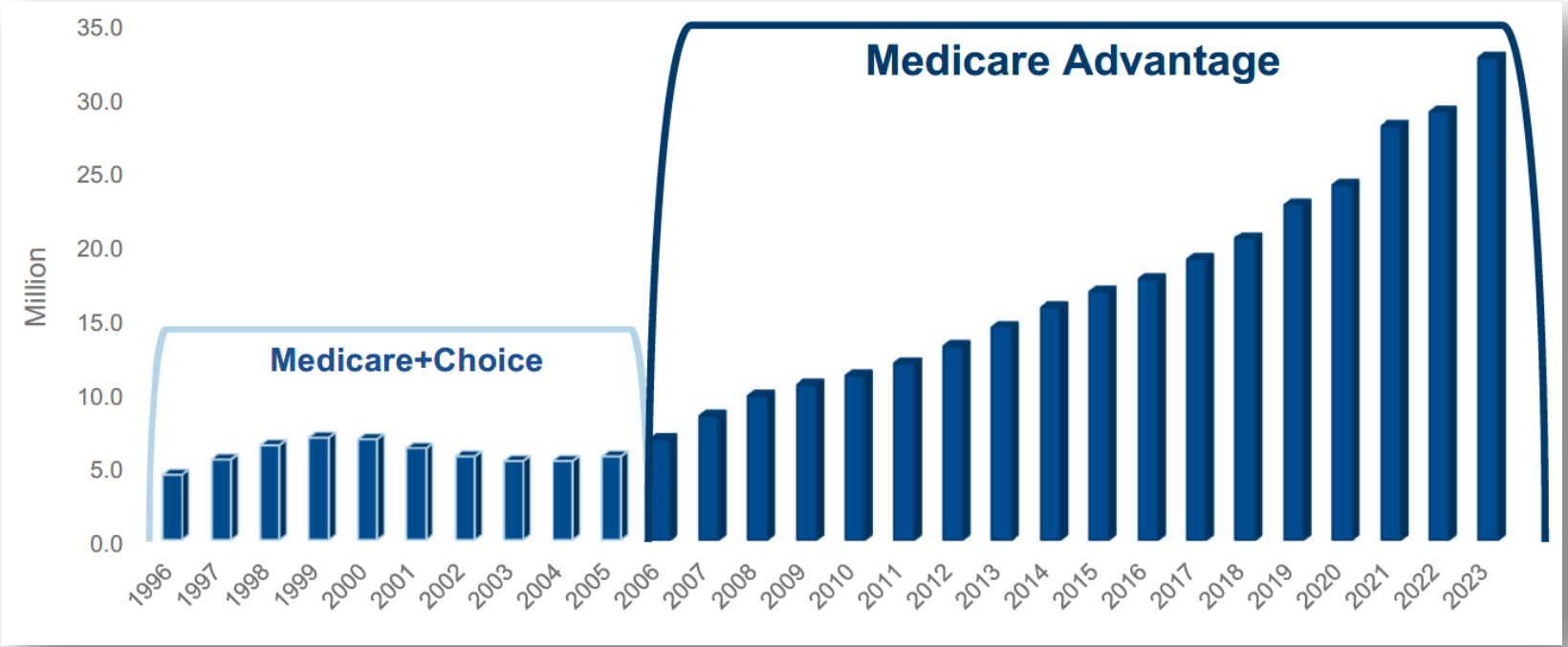
- Total Access Urgent Care - $9 million settlement by urgent care clinics
  - Submitted claims for physician E&M services performed by non-physicians
  - Self-disclosed upcoding of COVID-19 testing claims.

- CRH Healthcare - $1.6 million by physician group
  - Upcoded E&M levels and COVID-19 tests

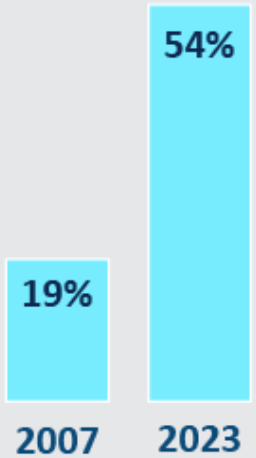
Telehealth Enforcement

- September 2023, two pharmacy operators and a pharmacist were indicted in NJ in a kickback scheme allegedly executed in collaboration with marketing and telehealth companies, under which Medicare and TRICARE beneficiaries were pressured via telephone to accept expensive prescription creams, resulted in over $33 million in Medicare and TRICARE claims.
- https://www.justice.gov/usao-nj/pr/pharmacy-operators-and-pharmacist-charged-33-million-health-care-fraud-wire-fraud-and
- June 2023, the USAO-S.D. Fla. charged owners of internet-based platform with coordinating kickback arrangements between telemedicine companies and DME suppliers, pharmacies, and telemarketers, resulting in submission of $1.9 billion in false claims to Medicare and other government insurers by the DME suppliers and pharmacies.
- https://www.justice.gov/criminal/criminal-fraud/health-care-fraud-unit/2023-national-hcf-case-summaries

Medicare Advantage Enrollment Growth



By the Numbers



54% of Medicare enrollees received care through Medicare Advantage in 2023.

81% of current Medicaid enrollees receive at least one component of care through managed care.

$454B in estimated Government spending on Medicare Advantage in 2023.

$254B Federal match for Medicaid managed care in 2021.

Managed Care Featured Topic
OIG.HHS.GOV

Medicare Advantage Fraud

- U.S. continues to litigate multiple FCA cases against Medicare Advantage organizations
- Cigna settlement, September 2023
  - $135 million (EDPa) + $37 million (SDNY) = $172 million
  - Corporate Integrity Agreement
  - Allegations:
    - Cigna used “chart review” to add diagnosis codes but did not withdraw previously listed diagnosis codes found to be inaccurate (EDPa)
    - Cigna knowingly submitted and/or failed to delete inaccurate diagnosis codes for morbid obesity (EDPa)
    - Cigna added diagnosis codes identified by vendors paid to conduct in-home assessments of enrollees, without supporting diagnostic testing or imaging or other clinical information (SDNY/MDTN)
  - Relator in SDNY/MDTN case was former part-owner of a vendor hired to conduct home visits
- https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations

Medicaid Managed Care Fraud

- County organized health system CenCal Health, along with several non-profit providers, entered into $68 million settlement in June 2023 with US and CA.
  - Resolved allegations that settling parties knowingly submitted or caused to be submitted false claims to Medi-Cal for “Enhanced Services” purportedly provided to Adult Expansion Medi-Cal members, where CenCal payments to providers were:
    - Not for “allowed medical expenses”;
    - For pre-determined amounts that did not reflect FMV of Enhanced Services provided;
    - Duplicative of services already required to be rendered;
    - Unlawful gifts of public funds in violation of CA constitution.
  - Followed December 2022 settlement with other for-profit and non¬profit providers relating to arrangement with CenCal.
  - Initiated by relator who was former CMO of CenCal.
- https://www.justice.gov/opa/pr/california-county-organized-health-system-and-three-health-care-providers-agree-pay-68

Fraud Focused on Mid-Level Practitioners

Detroit Medical Center, Vanguard Health Systems, and Tenet Healthcare Corporation Agree to Pay Over $29 Million to Settle False Claims Act Allegations

Wednesday, May 31, 2023

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For Immediate Release

Office of Public Affairs

VHS of Michigan Inc., doing business as, The Detroit Medical Center Inc. (DMC), Vanguard Health Systems Inc. (Vanguard), and Tenet Healthcare Corporation (Tenet), has agreed to pay $29,744,065 to the government to resolve allegations that they violated the False Claims Act by providing kickbacks to certain referring physicians.

DMC operates hospitals in and around Detroit, including Sinai Grace Hospital and Harper University Hospital. In October 2013, Tenet acquired Vanguard owned-and-operated hospitals

HHS-OIG's General Compliance Program Guidance

November 2023: HHS-OIG released guide highlighting 7 elements of an effective compliance program:

1. Written policies and procedures;
2. Compliance leadership and oversight;
3. Training and education;
4. Effective lines of communication with the Compliance Officer and disclosure programs;
5. Enforcing standards: consequences and incentives;
6. Risk assessment, auditing, and monitoring; and,
7. Responding to detected offenses and developing corrective action initiatives.

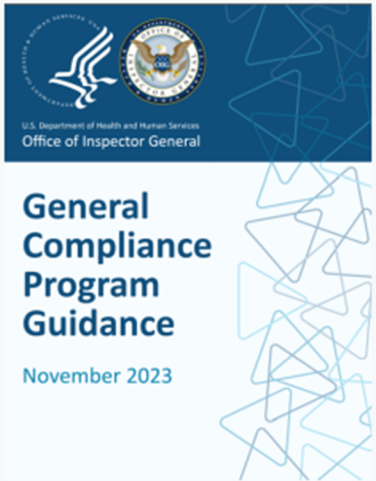
General Compliance Program Guidance

The General Compliance Program Guidance (GCPG) is a reference guide for the health care compliance community and other health care stakeholders. The GCPG provides information about relevant Federal laws, compliance program infrastructure, OIG resources, and other information useful to understanding health care compliance.

The GCPG is voluntary guidance that discusses general compliance risks and compliance programs. The GCPG is not binding on any individual or entity. Of note, OIG uses the word "should" in the GCPG to present voluntary, nonbinding guidance.

You may download the guidance in whole, or access individual sections below.

Download Complete Guidance



Individual Sections

I. Introduction

II. Health Care Fraud

Old CPG	New CPG
Published in Federal Register	Published on OIG website https://oig.hhs.gov/compliance/compliance-guidance/
Covered both general compliance considerations and tailored risk areas specific to industry sectors	GCPG – consolidated, generally applicable compliance considerations and legal overview ICPGs – focused fraud and abuse risk areas specific to industry sectors and entities involved in health care
Standalone documents	Hub (GCPG) and spoke (ICPGs) approach
Remain good guidance as applicable No additional FR supplements will be issued	Greater flexibility to update on our website • GCPG updated as needed • ICPGs updated more frequently as new risk areas emerge
Sought comments through FR process	Seek feedback and suggestions for new risk areas on an ongoing basis at compliance@oig.hhs.gov
Available as archived material on OIG website	Current information on OIG website

Policy Updates: Health Related Social Needs & Social Determinations of Health

CMS Efforts to Advance Health Equity

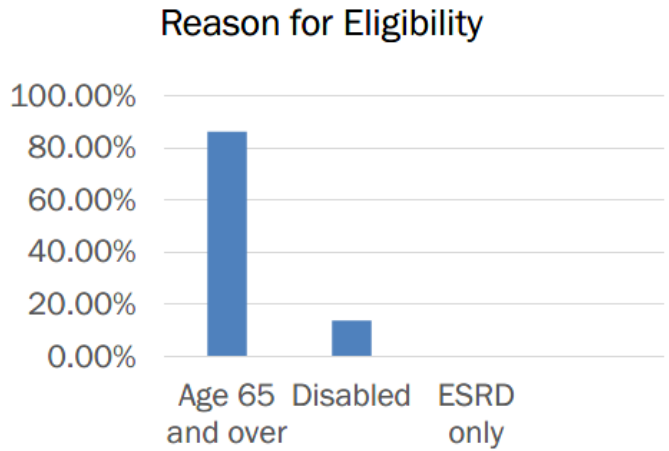
CMS Framework for Health Equity 2022 – 2032: 5 Priorities

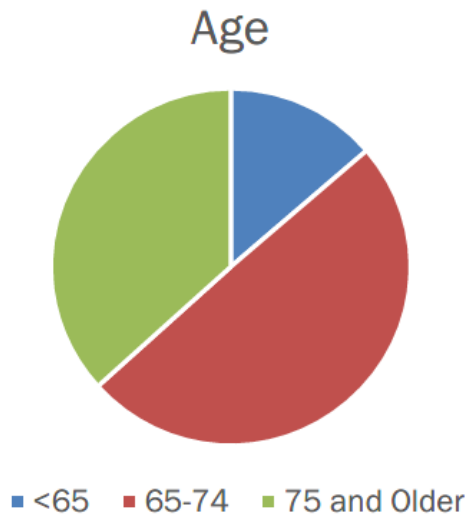
- Expand standardized data collection, reporting, and analysis
- Assess causes of disparities and work to close gaps within CMS
- Build capacity to reduce disparities with healthcare organizations and the workforce
- Advance language access, health literacy, and culturally tailored services
- Increase accessibility to health care services and coverage
- https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework

CMS held its 2nd health equity conference in May 2024.

Characteristics of Medicare Enrollees, 2019

62.5 Million Enrollees Across all parts of Medicare A, B, C, and D





https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf

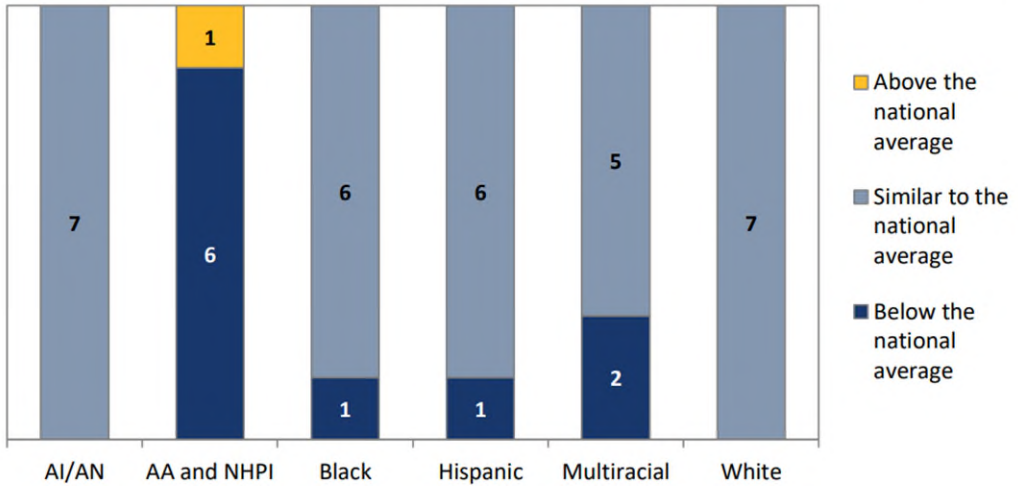
Distributions of 2022 MA and FFS populations

Beneficiary Characteristic	Medicare Advantage, %	Medicare Fee-for-Service, %
Race or ethnicity		
AI/AN	0.3 (28.8)	0.7 (71.2)
AA and NHPI	4.7 (47.5)	4.1 (52.5)
Black	11.4 (52.6)	8.1 (47.4)
Hispanic	12.5 (60.4)	6.4 (39.6)
White	69.4 (40.7)	79.3 (59.3)
Multiracial	1.7 (46.9)	1.5 (53.1)
Sex		
Female	56.2 (46.0)	52.2 (54.0)
Male	43.8 (42.0)	47.8 (58.0)

Racial and ethnic disparities – Patient experience

Figure 1. Disparities in Care by Race and Ethnicity: All Patient Experience Measures

Number of patient experience measures (out of 7) for which members of selected racial and ethnic groups reported experiences that were above, similar to, or below the national average in 2022



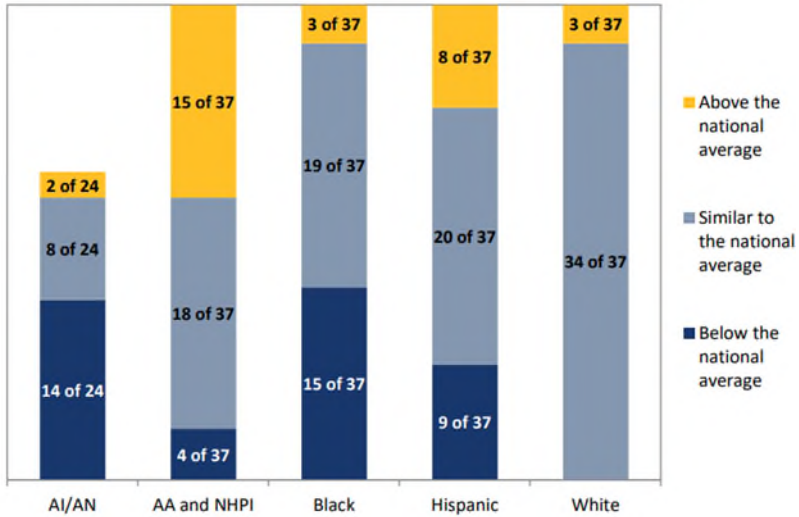
SOURCE: This chart summarizes data from all MA enrollees nationwide who participated in the 2022 Medicare CAHPS survey.

NOTES: AI/AN = American Indian and Alaska Native. AA and NHPI = Asian American and Native Hawaiian or other Pacific Islander. Racial groups such as Black and White are non-Hispanic. Those who endorsed Hispanic ethnicity were classified as Hispanic regardless of race.

Racial and ethnic disparities – Clinical care

Figure 2. Disparities in Care by Race and Ethnicity: All Clinical Care Measures

Number of clinical care measures for which members of selected racial and ethnic groups had results that were above, similar to, or below the national average in Reporting Year 2022



SOURCE: This chart summarizes clinical quality (HEDIS) data collected in 2021 from MA plans nationwide.

NOTES: AI/AN = American Indian and Alaska Native. AA and NHPI = Asian American and Native Hawaiian or other Pacific Islander. For reporting clinical care (HEDIS) data stratified by race and ethnicity, racial and ethnic group membership is estimated using a methodology that combines information from CMS administrative data, surname, and residential location. Estimates for AI/AN MA enrollees are less accurate than for other racial and ethnic groups for some measures; for this reason, this report excludes scores for AI/AN MA enrollees when the accuracy of those scores does not meet the standards described on page 4. Racial groups such as Black and White are non-Hispanic. Hispanic ethnicity includes all races.

Hospital Quality Reporting Programs

- Quality metrics to advance health equity added for CY 2023

Hospital Commitment to Health Equity	Screening for Social Drivers of Health	Screen Positive Rate for Social drivers of Health
1. Equity is a Strategic Priority 2. Data Collection 3. Data Analysis 4. Quality Improvement 5. Leadership Engagement	1. Food Insecurity 2. Housing Instability 3. Transportation Needs 4. Utility Difficulties 5. Interpersonal Safety	1. Hospitals report proportion of patients who screened positive on date of admission for one of 5 HRSNs 2. Rate calculated and reported separately for each HRSN

Hospital Quality Reporting Programs

- Continued addition of quality metrics to advance health equity in CY 2024

Hospital Harm – Pressure Injury	Hospital Harm – Acute Kidney Injury	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)
• Inpatient hospitalizations for patients with pressure injury not present on admission • Inpatient hospitalizations for patients 18 years and older	• Inpatient hospitalizations for patients 18 years and older who develop an AKI during an encounter • Inpatient hospitalizations for patients 18 years and older	1. New web-first modes to survey 2. Permit proxy respondents 3. Extend data collection periods 4. Require official Spanish translation

Health Equity Metrics

Measurement

- Health equity measurement initially introduced to Inpatient Quality Reporting in 2023
- 2024: further standardize equity measures and improve data collection
- Use reported SDOH ICD-10 codes to analyze severity of illness, complexity of services, and resource consumption
- Account for geographic as well as individual patient characteristics to support rural health

Payment adjustments

- Hospital value-based purchasing adds to hospitals' total performance scores based on quality metrics and dual eligible patient population
- 2024 IPPS Final Rule includes SDOH codes related to homelessness as a complication/comorbidity for inpatient DRGs
- Medicare Shared Savings Program payment adjustment for ACOs serving more low-income patients
- Medicare Advantage Health Equity Index reward
- Value-Based Insurance Design model tests whether more flexibility in MA benefit design can better serve patients with chronic conditions and address health-related social needs

New Care Management Services
Physician Fee Schedule

Community Health Integration (CHI)

- Addresses SDOHs that are barriers to the patient's treatment
- By trained staff such as social workers, nurse case managers, or community health workers with certain competencies
- After an initial E&M or AWV with a physician/NPP
- Coinsurance – verbal consent required

Principal Illness Navigation (PIN)

- Focuses on social aspects of care not covered by more clinically focused care management
- Trained/certified patient navigators or peer support specialists help patients through a high-risk disease expected to last at least 3 months
- Initiating visit with a physician, NPP, or psychologists
- Patient may or may not have SDOH needs
- Coinsurance – verbal consent required

New Care Management Services
Physician Fee Schedule

SDOH risk assessment (HCPCS G0136)

- Using a standardized tool including food, housing, utilities, and transportation at a minimum
- In conjunction with an E&M or psych eval visit when the physician/APC *has reason to believe* unmet SDOH needs are interfering with treatment
- Can be performed via telehealth
- Screening only (such as a pre-visit questionnaire) is not billable
- No more than every 6 months

Caregiver Training Services (CTS)

- Group or individual sessions for family/friends who provide unpaid assistance to people with chronic or disabling conditions (patient not required to be present)
- Part of patient's treatment plan or rehab plan of care
- Coinsurance – verbal consent required
- Not eligible for telehealth

CMS Efforts to Expand Coverage Have Been Evolving Rapidly

- **2018**: Section 1115 Pilot Program in North Carolina
- **January 2021**: State Health Official (SHO) Letter #21-001, Opportunities in Medicaid and CHIP to Address Social Determinants of Health
- **December 2022**: All-States call announcing opportunities to address HRSN through Section 1115
- **January 2023**: State Medicaid Director (SMD) Letter #23-001, Use of In Lieu of Services and Settings (ILOS) in Medicaid Managed Care
- **May 2023**: Notice of Proposed Rulemaking (NPRM), Medicaid and CHIP Managed Care Access, Finance, and Quality
- **November 2023**: CMCS Informational Bulletin (CIB), Coverage of Services and Supports to Address Health-Related Social Needs in Medicaid and the Children's Health Insurance Program

December 2022 Guidance on 1115 Waivers

- In an All-States call in December 2022, CMS announced that it was offering a new 1115 demonstration opportunity to support States in addressing HRSN, with the goals of improving coverage, access, and health equity across Medicaid beneficiaries.
- As summarized by CMS, the 1115 option:
  - allows States to take a more nuanced approach to defining target populations for HRSN services than permitted through other CMS authorities;
  - requires States to agree to additional requirements and guardrails;
  - gives HRSN services a “unique treatment” in budget neutrality calculations.

HRSNs

- **Example HRSN Services Authorized by 1115 Waivers:**

State	HRSN Initiatives	Status
Arizona	• Rent or temporary housing for up to 6 months • Utility costs including activation expenses and back payments	Approved
Arkansas	• Tenants' rights education and eviction prevention • Nutrition education and healthy meal preparation	Approved
California	• Recuperative care for individuals transitioning out of institutions • Short-term post-hospitalization services	Approved
Delaware	• Securing a community-based home through apartment application fees and essential home furnishings • Financial coaching and employment support	Approved
Florida	• Behavioral health and supportive housing assistance, including advocacy and linkage with community resources to prevent eviction	Approved
Hawaii	• Community integration services, including tenancy sustaining services such as training in lease compliance	Approved
Illinois	• Supported employment, including career advancement services	Approved

HRSNs

- **Example HRSN Services Authorized by 1115 Waivers:**

State	HRSN Initiatives	Status
Maryland	• Housing case management, including assistance accessing supports to preserve independent living such as financial counseling or anger management	Approved
Massachusetts	• Housing deposits to secure housing • Medically necessary air conditioners • Transportation to HRSN services	Approved
New Jersey	• Short-term (no more than 30 days) grocery provision • Refrigeration units as needed for medical treatment	Approved
New Mexico	• Essential household furnishings required to occupy and use a community domicile, including furniture, window coverings, food preparation items, and bed/bath linens	Approved
New York	• Recuperative care and short-term pre-procedure and post- hospitalization housing for individuals experiencing homelessness • Rent/temporary housing for up to 6 months for individuals transitioning out of institutional settings • Cooking supplies that are necessary for meal preparation and nutritional welfare (e.g., microwave, refrigerator, utensils)	Approved

Behavioral Health Care

- CMS behavioral health strategy focuses on:
  - SUD prevention, treatment, recovery
  - Pain management
  - Improving mental health services
- Medicaid mobile crisis intervention programs approved for 15 states (as of 2/2/24)
  - Authorized by the American Rescue Plan of 2021 as rehabilitative mental health and substance use disorder (SUD) services
  - Multidisciplinary team goes to the person in crisis to offer de-escalation, stabilization, and connections to treatment and social support
- Innovation in Behavioral Health model announced Jan. 2024
  - “No wrong door” approach to meeting patients’ physical and behavioral health needs

Behavioral Health Professionals

New Professional Enrollment Categories

- Licensed Marriage and Family Therapists (LMFTs)
- Mental Health Counselors (MHCs)
  - Also includes addiction counselors who meet educational requirements
- Comparable to Licensed Clinical Social Workers
- 75% of PFS rate in ambulatory settings
- Included in facility payment for IOP, PHP
- May participate in hospice interdisciplinary teams and as RHC clinicians
- Added MFTs and MHCs to list of RHC/FQHC practitioners

Health Behavior Assessment and Intervention (HBAI)s

- 9 codes used for psychological assessment and treatment, when the primary diagnosis is a medical condition
- Evaluation of patient's responses to a medical condition, including coping strategies, motivation, and adherence to treatment
- Individual, group, or family services
- Can be billed by clinical social workers, MFTs, and MHCs

Outpatient Behavioral Health Services

Intensive Outpatient Programs (IOP)

- Consolidated Appropriations Act, 2023 provisions created a new benefit category for intensive outpatient program services for individuals with acute behavioral health needs.
- Patient needs at least 9 hours per week of treatment
- Requires physician certification every 60 days and treatment plan
- Can be furnished in RHCs, FQHCs, and Opioid Treatment Programs as well as hospitals and community mental health centers
- CMS treats Substance Use Disorders as diagnoses for medical necessity (in addition to traditional psychiatric diagnoses), but does not cover the SUD-specific CPT codes as IOP/PHP services
- IOP paid in addition to the OTP weekly bundle for naloxone/methadone treatment

Partial Hospitalization Program (PHP) update

- Patient needs at least 20 hours per week of treatment
- As an alternative to inpatient psychiatric care
- Requires physician certification every 60 days and treatment plan
- Added group therapy, psychological testing as primary behavioral health services
- 2 levels of per-diem payment in 2024
- 3 services per day (or fewer on days when the patient is unable to complete treatment)
- 4 or more services per day

Behavioral Health Services (cont.)

- Increase in wRVUs for patient one-on-one timed behavioral health services, to be implemented over a 4-year period.
  - **CPT codes: 90832, 90834, 90837, 90839, 90840, 90845, 90846, 90847, 90849, 90853, G0017, G0018**
- Allow general supervision for behavioral health services furnished incident to physician or NPP services in RHC/FQHC.
- Psychotherapy for crisis services
  - G0017 – Psychotherapy for crisis furnished in an applicable site of service; first 60 minutes
  - G0018 – Each additional 30 minutes (List separately in addition to code for primary service)
  - Furnished in any non-facility POS other than physician office setting
  - Payment at 150% of rate for physician office setting

Mental Health Parity Proposed Rule

- HHS, DOL, Treasury proposal would:
  - Enhance and standardize enforcement of the Mental Health Parity and Addiction Equity Act (2008)
  - Would require plans to apply a new mathematical test to determine whether certain limits on behavioral health coverage are no more restrictive than limits on medical coverage.
  - Plans have to document that the “processes, strategies, evidentiary standards and other factors” used to design and apply specific limits on behavioral health are comparable and not more stringent than those used to design and apply limits on medical benefits.
  - Implement Consolidated Appropriations Act, 2021 requirement for payers to analyze, document, and use non-qualitative treatment limits (NQTLs), such as prior authorizations, for behavioral health services
  - Require collection of outcome data on patient access to services
  - Clarify that eating disorders and autism spectrum disorders are considered mental health conditions for MHPAEA enforcement
- Final rule submitted to White House OMB on Jul. 1, 2024
- Will be 60-day period before any final rule becomes effective

SAMHSA Final Rule on Treatment for Opioid Use Disorder

- On Feb. 2, SAMHSA issued final rule intended to expand access to treatment for opioid use disorder (OUD), including permanently easing restrictions on take-home doses of methadone and the use of telehealth when initiating buprenorphine.
- Updates accreditation, certification and treatment standards for providing OUD medications, including making permanent certain flexibilities put in place during the COVID-19 public health emergency.
- Adds evidence-based practices such as split dosing, telehealth, and harm reduction activities, while removing stigmatizing language such as “detoxification.”
- Other provisions include modifying the definition of an OTP treatment practitioner to include any provider who is appropriately licensed by a state to prescribe or dispense approved medications; updating admission criteria, as required by statute, to remove significant barriers to entry, such as the one-year requirement for OUD, while also defining the scope and purpose of the “initial” and “periodic medical examinations”; and codifying the use of online/electronic forms.

New Value-Based Payment Models

Value-Based Legislative Changes on the Horizon?

- Value in Health Care Act (H.R. 5013)
  - Bipartisan support; referred to Health Subcommittee (Jul. 2023)
  - Would continue 5% APM incentive payment for two years
  - Would receive 50% revenue threshold physician in value-based models must meet to qualify for bonuses
  - Would give HHS authority to increase revenue threshold, but no more than 5% in any single year
  - Authorizes CMS to establish lower APM participation thresholds for episode models and other types of APMs
  - Eliminating revenue-based distinctions for ACOs (affects certain rural and safety net providers' share in the savings).
  - Creates more transparent process to set financial spending targets
  - Establishes voluntary, full-risk track for ACOs
  - Provides technical assistance for clinicians new to APMs
  - Studies ways to increase parity between APMs in traditional Medicare and Medicare Advantage
- Strengthening Innovation in Medicare and Medicaid Act (H.R. 6732)
  - Calls for study of APMs, various higher-level changes
  - Introduced in Dec. 2023; referred to Health Subcommittees

New Value-Based Models

- Making Care Primary Model
- Enhancing Oncology Model
- Dementia Care Model: GUIDE
- Changes in ACO REACH program
- Innovation in Behavioral Health Model
- Medicare Shared Savings Program
- States Advancing All-Payer Health Equity Approaches and Development (AHEAD)

New Dementia Care Payment Model: GUIDE

- On Jul. 31, 2023, CMS announced a new eight-year, voluntary payment model called the Guiding an Improved Dementia Experience (“GUIDE”) Model for Medicare providers and suppliers to offer a combination of care coordination for beneficiaries with dementia and support services for their caregivers.
- Under the Model, participants must maintain an interdisciplinary care team, including:
  - Clinician with dementia proficiency
  - Trained care navigator who connects beneficiaries and caregivers with support services
- Beneficiaries receiving care will be placed in one of five tiers depending on the disease stage and caregiver status – and payment will increase by tier:
  - New safety net providers will be eligible for a one-time, lump sum infrastructure payment
  - All participants will receive a monthly, per beneficiary amount for providing care management and coordination
  - Participants may bill for respite services up to an annual cap, for caregivers of beneficiaries with moderate to severe dementia

BENEFICIARY TIERS

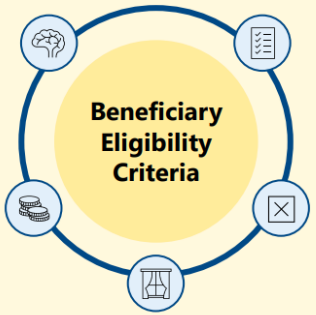
People with Medicare who receive care from model participants will be placed in one of five "tiers," based on a combination of their disease stage and caregiver status. Beneficiary needs, and correspondingly, care intensity and payment, increase by tier.

	TIER	CRITERIA
Beneficiaries **with** a caregiver	Low complexity	Mild dementia
	Moderate complexity	Moderate or severe dementia and low to moderate caregiver strain
	High complexity	Moderate or severe dementia and high caregiver strain
Beneficiaries **without** a caregiver	Low complexity	Mild dementia
	Moderate to high complexity	Moderate or severe dementia

MODEL BENEFICIARY ELIGIBILITY

The GUIDE Model's intended beneficiary population is community-dwelling Medicare fee-for-service beneficiaries, including beneficiaries dually eligible for Medicare and Medicaid, living with dementia. Eligible beneficiaries must meet the following criteria:

- ✓ Beneficiary has a diagnosis of dementia, as confirmed by clinician attestation.
- ✓ Have Medicare as their primary payer.



- ✓ Enrolled in Medicare Parts A and B (not enrolled in Medicare Advantage, including Special Needs Plans and PACE).
- ✓ Not enrolled in Medicare hospice benefit.
- ✓ Not residing in a long-term nursing home.

PAYMENT OVERVIEW

INFRASTRUCTURE PAYMENT

Certain safety net providers in the new program track will be eligible for a one-time, lump sum infrastructure payment to support program development activities.

PER-BENEFICIARY-PER-MONTH PAYMENT

Participants will receive a monthly, per-beneficiary amount for providing care management and coordination and caregiver education and support services to beneficiaries and caregivers.

RESPITE CARE PAYMENT

Participants will be able to bill for respite services for beneficiaries with a caregiver and moderate to severe dementia, up to an annual respite cap amount.

MODEL TIMELINE

	Fall '23-Winter '24	July '24-June '25	July '25-June '26	July '26-June '27	July '27-June '28	July '28-June '29	July '29-June '30	July '30-June '31	July '31-July '32
ESTABLISHED PROGRAM	Application Period	Performance Year (PY) 1	PY 2	PY 3	PY 4	PY 5	PY 6	PY 7	PY 8
NEW PROGRAM	Application Period	Pre-Implement-ation (PI) Period	PY 1	PY 2	PY 3	PY 4	PY 5	PY 6	PY 7

Conditions of Coverage & Conditions of Payment

Quality & Safety: Nursing Homes

QCOR
Quality, Certification & Oversight Reports

Search

Provider Reports
Active Provider and Supplier Counts
New Provider and Supplier Counts
Terminated Provider Counts

Survey Reports
Overdue Recertification Surveys
Recertification Survey Counts
Survey Activity Report
Frequency of Data Entry (F4)

Deficiency Reports
Deficiency Count
Average Number of Deficiencies
Citation Frequency
Double G Citations Report

Enforcement Reports
Enforcement Actions
Civil Money Penalty (CMP)
CMP Tool

Abuse Reports
Abuse Citation Rates

Nursing Home Provider Reports

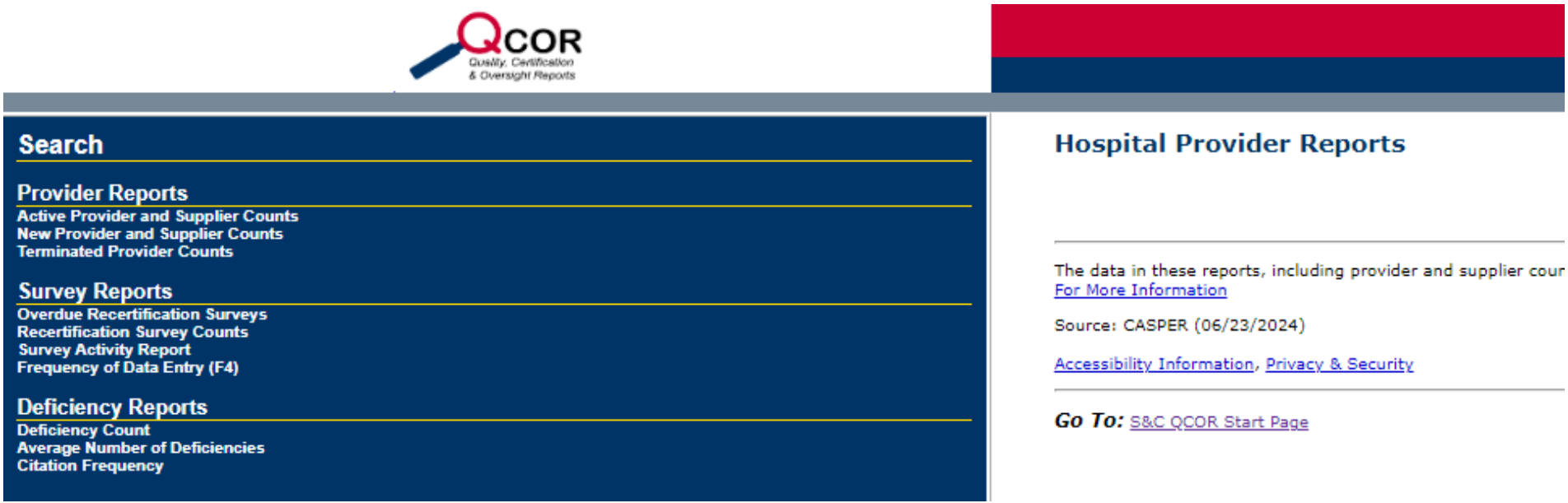
The data in these reports, including provider and supplier
For More Information

Source: CASPER (06/23/2024)

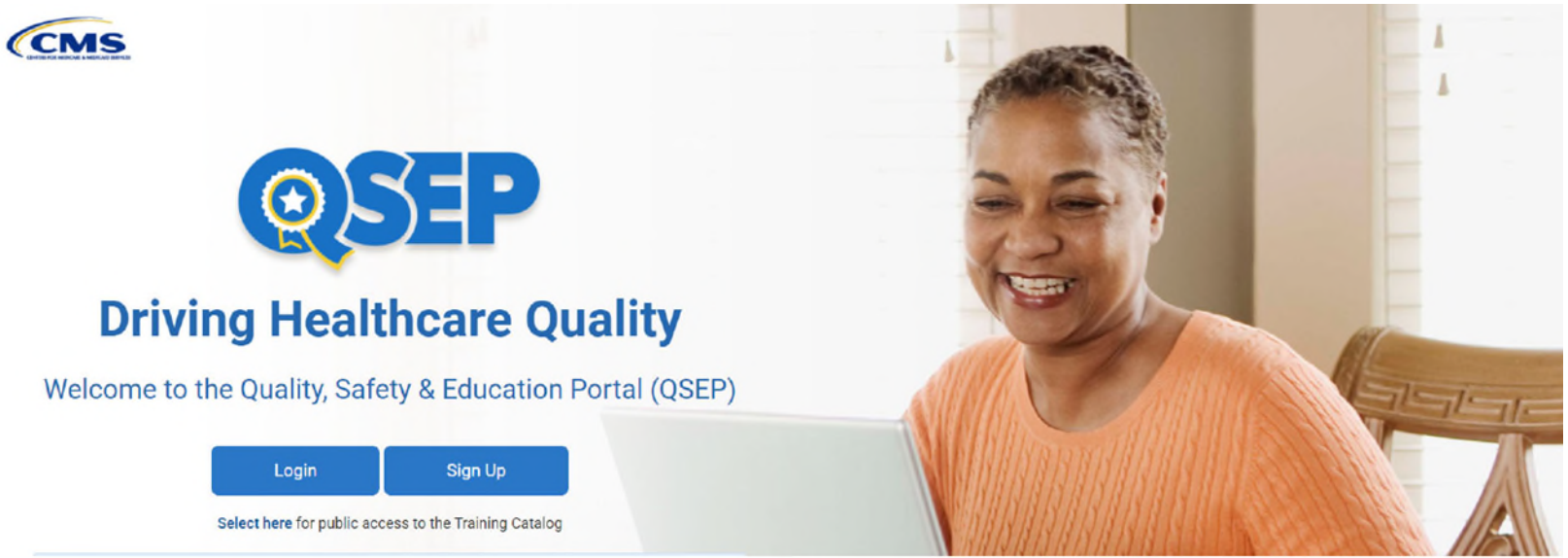
Accessibility Information, Privacy & Security

Go To: S&C QCOR Start Page

Quality & Safety: Hospitals (including CAHs and REHs)



- The Quality, Safety & Education Portal (QSEP) provides the full curriculum of surveyor training and guidance on health care facility regulations.
- https://qsep.cms.gov/welcome.aspx



Driving Healthcare Quality

Welcome to the Quality, Safety & Education Portal (QSEP)

Quality in Focus (QIF) Provider Specific Training Courses

https://qsep.cms.gov/ProvidersAndOthers/publictraining.aspx

QIF interactive videos are currently available for:

- **Ambulatory Surgical Center (ASC)** - *Infection Control Citations*
- **Intermediate Care Facility for Individuals with Intellectual Disabilities (IICF/IID)** - *Program Implementation Citations*
- **Community Mental Health Center (CMHC)** - *Local, State, Tribal Collaboration Process Citations*
- **Hospice** - *Plan of Care Citations*
- **Psychiatric Residential Treatment Facility (PRTF)** - *Post-Intervention Debriefing Citations*
- **Skilled Nursing Facility/Nursing Facility (SNF/NFs)** - *Treatment and Prevention of Pressure Ulcer Citations; Free of Accident Citations; Medication Error Citations.*
- **Outpatient Physical Therapy (OPT)** - *Equipment, Buildings, and Grounds Maintenance Citations*
- **Comprehensive Outreach Rehabilitation Facility (CORF)** - *Local, State, Tribal Collaboration Process Citations*
- **Home Health Agency (HHA)** - *Incomplete Individualized Plan of Care Citations*
- **Rural Health Clinic (RHC)** - *Preventative Maintenance Program Citations*
- **Portable X-ray** - *Personnel Monitoring Citations*
- **End Stage Renal Disease (ESRD)** - *Cleaning and Disinfecting Citations*
- **Hospital** - *Patient Safety*

Proposed Rule on Oversight of Accrediting Organizations

- On Feb. 15, 2024 CMS issued proposed rule intended to strengthen oversight of accrediting organizations (AOs)
- Comment period ran through Apr. 15, 2024
- Changes in NPRM affect all AOs except those that accredit clinical labs and noncertified suppliers (ADI, HIT, DSMT, DMEPOS)
- Impetus for rule includes several concerns identified by CMS in recent years:
  - Providers and suppliers that have been terminated from Medicare / Medicaid but retain accreditation despite significant quality and safety concerns;
  - AOs provide fee-based consulting services to the providers and suppliers they accredit, potentially affecting the integrity of the onsite survey process and decreasing public trust by creating conflicts of interest;
  - Inconsistent survey results due to differing AO standards or practices (such as AOs notifying facilities of the date of their onsite surveys in advance contrary to CMS policies).

Proposed Rule on Oversight of Accrediting Organizations

- Proposed rule would make a number of changes, including:
  - Holding AOs accountable to the same standards as State SAs, that also conduct surveys on behalf of CMS.
  - Placing certain limitations on the fee-based consulting services AOs provide to the health care facilities they accredit.
  - Prohibiting AO owners, surveyors, and other employees, and as well as their immediate family members that have an interest in or relationship with a health care facility accredited by the AO from participating in surveys, having input into the survey results and involvement in pre- or post-survey activities of that facility, or from having access to survey records related to that facility.
  - Addressing potential and actual conflicts of interest by requiring AOs to report specific information to CMS about how they will monitor, prevent, and handle conflicts of interest and fee-based consulting services they provide.
  - Requiring AOs with poor performance to submit a publicly reported correction plan to CMS.
  - Improving consistency and standardization in surveys nationwide by more closely aligning AO survey activity requirements and staff training with those of SAs.

Space Sharing Continues to Vex Us

- CMS QSO-19-13: Guidance for Hospital Co-Location
  - CMS stated that QSO-19-13 addresses survey and certification requirements only and does not address provider-based status BUT, provider-based rules require compliance with Medicare COPs. So, non-compliance with co-location requirements could impact provider-based status.
- Provider-based rule and "public awareness"
  - Held out as part of the provider to public and third parties
  - *Borgess Medical Center*, DAB Dec. No. CR5185 – signage must inform patients *when they enter* the clinic (*not* after they are inside) that they are in the main hospital (not simply the health system).
  - *Cleveland Clinic Foundation*, DAB Dec. No. 5903 – sleep center located in hotel met public awareness requirement because the center was clearly marked and comprised "separate physical space" within hotel.

Related Survey & Certification Developments

- Minimum Staffing Rule: https://www.federalregister.gov/documents/2023/09/06/2023-18781/medicare-and-medicaidprograms-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid
- Hospices: https://www.cms.gov/files/document/qso-22-01-hospice.pdf
- OPOs: https://www.cms.gov/files/document/qso-21-23-opo.pdf
- Rural Emergency Hospitals: https://www.cms.gov/files/document/qso-23-07-reh.pdf
- Primarily Engaged Hospitals: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-44.pdf
- Workplace Safety: https://www.cms.gov/files/document/qso-23-04-hospitals.pdf
- Co-Location: https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf
- Ligature Risk: https://www.cms.gov/files/document/qso-23-19-hospitals.pdf

HRSA Ends 340B Offsite Facility Registration COVID-19 Waiver

- During the COVID-19 Public Health Emergency, HRSA waived its enforcement of the requirement that an offsite, outpatient facility be listed as reimbursable on the hospital's Medicare Cost Report and be registered with OPAIS in order to use 340B drugs
  - Covered entities argued that this created long delays in actually receiving the drugs because OPAIS registration is conducted quarterly and Medicare Cost Report are filed annually
  - In the meantime, other drug discounts were not available
- In May 2023, the COVID-19 PHE officially ended
- In Oct. 2023, HRSA announced that the waiver for 340B hospital offsite facility registration requirements would end
  - Covered entities given 90-day period to come into compliance
  - HRSA determined that the waiver policy hampered compliance verification and auditing

$9 Billion to be Returned to 340B Hospitals

- On Nov. 2, 2023, CMS issued a final rule to remedy underpayments made to 340B hospitals
  - Underpayments were attributed to changes to the OPPS held to be unlawful by the Supreme Court in *American Hospital Association v. Becerra* (142 S. Ct. 1896 (2022))
  - Supreme Court had held that the payment rates to 340B hospitals were invalid because prior to implementing the rates in 2018, HHS failed to conduct a survey of hospitals' acquisition costs
  - Approximately 1,700 340B hospitals were affected

- CMS finalized a policy to give affected providers a one-time lump sum payment
  - CMS estimates that for 2018 through 2022, certain OPPS providers received $10.6 billion less in 340B drug payments then they would have without the 340B policy
  - However, affected providers already received $1.6 billion through reprocessed claims for 340B drugs from Jan. 1, 2022 through Sep. 27, 2022
  - CMS will offset these payments prospectively. Will occur through reduction in OPPS conversion factor by a negative 0.5% adjustment each year beginning in 2026. Will take approximately 16 years to recoup amount.

Definition of “Patient” for 340B Purposes

- In November 2023, a South Carolina federal district court rejected HRSA’s definition of “patient” as used in 340B program
  - Plaintiff Genesis Health Care, a FQHC, argued that HRSA’s interpretation of an eligible “patient” was unduly restrictive
  - Case arose from HRSA audit. In audit enforcement letter, HRSA asserted that 340B eligibility available only for patients whose prescriptions originated from care provided by the covered entity
  - Genesis had been being removed from the 340B Program because the government determined Genesis was dispensing a high volume of 340B drugs to individuals who were not 340B “patients”
  - HRSA decision led to lawsuit by Genesis
  - After Genesis filed suit, HRSA reversed the audit’s findings but Genesis appealed regardless

Definition of “Patient” for 340B Purposes

- Court held that the only requirement under the statute for 340B eligibility is for the individual to be a “patient” of a “covered entity
  - The prescription for a 340B drug does not need to originate from a health care encounter with the covered entity, as long as the individual has an ongoing patient relationship with the covered entity
  - Ongoing relationship not defined
  - Court provides that “[i]f there is a desire to restrict the 340B Program and limit the ability of ‘covered entities’ to remain profitable in the face of prescription drug price increases, Congress is the appropriate entity to take the necessary action. It is not the role of HRSA to legislate and limit the 340B program by restricting the definition of the term ‘patient,’ thereby frustrating the ability of the 340B statute to accomplish its purpose.”

SUSTAIN 340B Act

- The Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act
- Bipartisan support in Senate
- Proposes a number of changes to 340B program, including:
  - Covered entities can use contract pharmacies in accordance with HRSA's 2010 guidance; arrangements must be registered annually; HHS must issue regulations related contract pharmacy arrangements; additional CMP authorities against manufacturers.
  - Senators acknowledge lack of clarity exists on how "patient" should be defined under 340B program; solicits feedback on appropriate manner for defining that term.
  - Guidelines on child sites, including that child sites must be wholly-owned by and clinically / financially integrated with covered entity; must provide care consistent with covered entities' policies.
  - Covered entities required to report specific information about their use of 340B program in cost reports.
  - Expanded program integrity (audits, contract only with vendors who agree to make certain reports to HHS, expanded use of financial assistance policies).
  - Use of national clearinghouse to prevent duplicate discounts between 340B and Medicaid.

Potential Federal Legislative Changes to 340B

- 340B PATIENTS Act (HR 7635)
  - Strengthens the 340B statute by clarifying that unilateral drug company restrictions on 340B pricing are unlawful
  - Preserves access to 340B drugs for dispensing through contract pharmacies
- Bucshon Bill (HR 3290)
  - Burdensome data reporting for DSH hospital CEs
  - Additional penalties for CE non-compliance
- PROTECT 340B Act (HR 2534)
  - Prohibit PBM discrimination against 340B covered entities and pharmacies
- 340B Accountability Act (S 1133)
  - Require auditing of use of 340B savings
- Drug Pricing Transparency and Accountability Act (HR 198)
  - New reporting and transparency requirements for 340B covered entities
  - Moratorium on new non-rural 340B hospitals and child sites
  - Requires the HHS Secretary to issue new standards for child sites
- 340B Reporting and Accountability Act (S 1182)

Background on Lab Developed Tests (LDTs)

- What is an LDT? One definition:
  - In vitro diagnostic test that is intended designed, manufactured and used within a single site CLIA-certified laboratory that meets the requirements for high complexity testing
- Compared to commercially marketed lab tests (manufactured by medical device companies and sold to providers)
  - Need to be cleared by FDA through premarket notification / premarket approval process
- FDA has claimed that 1976 Medical Device Amendments Act gives it jurisdiction over LDTs
- Agency has historically exercised enforcement discretion over LDTs
- Some labs and various other parties have asserted LDTs are clinical services (not medical products) and thus not within scope of FDA authority
- The FDA issued a proposed rule son Oct. 3, 2023 aimed at settling the agency's long-disputed authority to regulate in vitro diagnostic products ("IVDs") manufactured within a single laboratory
- Final rule issued Apr. 29, 2024

Phaseout of LDT Enforcement Discretion

Phases	Time from publication of final phaseout policy	Phaseout general enforcement discretion form specific FDA requirements:
Stage 1	May 6, 2025	MDR requirements, correction and removal reporting requirements and QS requirements regarding complaint files
Stage 2	May 6, 2026	Compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.
Stage 3	May 6, 2027	QS requirements
Stage 4	Nov. 6, 2027	Premarket review requirements for high-risk IVDs
Stage 5	May 6, 2028	Premarket review requirements for moderate risk and low risk IVDs (that require premarket submissions)

Categories of Tests Not Affected by Phaseout Policy

- For certain categories of tests, FDA has generally expected applicable requirements to be met. Approach is not changing:
  - Tests intended for emergencies, potential emergencies or material threats declared under Section 564 of FD&C Act
  - Tests intended as blood donor screening or human cells, tissues and cellular and tissue-based products (HCT/Ps) donor screening tests required for infectious disease testing or for determination of blood group and Rh factors
  - Direct to consumer

- FDA will use enforcement discretion and not enforce some or all requirements for certain categories of IVDs. For example:
  - “1976-Type LDTs”
  - Forensic tests (intended solely for law enforcement purposes)
  - Human leukocyte antigen (HLA) tests for transplantation
  - Public health surveillance tests: intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control (and test results are not reported to patients or their healthcare providers)

Federal Pricing Transparency Rule for Hospitals

- In a supplement to the 2020 OPPS Final Rule, published November 27, 2019, CMS added 45 CFR Section 180, which became effective 1/1/2021.
- Updated under 2022 OPPS Final Rule effective Jan. 1, 2022.
- Updated under 2024 OPPS Final Rule effective Jan. 1, 2024 (staggered implementation).
- All hospitals (federal owned and operated hospitals are deemed to be in compliance) must make public:
  - A **machine-readable** file (MRF) containing a list of all standard charges for **all items and services**, and
  - A **consumer-friendly list** of standard charges for **shoppable services**.

Hospital Price Transparency: 2024 Requirements

- **New Machine-Readable File Requirements**
- ***Good Faith Effort (1/1/24) and Affirmation (7/1/24)***: Ensure standard charge information is true, accurate, and complete and affirm compliance
- ***CMS Template (7/1/24)***: Beginning July 1, 2024, file must conform to a CMS template layout, data specifications, and data dictionary
- ***Hospital Data (7/1/24)***: Include hospital information as data elements (including inpatient and freestanding ED locations)
- ***Additional Standard Charge, Service, and Coding Data (7/1/24 and 1/1/25)***: Adds various data elements for standard charges, items and services, and coding. E.g.:
  - Standard charge method (e.g., per diem, case rate)
  - Estimated allowed amount in dollars (starting January 1, 2025) for standard charges expressed as percentage or algorithm.
  - Drug unit and type of measurement (January 1, 2025)
  - Modifiers that may change the standard charge (January 1, 2025)

Hospital Price Transparency: 2024 Requirements

- **Accessibility and Enforcement**
- ***Website Accessibility***: Beginning January 1, 2024, ensure:
  - .txt file in the root folder of the website that hosts the file
  - "Price Transparency" link in website footer (including homepage) that links directly to the page hosting the link to the machine-readable file
- ***Monitoring and Enforcement***:
  - May require submission of certification by an authorized hospital official as to accuracy and completeness and submission of additional documentation
  - Requires acknowledgment of receipt of warning notice
  - May notify health system leadership of compliance action and work with leadership to address similar deficiencies for hospitals across the system.
- ***Publicizing Actions***: May publicize information related to CMS' assessment of compliance, any compliance action taken (including status and outcome), and notification to system leadership.

Compliance Challenges and Opportunities

- Compliance is highly inconsistent.
- Survey data from a PatientRightsAdvocate.org study published in July 2023 found that only 36% of 2,000 hospitals surveyed were posting complete pricing information.
- https://www.patientrightsadvocate.org/july-semi-annual-compliance-report-2023

FORBES > INNOVATION > HEALTHCARE

Price Transparency: A Boon For Patients, A Bust For Hospitals?

Seth Joseph Contributor ⓘ

I write about the intersection of health care, technology and policy

Follow

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May 31, 2023, 10:36am EDT

https://www.forbes.com/sites/sethjoseph/2023/05/31/price-transparency-a-boon-for-patients-a-bust-for-hospitals/?sh=6eb6442717ef

Report: Only quarter of hospitals analyzed complied with key price transparency rule

By **Robert King** · Feb 6, 2023 12:22pm

https://www.fiercehealthcare.com/providers/report-only-quarter-hospitals-analyzed-complied-key-price-transparency-rule

CMS Enforcement and Hospital Compliance

- CMS conducted website assessments between September and November 2022 of 600 hospitals randomly sampled from the Homeland Infrastructure Foundation-Level Data.
- Of the 600 acute care hospitals sampled for the 2022 analysis, 493 (82%) posted a consumer-friendly display that met the consumer-friendly display website assessment criteria, 490 (82%) posted a machine-readable file that met the website assessment criteria, and 421 (70%) did both.
- As of September 2023, CMS had issued nearly 989 warning notices and over 631 requests for corrective action plans since the initial implementing regulation went into effect in 2021. Over 738 hospitals have addressed problems and have become compliant with the regulations, leading to closure of their cases.
- As of January 19, 2024, while CMS has issued monetary penalties to 14 hospitals since 2021 (3 remain under review), every other hospital that was reviewed has corrected its deficiencies.

CMS Enforcement and Hospital Compliance

- Old approach. If found in noncompliance, CMS can
  - Provide a written warning
  - Request a corrective action plan for material violations
  - Impose a civil monetary penalties and publicize the penalty on a CMS website if failure to respond to a CAP.

- New approach (Apr. 2024)
  - CMS requires full compliance within 90 days from corrective action plan (CAP) request (previously allowed hospital to propose a CAP completion date).
  - Automatically impose CMP for failure to submit CAP within 45 days and failure to comply with CAP within 90 days.
  - Immediately request CAP for hospitals that make no attempt to satisfy requirements (previously sent warning letter)

Civil Monetary Penalties

- For every day a hospital is determined to be out of compliance:
- For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.
- For a hospital with at least 31 and up to and including 550 beds, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.
- For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

Hospital Name	CMP Amount	Date Action Taken
Northside Hospital Atlanta	$883,180.00	2022-06-07
Northside Hospital Cherokee	$214,320.00	2022-06-07
Frisbie Memorial Hospital	$102,660.00	2023-04-19
Kell West Regional Hospital *Under Review**	$117,260.00	2023-04-19
Falls Community Hospital &Clinic	$70,560.00	2023-07-20
Fulton County Hospital *Under Review**	$63,900.00	2023-07-20
Community First Medical Center *Under Review**	$847,740.00	2023-07-24
Hospital General Castaner	$101,400.00	2023-08-22
Samaritan Hospital - Albany Memorial Campus	$56,940.00	2023-08-22
Doctors' Center Hospital Bayamón	$102,200.00	2023-08-22
Doctors' Center Hospital Bayamón	$99,540.00	2023-08-23
Betsy Johnson Hospital	$979,000.00	2023-08-23
UF Health North	$325,710.00	2023-09-05
Holy Cross Hospital	$677,440.00	2023-09-05
Saint Elizabeths Hospital	$883,180.00	2022-06-07

Stark Law: Physician-Owned Hospitals

- Stark whole hospital and rural provider exceptions
- ACA sec. 6001(a)(3) froze the number of operating rooms, procedure rooms, and beds for POHs in 2010
- IPPS 2024 rule revises process for POHs to request exceptions (New 42 CFR sec. 411.363)
  - 88 Fed. Reg. 58640, 59283 (Aug. 28, 2023)
- Eligibility as an “applicable hospital” or a high Medicaid facility
- Determining the baseline size of the facility
- Data and information required for expansion exception requests
  - CMS seeks “more robust” community input
- Reinstating certain restrictions on expansion requests for high Medicaid facilities

Provider Enrollment Developments

Provider Enrollment Rulemaking

- New revocation and denial authority for FCA civil *judgments*
- New enrollment action: “Stay of Enrollment”
  - Preliminary, interim status—prior to any subsequent deactivation or revocation
  - Non-compliance with enrollment requirements
  - Retroactive payment possible if certain conditions are met (change from NPRM)
- Clarification of revocation authority when debts are referred to the U.S. Department of Treasury
- Revocation / denial authority for misdemeanors *not* finalized
- 88 Fed. Reg. 78818 (Nov. 16, 2023)

Provider Enrollment Rulemaking

- Hospice certifying physicians must be enrolled or have formally opted-out (effective May 1, 2024)
- Hospices moved to a higher level of enrollment screening
- “36 Month Rule” now applies to hospices
- Period of Medicare non-billing for which a provider or supplier can be deactivated reduced to six months from 12 months.
- 88 Fed. Reg. 51164, 51186 (Aug. 2, 2023); and
- 88 Fed. Reg. 77676, 77843 (Nov. 13, 2023)

New Nursing Home Transparency Rules

- Require disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities and Medicaid nursing facilities.
- Implement section 6101 of the Affordable Care Act (section 1124(c) of the Social Security Act)
- Disclosure tied to provider enrollment and the CMS-855A enrollment application
- CMS noted its concern about the quality of care at nursing homes, especially those owned by private equity companies and other types of investment firms
- Consistent with the statute, data will be made public

New Nursing Home Transparency Rules

- Information to be disclosed includes those who:
  - Exercise operational, financial, or managerial control over the facility or a part of it
  - Lease or sublease real property to the facility
  - Provide financial or cash management services to the facility
- Provide the “organizational structure” of disclosed entities
- New definitions of:
  - Private Equity Company
  - Real Estate Investment Trust
- 88 Fed. Reg. 80141 (Nov. 17, 2023)

Expansion of CMS Denial and Revocation Authorities

- Noncompliance with Enrollment Requirements in “title 42, or the enrollment application”
- Civil Judgements Entered after **1/1/24**
  - Effective 1/1/24, CMS has discretionary denial or revocation authority if a provider/ supplier, or any owner, managing employee or organization, officer, or director has had an FCA civil judgment entered against them within the previous 10 years.
  - “Civil judgment” does not include False Claims Act settlement agreements
- Noncompliance with Standards/Conditions (IDTF, DMEPOS, OTP, HIT, MDPP)
- **No** Expansion of CMS Denial/Revocation Authorities for Certain Misdemeanors

Reduction of Timeframe for Reversing Revocation

- Revocation due to adverse action by a party (e.g., owner, managing employee, authorized or delegated official, supervising physician) may be reversed if the provider/supplier terminates its business relationship with the party within **15 days** of the revocation notice and submits proof of such termination.

Expansion of Retroactive Revocation Authority

CMS may retroactively revoke enrollment in the following situations:

- State license surrender in lieu of further disciplinary action
- Termination from a federal healthcare program other than Medicare
- Revocations based on termination of a provider agreement under 42 CFR part 489
- Revocations of an IDTF, DMEPOS supplier, OTP, HIT supplier or MDPP's enrollment for a violation of standard or condition

New Regulatory Definitions

Added definition of “**indirect ownership interest**,” to clarify precisely what constitutes indirect ownership interest, and how to calculate such indirect ownership interest

Amended definition of “**supplier**” at 42 C.F.R. 424.502 to include physical therapists in private practice, occupational therapists in private practice and speech-language pathologists.

Amended definition of “**authorized official**” to clarify that the “organization” referenced in the definition is meant to refer to the enrolling **entity**, as defined by its legal name and tax identification (rather than the provider or supplier **type** the entity is enrolling as).

Other Enrollment Changes

- Changes in Timeline for Reporting Change of Location:
  - Effective 1/1/24, all providers and suppliers must report a change in practice location **within 30 days of the change**.
  - Change in practice location includes adding a new location or deleting an existing location.
- New practitioner enrollment categories
  - MFTs and MHCs may now enroll as Medicare suppliers
    - Eligible to bill for services rendered on or after 1/1/24
  - Through CY 2024, telehealth practitioners may use their currently enrolled practice location instead of using their home address when providing services from their home
- Expansion of reapplication bar (applies to all providers / suppliers):
  - CMS may bar reapplication for a prospective provider/supplier for up to 10 years if enrollment application denied because of false/misleading or missing information
    - Only used when factors described in regulation indicate that it is warranted
  - Provider/supplier that sis currently subject to a reapplication bar may not order, refer, certify, or prescribe Medicare-covered services, items, or drugs

Resources

- 2024 Medicare Physician Fee Schedule Final Rule (88 FR 78,818 (November 16, 2023))
- 2024 Home Health Prospective Payment System Final Rule (88 FR 77,676 (November 13, 2023))
- Final Rule re Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities (88 FR 80,141 (November 17, 2023))
- CMS-855A (9/23)

Medicaid Unwinding

- Legislation ended the Medicaid continuous enrollment condition on March 31, 2023.
- The same legislation gave CMS new enforcement tools when states fail to meet federal Medicaid renewal requirements during the period from April 1, 2023, to June 30, 2024.
- HHS is focused on helping to ensure eligible people retain their coverage as unwinding continues.
- HHS is actively monitoring state unwinding activities and will continue to hold states accountable for following federal Medicaid renewal requirements.

Medicaid Unwinding

- CMS has suggested numerous strategies for states to adopt and has approved hundreds of waivers to make renewals easier.
- In summer 2023, CMS promptly responded when it learned that several states might be conducting ex parte renewals at the household rather than the individual level, potentially resulting in disenrollments of eligible individuals.
- In December 2023, CMS issued an interim final rule implementing the new enforcement authorities Congress gave CMS in the legislation ending the continuous enrollment condition.

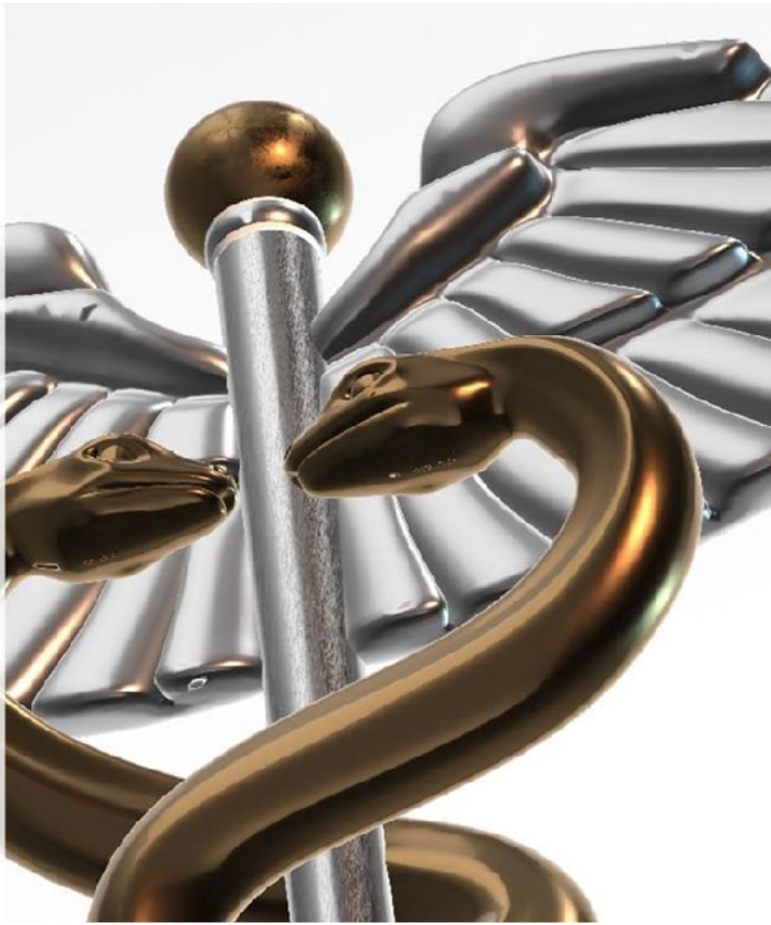
Miscellaneous Payment Updates

Patient Status Appeals

- Proposed rule for patients to appeal being reclassified from inpatient to outpatient/observation (12/27/2023)
  - https://edit.cms.gov/files/document/medicare-appeal-rights-certain-changes-patient-status-factsheet.pdf
- Creates appeals procedures to implement the court order in Alexander v. Azar, 613 F. Supp. 3d 559 (D. Conn. 2020), aff'd sub nom., Barrows v. Becerra, 24 F.4th 116 (2d Cir. 2022).
  - https://www.govinfo.gov/content/pkg/FR-2023-12-27/pdf/2023-28152.pdf
- Expedited process for eligible beneficiaries to appeal while they are still in the hospital
- Standard appeals for patients to file appeals after leaving the hospital
- Retrospective process for beneficiaries with hospital admissions on or after 1/1/2009

2024 Conversion Factor

- **Finalized:**
  - **Physician: $32.7476 (-3.36%)**
  - **Anesthesia: $20.4370 (-3.26%)**
- Continued negative adjustments since 2021 in the midst of inflation and workforce shortages, but Congress has not yet intervened.
- H.R. 2474, the Strengthening Medicare for Patients and Providers Act
  - Creates a permanent annual update to the CF equal to the Medicare Economic Index
- Negative reimbursement impact to proceduralist and surgical practices



Transitional Coverage of Emerging Technologies

- Faster pathway to coverage for “Breakthrough Devices”
- Uses national coverage determination (NCD), and coverage with evidence development (CED) processes to expedite Medicare coverage of certain Food and Drug Administration-approved technologies to treat life-threatening or irreversible debilitating medical conditions.

- FY 2025 NTAP Changes:
  - 42 CFR §412.87(e)(2) requires: “...documentation of FDA **acceptance or filing** of the request...” (Bold added) prior to the NTAP application filing deadline
  - “Acceptance” means an “FDA Acceptance Letter” while “filing” means a “FDA Filing Review Notification” CMS is requiring BOTH even though the regulation says one or the other is required
  - Must receive FDA approval or clearance by May 1 (rather than July 1) of year prior to beginning of FFY (except for applications under alternative pathway for certain antimicrobial products)

Evaluation & Management Services

E&M Complexity Add-On Code G2211

- Add on to office/outpatient visits for "*complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*"
- Focus is on longitudinal relationships between patients and physicians
- Not billable with minor procedures and E&M + modifier 25
- CMS expects G2211 to be reported with many office visits – 38% to 54 %

Split/Shared Visits

- Same-day E&M facility services by physicians and APCs in the same group
- Visit billed by the professional who performs medical decision making or more than 50% of the time
- Usual incident to rules apply to office visits that involve physicians and APCs

Split/Shared Visit

An E/M visit performed by a physician and a non-physician practitioner (NPP) in the facility setting on the same calendar date

Does not apply to non-facility settings

Since 2022, critical care and SNF services are permitted to be billed as split/shared services

Combined service must be billed under one provider if in the same group practice

When the NPP bills, 85% of the MPFS is reimbursed

History of Split/Shared Rule (2022 – 2023)

- **2022:**
  - NPP or Physician performs face-to-face visit
  - Substantive portion based on time, or
  - History, Exam, or MDM – per 1995 or 1997 E/M Documentation Guidelines
- **2023:**
  - NPP or Physician performs face-to-face visit
  - Substantive portion based on time, or
  - History, Exam, or MDM – per 2023 E/M Documentation Guidelines
  - **Issue**: History and Exam no longer a part of level determination (Subjective)
  - **2023 Note**: Critical care changes were not delayed, and CMS corrected its error in the guidelines and reiterates that the full 30 minutes must be met to bill for the 99292 (104 minutes).

Source: https://www.cms.gov/files/document/mm13473-how-use-office-and-outpatient-evaluation-and-management-visit-complexity-add-code-g2211.pdf

2024 MPFS Final Rule Update

- The implementation of time only will not be finalized.
- Maintains requirement of substantive portion to determine the billing provider
- NPP or Physician performs face-to-face visit
- More than half of the time spent by the physician or NPP – ***or*** –
- Substantive part of the MDM

Telehealth & Virtual Care

- Consolidated Appropriations Act, 2023 extended telehealth services for patients in their homes covered under the Physician Fee Schedule to 12/31/24
- Includes selected services performed by hospital staff but paid under the PFS, such as physical therapy
- Expanded services
  - Health and Well-Being coaching (0591T, 0592T, 0593T) – temporary coverage through 2024
  - SDOH health risk assessment (G0136)
  - Diabetes Self-Management Training (G0108 – G0109)
- Federal legislation needed to extend coverage into 2025
  - Except for behavioral health services and traditional facility-based telehealth for rural areas
  - Requirement for periodic in-person visits for behavioral health patients on hold until 2025

More Telehealth

- **Billing and payment:**
  - **Beginning January 1, 2024**, use POS 02 (telehealth provided other than in patient's home) or POS 10 (telehealth provided in patient's home).
    - **Discontinue use of 95 modifier + POS if service had been furnished in person.**
  - POS 02 to be paid at facility rate; POS 10 to be paid at non-facility rate.
- Suspend frequency limitations for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultations.
- Permanently eliminate in-person requirement for injection training for Diabetes Self-Management Training; expands list of eligible DSMT distant site providers.
- Continue to permit Opioid Treatment Programs to furnish periodic assessments via audio-only telecommunications through end of 2024.
- For 2024, originating site facility fee (Q3014) will be $29.92 (up from current $28.64) (based on increase in Medicare Economic Index).

Direct Supervision vs. Virtual Supervision

- **Direct supervision required for:**
  - Incident-to billing
  - Certain diagnostic tests
  - Pulmonary rehab
  - Cardiac rehab and intensive cardiac rehab
- **Pre-PHE**: Supervising practitioner physically present and immediately available to provide assistance.
- **During PHE**: Virtual presence using real-time audio/video technology.
- **Post-PHE**: Continue virtual presence thru 2024; potentially, revert to direct supervision requirements per clinic and outpatient hospital department guidelines.

Virtual Supervision for Teaching Physician Services

- Continue to permit teaching physician to have virtual presence when service furnished via telehealth (three-way telehealth visits).
- Teaching physician must present for the critical portions of the procedure and immediately available
  - Surgical, high risk, interventional, endoscopic, or other complex procedures

Remote Physiologic Monitoring (RPM) & Remote Therapeutic Monitoring (RTM)

- RPM = monitoring of vital signs and other indicators
- RTM = monitoring therapy adherence, response to treatment
- Monthly fees for monitoring patients via technology and communicating with them
- Collect data at least 16 of 30 days
- Allowed during global surgical period for clinicians other than the proceduralist
- CPT rules prohibit reporting both in the same month
- Can be billed with care management codes as long as time is not counted twice

RPM – What's New?

- Revises regulations to permit Medicare-enrolled PTs and OTs to bill for RTM services furnished by PTAs/OTAs under general supervision.
- Clarifies that RPM or RTM may be furnished to patients within a global surgery period for surgery if services unrelated to diagnosis for which surgery performed, and addresses episode of care distinct from surgical episode.
- While RTM does not have established patient requirement, such services would be furnished after treatment plan established.
- Adds certain RPM and RTM codes to to list of RHC/FQHC care management services reimbursed under G0511.
  - Includes monthly monitoring (CPT 99454, 98976, 98977, 98978) and treatment management services (CPT 99457 and 98980).

“The Medicaid statute (as is true of other parts of the Social Security Act) is an aggravated assault on the English language, resistant to attempts to understand it. The statute is complicated and murky, not only difficult to administer and to interpret but a poor example to those who would like to use plain and simple expressions.”

~ Friedman v. Berger, 409 F. Supp. 1225 (S.D.N.Y. 1976)

In-House Counsel Panel

What Keeps You Up at Night

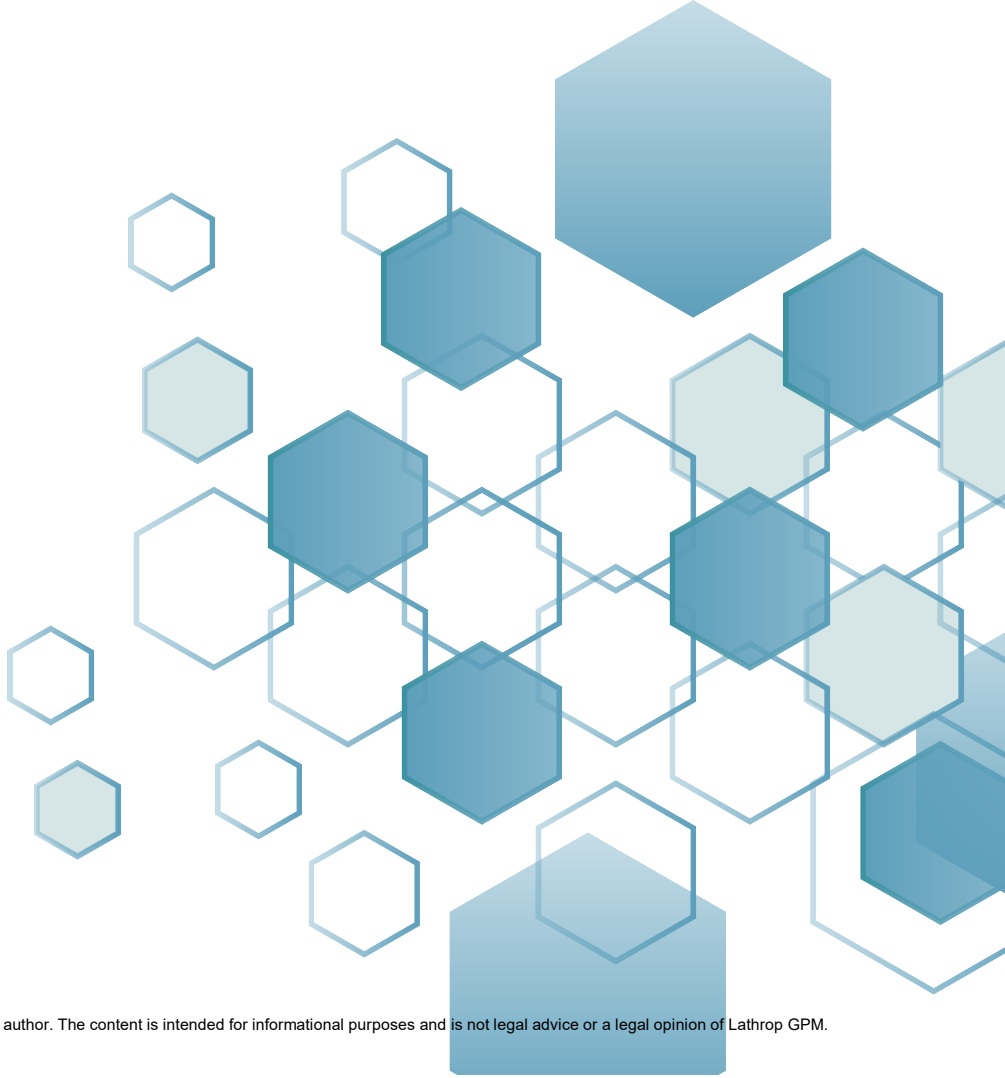
Santo Cruz, CentraCare
Henry Parkhurst, Hennepin Healthcare System
Emily Pryor Winton, Children's Minnesota
Jennifer Reedstrom Bishop, Lathrop GPM

Break

Lathrop GPM

The Evolving AI Legal Landscape and Impacts to Health Care

Greg Thole, CHC, Oracle
Kathleen Fisher Enyeart, Lathrop GPM



Why be Worried about AI?

DARKNESS OVER AMERICA!
Zoo animals freak...
Woman shooting at cars says 'God made me do it'...

AI WARNING: 'SOCIAL ORDER COULD COLLAPSE'

DRUDGE REPORT

DRAMA: Appeals court judge DENIES Trump's bid to delay next week's criminal trial... Developing...

'Zombie case' brought back to life...

Librarians fear new penalties, even prison, as activists challenge books...

McConnell calls for TIKTOK ban...

Drama builds for embattled Speaker...

Greene escalates pressure...

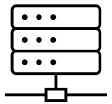
Inside surveillance law nightmare...

CHALLENGES AND RISKS

White House AI Bill of Rights – October 2022

Principles

- Safe and Effective Systems

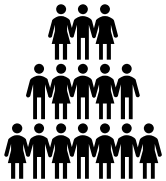


- Algorithmic Discrimination Protections

- Data Privacy

- Notice and Explanation

- Human Alternatives, Consideration and Fallback

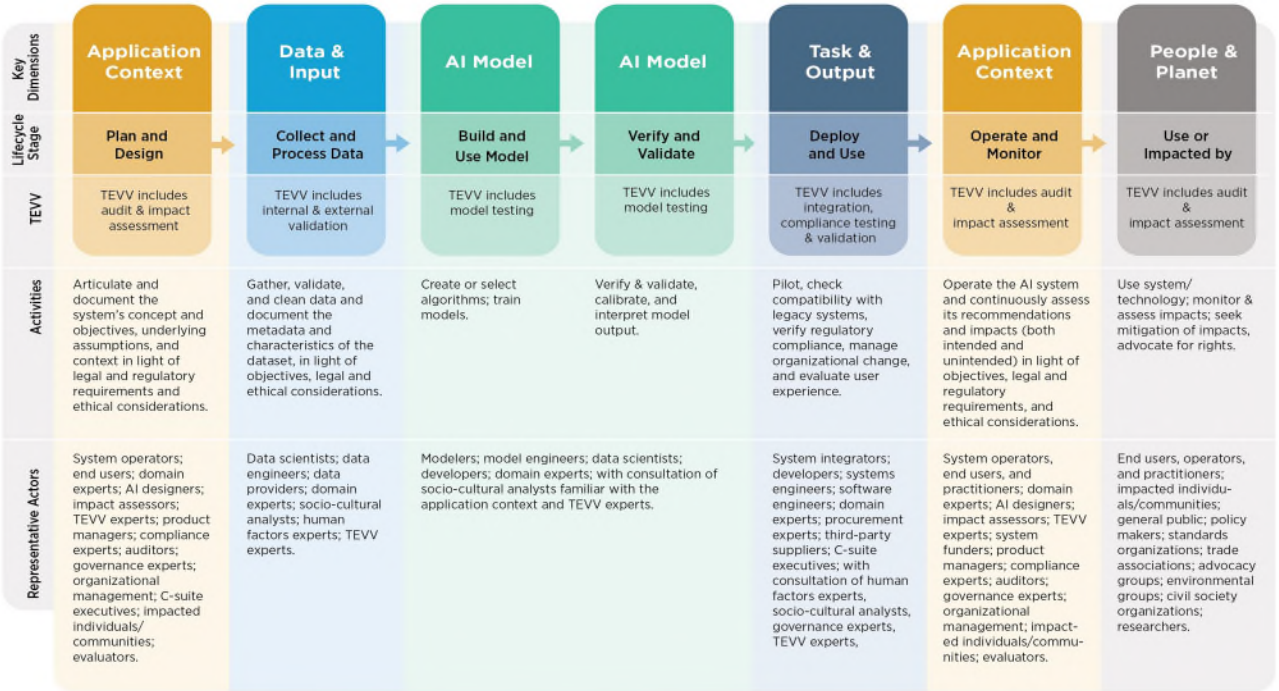


- **The framework applies to**
  - **(1) automated systems that**
  - **(2) have the potential to meaningfully impact the American public's rights, opportunities, or access to critical resources or services**

Biden Executive Order – October 30, 2023 – Directs Federal Entities to Implement Guidance over 8 policy areas

- Safety and security - develop and implement mechanisms to mitigate risks related to AI, including biosecurity, cybersecurity, national security, critical infrastructure.
- Innovation and competition. Attract AI talent to the US, understand novel IP questions, protect inventors/creators, promote AI innovation, including startups and small businesses.
- Worker support. Agencies should research and develop potential mitigations against workforce disruptions.
- AI bias and Civil Rights. Equity and civil rights should be considered when using AI in the criminal justice system and the administration of federal government programs and benefits.
- Consumer protection. Enforce existing authorities to minimize harms to consumers.
- Privacy. Evaluate and mitigate privacy risks associated with collection, use, retention of user data.
- Federal use of AI. Office of Management and Budget establish interagency council to coordinate AI use by federal agencies and develop guidance on AI governance and risk management activities for agencies.
- International leadership. The US should be a global leader in AI development and adoption by engaging with international allies and partners, leading efforts to develop common AI regulatory and accountability principles, and advancing responsible global technical standards for AI.

NIST Risk Management Framework for AI



Categories of Legislation to Regulate AI

- Anti-Discrimination
- AI Bill of Rights
  - Transparency around use of AI
- Automated Employment Decision Making
- Risk Management Requirements for Responsible Use of AI

New AI Act in EU

Passed by EU Parliament on March 13, 2024

World's first comprehensive AI legislation

Expected to be enacted

Applies to AI products in the EU market even if developed outside of EU

Fines of up to 7% of a company's worldwide revenue

Four Categories of Risk

- Unacceptable Risk: Prohibited with limited exceptions
- High Risk: Requires assessments before AI is released in the market. Requires rigorous testing, documentation of data quality, accountability framework. High risk includes self-driving vehicles, med devices, critical infrastructure, education, government services
- Limited Risk: Must be transparent, e.g. hu mans must be informed about their interaction with the Alany deep fakes should be denoted as such. For example, chatbots classify as limited risk.
- Low/Minimal Risk: No restrictions or mandatory requirements. Applies to AI systems that do not fall into other categories, such as a spam filter.

Global AI Regulations

- **Canada** - AI and Data Act – Bill C-27 – Currently in Committee
  - Requires developers to conduct risk assessments, establish risk mitigation measures, ensure continuous monitoring, and publicly disclose information about the functioning, intended use, and risk management of high-impact AI systems.
  - Establishes the role of AI and Data Commissioner to oversee compliance and introduces substantial fines to deter reckless or malicious AI use.
- **India** – Proposed Digital India Act
- **China** – Many Regulations Already in Force, Comprehensive Legislation Underway
  - Current Regulations: Algorithmic Recommendation Management Provisions • Interim Measures for the Management of Generative AI Service • Deep Synthesis Management Provisions • Scientific and Technological Ethics Regulation
  - New Draft Artificial Intelligence Law – Draft of Scholars' Suggestions

Evolving State Regulations

More than 1/4 US States have proposed or enacted legislation

Some laws address AI risks through data privacy legislation

California Senate Bill 1047: Safe and Secure Innovation for Frontier AI Models Act

- Safety Assessment Requirement & Third Party Model Testing
- Shutdown Capability
- Annual Compliance Certification
- Safety Incident Reporting
- Policies for Computing Clusters, requiring cloud computing centers to be aware of customer AI models

Colorado Insurance Regulation and AI Act SB 205 - Anti-Discrimination

- Life Insurers using external consumer data and information sources (ECDIS) including algorithms and predictive models, must meet governance and risk management requirements
- AI Act SB 205: Anti-discrimination law that regulates high-risk AI systems through requirements on *developers and deployers*
- Companies conducting business in CO must disclose to AG “any known or reasonably foreseeable risk of algorithmic discrimination, within 90 days after the discovery or receipt of a credible report.”
- Signed by Governor May 17, goes into effect February 1, 2026

AI Bill of Rights Utah SB 149 - May 1, 2024 Oklahoma HB 3453 proposed

- **Right to Be Informed:** Right to be informed when interacting with AI, rather than a human counterpart.
- **Right to Be Notified:** Right to be notified when their personal data is utilized in AI models, coupled with the ability to opt-out.
- **Right to Know:** Right to know when content is created solely by AI. This ensures that individuals are not misled into believing AI-generated content as human-authored.
- **Right to Approve:** Right to approve any use of one’s likeness or voice generated by AI.
- Similar bill pending in NY A8129

Employment – Automated Employment Decision Tools
NYC Local Law 144

Applies to employers and agencies using AEDTs to evaluate candidates for employment or employees for promotion that reside in NYC.

AEDT – Defined as a computation process derived from machine learning, statistical modelling, data analytics, or AI used for a simplified output, such as a score, classification or recommendation, where the output substantially assists or replaces discretionary decision making.

Requires annual independent, impartial Bias Audits of AEDTs. Audit must asess whether AEDT results in disparate impact based on race/ethnicity and/or sex/gender.

Requires transparency and notice requirements including results of a Bias Audit before using the AEDT, notice that AEDT will be used and the option for candidates to request an alternative procedure

Illinois AI Video Interview Act and Maryland HB 1202 Enacted

Proposed bills Massachusetts (H 1873), New Jersey (S1588), NY State (several proposals) and Vermont (H 114)

Agency Regulations and Actions

EEOC

- Artificial Intelligence and Algorithmic Fairness Initiative (2022)
- Public Hearing (January 2023)
- The Americans with Disabilities Act and the Use of Software, Algorithms, and Artificial Intelligence to Assess Job Applicants and Employees (May 2022)
- Select Issues: Assessing Adverse Impact in Software, Algorithms, and Artificial Intelligence Used in Employment Selection Procedures Under Title VII of the Civil Rights Act of 1964 (May 2023)
- 2023 Strategic Enforcement Plan “Recognizes employers' increasing use of automated systems, including artificial intelligence or machine learning, to target job advertisements, recruit applicants, and make or assist in hiring decisions” (September 2023)

FTC Actions Targeting AI

- FTC v. RiteAid – banning use of facial technology in stores
- FTC v. Alexa – penalties for failure to delete voice recordings of minors
- FTC v. Ring – illegally surveilled customers and failed to stop hackers from taking control of users’ cameras
- FTC warning that companies should notify consumers when AI tools are being utilized, i.e., a chatbot, warning should advise consumer they are not interacting with a human

SEC – Enforcement and Use of AI

First Enforcement Actions against AI Washing

Charged Two Investment Advisers For False And Misleading Statements About Purposed Use Of AI

Director Of Enforcement Warns That If Investors Represent They Are Using AI, Representations Must Not Be False Or Misleading

Publicly Traded Companies Could Mislead Through AI Washing In SEC Filings, Press Releases Or Websites

Use of AI to Identify Insider Trading

- SEC uses AI to detect trends in tips, complaints and referrals received
- Uses data analytics to uncover potential insider trading and inaccuracies in financial reporting, as well as money laundering, bribery, etc
- At the same time DOJ is weighing the use of AI in the criminal justice system and considering the risks of bias and other inequities

Healthcare

Health AI Areas of Activity

Applicable Federal Policies		
Nondiscrimination in Health Programs and Activities Proposed Rule (Section 1557 of the Affordable Care Act)	**CDS and Device Software Function-related Guidance Documents**	**ONC Health IT Certification Program *(HTI-1 rulemaking)***
Who Must Comply?		
Health care provider and health plan using AI to support decision-making in covered health programs and activities	*Manufacturer of device software functions (e.g., AI-enabled software that meets the definition of medical device)*	*Developers of certified health IT that supply a predictive DSI as part of a Health IT Module*
What Must Be Done?		
Not use clinical algorithms in discriminatory ways	Receive FDA-approval for demonstrating the device software function's safety and effectiveness	Provide transparency information about predictive DSI's to clinical customers and engage in risk management practices

ONC HTI-1 Final Rule – Decision Support Interventions (DSI)

- ✓ Applies to certified EHR technology (CEHRT)
- ✓ Imposes requirements on certified EHR developers related to both "predictive" and "evidence-based" DSIs
- ✓ Summary of requirements for certified EHR developers:
  1. Enable customers to create or implement their own DSIs
  2. Make "source attributes" available to users for DSIs supplied by the developer
  3. Enable customers to edit "source attributes" content supplied by the developer
  4. Enable customers to record "source attributes" for DSIs they implement or activate independently
  5. Enable users to provide real-time feedback on DSIs they interact with
  6. Establish intervention risk management policies/procedures for developer-supplied predictive DSIs
  7. Publicly publish summary documentation about risk management policies/procedures and governance

Predictive DSI

"Technology that supports decision-making based on algorithms or models that derive relationships from training data and then produces an output that results in prediction, classification, recommendation, evaluation, or analysis." (source)

Evidence-Based DSI

DSIs that "…rely on pre-defined rules based on expert consensus, such as computable clinical guidelines, to support decision-making." (source)

"…limited to only those DSIs that are **actively presented** to users in clinical workflow to enhance, inform, or influence decision-making related to the care a patient receives" (source)

What qualifies as a “predictive” DSI?

Criteria for determining qualification (all must = yes)

1. The product/feature is **deployed in US Markets**
2. The product/feature is **deployed or surfaced in ONC-certified EHR**
3. The product/feature **supports decision making** for system end-users (whether clinical, financial, administrative, or otherwise)
4. The product/feature **utilizes algorithms or models that derive relationships from training data** (i.e., AI/ML-based as opposed to utilizing pre-defined rules based on consensus clinical guidelines, bespoke business processes, or organizational policies)
5. The product/feature **produces an output** resulting in prediction, classification, recommendation, evaluation, or analysis

Examples that would qualify as “predictive” DSIs

Models that predict whether a given image contains a malignant tumor or that predict patient reported pain based on an image, trained based on relationships observed in large data sets often using neural networks

Models that pre-selected or highlighted a default order from an order set based on relationships in training data indicating that order was most likely to be selected

Models that predict risk of sepsis, readmission (e.g., LACE+), eGFR, or risk of suicide attempt, which have been trained based on relationships observed in large data sets, often using logistic regression and machine learning techniques, and are used to support decision making

Models that generate clinical notes or draft clinical notes and that were trained based on relationships in large data sets of free text, including large language models, and support decision making about what to document in the clinical note

Models that use NLP to route secure messages, which were trained based on the relationship between message contents and the individual who responded to similar messages in the past

Source: https://www.federalregister.gov/d/2023-28857/p-741

Examples that would not qualify as a “predictive” DSI

Indices and classification systems developed by expert consensus rather than in empirical data, such as the SOFA index and NYHA Heart Failure classification (would instead qualify as evidence-based DSIs)

Rules-based algorithms for routing secure messages based on the type of message, rather than relationships in training data (not based on relationships derived from training data)

Growth charts, for instance percentile calculations based on a lambda-mu-sigma transformation of similar age children’s weights, with parameters learned in training data from a national sample of children (based on a single variable instead of relationships between variables)

Patient matching algorithms based on indices of similarities, rather than by relationships in training data where an outcome is known (qualifies as unsupervised machine learning, which does not predict an unknown value)

Optical character recognition, used simply to make a PDF readable or searchable to end users (does not support decision-making)

Source: https://www.federalregister.gov/d/2023-28857/p-741

Predictive DSI “Source Attributes”

- Details and output of the intervention
- Purpose of the intervention
- Cautioned out-of-scope use of the intervention
- Intervention development details and input features
- Process used to ensure fairness in development of the intervention
- External validation process
- Quantitative measures of performance
- Ongoing maintenance of intervention implementation and use
- Update and continued validation or fairness assessment schedule

Evidence-Based DSI “Source Attributes”

Bibliographic citation

Developer

Funding source

Release/revision dates

Specific data used in the intervention

Predictive DSI Intervention Risk Management

Risk Analysis

- Assess for: Validity, Reliability, Robustness, Fairness, Intelligibility, Safety, Privacy, Security
- Estimating likelihood and magnitude of negative impacts (harm) or consequences
- Identifying to whom the risk applies
- Identifying source of the risk

Risk Mitigation

- Prioritizing identified potential risks
- Mitigating or minimizing identified potential risks
- Establishing change control plans or ongoing validation processes
- Establishing processes to deactivate a DSI where appropriate
- Inclusion of SMEs in processes

Governance

- Implementing controls and oversight to enforce adherence to IRM policies and procedures
- Establishing policies and controls for how data are acquired, managed, and used for predictive DSIs

Clarifying DSI requirements for healthcare providers

What is required

- ✓ Equipping your EHR system with the ability to support enablement of DSIs at your discretion
- ✓ Supporting ability for users to provide feedback on DSIs they interact with
- ✓ Supporting ability to export feedback submitted by users for review
- ✓ Supporting ability for users to access, modify, and record source attributes for DSIs enabled in the EHR

What is <u>not</u> required

- × Use of specific DSIs or other types of AI/ML
- × Adoption or creation of any new DSIs using the enhanced capabilities
- × End-users leveraging the new feedback capability
- × Exposing source attributes for all DSIs in your system
- × Recording source attributes for DSIs you create or implement
- × End-users accessing or actively utilizing source attribute information

FDA Medical Device Regulation

AI/ML technology that meets the definition of a “medical device” is subject to FDA regulation in the US

- AI/ML technology providing recommendations to health care providers (HCPs) must meet all criteria below to be excluded from the definition of a medical device
  - Note that ONC source attributes are designed to align with these FDA criteria – particularly #3 (see here for more details)

Factors to qualify as non-device clinical decision support under FDA regulation

- Software function does NOT acquire, process, or analyze medical images, signals, or patterns
- Software function displays, analyzes, or prints medical information normally communicated between HCPs
- Software function provides *recommendations* to an HCP rather than provide a specific output or directive
- Software function provides basis of recommendations so that the HCP does not rely primarily on any recommendations to make a decision

Source: https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device

OCR Regulation – Nondiscrimination in Health Programs

Nondiscrimination in the Use of Patient Care Decision Support Tools (effective April 2025)

- Prohibition of discrimination on the basis of **race, color, national origin, sex, age, disability** or any combination thereof
- **Patient care decision support tool**
- Any automated or non-automated tool, mechanism, method, technology, or combination thereof used to support clinical decision-making in its health programs or activities.
  - Includes all automated decision systems and AI used to support clinical decision-making
  - Includes predictive DSI as defined by ONC
  - Includes non-automated and evidence-based tools that rely on rules, assumptions, constraints, or thresholds, as these also have the potential to result in discrimination.
- Other examples of patient care decision support tools:
  - Flowcharts; formulas; equations; calculators; algorithms; utilization management applications
  - Software as medical devices (SaMDs); software in medical devices (SiMDs);
  - Screening, risk assessment, and eligibility tools; and diagnostic and treatment guidance tools.

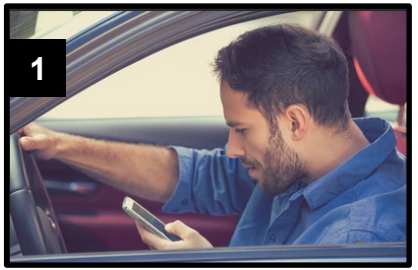
Healthcare Provider Impacts and takeaways

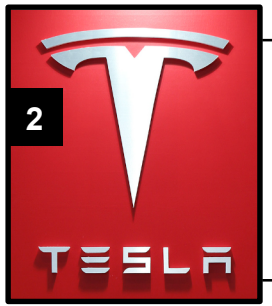
- Applies to all health programs and activities that receive federal financial assistance from HHS (including Medicare Part A and B reimbursements)
- Expectation is to take steps to identify and mitigate any discrimination via use of AI and other forms of decision support tools in patient care
  - Identify patient care decision support tools used in health programs and activities that employ or measure relevant input variables
  - Make reasonable efforts to mitigate the risk of discrimination resulting from applicable tools' use
  - Utilize ONC's HTI-1 requirements to learn about the data used in DSIs via vendors' source attributes and intervention risk management practices.

Source: https://www.federalregister.gov/d/2024-08711

Evolving AI Legal Standards in Litigation

1. Identifying the Responsible Party:





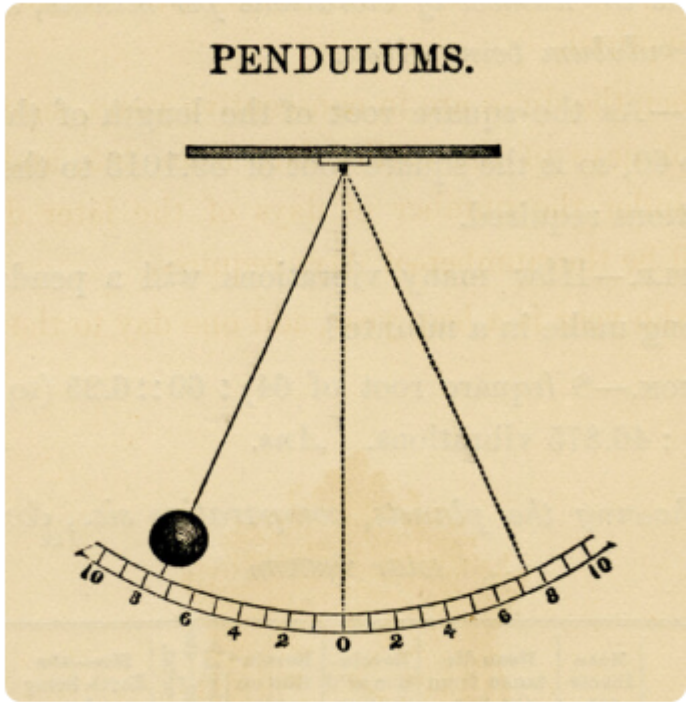
2. Standard of Care and Negligence:

MO jury instruction on standard of care: The phrase “ordinary care” means that degree of care that an ordinarily careful person would use under the same or similar circumstances. MAI 11.05.

KS jury instruction defining “negligence”: Negligence is the lack of reasonable care. It is the failure of a person to do something that a reasonable person would do, or doing something that a reasonable person would not do, under the same circumstances.

MN jury instruction defining “negligence”: Negligence is defined as “the failure to exercise such care as persons of ordinary prudence usually exercise under similar circumstances.” Jury Instruction 25.10; Mingo v. Extrand, 230 N.W. 895 (Minn. 1930

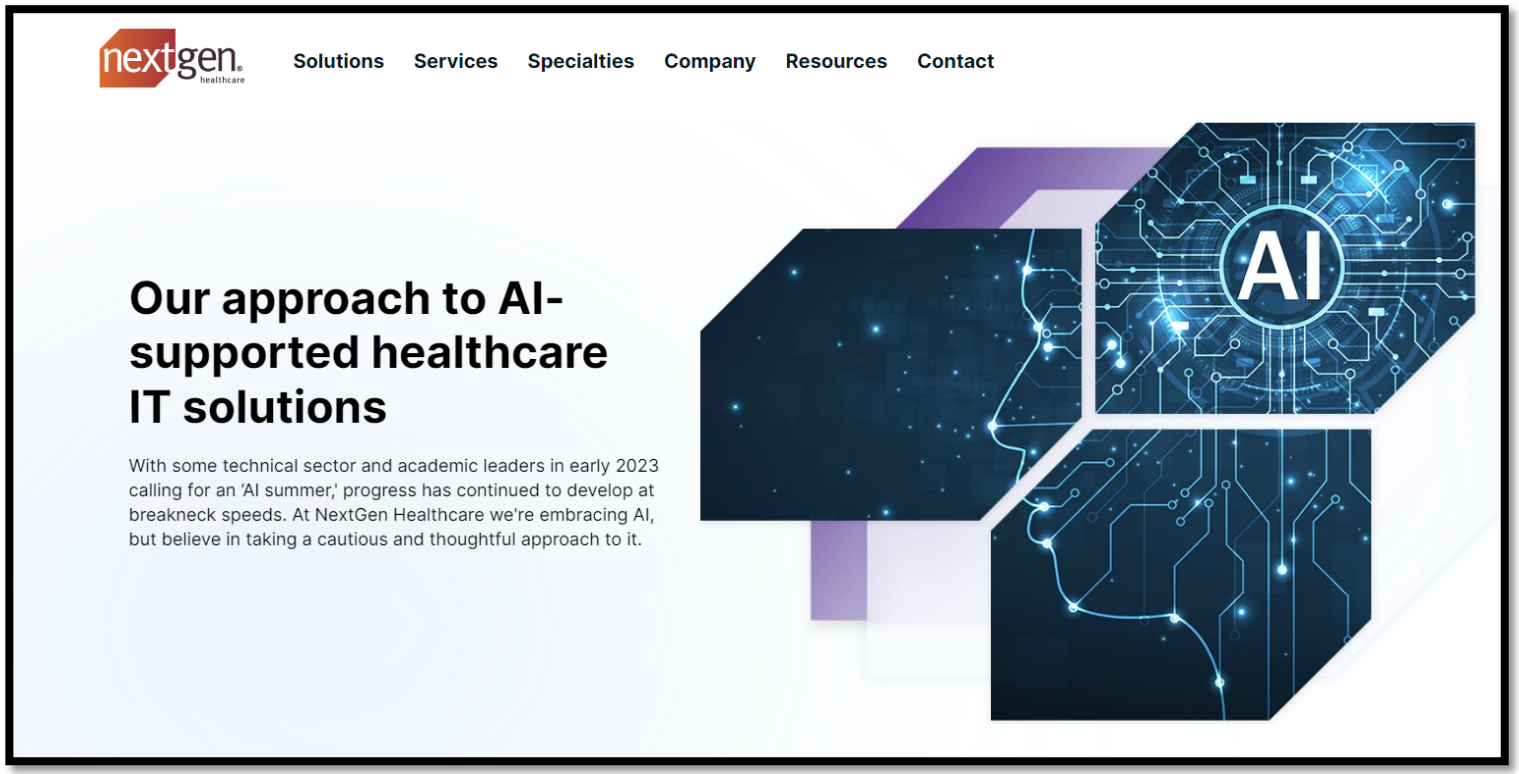
2. Standard of Care and Negligence:

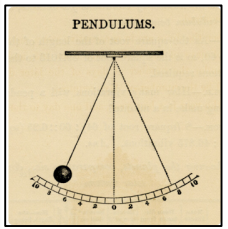


Old way: Software is not intended to be a substitute for the advice and professional judgment of a specialist.

New way: Software will augment and assist the specialist in arriving at a professional judgment.

2. Standard of Care and Negligence:





2. Standard of Care and Negligence:

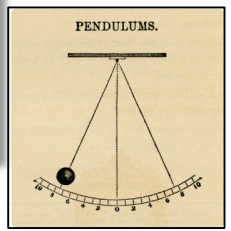
AUTOMATION IN HEALTHCARE IT

Where AI and healthcare meet

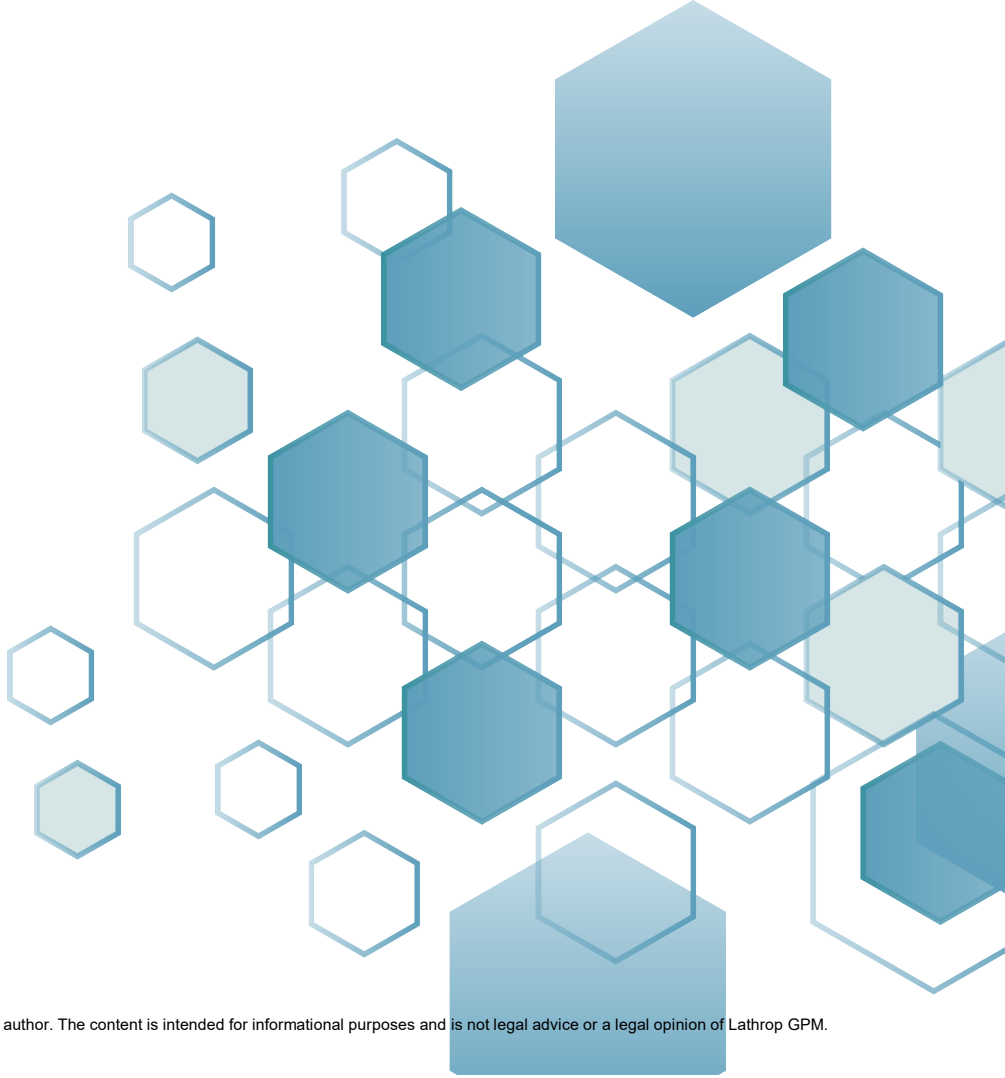
- Voice as an interface →
- Rules-based systems →
- **Diagnosis & documentation analytics →**
- Administration automation →

Diagnosis & Documentation Analytics

This is where task automation and generative AI meet. Think of diagnosis automation as crowd-sourcing existing diagnostic work to cover any blind spots an individual might miss . This technology isn't replacing your expertise; just giving you access to the expertise of countless others.

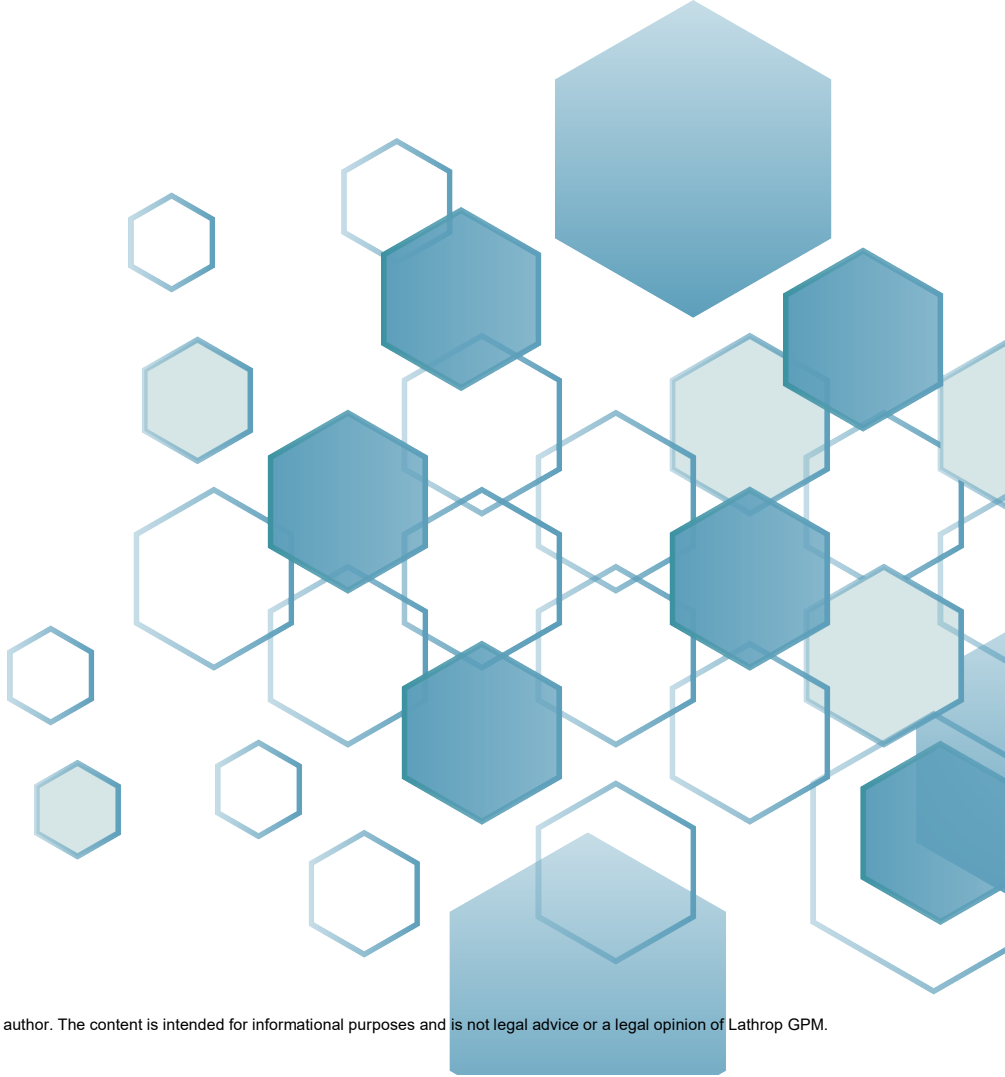


Lightning Round: Session 1



Recent Changes in Employment Law for Health Care Providers

Megan Anderson, Lathrop GPM



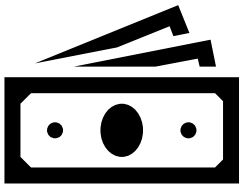
Wage and Hour Update – Exempt Employee Pay

- **U.S. Department of Labor (US DOL) Final Rule on Salary Requirements Under Fair Labor Standards Act (FLSA)**

Earnings Threshold	Current Amount	Starting July 1, 2024	Starting January 1, 2025
White Collar Exemptions (Executive, Professional, Administrative)	$684 per week (e.g. $35,568 annual salary)	$844 per week (e.g. $43,888 annual salary)	$1,128 per week (e.g. $58,656 annual salary)
Total Annual Compensation for Highly Compensated Employees (HCEs)	$107,432 per year, including at least $684 per week paid on a salary or fee basis	$132,964 per year, including at least $844 per week paid on a salary or fee basis	$151,164 per year, including at least $1,128 per week paid on a salary or fee basis

Wage and Hour Update – MN Minimum Wage

- **Elimination of Alternative Minimum Wages – Effective Jan. 1, 2025**
  - Elimination of different minimum wages for large vs. small employer resulting in same minimum wage regardless of employer size
  - Elimination of lower minimum wage for minor employee - as of 1/1/25, an employee under age 20 can be paid a lower minimum wage only for first 90 days of employment
    - To guard against provision being used to lower costs, MN law states, that no employer may displace an employee (including a partial displacement through a reduction in hours, wages, or employment benefits) to hire an employee at the lower wage.



Wage and Hour Update – Contractor Classification

- **US DOL Final Rule on FLSA Contractor Classification Test – Effective March 11, 2024**
  - Economic Realities Test
  - DOL will Analyze and Balance 6 Factors:
    (1) Opportunity for profit or loss depending on managerial skill
    (2) Investments by the worker and the potential employer
    (3) Degree of permanence of the work relationship
    (4) Nature and degree of control
    (5) Extent to which the work performed is an integral part o the potential employer's business
    (6) Skill and initiative
    (7) Additional factors

Minnesota Update – Contractor Classification

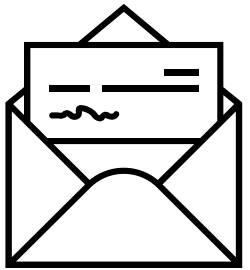
- **New MN Contractor Classification Law – Effective July 1, 2024**
  - For the construction industry, creates new 14 factor test
  - For all other industries, MN Department of Labor and Industry (DOLI) - which oversees MN wage/hour laws, MN OHSA, and MN workers' compensation matters - uses state's workers compensation or unemployment compensation tests
  - Law prohibits misclassification, failing to report an individual as an employee as required by law, and requiring employee to misclassify themselves
  - New penalties for misclassification for all industries
    - Up to $10,000 per violation, plus additional possible penalties
    - Individual liability for owners, officers or agents for knowing or repeated violations

Joint Employer Update

- **NLRB Issued New Joint Employer Rule**
  - Was to be effective in March 2024
  - Would have expanded joint employer status - an entity could be a joint employer of another entity's employees if (i) the two share or codetermine essential terms and conditions of employment; and (ii) the entity possesses or reserves authority to control one or more of an employee's essential terms and conditions of employment regardless of whether control is actually exercised
  - March 2024 – Texas federal court invalidated the rule as exceeding the NLRB's authority
  - July 19, 2024 - NLRB withdraws appeal of Texas court's ruling
  - Effect is that NLRB 2020 Joint Employer rule remains effective
    - Under that test, an entity is a joint employer of another entity's employees if it actually exercises "substantial direct and immediate control" over the essential terms and conditions of another company's employees.

Additional Minnesota Updates

- **Pay Transparency Law – Effective Jan. 1, 2025**
  - Applies to employers with 30 or more employees in Minnesota
  - Requires that all job postings include:
    - A starting salary range, or if no range, a fixed pay rate; a range must include a minimum and a maximum amount based on employer's good-faith estimate and cannot be open-ended
    - A description of all the benefits and other compensation, including but not limited to any health or retirement benefits associated with the position
  - Job posting is broadly defined to include "any solicitation intended to recruit job applicants for a specific available position, including recruitment done directly by an employer or indirectly through a third party, and includes any postings made electronically or via printed hard copy, that includes [sic] qualifications for desired applicants."
  - The law does not address whether it applies to postings for positions requiring physical presence in Minnesota or is also intended to apply to remote workers



Additional Minnesota Updates

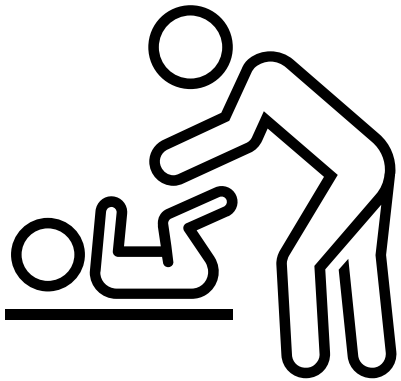
- **Amendments to MN Earned Sick and Safe Time (ESST) Law – Effective Immediately***
  - Pay for ESST time is to be calculated based on the employee's "base rate" of pay.
    - For example, if an hourly employee earns a premium rate for working weekends, their use of ESST time off on the weekend is paid at their regular base, not premium weekend pay
  - Funeral leave was added as a permissible ESST reason
  - Employer may not require reasonable documentation to support the use of ESST time until the employee takes leave for more than three consecutive *scheduled work* days
  - * If an employer uses a paid time off policy that is more generous than the MN ESST law, the employee protections of the ESST law apply to all of the employee's available time off benefits
    - *This provision is effective Jan. 1, 2025*

Additional Minnesota Updates

- **Amendments to MN Earned Sick and Safe Time (ESST) Law – Effective Immediately***
  - Employers will no longer be required to provide ESST time on pay statements and may "choose a reasonable system" to provide each employee's total number of EEST hours available and those used during each pay period.
  - Employers will no longer be required to provide ESST time in increments smaller than 15 minutes, but are prohibited from requiring the use of ESST in greater than 4-hour increments.
  - An employer who fail to allow the use of ESST under MN law is liable for an amount of money equal to the ESST time that was not provided or allowed to be used, *plus* an additional equal amount as liquidated damages.

Additional Minnesota Updates

- **MN Parental and Pregnancy Leave Enhancements – Effective August 1, 2024**
  - 12 weeks of leave under the MN Parental Leave Act may not be reduced by any period of paid or unpaid leave for prenatal care medical appointments
    - This creates potential for employee to be able to use more than 12 weeks of protected time away if they take pre-delivery time off for prenatal care before birth of child
  - Under MN Pregnancy Accommodation law, employers must continue providing insurance benefits for employees on a pregnancy accommodation leave, as well as for their dependents, as if the employees were not on leave. This brings state law in line with FMLA



Additional Minnesota Updates

- **Amendments to MN Paid Family and Medical Leave Law – Effective Jan. 1, 2026**
  - MN Paid FMLA law will be effective 1/1/26, and employers may participate in state administered paid leave program or a private plan if they meet opt out requirements
  - Amendments include, among other things:
    - Increasing the payroll tax from 0.7% established in 2023 to 0.88%
    - Allowing an authorized representative to apply for leave on the employee's behalf
    - Adding or clarifying several definitions, including, among others, terms such as "benefit year," "financially eligible," "initial paid week"
    - Providing a mechanism for excluded entities to opt into coverage
    - Requiring employers to grant leave in minimum increments of one calendar day

Additional Minnesota Updates

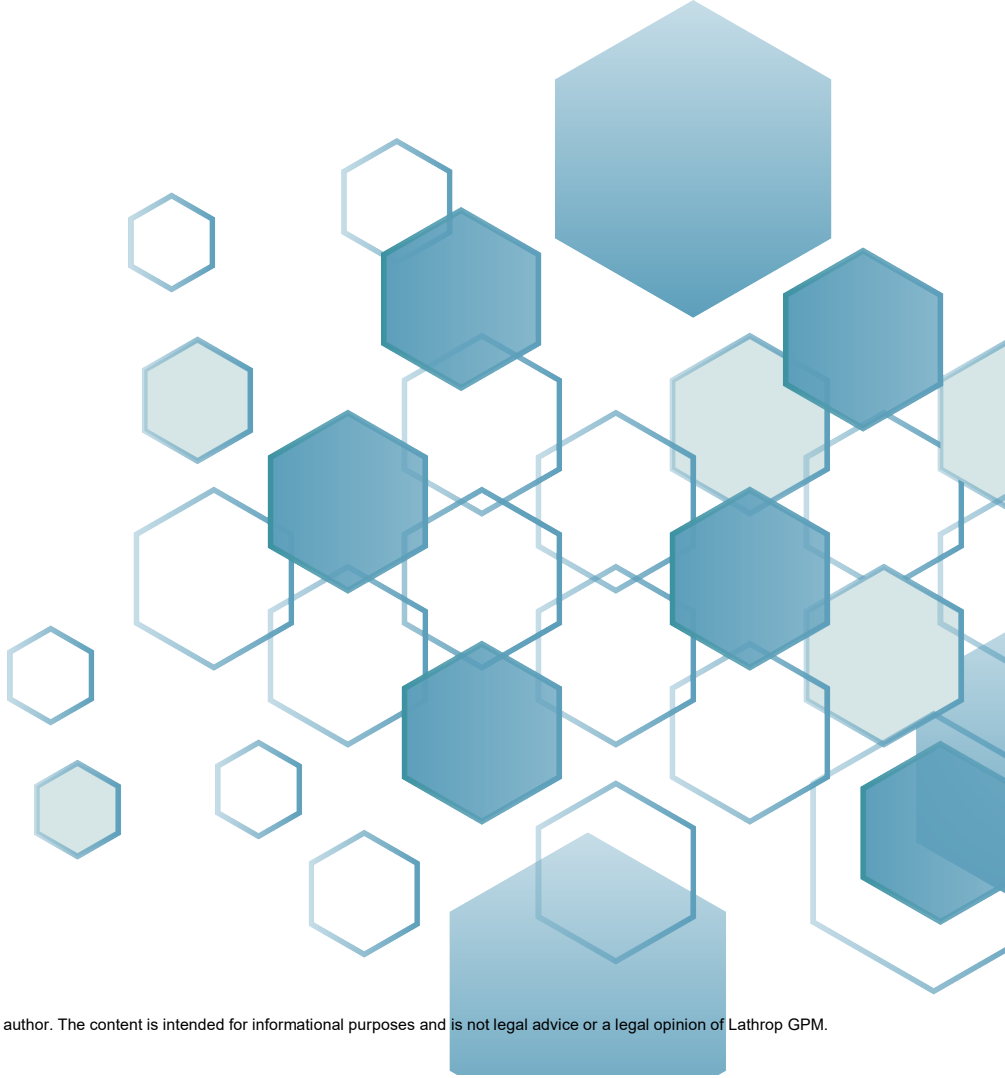
- **Amendments to MN Paid Family and Medical Leave Law – Effective Jan. 1, 2026**
  - Amendments include, among other things:
    - Employers may provide employees with wage replacement during an absence - if the total amount of paid benefits and supplemental benefits paid exceed the employee's usual salary, the employee must refund the excess to the employer or the MN paid leave division.
    - If an employer provides wage replacement to an employee for weeks that should be paid by the division, the division may reimburse the employer for those weeks.
    - Employees may receive disability insurance payments in addition to family and medical leave benefits, and disability insurance benefits may be offset by family and medical leave benefits paid to the employee pursuant to the terms of a disability insurance policy.

Additional Minnesota Update

- **Amendments to MN Human Rights Act – Effective August 1, 2024**
  - Expanded definition of discriminate, disability, and familial status
    - Discrimination includes harassment
    - Disability covers intermittent conditions even if in remission
    - Familial status encompasses caregivers
  - Expanded damages provisions, penalties, and removal of cap on punitive damages
  - Expanded period to file suit after MN Department of Human Rights dismissal – to 90 days
- **Amendments to MN Drug and Alcohol Testing Act – Effective Aug. 1, 2024**
  - Oral fluid testing now permitted

Non-Competes Are No Longer – Now What?

Catie Bitzan Amundsen, Lathrop GPM



Restrictive Covenants: Lay of the Land

- State and federal efforts to significantly limit non-competes
- Generally disfavored as a restraint on trade
- Public policy debate in healthcare sector
- Forms of restrictive covenants:
  - Non-Compete
  - Non-Solicitation
  - Non-Poaching
  - Confidentiality / Trade Secret

Recent MN Developments

- Prohibition on Most Employment Non-Competes (July 1, 2023)
  - Bans non-competes with employees and independent contractors
  - All contracts entered into on or after July 1, 2023
    - Does not affect existing non-competes
    - Be careful about “reaffirming” existing non-competes
  - Does not apply to confidentiality or non-solicitation provisions
  - Exception for sale of business
  - Can’t avoid the law by opting into another state’s law to govern
  - Employees or contractors can recover attorneys’ fees to enforce compliance

Recent MN Developments

- Prohibition on Restrictive Employment Covenants in Service Contracts (July 1, 2024)
  - Bans agreements between a service provider and customer that would prevent the customer from hiring employees or independent contractors of the service provider
  - Applies to all contracts entered into on or after July 1, 2024
  - "Service Provider" definition is open to interpretation
    - PSAs?
    - Vendors?
    - Temporary staffing agencies?
    - But it's about long-term relationships
  - Exemption for computer software development consultants
  - AG has authority to enforce
  - If employer enters into agreement that violates law, must notify employees

FTC Non-Compete Rule

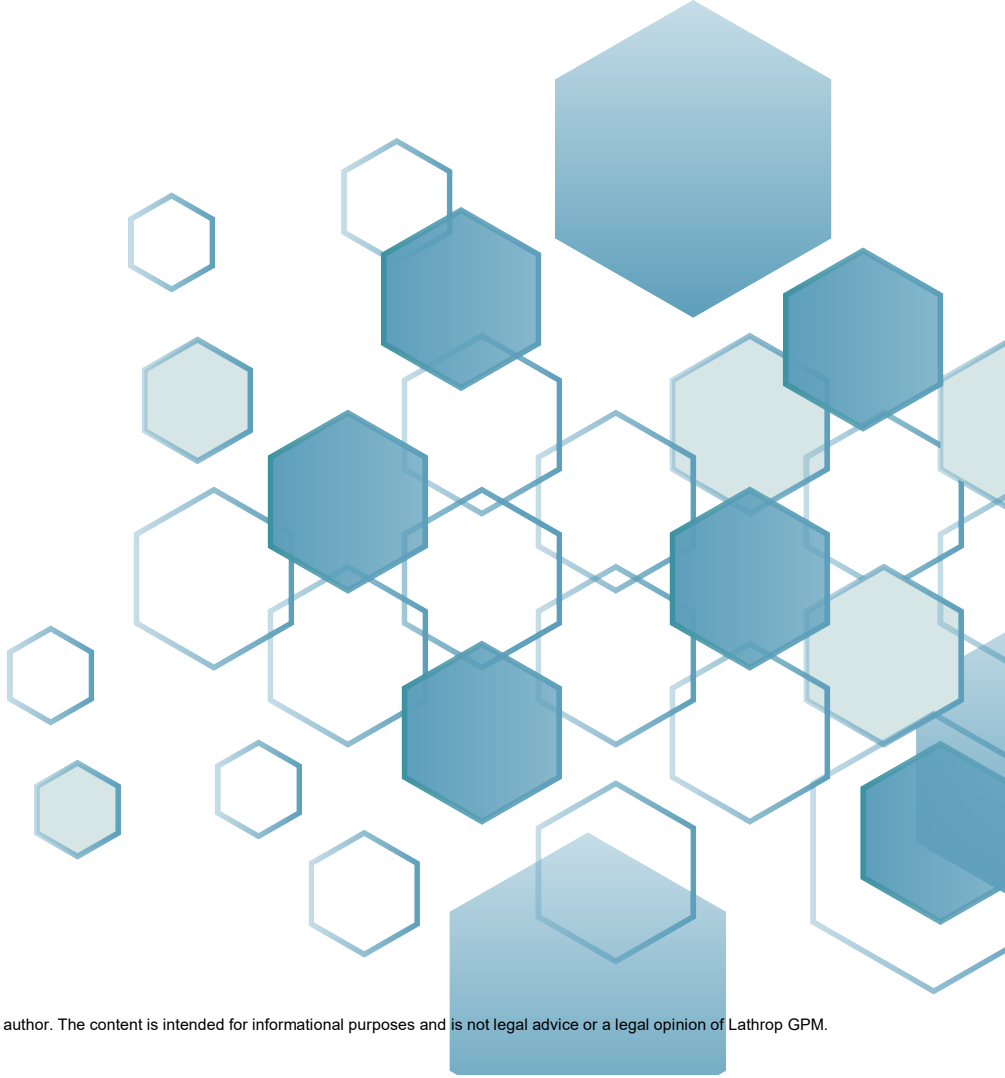
- Broad prohibition on post-employment non-competes with all workers
- Rule would be effective mid-September 2024
  - Applies prospectively to all non-competes
  - Applies retroactively to all non-competes except those with “senior executive”
    - Senior Executive = Earns more than $151,164 annually and in a policy-making position
- Sale of business exception
- Does not ban non-solicitations so long as don’t function as a *de facto* non-compete
- Possible exception for nonprofit employers
- Temporary injunction in Texas limited to the plaintiffs in that case
- SCOTUS decision limiting *Chevron* doctrine has further limited FTC’s authority

What tools are still in the toolbox?

- Financial tools
  - Long-term incentive compensation
  - Signing bonuses
  - Stay bonuses
  - Ownership interests (where applicable)
- Strategies to facilitate greater investment of employees in culture and workplace
- Other restrictive covenants
  - Confidentiality / Trade Secret Agreements
  - Non-Poaching Agreements
- Interference with contract claims against hiring employer

Issues with Providing Medical Services Across State Lines

Randy Schultz, Lathrop GPM

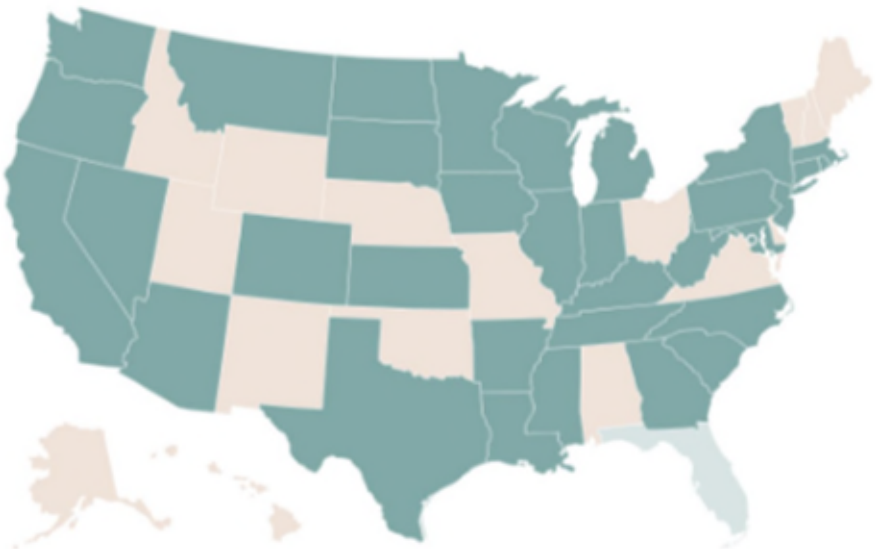


Corporate Practice of Medicine

- Minnesota, Wisconsin, the Dakotas, Iowa, Kansas and others **prohibit it**
- Missouri, Nebraska and others **permit it**
- Full 50 state guide

CPOM States and Non-CPOM States: A Guide by **Permit**

Permit Health's guide to prohibitions on the corporate practice of medicine (CPOM)



CPOM STATE
The state prohibits the corporate practice of medicine.

NON-CPOM STATE
There's not a ban on the corporate practice of medicine.

IT'S COMPLICATED
While there's not a formal CPOM ban, other restrictions can apply.

What is the legal strategy for conducting business across state lines?

Key Multi-State Business Issues

- Scope of practice/services available in each state
  - Full 50 state guide for nurse practitioner scope of practice laws
- Telemedicine….do you need to be licensed in the state where the patient resides?
  - Telehealth licensing across state lines
- Malpractice insurance:
  - Kansas Health Care Stabilization Fund does not allow foreign medical practices.
  - Unique professional liability insurance requirements by state

Key Multi-State Business Issues

- Tax considerations (will your facility remain not for profit)
- Government subsidies not providing funding for cross-state line medical services
- Facility licensing and regulatory and reporting issues – Certificate of Need requirements
- Employee Benefits when crossing state lines….carrier license and need for self insured plans….reproductive rights
- International medical practice (Mayo Clinic expanding to Norway)
- How to be ready for a sale to an equity investor

Key Federal Healthcare Regulations and Laws

- When it comes to compliance standards and regulations themselves, healthcare providers and organizations must comply with the following:
  - Health Insurance Portability and Accountability Act (HIPAA). HIPAA sets the standard for protecting sensitive patient data. It requires healthcare providers to maintain the privacy and security of patient health information.
  - Emergency Medical Treatment and Labor Act (EMTALA). EMTALA mandates that healthcare facilities provide emergency medical treatment to patients regardless of their ability to pay. It prevents “patient dumping” and ensures proper care in emergency situations.
  - Health Information Technology for Economic and Clinical Health Act (HITECH). HITECH expands on HIPAA by addressing the electronic transmission of health information. It promotes the adoption of electronic health records (EHRs) while maintaining privacy and security standards.

Key Federal Healthcare Regulations and Laws (Cont.)

- Clinical Laboratory Improvement Amendments (CLIA). CLIA establishes quality standards for all laboratory testing to ensure accurate and reliable results. Compliance with CLIA is crucial for laboratories to operate legally.
- Anti-Kickback Statute (AKS): The AKS prohibits offering, paying, soliciting, or receiving anything of value in exchange for patient referrals. It aims to prevent financial incentives from influencing medical decisions.
- Stark Law: Also known as the Physician Self-Referral Law, Stark Law prohibits physicians from referring patients for certain designated health services to entities with which they have a financial relationship.

Key Federal Healthcare Compliance Requirements? Compliance Governing Agencies

- There are a number of federal agencies and governing bodies responsible for passing down healthcare compliance requirements to healthcare organizations, providers, and practicing professionals. These federal compliance governing agencies regulate the industry at the national level:
  - Centers for Medicare & Medicaid Services (CMS). CMS plays a crucial role in overseeing federal healthcare programs, including Medicare and Medicaid. They establish regulations that impact reimbursement, quality of care and patient safety for healthcare providers participating in these programs.
  - Occupational Safety and Health Administration (OSHA). OSHA focuses on the safety and health of workers, including those within the healthcare sector. Healthcare facilities must adhere to OSHA guidelines to ensure a safe environment for both employees and patients.
  - Office for Civil Rights (OCR). OCR enforces the HIPAA Privacy Rule, which protects patients' health information privacy rights. Healthcare organizations are required to safeguard patient data and provide individuals with their rights regarding their health information.

Key Federal Healthcare Compliance Requirements? Compliance Governing Agencies (Cont.)

- Office of Inspector General (OIG). The OIG oversees federal healthcare programs to prevent fraud, waste, and abuse. Healthcare organizations must implement compliance programs to detect and prevent unethical or illegal activities.
- Health Resources and Services Administration (HRSA). HRSA focuses on improving access to healthcare services, particularly for underserved populations. Compliance with HRSA guidelines is essential for organizations that receive federal funding to provide healthcare services.

State Healthcare Compliance Requirements

- State healthcare compliance requirements refer to regulations, laws, and standards that individual states impose on healthcare organizations operating within their jurisdiction. While federal regulations provide a baseline for healthcare practices, states have the authority to tailor certain aspects of healthcare delivery to their needs and priorities.
- These state-level requirements often address licensing and credentialing of healthcare professionals, reporting obligations for specific diseases or conditions, medical record retention periods, and other aspects of healthcare administration.
- For example, states may have their own laws governing the scope of practice for various healthcare professionals, such as nurse practitioners or physician assistants. These laws outline the procedures and responsibilities that these professionals can undertake without direct physician oversight. State-specific reporting requirements can also extend to disease outbreaks or public health emergencies, to ensure that healthcare facilities promptly report certain conditions to the appropriate state agencies.

State Healthcare Compliance Requirements

- Additionally, some states, like California, have enacted specific laws related to patient data breach notifications that go beyond the federal regulations outlined in HIPAA. These laws mandate that healthcare organizations notify patients and relevant authorities in the event of a data breach that compromises patients' personal or medical information. States may also have unique regulations related to informed consent, end-of-life care, and telemedicine practices.

Questions?

Issues With Providing Medical Services Across State Lines

Randal L. Schultz, Esq.
913-271-4347

Networking Lunch

Lathrop GPM

Cybersecurity Issues and HIPAA

Office for Civil Rights (OCR)
U.S. Department of Health and Human Services

Presented to Lathrop GPM Health Law Seminar

July 24, 2024

Who We Are

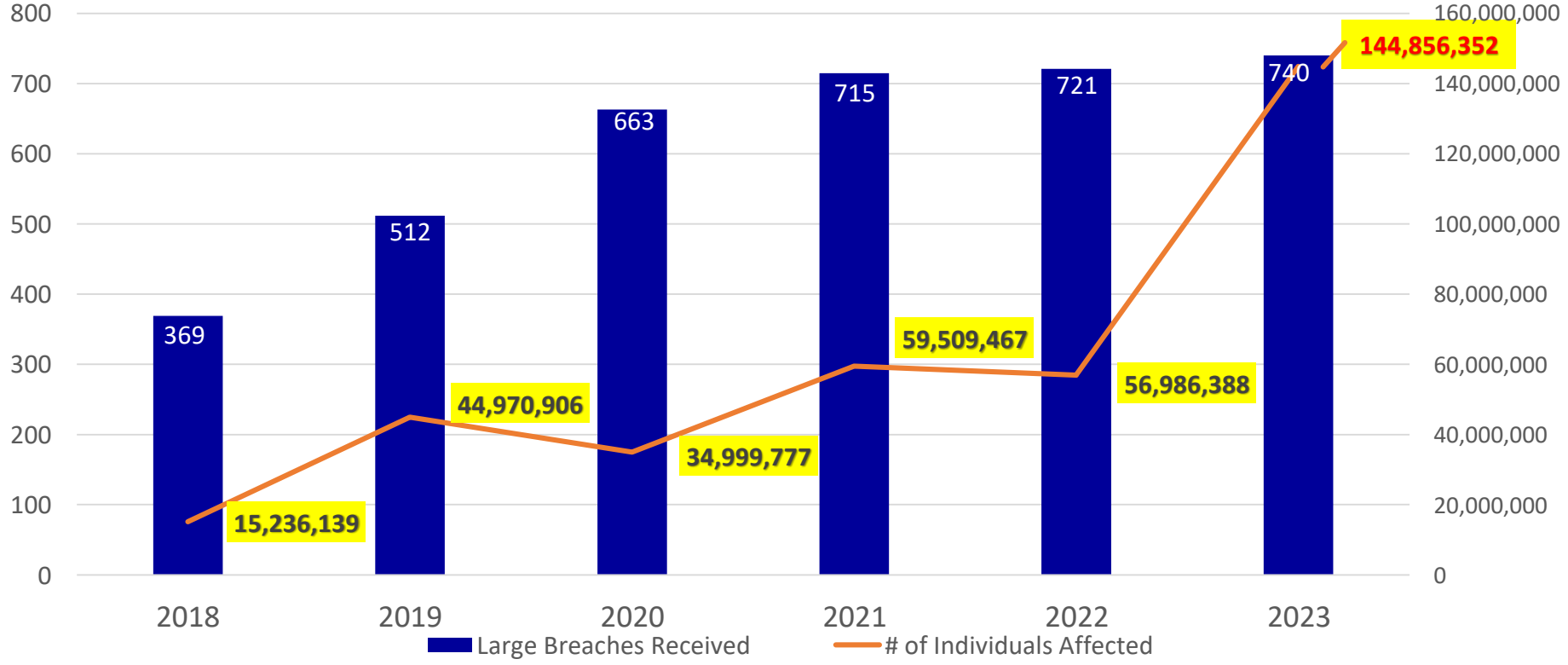
As the Department's civil rights, conscience and religious freedom, and health information privacy rights law enforcement agency, OCR investigates complaints and breach reports, enforces rights, and promulgates regulations, develops policy, and provides technical assistance and public education to ensure understanding of and compliance with non-discrimination and health information privacy laws.

BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

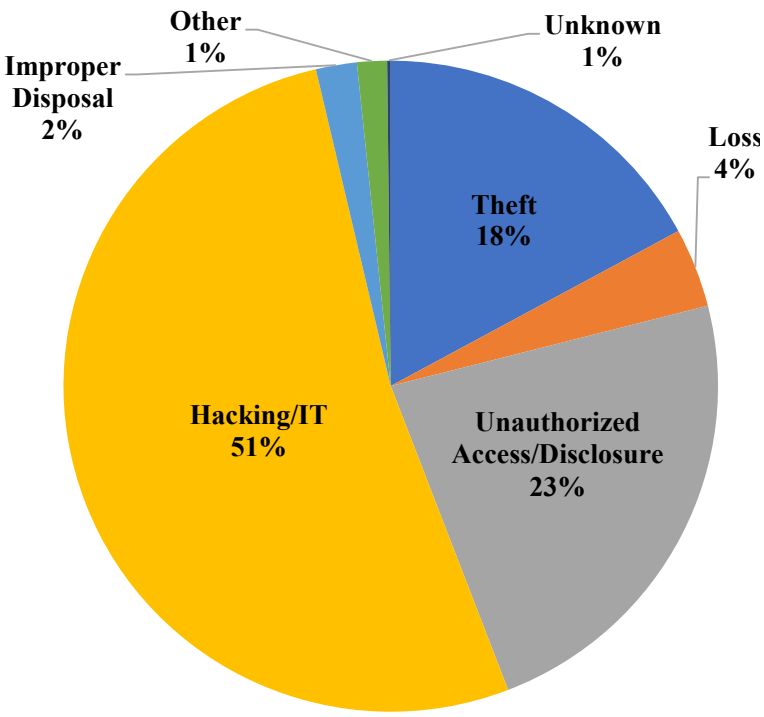
What Happens When OCR Receives a Breach Report

- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
  - Public can search and sort posted breaches
  - Received 740 breach reports affecting 500+ individuals in 2023
- OCR opens investigations into breaches affecting 500+ individuals, and into a number of smaller breaches
- OCR breach investigations examine:
  - Underlying cause of the breach
  - Actions taken to respond to the breach (breach notification) and prevent future incidents
  - Entity's compliance prior to the breach

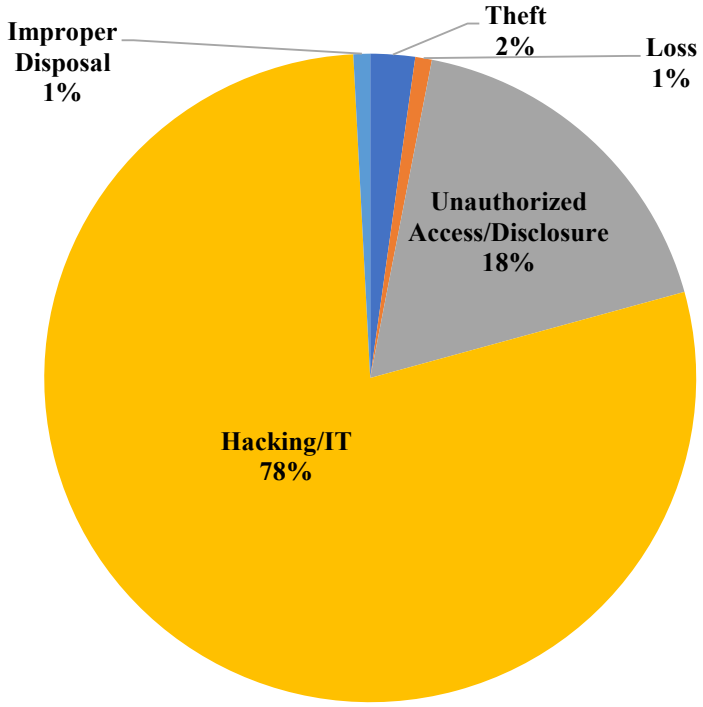
Large Breaches Received and # of Individuals Affected 2018 - 2023



500+ Breaches by Type of Breach

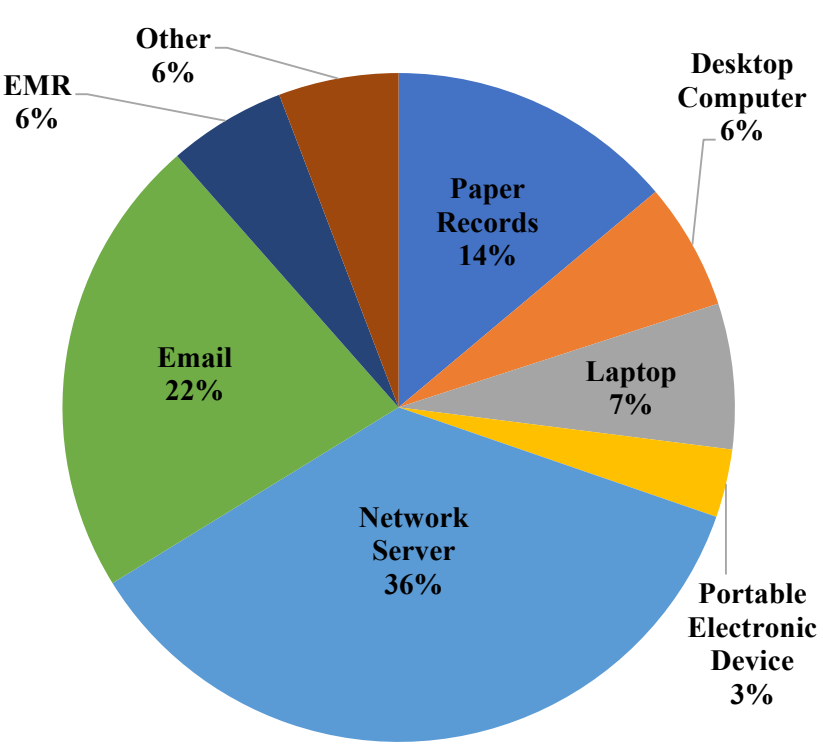


September 23, 2009 through Dec 31, 2023



January 1, 2024 through June 30, 2024

500+ Breaches by Location of Breach



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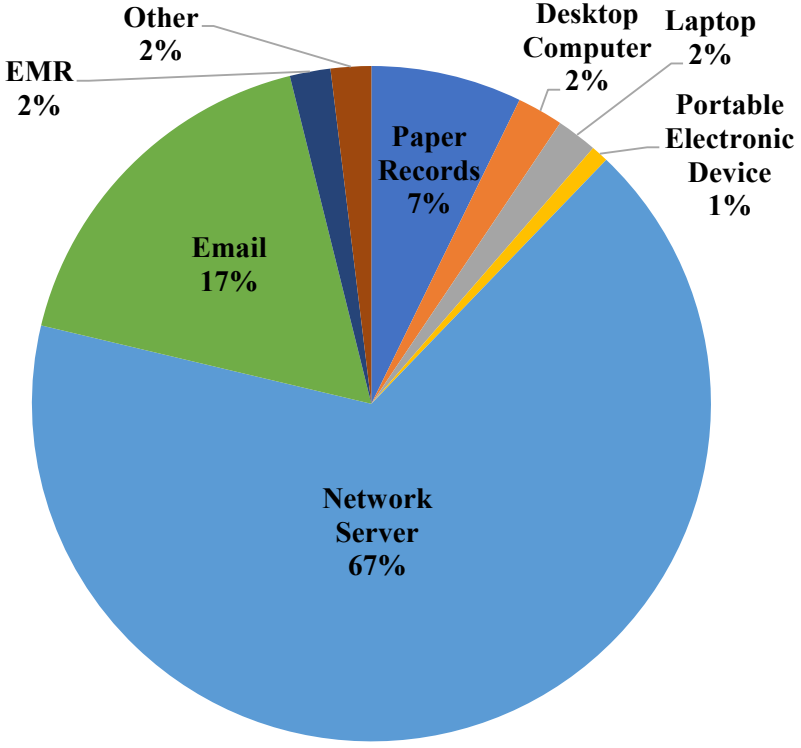
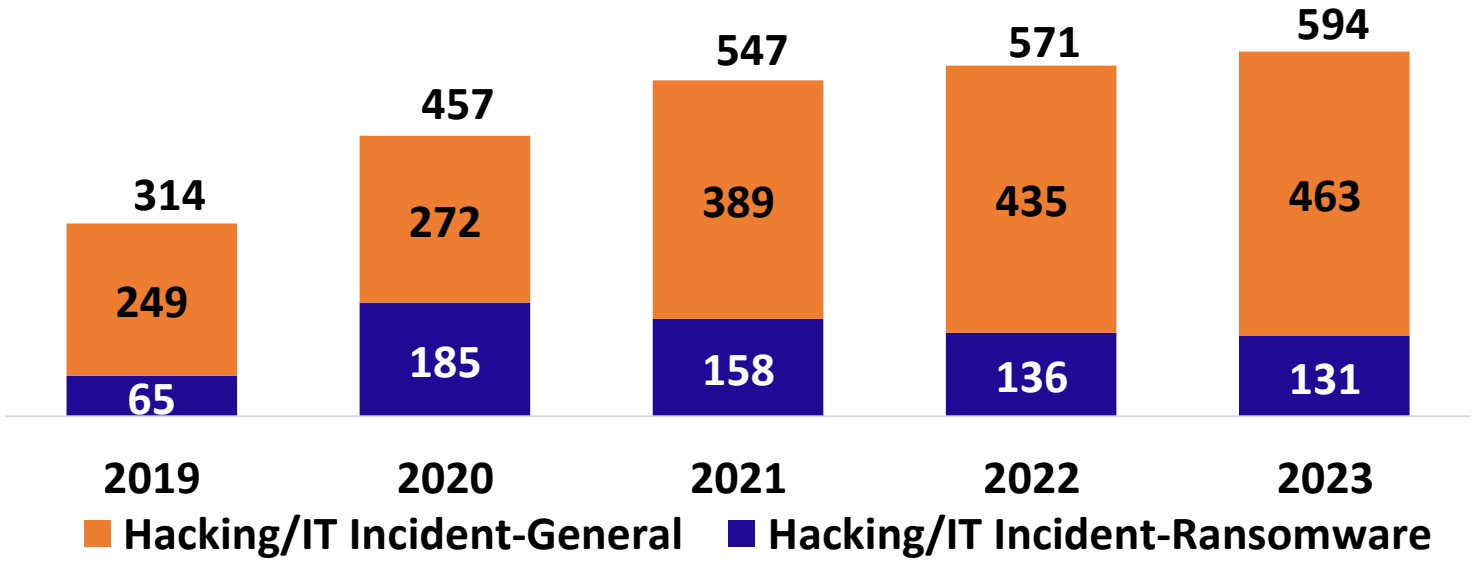


January 1, 2024 through June 30, 2024

Breaches Affecting 500 or More Individuals
Reports Received Involving Hacking/IT Incidents

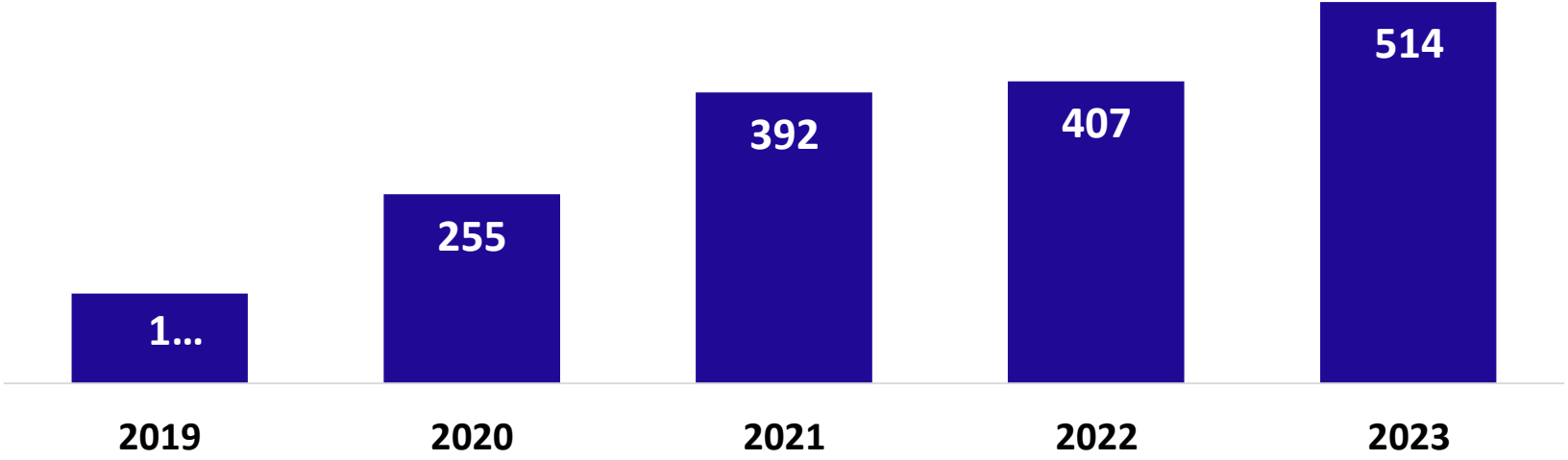
Calendar Years 2019 – 2023

2019 - 2023
89% increase in hacking
102% increase in ransomware



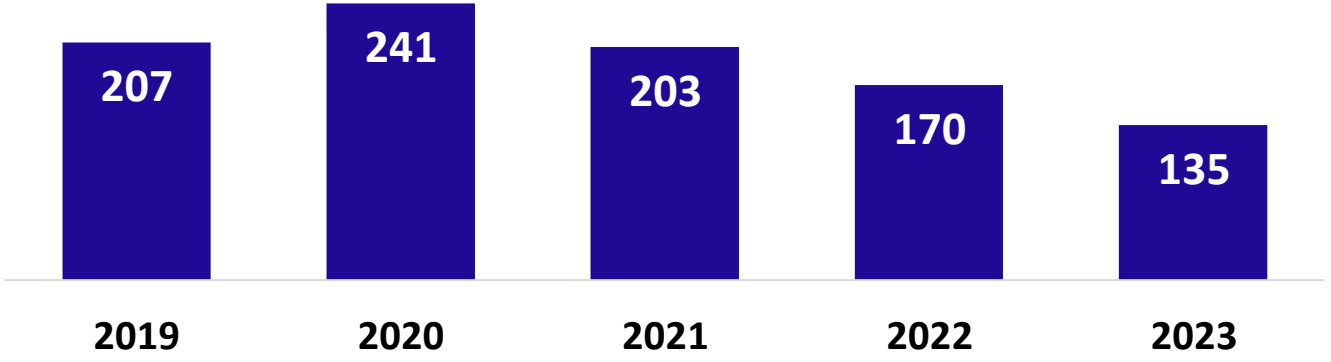
Breaches Affecting 500 or More Individuals
Reports Received of Breaches Involving Network Servers

Calendar Years 2019 - 2023



Breaches Affecting 500 or More Individuals
ts Received of Breaches Involving Email Acc

Calendar Years 2019 - 2023



General HIPAA Enforcement Highlights

- OCR received 31,731 HIPAA cases in 2023.
- In most cases, entities are able to demonstrate satisfactory compliance through voluntary cooperation and corrective action.
- In some cases, the nature or scope of indicated noncompliance warrants additional enforcement action.
- Resolution Agreements/Corrective Action Plans
  - 139 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 9 civil money penalties

Recent Announced OCR HIPAA Enforcement Actions

June-23	Manasa Health Center	$30,000
June-23	Yakima Valley Memorial Hospital	$240,000
June-23	iHealth Solutions, LLC	$75,000
Aug-23	United Healthcare Insurance Company	$80,000
Sep-23	LA Care Health Plan	$1,300,000
Oct-23	Doctors' Management Services	$100,000
Nov-23	St. Joseph's Medical Center	$80,000
Dec-23	Lafourche Medical Group	$480,000
Jan-24	Optum Medical Care of New Jersey	$160,000
Feb-24	Montefiore Medical Center	$4,750,000
Feb-24	Green Ridge Behavioral Health, LLC	$40,000
Mar-24	Phoenix Healthcare	$35,000
Apr-24	Essex Residential Care, LLC	$100,000
June-24	Heritage Valley Health System	$950,000

$4.75 Million Settlement with Montefiore Medical Center

- OCR investigation opened following receipt of a breach report revealing that an employee inappropriately accessed patient the electronic protected health information of 12,517 patients and sold it to an identity theft ring.
- OCR's investigation revealed multiple potential violations of the HIPAA Security Rule, including failures to:
  - Analyze and identify potential risks and vulnerabilities to PHI,
  - Monitor and safeguard its health information systems' activity, and
  - Implement hardware and software and procedural mechanisms that record and examine activity in information systems containing or using ePHI.
- Montefiore paid $4,750,000 to OCR and agreed to implement a corrective action plan with 2 years of OCR monitoring that will improve protections to the security of ePHI.

Ransomware Settlement with Green Ridge Behavioral Health

- OCR investigation opened following receipt of a breach report revealing network server infected with ransomware (Affected more than 14,000 patients)
- OCR's investigation revealed multiple potential violations of the HIPAA Security Rule, including failures to:
  - Have in place an analysis to determine the potential risks and vulnerabilities to electronic protected health information (ePHI);
  - Implement security measures to reduce risks and vulnerabilities; and
  - Have sufficient monitoring of its health information systems' activity to protect against a cyber-attack.
- Green Ridge paid $40,000 to OCR and agreed to implement a corrective action plan with 3 years of OCR monitoring to improve their security of ePHI.

Ransomware Settlement with Heritage Valley Health System

- OCR investigation opened following media reports concerning a data security incident and a potential ransomware attack.
- OCR's investigation revealed multiple potential violations of the HIPAA Security Rule, including failures to:
  - Conduct a compliant risk analysis to determine the potential risks and vulnerabilities to electronic protected health information (ePHI) in its systems;
  - Implement a contingency plan to respond to emergencies; and
  - implement policies and procedures to allow only authorized users access to ePHI.
- Heritage Valley paid $950,000 to OCR and agreed to implement a corrective action plan with 3 years of OCR monitoring to improve their security of ePHI.

Right of Access Initiative

- HIPAA Privacy Rule gives individuals a right to timely access to their health records (30 days with a possibility of one 30-day extension), and at a reasonable, cost-based fee.
- OCR receives many complaints alleging denial or no access to health records.
- Announced Enforcement Initiative in February 2019.
  - Investigations launched across the country.
  - To date: forty-five settlements and three CMPs.
- More information on HIPAA right of access available at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

Risk Analysis Initiative

- New Enforcement Initiative
- Focus on compliance with key HIPAA Security Rule requirement
- Most OCR large breach investigations reveal a lack of a compliant risk analysis
- Drive better practices to protect electronic protected health information (ePHI)
- Better overall security of data

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- 9 civil money penalties

Recent Announced OCR HIPAA Enforcement Actions

May-23	David Mente, MA, LPC	$15,000
May-23	MedEvolve, Inc.	$350,000
June-23	Manasa Health Center	$30,000
June-23	Yakima Valley Memorial Hospital	$240,000
June-23	iHealth Solutions, LLC	$75,000
Aug-23	United Healthcare Insurance Company	$80,000
Sep-23	LA Care Health Plan	$1,300,000
Oct-23	Doctors' Management Services	$100,000
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Recurring Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Manage Identified Risk, e.g. Encrypt
- Lack of Transmission Security
- Lack of Appropriate Auditing
- No Patching of Software
- Insider Threat
- Lack of Access controls
- Improper Disposal
- Insufficient Data Backup and Contingency Planning

Lack of Business Associate Agreements

HIPAA generally requires that covered entities and business associates enter into agreements with their business associates to ensure that the business associates will appropriately safeguard protected health information. *See 45 CFR § 164.308(b).* Examples of Potential Business Associates:

- A collections agency providing debt collection services to a health care provider which involve access to protected health information.
- An independent medical transcriptionist that provides transcription services to a physician.
- A subcontractor providing remote backup services of PHI data for an IT contractor-business associate of a health care provider.

Incomplete or Inaccurate Risk Analysis

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the [organization]. *See 45 CFR § 164.308(a)(1)(ii)(A).*

- Organizations frequently underestimate the proliferation of ePHI within their environments. When conducting a risk analysis, an organization must identify all of the ePHI created, maintained, received or transmitted by the organization.

- Examples: Applications like EHR, billing systems; documents and spreadsheets; database systems and web servers; fax servers, backup servers; etc.); Cloud based servers; Medical Devices Messaging Apps (email, texting, ftp); Media

The Risk Analysis Process: Key Activities Required by the Security Rule

- **Inventory** to determine where ePHI is stored
- **Evaluate** probability and criticality of potential risks
- **Adopt** reasonable and appropriate security safeguards based on results of risk analysis
- **Implement/Modify** security safeguards to reduce risk to a reasonable and appropriate level
- **Document** safeguards and rationale
- **Evaluate** effectiveness of measures in place
- **Maintain** continuous security protections
- Repeat

Failure to Manage Identified Risk

- The Risk Management Standard requires the "[implementation of] security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with [the Security Rule]." *See 45 CFR § 164.308(a)(1)(ii)(B).*
- Investigations conducted by OCR regarding several instances of breaches uncovered that risks attributable to a reported breach had been previously identified as part of a risk analysis, but that the organization failed to act on its risk analysis and implement appropriate security measures.
- In some instances, encryption was included as part of a remediation plan; however, activities to implement encryption were not carried out or were not implemented within a reasonable timeframe as established in a remediation plan.

Lack of Transmission Security

- When electronically transmitting ePHI, a mechanism to encrypt the ePHI must be implemented unless not reasonable and appropriate. *See 45 CFR § 164.312(e)(2)(ii).*
- Applications for which encryption should be considered when transmitting ePHI may include:
  - Email
  - Texting
  - Application sessions
  - File transmissions (e.g., ftp)
  - Remote backups
  - Remote access and support sessions (e.g., VPN)

Lack of Appropriate Auditing

- The HIPAA Rules require the "[implementation] of hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information." *See 45 CFR § 164.312(b).*

- Once audit mechanisms are put into place on appropriate information systems, procedures must be implemented to "regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports." *See 45 CFR § 164.308(a)(1)(ii)(D).*

- Activities that could warrant additional investigation:
  - Access to PHI during non-business hours or during time off
  - Access to an abnormally high number of records containing PHI
  - Access to PHI of persons for which media interest exists
  - Access to PHI of employees
  - Failed log-in attempts

No Patching of Software

- The use of unpatched or unsupported software on systems that access ePHI could introduce additional risk into an environment.
- Continued use of such systems must be included within an organization's risk analysis and appropriate mitigation strategies implemented to reduce risk to a reasonable and appropriate level.
- In addition to operating systems, EMR/PM systems, and office productivity software, software that should be monitored for patches and vendor end-of-life for support include:
  - Router and firewall firmware
  - Anti-virus and anti-malware software
  - Multimedia and runtime environments (e.g., Adobe Flash, Java, etc.)

Insider Threat

- Organizations must "[i]mplement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information … and to prevent those workforce members who do not have access … from obtaining access to electronic protected health information," as part of its Workforce Security plan. *See 45 CFR § 164.308(a)(3).*
- Appropriate workforce screening procedures could be included as part of an organization's Workforce Clearance process (e.g., background and OIG LEIE checks). *See 45 CFR § 164.308(a)(3)(ii)(B).*
- Termination Procedures should be in place to ensure that access to PHI is revoked as part of an organization's workforce exit or separation process. *See 45 CFR § 164.308(a)(3)(ii)(C).*

Disposal

- When an organization disposes of electronic media which may contain ePHI, it must implement policies and procedures to ensure that proper and secure disposal processes are used. *See 45 CFR § 164.310(d)(2)(i).*
- The implemented disposal procedures must ensure that "[e]lectronic media have been cleared, purged, or destroyed consistent with *NIST Special Publication 800–88: Guidelines for Media Sanitization*, such that the PHI cannot be retrieved."
- Electronic media and devices identified for disposal should be disposed of in a timely manner to avoid accidental improper disposal.
- Organizations must ensure that all electronic devices and media containing PHI are disposed of securely; including non-computer devices such as copier systems and medical devices.

Insufficient Backup and Contingency Planning

- Organizations must ensure that adequate contingency plans (including data backup and disaster recovery plans) are in place and would be effective when implemented in the event of an actual disaster or emergency situation. *See 45 CFR § 164.308(a)(7).*
- Leveraging the resources of cloud vendors may aid an organization with its contingency planning regarding certain applications or computer systems, but may not encompass all that is required for an effective contingency plan.
- As reasonable and appropriate, organizations must periodically test their contingency plans and revise such plans as necessary when the results of the contingency exercise identify deficiencies. *See 45 CFR § 164.308(a)(7)(ii)(D).*

Best Practices

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
- Risk analysis and risk management should be integrated into business processes; conducted regularly and when new technologies and business operations are planned
- Dispose of PHI on media and paper that has been identified for disposal in a timely manner
- Incorporate lessons learned from incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis; reinforce workforce members' critical role in protecting privacy and security

Resources

HITECH Amendment on Recognized Security Practices and Video

- 2021 HITECH Amendment requires OCR to consider whether a regulated entity has adequately demonstrated that recognized security practices were "in place" for the prior 12 months.
- Can mitigate civil money penalties, other remedies in settlement agreements, or early, favorable termination of audits.
- No liability for electing not to implement recognized security practices.
- OCR published a video in October 2022 that covers:
    - The 2021 HITECH Amendment
    - How regulated entities can adequately demonstrate that RSPs are in place
    - How OCR is requesting evidence of RSPs
    - Resources for information about RSPs
    - OCR's 2022 Request for Information on RSPs
- The video may be found on OCR's YouTube channel at: https://youtu.be/e2wG7jUiRjE

OCR Common Cyber-Attacks Video

- Video on how the HIPAA Security Rule can help regulated entities defend against common cyber-attacks
- Topics covered include:
  - OCR breach and investigation trend analysis
  - Common attack vectors
  - OCR investigations of weaknesses that led to or contributed to breaches
  - How Security Rule compliance can help regulated entities defend against cyber-attacks

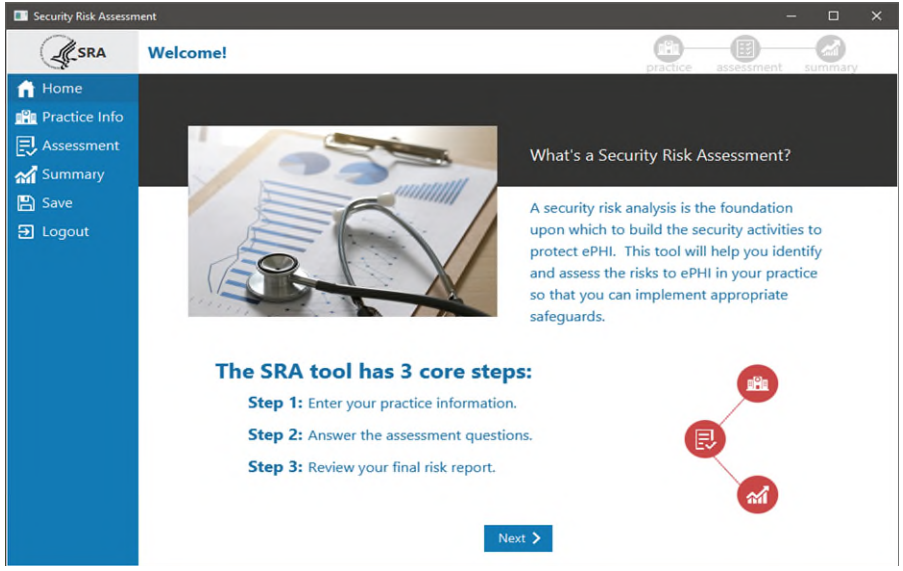
- The video may be found on OCR's YouTube channel at: http://youtube.com/watch?v=VnbBxxyZLc8
- The video in Spanish may be found on OCR's YouTube channel at: http://youtube.com/watch?v=3oVarCxLcB8

OCR HIPAA Risk Analysis Webinar

- Video on the HIPAA Security Rule Risk Analysis requirement.
- Discusses what is required to conduct an accurate and thorough assessment of potential risks and vulnerabilities to ePHI and review common risk analysis deficiencies OCR has identified in investigations.
- Topics covered include:
  - How to prepare for a risk analysis
  - How should ePHI be assessed
  - What does it mean to be accurate and thorough
  - What purpose does a risk analysis serve once completed
  - Examples from OCR investigations
  - Resources

The video may be found on OCR's YouTube channel at: https://www.youtube.com/watch?v=hxfxhokzKEU

SRA Tool



https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool

Designed to assist small to medium sized organizations in conducting an internal security risk assessment to aid in meeting the security risk analysis requirements of the HIPAA Security Rule and the CMS EHR Incentive Program.

The SRA tool guides users through a series of questions based on standards identified in the HIPAA Security Rule. Responses are sorted into Areas of Success and Areas for Review.

Not all areas of risk may be captured by the tool. Risks not identified and assessed via the SRA Tool must be documented elsewhere.

Resources for Mobile Health App Developers

- Mobile Health Apps Interactive Tool
- Health App Use Scenarios & HIPAA
- HIPAA Right of Access, Apps, and APIs
- Health Information Technology FAQs

https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html

Cloud Guidance

- OCR released guidance clarifying that a Cloud Service Provider (CSP) is a business associate – and therefore required to comply with applicable HIPAA regulations – when the CSP creates, receives, maintains or transmits identifiable health information (referred to in HIPAA as electronic protected health information or ePHI) on behalf of a covered entity or business associate.
- When a CSP stores and/or processes ePHI for a covered entity or business associate, that CSP is a business associate under HIPAA, even if the CSP stores the ePHI in encrypted form and does not have the key.
- CSPs are not likely to be considered "conduits," because their services typically involve storage of ePHI on more than a temporary basis.
- http://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html
- http://www.hhs.gov/hipaa/for-professionals/faq/2074/may-a-business-associate-of-a-hipaa-covered-entity-block-or-terminate-access/index.html

Ransomware Resources

HHS Health Sector Cybersecurity Coordination Center Threat Briefs:

- https://www.hhs.gov/about/agencies/asa/ocio/hc3/products/index.html#sector-alerts

Section 405(d) of the Cybersecurity Act of 2015 Resources:

- Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients https://405d.hhs.gov/Documents/HICP-Main-508.pdf
- 405(d) Products, Publications and Materials https://405d.hhs.gov/resources

OCR Guidance:

- Ransomware https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf
- Cybersecurity https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html
- Risk Analysis https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf

HHS Security Risk Assessment Tool: https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool

CISA Resources:

- https://www.cisa.gov/stopransomware
- https://www.cisa.gov/sites/default/files/publications/CISA_Fact_Sheet-Protecting_Sensitive_and_Personal_Information_from_Ransomware-Caused_Data_Breaches-508C.pdf
- https://www.cisa.gov/sites/default/files/publications/CISA_MS-ISAC_Ransomware%20Guide_S508C_.pdf

FBI Resources:

- https://www.fbi.gov/scams-and-safety/common-scams-and-crimes/ransomware
- https://www.ic3.gov/Media/Y2019/PSA191002

Cybersecurity Guidance Material

OCR has a Cybersecurity Guidance Material webpage, including a Cybersecurity Checklist and Infographic, which explain the steps for a HIPAA covered entity or its business associate to take in response to a cyber-related security incident.

- Cybersecurity Checklist - PDF
- Cybersecurity Infographic [GIF 802 KB]

https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html

Cybersecurity Newsletters

- Recent Topics Include:
  - Cybersecurity Authentication
  - Security Incident Procedures
  - Defending Against Common Cyber-Attacks
  - Securing Your Legacy [System Security]
  - Controlling Access to ePHI
  - HIPAA and IT Asset Inventories
  - Preventing, Mitigating, and Responding to Ransomware
  - Advanced Persistent Threats and Zero Day Vulnerabilities
  - Managing Malicious Insider Threats
  - Phishing
- Sign up for the OCR Listserv:
  http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html

Connect with Us

Office for Civil Rights

U.S. Department of Health and Human Services

www.hhs.gov/hipaa

Join our Privacy and Security listservs at
https://www.hhs.gov/hipaa/for-professionals/list-serve/

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Contact Us

Office for Civil Rights

U.S. Department of Health and Human Services

ocrmail@hhs.gov
www.hhs.gov/ocr

Voice: (800) 368-1019
TDD: (800) 537-7697
Fax: (202) 519-3818

200 Independence Avenue, S.W.
H.H.H Building, Room 509-F
Washington, D.C. 20201

Contact me

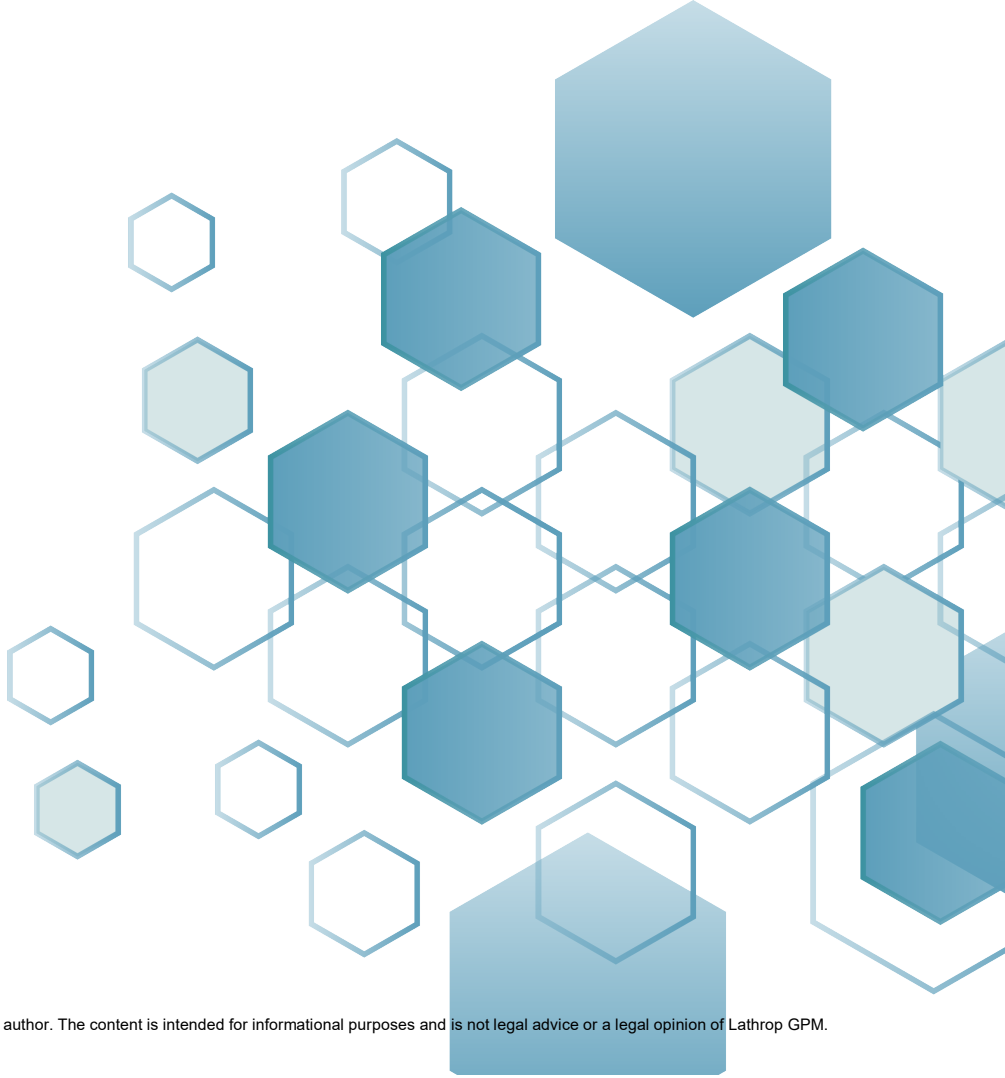
steven.mitchell@hhs.gov

(816)426-7278

Break

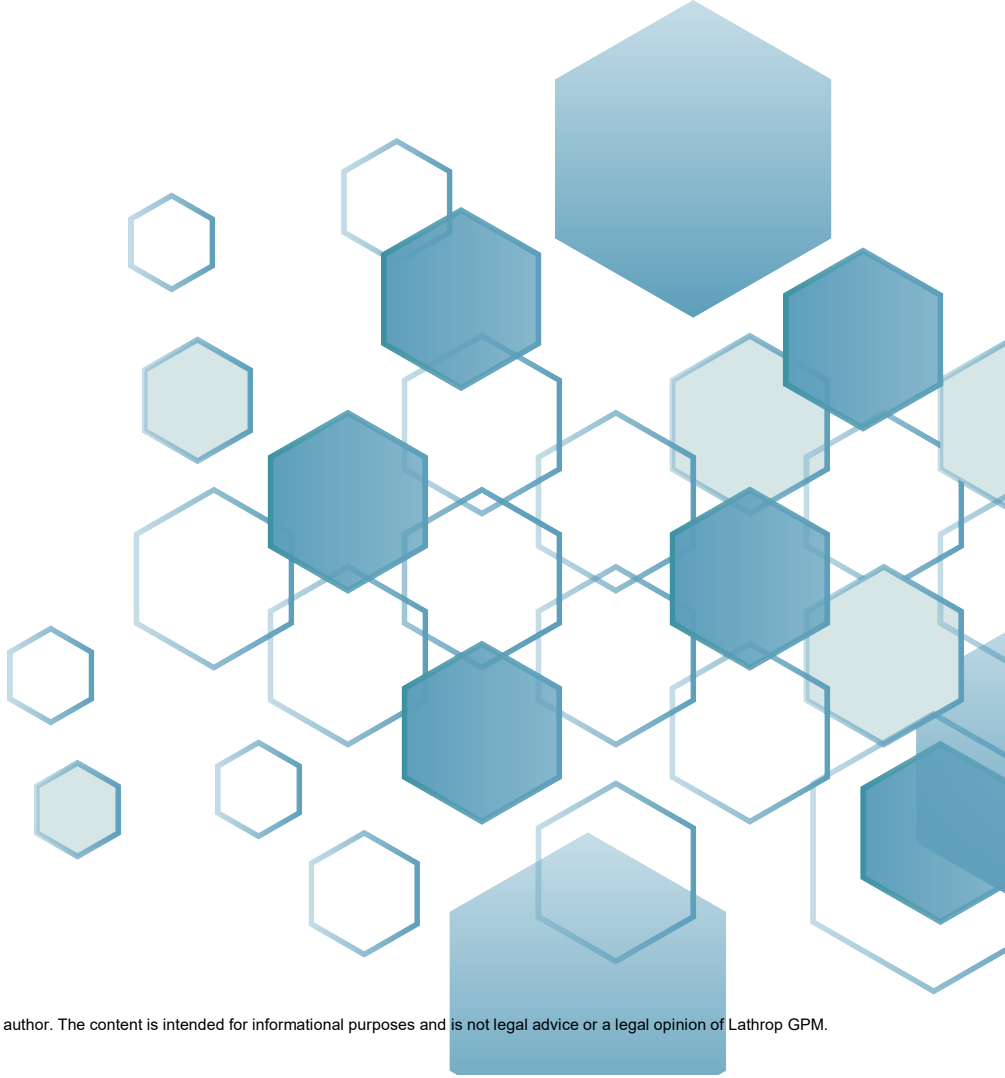
Lathrop GPM

Lightning Round: Session 2



Antitrust & Health Policy Litigation Update

Jesse Berg, Lathrop GPM



Agenda

- Overview of antitrust in healthcare
- New FTC and DOJ merger guidelines
- Merger enforcement
- Withdrawal of Enforcement Statements in Health Care & other policy developments
- FTC ban on non-competes
- End of Chevron deference and other key health care litigation developments

Antitrust in Healthcare

Purpose and Key Statutes

- Protect free and fair competition on the sell side (products/service) and buy side (inputs such as labor)

- Increased competition may lead to:
  - Lower prices
  - Improvement in quality
  - More choice, access, innovation
  - Increase in wages, better benefits

- Clayton Act Sections 7 and 7A
- Clayton Act Section 2
- Sherman Act Sections 1 and 2
- FTC Act
- State Antitrust Law

An Antitrust Primer: Key Principles

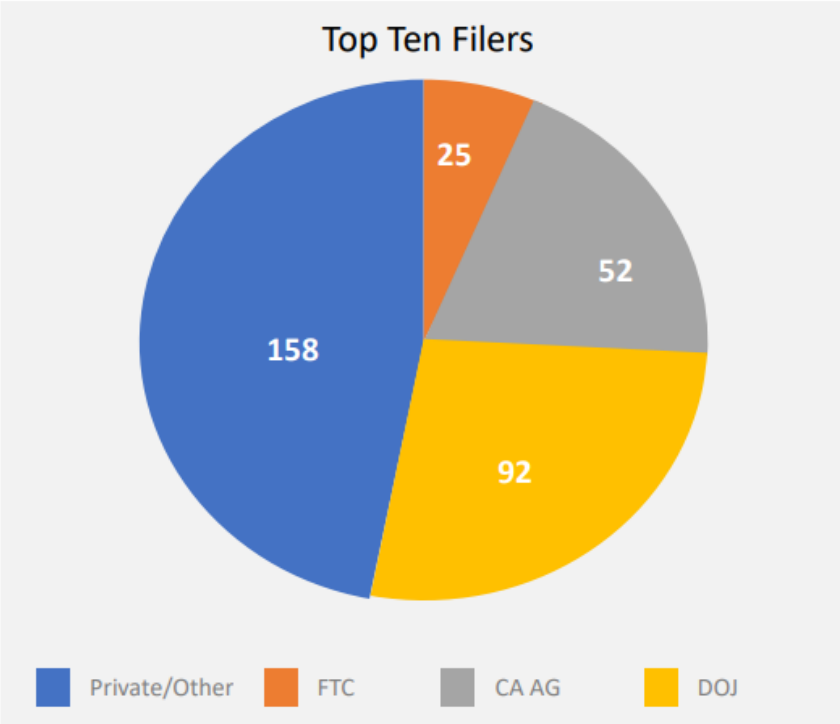
- The importance of “competitors”
- Is it illegal to have a monopoly?
- Horizontal agreements among competitors
  - Agreements on price
  - Agreements to restrict output
  - Boycotts
  - Market allocation
  - Codes of ethics
  - Other restrictions
- Vertical agreements between buyers and sellers
  - Tying
  - Resale price maintenance
  - Non-price agreements
- Difference between “per se” and “rule of reason” analysis (and why it matters)

Antitrust Enforcement of Healthcare M&A

Healthcare mergers, acquisitions, collaborations and joint ventures may be reviewed or challenged under the Sherman Act, Clayton Act, FTC Act, or state antitrust law

- Traditional antitrust law claims: Analysis used to evaluate mergers is the same whether the violation alleged is Sherman Act § 1 or Clayton Act § 7
  - State antitrust laws generally mirror federal laws
- DOJ, FTC and state AGs may investigate or challenge a proposed transaction even if no HSR filing is required
  - Monitor various industries and trade publications for M&A news
  - Federal and State enforcers may serve subpoenas or civil investigative demands to seek information and testimony regarding the proposed transaction
- If no HSR filing is required, enforcers' investigation is not constrained by HSR time limits
  - Parties free to close at any time if not investigated under HSR Act; federal agency or state AGs may seek preliminary and permanent injunctions to block deal
- Both DOJ (Business Review Letters) and FTC (Advisory Opinions) guidance can help

Where Are Cases Coming From?



1. Northern District of California
(353 Cases [11% of all new cases])*

2. Northern District of Illinois
(345 cases)**

3. Southern District of New York
(244 cases)

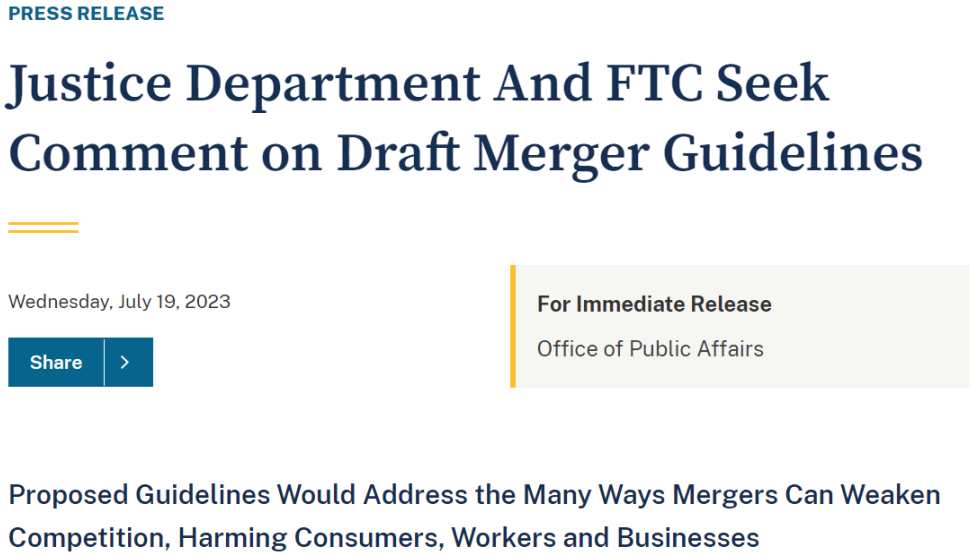
4. District of Columbia
(202 cases)

* Attributed to tech and health care industry
**Attributed to food processing industry

New FTC and DOJ Merger Guidelines

- On January 18, 2022, the FTC and DOJ Antitrust Division launched a joint public inquiry aimed at modernizing both the horizontal and vertical merger guidelines.
- In September 2022, AAG Kanter gave remarks indicating likely objectives for the Guidelines.
  - (1) Section 7 of the Clayton Act Requires showing that a transaction *may* substantially lessen competition, and
  - (2) direct evidence of competition dynamics can supplant a structural analysis of concentration in a clearly defined market.
- Chair Khan in January 2022:
  - “This inquiry launched by the FTC and DOJ is designed to ensure that our merger guidelines accurately reflect modern market realities and equip us to forcefully enforce the law against unlawful deals.”

DOJ / FTC Issue New Merger Guidelines



PRESS RELEASE

Justice Department And FTC Seek Comment on Draft Merger Guidelines

Wednesday, July 19, 2023

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For Immediate Release

Office of Public Affairs

Proposed Guidelines Would Address the Many Ways Mergers Can Weaken Competition, Harming Consumers, Workers and Businesses

- Merger Guidelines have changed many times over the years (1968, 1982, 1984, 1992, 1997, 2010 and 2020)
- In 2022, Agencies announced initiative to revise Horizontal and Vertical Guidelines
- 13 Guidelines that Agencies proposed for determining whether merger is anticompetitive
- Comment period on Guidelines ran through Sept. 18, 2023
- Final guidelines released on Dec. 18, 2023

DOJ / FTC Merger Guidelines – What Does the Government Care About?

2023 Revised DOJ / FTC Merger Guidelines

Horizontal Overlap
Continued focus on traditional overlap Between service lines and geographic markets

Vertical Concerns
How does the merger impact competitors' or suppliers' costs, access to inputs

Entrenchment or Expansion of Dominance
Is the merged entity too big on the buy or sell side

Impact on Labor Market
Does merger substantially lessen competition for labor

Serial Acquisitions

Focus on private equity rollups

Cross-Market Effects
How do mergers with parties in adjacent geographic regions impact the market

2023 DOJ / FTC Merger Guidelines

- 11 Guidelines:
  - Lower threshold for structural presumption that market power exists
  - New approach to vertical mergers
  - Mergers between buyers can harm competition as much as seller-based mergers
  - “Cross market” mergers (will transaction entrench position in a new market)
  - When a merger is part of a series of multiple acquisitions, the agencies may examine the whole series
  - Tougher standard for showing procompetitive efficiencies
  - Narrow approach for falling firm defense

Merger Guidelines

U.S. Department of Justice and the Federal Trade Commission

What's Been Happening in Merger Enforcement?

- FTC v. Reading (2010)
- FTC v. OSF Rockford (2012)
- FTC v. Phoebe Miley (2013)

- FTC v. ProMedica (2014)
- FTC and Idaho v. St. Luke's (2015)
- FTC and PA v. Penn State Hershey (2016)

- FTC v. Cabell (2016)
- FTC v. Advocate Health (2017), FTC v. Sanford (2018)
- UnitedHealth / Davits (2019)
- FTC and PA v. Jefferson-Einstein (2020)
- US. and PA v. Geisinger Health and Evangelical Community Hospital (2020)
- FTC and TN v. Methodist Le Bonheur and Tenant Healthcare (2020)
- US. v. UnitedHealth Group / Change Healthcare (2021)
- FTC v. HCA Healthcare/Steward (2022)
- FTC and RI v. LifeSpan, Care New England (2022)
- FTC v. U.S. Anesthesia Partners, Inc et at (filed Sept. 2023)
- FTC and California v. John Muir Health et al. (filed Nov. 2023)
- FTC v. Novant Health et al. (filed Jan. 2024)

What's Been Happening in Merger Enforcement?

- DOJ / FTC have promised strict enforcement of healthcare mergers
- May 9, 2024: Antitrust Division announces new "Health Care Monopolies and Collusion" Taskforce (HCMC)
- Apr. 18, 2024 DOJ / FTC release new online portal to report competition concerns
- Certain large cross-market transactions have cleared.
  - Advocate Aurora Health/Atrium Health: Following compliance with a Second Request, the FTC did not challenge the transaction forming a health system with $27B in revenue, 67 hospitals, 21k physicians, and 42k nurses. Transaction closed on December 2, 2023.
  - CVS/Signify: On October 19, 2022, CVS Health and Signify Health each received a Second Request from the DOJ. CVS announced in late March that it had completed its $8 billion acquisition of Signify Health.

Significant Transactions

- **UnitedHealth acquired Change Healthcare**
  - $13.8 billion transaction announced in January 2021; closed in October 2022 after surviving antitrust challenge by DOJ.
  - DOJ sued to stop transaction, arguing UnitedHealth would have access to competitor health plan information as a result. Judge ruled against DOJ after UnitedHealth executives stated they already have access to competitor data through certain Optum services.
  - District court required that Change Healthcare's claims software business be divested (sold to TPG Capital, private equity group, for $2.2 billion).
  - DOJ filed notice of appeal in November 2022; DOJ voluntarily dismissed challenge in March 2023.
- **Amazon acquired One Medical, digital primary care platform, despite FTC investigation**
  - Amazon closed the $3.9 billion acquisition of One Medical in February 2023.
  - FTC did not intervene but has stated will continue investigating possible harms to competition and Amazon's control and use of sensitive consumer health information held by One Medical.

Significant Transactions

- July 10, 2024: Sanford Health (largest rural health system) announced merger with Marshfield Clinic Health System
- Combination will bring together 56,000 employees, 56 hospitals, 4,300 providers, 2 fully integrated health plans and various ancillary operations
- Sanford Health is parent; Marshfield Clinic Health System will be region within Sanford Health and maintain regional leadership
- Expected to close by end of 2024, subject to regulatory review

Canceled Transactions

- **State University of New York Upstate Medical University and Crouse Health System Cancel Merger**
  - These two health systems called off a merger in February 2023, instead settling for a “strategic affiliation agreement.”
  - The FTC had voiced opposition to the deal claiming it would leave Syracuse with just two hospital systems.
  - In a combined statement, the two systems called the acquisition “impractical” after a financially difficult 2022.
- **CarolinaEast Health and UNC Health End Affiliation**
  - North Carolina based CarolinaEast Health ended its partnership with UNC Health in March 2023.
  - CarolinaEast said in a news release it was no longer in the best interests of both health systems to maintain the affiliation agreement.

Trends in Deal Cancellations

- **Expansion of Federal Antitrust Challenges**
  - Biden appointees at the FTC / DOJ have announced they want to adopt some less frequently deployed legal theories of antitrust enforcement.
  - The FTC has added cross-market theory questions to second requests in merger investigations, but it has yet to challenged a hospital or health system transaction based on a cross market theory of competitive harm.
  - The FTC has urged state lawmakers to avoid using COPAs to “shield otherwise anti-competitive hospital mergers.”
- **Expansion of State Oversight**
  - FTC and DOJ only receive notice of health care provider transactions over $92 million as required by the 2021 Hart Scott-Rodino Antitrust Improvements Act (HSR)
  - When State governments learn about significant healthcare transactions after the fact, they may start to worry about the future of the health care delivery system in their communities.
    - This is particularly true when unexamined healthcare transactions are affecting access or otherwise controversial.

Federal & State Cooperative Approach to Merger Enforcement

- States often investigate M&A in tandem with DOJ/FTC – use Merger Guidelines as roadmap
- States can investigate separately under state and/or federal antitrust laws – use Merger Guidelines as roadmap
- State and federal enforcers may rely on:
  - DOJ / FTC *Merger Guidelines* for substantive antitrust analysis
  - May consider cross-market and vertical theories of harm as well
  - Merging parties' documents and testimony
  - Economic modeling to prove likely anticompetitive price effects
- State AGs traditionally investigate a proposed healthcare merger if:
  - Local markets may be impacted and/or consumers / payors complain
  - Charitable trust, Certificate of Need, or change in control laws are implicated

Agencies Withdrawal of Healthcare Policy Statements

- On Feb. 2, 2023, the DOJ announced its withdrawal of three joint FTC / DOJ Statements related to antitrust enforcement policy in healthcare markets that had been in place for 3 decades (1993, 1996, 2011).
  - Statements guided healthcare companies by outlining the circumstances in which the agencies would or would not challenge certain types of transactions involving hospitals, physician group practices, and other companies in the industry. They also included guidance on information sharing through benchmarking.
- In their press release, the DOJ stated, “the Statements are overly permissive on certain subjects, such as information sharing, and no longer serve their intended purposes of providing encompassing guidance to the public on relevant healthcare competition issues in today’s environment.”
  - DOJ also stated that a case-by-case enforcement approach, rather than broad guidance, would allow it to better evaluate mergers and conduct in healthcare markets.

Agencies Withdrawal of Healthcare Policy Statements (cont.)

- Withdrawal marks a new period of uncertainty with respect to how Agencies will approach antitrust enforcement in the healthcare sector.
- In July 2023, FTC announced parallel withdrawal of Statements
- “Given the profound changes in these markets over the last 30 years, the statements no longer serve their intended purpose of providing accurate guidance to market participants. Rather, the Commission’s extensive record of enforcement actions, policy statements, and competition advocacy in health care provide more up-to-date guidance to the public. The Commission will continue its enforcement by evaluating on a case-by-case basis mergers and conduct in health care markets that affect consumers.”
- FTC will “rely on general principles of antitrust enforcement and competition policy for all markets….”

FTC Proposed Changes to Hart-Scott-Rodino Requirements

- Jun. 27, 2023, FTC announced proposed changes to Premerger Notification and Report Form (HSR Form) and instructions, as well as premerger notification rules implementing HSR. Comment period initially to run through Aug. 28, 2023.
- FTC estimates the proposed rule could extend time required to make HSR filing from 37 hours to 144 hours
- First major overhaul of HSR premerger requirements in 45 years. Key changes include:
  - Transaction details and certain draft documents
  - Competition narrative
  - New disclosures related to parties' prior acquisitions s
  - Strategic documents and reports created during the ordinary course
  - Identification of individuals / entities that have influence over decisions / access to confidential info
- On Aug. 10, 2023 FTC extended comment period through Sep. 27, 2023
- HSR reporting thresholds updated for 2024 (occurs annually)

Certificates of Public Advantage & Other State Actions

- On August 15, 2022, the FTC issued a policy paper highlighting the pitfalls of COPAs, which shield hospital mergers from antitrust laws under state action immunity.
- January 2023, LCMC Health announced acquisition of three Tulane University Hospitals from HCA under a COPA from the Louisiana Dept. of Justice. On April 19, LCMC and HCA filed for Declaratory Judgment in Louisiana federal court seeking a ruling that their COPA exempts them from the HSR process. April 20 the FTC sued the hospitals in D.C. district court seeking a TRO and preliminary injunction to halt the integration while FTC investigates under HSR.
- June 2023: FTC formally commented in opposition to proposed North Carolina Senate Bill 743, which would give UNC Health (as well as any private and public entities with which it collaborates) state action immunity from federal antitrust enforcement.

FTC Challenge to Amgen/Horizon Under Portfolio Theory

- On May 16, 2023, the FTC sued to block Amgen's proposed acquisition of Horizon in the N.D.IL., saying: the merger would "allow Amgen to leverage its portfolio of blockbuster drugs to entrench the monopoly position of Horizon medications."
- According to the FTC, Horizon's Tepezza and Krystexxa are innovative products with no current competitors. They allege this transaction would enable Amgen to use rebates on its existing blockbuster drugs to pressure insurance companies and pharmacy benefit managers (PBMs) into favoring these two drugs.
- The FTC is alleging a "conglomerate" or "portfolio" effects theory of harm, i.e., that the merged company would use its dominant position in one market to create barriers to entry in other markets.
- For decades, conglomerate theories of harm have been abandoned by US antitrust regulators. It's inclusion here is significant.
- Settled with FTC in Sep. 2023

FTC Act Section 5

- In November 2022, the FTC released a statement updating the agency's policy on enforcing the federal ban on unfair methods of competition under the FTC Act.
- The FTC's previous policy restricted oversight to a set of narrower circumstances, generally limited to using Section 5 of the FTC Act in antitrust cases where agreements or conduct also fall within Sherman and Clayton Act precedents.
- The November statement declares the agency's intent to exercise its full statutory authority against companies that use unfair competitive tactics to gain an advantage.

Statement by FTC Chair Lina Khan:

"When Congress created the FTC, it clearly commanded us to crack down on unfair methods of competition. Enforcersb have to use discretion, but that doesn't give us the right to ignore a central part of our mandate. Today's policy statement reactivates Section 5 and puts us on track to faithfully enforce the law as Congress designed."

FTC Final Rule on Non-Competes

- On April 23, 2024, the FTC approved the issuance of a final rule that largely tracks the proposed rule, with a few significant modifications.
- If it goes into effect, will make future employment non-compete agreements unenforceable and will retroactively void most existing employment non-compete agreements.
- Creates a limited exception allowing for the enforcement of existing non-compete agreements with certain senior executives that were entered into before the rule's effective date
  - Prohibits employers from entering into new non-competes with all workers, including senior executives, after the effective date.
- Also does not apply to non-competes entered into pursuant to a bona fide sale of a business entity.
- Although nonprofit organizations are likely exempt, the FTC stated that merely claiming nonprofit status, and/or receiving recognition of tax-exempt status from the IRS is not, in and of itself, sufficient
  - The FTC pointed to caselaw holding that, if the organization confers more than incidental private benefits to itself or its members (or other insiders, including for-profit businesses), the organization is subject to FTC jurisdiction.
  - The FTC uses a two-part test to determine if an entity is organized for profit for purposes of the FTC's jurisdiction.
- Scheduled to become effective on September 4, 2024, if not delayed or derailed by legal challenges.
- On Jul. 3, 2024 Texas district court enjoined FTC rule from going into effect

FTC Challenges Non-Competes

- On January 4, 2023, the FTC filed complaints and issued simultaneous consent orders to resolve claims against several companies that their non-compete clauses constituted "unfair methods of competition":
  - In the Matter of Prudential Security: Under the consent order, the company and any business ventures (of the same owners) are banned from enforcing, threatening to enforce, or imposing non-compete clauses on any employees.
  - In the Matter of Ardaugh Group and In the Matter of O-I Glass: The consent order banned all non-competes with employees and required the companies to provide clear notice to employees of their right to freely see and accept new jobs from rival employers.
- In the Matter of Anchor Glass:
  - On June 2, 2023, the FTC finalized a consent order settling charges that Anchor Glass Container illegally imposed non-compete restrictions on more than 300 employees. The order bans Anchor from entering into, maintaining, enforcing or attempting to enforce, or threatening to enforce non-compete restrictions on relevant workers.

DOJ Criminal Labor Cases

- **Wage Fixing: A Win**. On October 27, 2022, VDA OC LLC, a healthcare staffing company, plead guilty and was sentenced for entering into and engaging in a conspiracy with a competitor to allocate employed nurses and to fix their wages.
  - AAG Jonathan Kanter said the win "*demonstrates our commitment to ensuring that workers receive competitive wages and a fair chance to pursue better work.*"
  - "*Protecting workers from antitrust schemes – such as wage-fixing and employee allocation – remains a priority for the U.S. Attorney's Office,*" said U.S. Attorney Frierson for the District of Nevada.
- **No Poach: Another Loss**. On March 22, 2023, a U.S. federal jury acquitted four Maine residents of criminal antitrust charges that they fixed wages and entered into no-poach agreements affecting home healthcare workers.
  - This is the DOJ's third loss in a criminal labor case, following losses in Texas and Colorado last year.

Supreme Court Considers *Chevron* Deference

- 1984 SCOTUS case created presumption that agencies have expertise and the leeway to interpret laws.
  - Chevron deference has been a factor in many lawsuits related to Medicare
- Both *Loper Bright and Relentless* deal with the Magnuson-Stevens Act that governs fishery management in federal waters and provides that the National Marine Fisheries Service may require vessels to carry federal observers onboard to enforce the agency's regulations and pay their salaries.
- Both challenged the validity of the application of *Chevron* deference.
- The Court heard oral arguments on both cases on January 17, 2024.
- Decision issued on June 18, 2024

Chevron at the Supreme Court

- **Arguments for Overruling *Chevron***
  - *Chevron* deference violates the Constitution's separation of powers by making the agency both the interpreter and executioner of the law and by violating the Constitution's instruction that it is the judiciary's duty to interpret the law.
  - *Chevron* is at odds with APA Sec. 706 which states: "[T]he reviewing court *shall decide* all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."
  - *Chevron* has had negative consequences.
    - Different judges have different conceptions of whether a particular statute is ambiguous, generating inconsistency (Judge Kethledge, *e.g.*, never found a case that required going past Step One while Judge Silberman has said in most cases the statute was ambiguous).
    - Agencies can change interpretations at will and still be upheld as long as each interpretation is "reasonable".
    - Congress can abdicate its responsibility to make law by knowing that an agency will be given wide-latitude in its interpretation of existing statutes.

Chevron at the Supreme Court

- **Arguments Against Overruling *Chevron***
- *Chevron* is a “bedrock principle” of administrative and has clear ground rules.
- *Chevron* gives appropriate weight to agency expertise, encourages national uniformity in federal law, and keeps courts out of policymaking.
  - Federal agencies possess scientific and technical expertise that make them better suited than courts to resolve statutory ambiguities [is this already accounted for under *Skidmore*?]
- *Stare decisis* principles (but does that apply just to the substantive holding in *Chevron*, which wasn’t being challenged?)

End of Chevron

- 2024 Loper Bright decision effectively transfers leeway to judiciary where statutory language is unclear.
- Implications?
  - Loper Bright (and related decision) likely will invite more lawsuits
  - Agencies may rely on nonbinding guidance and enforcement activity more (and use of formal rulemaking less)
  - Where agencies do issue rules, they will likely be very narrow
  - Will Congress really try and write statutes with more specificity and reduce flexibility agencies have to adapt laws to changing circumstances?
  - Courts will be forced to resolve technical regulatory and other granular questions
  - Courts have not generally applied Chevron deference to FTC / DOJ interpretation of substantive antitrust statutes
  - Courts have applied Chevron deference to FTC's statutory interpretations of HSR Act
  - FTC has argued for Chevron deference in FTC Act Section 5 cases

False Claims Act Hot Topic - Scienter

- FCA liability requires acting “knowingly”
- Definition encompasses three levels of knowledge
  - Actual knowledge
  - Reckless disregard
  - Deliberate ignorance (e.g., “head buried in the sand”)
- Knowledge of materiality/falsity
- Proof of intent to defraud not necessary

Supreme Court Clarifies the FCA Scienter Element (Schutte)

- Supreme Court unanimously ruled that liability under the FCA depends on the defendant's **subjective belief** about whether a claim was false.
- Supreme Court rejected the 7th Circuit's application of the objective scienter standard from ***Safeco Insurance Co. of America v. Burr***, 551 U.S. 47 (2007).
- Court will review what the defendant believed "at the time they submitted their claims," and not what an objectively reasonable person may have known or believed or "post hoc interpretations that might have rendered their claims accurate."
- Requisite scienter under the FCA may be established by showing that defendants: (1) actually knew that their claims were false; (2) were aware of a substantial risk that their claims were false and intentionally avoided learning whether they were accurate; or (3) were aware of such a substantial and unjustifiable risk that the claims were false but still submitted the claims.

United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739 (2023)

Supreme Court's Ruling on the Government's Authority to Seek Dismissal of a *Qui Tam* (Polansky)

- Supreme Court clarifies the standard under which the government can intervene and dismiss FCA actions.
  - Affirms that the government has broad dismissal authority.
- In Polansky, the government had declined to intervene while the case was under seal but filed a motion to dismiss after deciding the burdens of the suit outweighed its potential value.
  - Supreme Court held that the government may move to dismiss when it has ***first intervened in the action*** – "so long as it intervened sometime in the litigation, whether at the outset or afterward."
  - Rejects the government's contention that it may move to dismiss an FCA action even if it has never intervened.
- Courts should assess dismissal pursuant to Federal Rule of Civil Procedure 41 – where a defendant has not served an answer or MSJ, the plaintiff need only file a notice of dismissal. Otherwise, dismissal requires a court order.
- *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023)

AKS/FCA Causation Standard

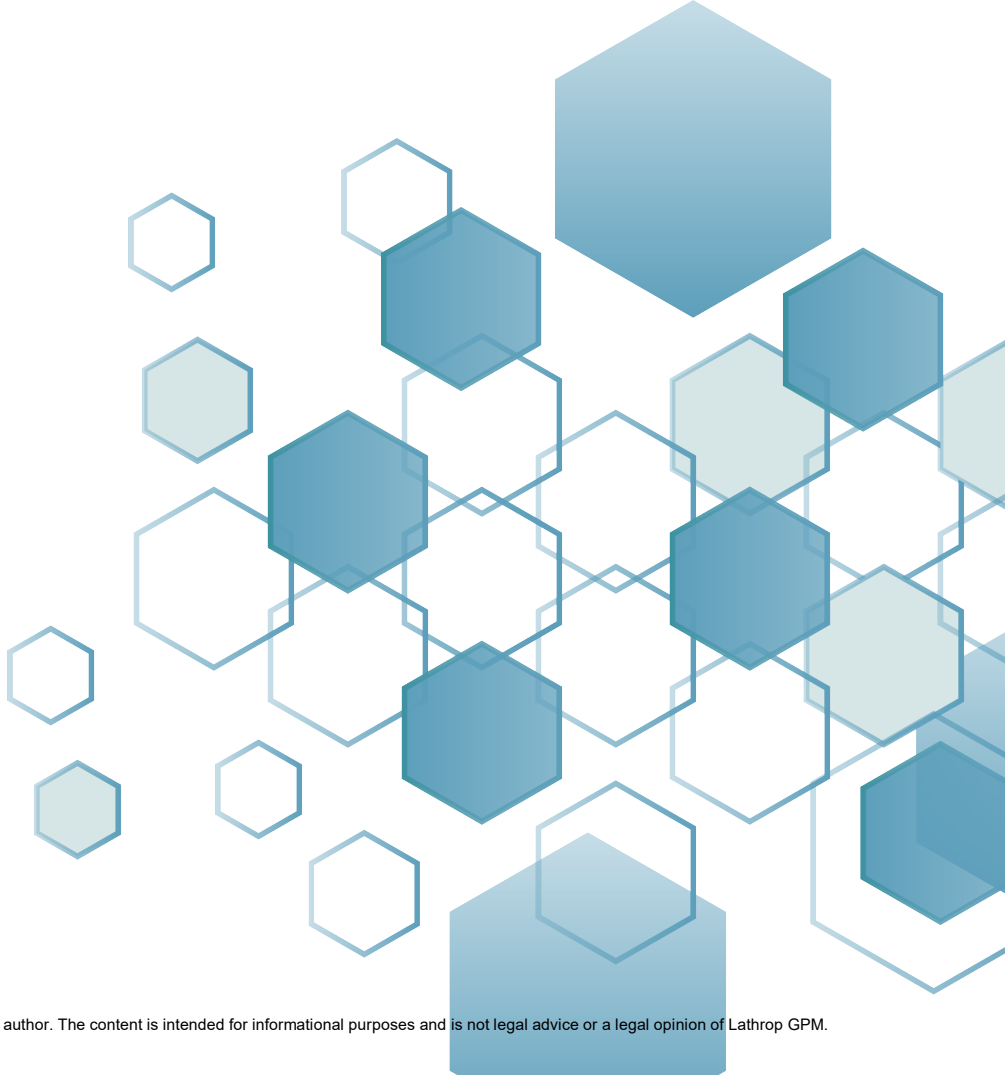
- Pre- 2010, most case law held that compliance with the AKS was a condition of payment under federal health care programs and that an AKS violation triggered FCA liability for all claims “tainted” by the FCA violation.
- ACA in 2010 added 42 U.S.C. §1320a-7b (g): “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].”
- Majority of courts initially held that “resulting from” codifies earlier tainted claim theory.
  - *See, e.g., U.S. ex rel. Greenfield v. MedCo Health Sols., Inc.*, 880 F.3d 89 (2018) (relying on legislative history to require only a "link" between the kickback and the claim without need to show but-for causation).

AKS/FCA Causation Standard

- More recently, several courts have applied stricter “but for” causation standard:
  - *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023), cert denied, 2023 WL 6378570 (10/2/2023) (claims “result from” an AKS violation only if the kickback was a “but-for” cause of the claims)
  - *U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828 (8th Cir. 2022) (holding that the “resulting from” language in the statute imposes a “but-for causal requirement between an anti-kickback violation and the 'items or services' included in the claim”; plaintiff must prove that the claims “would not have included particular 'items or services' absent the illegal kickbacks.”)
  - Conflicting 2023 holdings in D. Mass. (*United States v. Teva Pharms. USA, Inc.*, and *United States v. Regeneron Pharmaceuticals, Inc.*) have led to certification of interlocutory appeal by 1st Circuit
- Even “but for” causation may require only that violation was “a substantial factor in bringing about” the false claim. *United States v. Regeneron Pharms., Inc.*, No. 20-cv-11217, 2023 WL 6296393, at *12 & n.15 (D. Mass. Sept. 27, 2023).

Lessons Learned – MN Health Care Entity Transactions Reporting Law

Julia Reiland, Lathrop GPM



Lessons Learned – MN Health Care Entity Transactions Reporting Law

MN Health Care Entity Transactions Reporting Law

Requires transacting parties to provide AGO and MDH with notice and information prior to close of transaction.

Gives AGO authority to sue to enjoin a transaction that (a) violates antitrust law, (b) violates charities law, or (c) is otherwise not in the public interest.

Allows MDH to collect data on transactions that fall below the notice threshold.

MN Health Care Entity Transactions Reporting Law

- Requires reporting of transactions where:
  - the health care entity involved in the transaction has average revenue of at least $**80M** per year; or
  - the transaction will result in an entity projected to have average revenue of at least **$80M** per year once the entity is operating at full capacity
- Notice must be provided at least 60 days before the proposed completion date of the transaction
  - Provided to Attorney General and the Commissioner
  - Notice period may be waived
  - The Attorney General may extend the notice and waiting period for an additional 90 days

Key Terms

Health care entity (Minn. Stat. 145D.01, Subd. 1 (e)):

(1) a hospital;

(2) a hospital system;

(3) a captive professional entity;

(4) a medical foundation;

(5) a health care provider group practice;

(6) an entity organized or controlled by an entity listed in clauses (1) to (5); or

(7) an entity that owns or exercises control over an entity listed in clauses (1) to (5).

Key Terms

Transaction (Minn. Stat. 145D.01, Subd. 1 (j)):

a single action, or a series of actions within a 5-year period, which occurs in part within MN or involves a health care entity formed or licensed in MN, that constitutes:

(1) a merger or exchange of a health care entity with another;

(2) the sale, lease, or transfer of 40 % or more of the assets of a health care entity to another;

(3) the granting of a security interest of 40 % or more of the property and assets of a health care entity to another entity;

(4) the transfer of 40 % or more of the shares or other ownership of a health care entity to another entity;

(5) an addition, removal, withdrawal, substitution, or other modification of one or more members of the health care entity's governing body that transfers control, responsibility for, or governance of the health care entity to another entity;

(6) the creation of a new health care entity;

(7) an agreement or series of agreements that results in the sharing of 40% or more of the health care entity's revenues with another entity, including affiliates of such other entity;

(8) an addition, removal, withdrawal, substitution, or other modification of the members of a health care entity formed under chapter 317A that results in a change of 40 percent or more of the membership of the health care entity; or

(9) any other transfer of control of a health care entity to, or acquisition of control of a health care entity by, another entity.

Disclosure Requirements (Subd. 2(c))

Health care entity must **affirmatively disclose** the following:

(1) the entities involved in the transaction;

(2) the leadership of the entities involved in the transaction, including all board members, managing partners, member managers, and officers;

(3) the services provided by each entity and the attributed revenue for each entity by location;

(4) the primary service area for each location;

(5) the proposed service area for each location;

(6) the current relationships between the entities and the affected health care providers and practices, the locations of affected health care providers and practices, the services provided by affected health care providers and practices, and the proposed relationships between the entities and the affected health care providers and practices;

(7) the terms of the transaction agreement or agreements;

(8) all consideration related to the transaction;

(9) markets in which the entities expect postmerger synergies to produce a competitive advantage;

(10) potential areas of expansion, whether in existing markets or new markets;

(11) plans to close facilities, reduce workforce, or reduce or eliminate services;

(12) the brokers, experts, and consultants used to facilitate and evaluate the transaction;

(13) the number of full-time equivalent positions at each location before and after the transaction by job category, including administrative and contract positions; and

(14) any other information relevant to evaluating the transaction that is requested by the attorney general or commissioner.

Submission Requirements (Subd. 2(d))

Health care entity must **affirmatively submit** the following:

(1) the current governing documents for all entities involved in the transaction and any amendments to these documents;

(2) the transaction agreement or agreements and all related agreements;

(3) any collateral agreements related to the principal transaction, including leases, management contracts, and service contracts;

(4) all expert or consultant reports or valuations conducted in evaluating the transaction, including any valuation of the assets that are subject to the transaction prepared within three years preceding the anticipated transaction completion date and any reports of financial or economic analysis conducted in anticipation of the transaction;

(5) the results of any projections or modeling of health care utilization or financial impacts related to the transaction, including but not limited to copies of reports by appraisers, accountants, investment bankers, actuaries, and other experts;

(6) for a transaction described in subdivision 1, paragraph (j), clauses (1), (2), (4), or (7) to (9), a financial and economic analysis and report prepared by an independent expert or consultant on the effects of the transaction;

(7) for a transaction described in subdivision 1, paragraph (j), clauses (1), (2), (4), or (7) to (9), an impact analysis report prepared by an independent expert or consultant on the effects of the transaction on communities and the workforce, including any changes in availability or accessibility of services;

(8) all documents reflecting the purposes of or restrictions on any related nonprofit entity's charitable assets;

(9) copies of all filings submitted to federal regulators, including any filing the entities submitted to the Federal Trade Commission under United States Code, title 15, section 18a, in connection with the transaction;

(10) a certification sworn under oath by each board member and chief executive officer for any nonprofit entity involved in the transaction containing the following: an explanation of how the completed transaction is in the public interest, addressing the factors in subdivision 5, paragraph (a); a disclosure of each declarant's compensation and benefits relating to the transaction for the three years following the transaction's anticipated completion date; and a disclosure of any conflicts of interest;

(11) audited and unaudited financial statements from all entities involved in the transaction and tax filings for all entities involved in the transaction covering the preceding five fiscal years; and

(12) any other information or documents relevant to evaluating the transaction that are requested by the attorney general or commissioner.

Additional Requirements for Nonprofit Health Care Entity Transactions (Subd. 4)

A health care entity that is incorporated under chapter 317A (or a subsidiary of any such entity) must ensure that:

1. The transaction complies with chapters 317A and 501B and other applicable laws;
2. The transaction does not involve or constitute a breach of charitable trust;
3. The entity being acquired will receive full and fair value for its public benefit assets;
    - Unless the discount will further the nonprofit purposes of the nonprofit health care entity or is in the public interest
4. The value of the public benefit assets to be transferred has not been manipulated in a manner that causes or has caused the value of the assets to decrease;
5. The proceeds will be used in a manner consistent with the public benefit for which the assets are held;
6. The transaction will not result in a breach of fiduciary duty; and
7. There are procedures and policies in place to prohibit any officer, director, trustee, or other executive of the nonprofit health care entity from directly or indirectly benefiting from the transaction.

Additional MDH Reporting Requirements

- Effective January 1, 2024 (Minn. Stat. 145D.02)
- Applies to transactions where:
  - The health care entity involved in the transaction has average revenue between **$10M-$80M** per year; or
  - The transaction will result in an entity projected to have average revenue between **$10M-$80M** per year once the entity is operating at full capacity.
- Requires disclosure/submission of a subset of information
  - Information includes leadership and ownership structures; services provided; operating and nonoperating revenue for each entity by location for the last 3 years; terms of transaction agreement(s); plans to close facilities, reduce workforce, or reduce or eliminate services; etc.
  - Goal is data collection
- Secure data submission portal with Excel workbook

Lesson #1

Determine whether reporting is required at the LOI stage (or as soon as possible).

Lesson #2

The Attorney General's Office will often provide informal guidance as to whether reporting is required.

Lesson #3

Don’t underestimate the amount of time it will take to report – strategize the submission and start early

Lesson #4

Submit on a rolling basis – don't hold everything until the end

Is there information that can be provided in advance of submitting all the notice requirements?

Yes, entities are encouraged to provide the following statutorily required information in advance of its full submission in order to facilitate timely review of materials:

Initial Submission

Minn. Stat. § 145D.01 Subd. 2(c)

(1) the entities involved in the transaction (and whether the entities are non-profit)

(2) the leadership of the entities involved in the transaction, including all board members, managing partners, member managers, and officers;

(3) the services provided by each entity and the attributed revenue for each entity by location;

(4) the primary service area for each location;

(6) (partial)

- the current relationships between the entities and the affected health care providers and practices,
- the locations of affected health care providers and practices,
- the services provided by affected health care providers and practices

(12) the brokers, experts, and consultants used to facilitate and evaluate the transaction;

(13) (partial)

- the number of full-time equivalent positions at each location before the transaction by job category, including administrative and contract positions; and

Minn. Stat. § 145D.01 Subd. 2(d)

(1) the current governing documents for all entities involved in the transaction and any amendments to these documents;

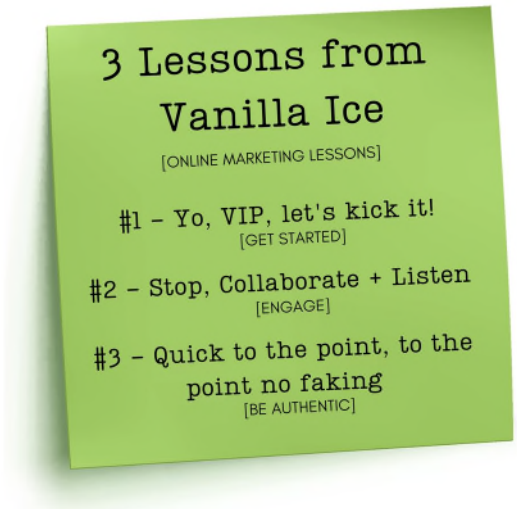
(8) all documents reflecting the purposes of or restrictions on any related nonprofit entity's charitable assets;

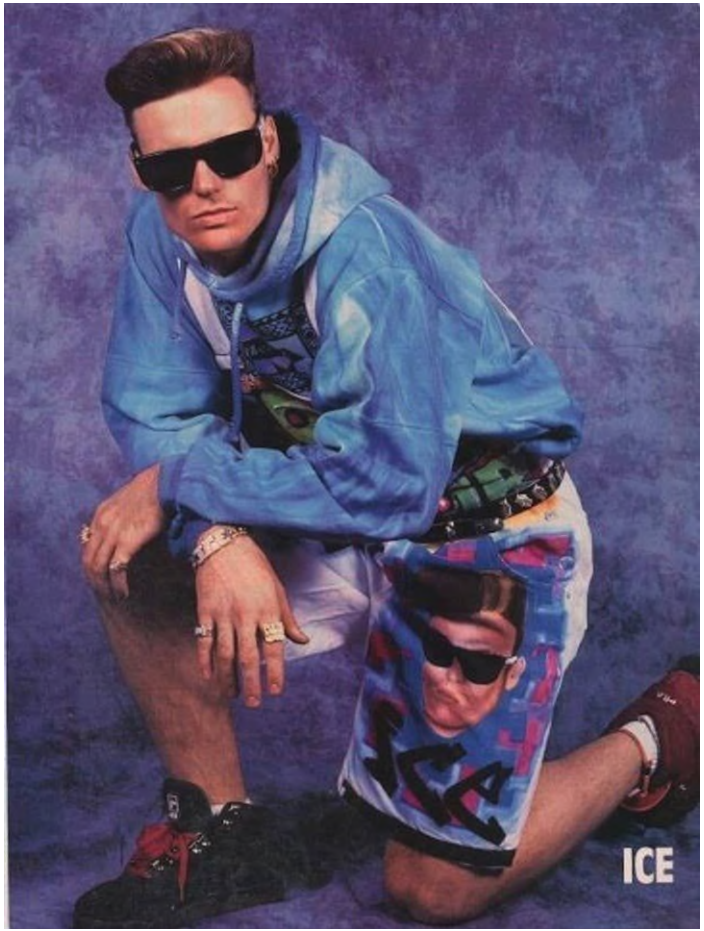
(9) copies of all filings submitted to federal regulators, including any filing the entities submitted to the Federal Trade Commission under United States Code, title 15, section 18a, in connection with the transaction; *(if any have been submitted)*

(11) audited and unaudited financial statements from all entities involved in the transaction and tax filings for all entities involved in the transaction covering the preceding five fiscal years

Lesson #5

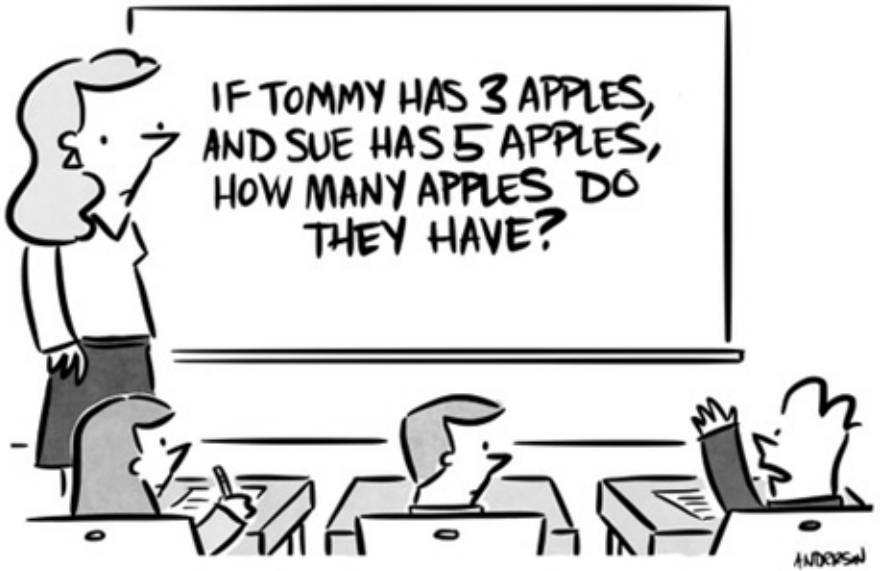
Collaborate and coordinate with the other party when preparing your submission – but submit independently





Lesson #6

Be prepared to respond to additional requests – and some may be unrelated to the transaction at hand



Lesson #7

When appropriate, request waivers of certain submission and disclosure requirements

Public Links/Resources

- Attorney General public-facing webpage: www.ag.state.mn.us/Health-Care/Transactions/
- Attorney General dedicated email: Health.Notices@ag.state.mn.us
- Minnesota Department of Health public-facing webpage: https://www.health.state.mn.us/data/mrktoversight/notices.html
- Minnesota Department of Health dedicated email: health.hctransactions@state.mn.us
- Community input form: www.ag.state.mn.us/Health-Care/Transactions/Input.asp

Thank You for Attending

Lathrop GPM