AI & HEALTH INSURANCE: *Policy Considerations for Balancing Innovation and Oversight*

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Agenda

- Introduction
- Healthcare UM Tools
- Healthcare UM Algorithms
- UM Algorithms: Governance & Policy
  - Federal
  - State
- Proposed Reforms & Challenges

INTRODUCTION

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Jennifer Oliva

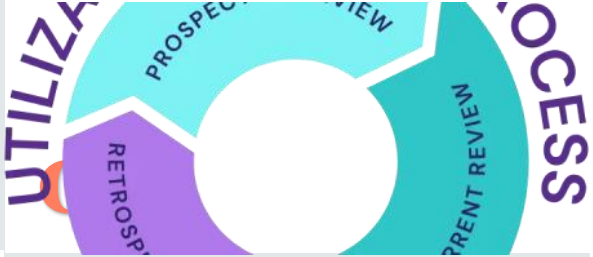
- Clinical Algorithms
  - *Dosing Discrimination: Regulating PDMP Risk Scores*, 110 CAL. L. REV. 47 (2022)
  - *Expecting Medication Surveillance*, 93 FORDHAM L. REV. 509 (2024)
  - *Disability Discrimination by Clinical Algorithm*, 103 N.C. L. REV. 187 (2024) (w/Pendo)
  - *Challenging Disability Discrimination in the Clinical Use of PDMP Algorithms*, 54 HASTINGS CTR. REP. 3 (2024) (w/Pendo)
- Healthcare Coverage Algorithms
  - *Regulating Healthcare Coverage Algorithms*, 100 IND. L.J. __ (forthcoming 2025)
  - Featured in *Algorithms Deny Humans Health Care*, U. PENN. L. REG. REV. (Mar. 18, 2025) & *What We're Reading this Week*, U. PENN L. REG. REV. (Dec. 20, 2024)
  - *How Artificial Intelligence Controls Your Health Insurance Coverage*, THE CONVERSATION (forthcoming 2025)
  - Next: ERISA & UM Algorithm Regulation

HEALTHCARE UM TOOLS

Typical UM Processes

Pre-Claim or
Prior Authorization Review

Concurrent Review



Post-Claim or
Retrospective Review

UM Tool Purposes

- Decades ago, health insurers rarely denied a provider-recommended treatment or service (denials were reserved for a tiny fraction of expensive treatments)
- Providers & healthcare facilities, however, might be incentivized to over-provide (and over-bill) for wasteful and potentially harmful treatment
- Insurers, in turn, began to employ enhanced UM tools to control costs & improve patient outcomes by ensuring safe, timely, and medically necessary care
- Today, UM processes have been subject to critique by investigative journalists, state insurance commissioners, federal regulators, and various stakeholders

Prior Authorization Review

- When an insurer receives a request for coverage of provider-recommended treatment/services subject to PA:
- The insurer conducts an independent evaluation *before such treatment/services are provided* whether:
- (1) Treatment/services are “medically necessary,” reasonable, and not experimental AND
- (2) Treatment/services are subject to plan coverage (e.g., not categorically excluded under the plan contract/terms)
- PA review is expansive (applies all stages of care and to abundant categories of intervention) in private health insurance and Medicare Advantage (but rarely utilized in traditional Medicare)

PA Review Outcomes

01 | Insurer can approve the care based on the clinical documentation submitted by the provider and can proceed with the covered treatment

02 | Insurer can seek additional information from the provider, which can be resource-intensive and delay care, before reaching a final coverage determination

03 | Insurer can demand that the patient proceed with ”step therapy” (which is sometimes characterized as a “fail first” strategy) as a prerequisite to the provider-recommended treatment under review

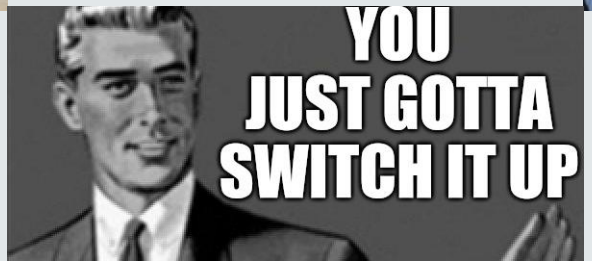
04 | Insurer can deny the claim

BRING ON TOMORROW

Claim Denials: Patient Options

Appeal the Claim Denial

Switch to Alternate Covered Treatment

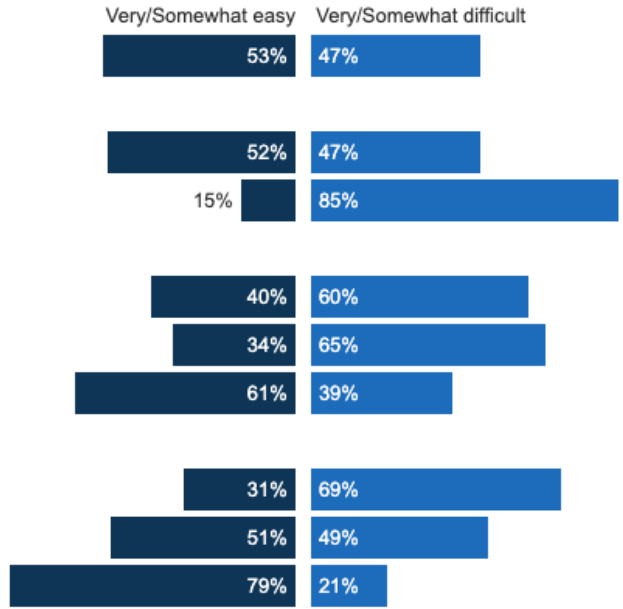


Proceed w/Treatment & Pay Out-of-Pocket

Figure 1

Half Of Adults Say It Is Difficult To Afford Health Care Costs, Including Large Shares Of The Uninsured, Black And Hispanic Adults, And Those With Lower Incomes

In general, how easy or difficult is it for you to afford your health care costs?



NOTE: See topline for full question wording.
SOURCE: KFF Health Care Debt Survey (Feb. 25-Mar. 20, 2022) • PNG

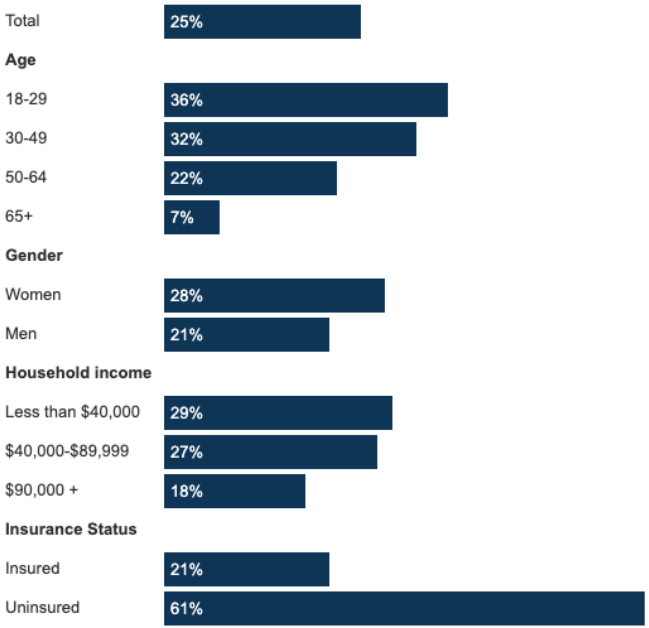
KFF

Figure 3

Six In Ten Uninsured Adults Say They Have Skipped Or Postponed Getting Health Care They Needed In The Past 12 Months Due to Cost

Total | Hispanic | Black | Asian | White

Percent who say, in the past 12 months, they have skipped or postponed getting health care they needed because of the cost:



NOTE: Black and Asian groups include multiracial and single-race adults of Hispanic and non-Hispanic ethnicity. Hispanic group includes those who identify as Hispanic regardless of race. White includes single-race non-Hispanic adults only. See topline for full question wording.
SOURCE: KFF Survey on Racism, Discrimination, and Health (June 6- August 14, 2023) • PNG

KFF

Claim Denial Data

- It's difficult to get good data on the frequency of claim denials because
- Federal regulators have fallen down on the job (they are required to collect denial data under the ACA and authorized to do so under ERISA)
- State insurance commissioners generally collect but do not release such data to the public
- Est: ~20% of ACA marketplace plan claims are denied (KFF)
- Appeals? Less than 1% (KFF)

PROPUBLICA

Health Care

How Often Do Health Insurers Say No to Patients? No One Knows.

Insurers' denial rates — a critical measure of how reliably they pay for customers' care — remain mostly secret to the public. Federal and state regulators have done little to change that.

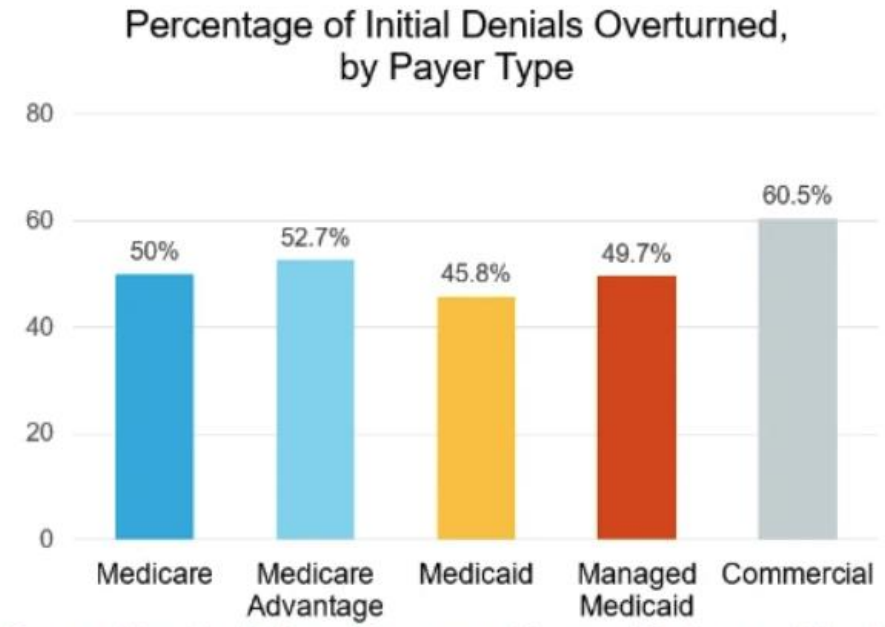
By — Elisabeth Rosenthal, KFF Health News

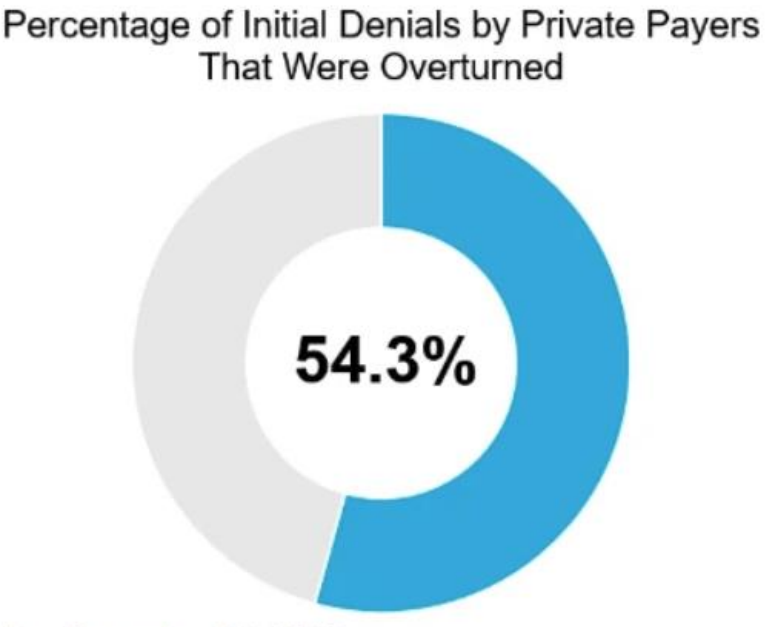
Leave your feedback

Share

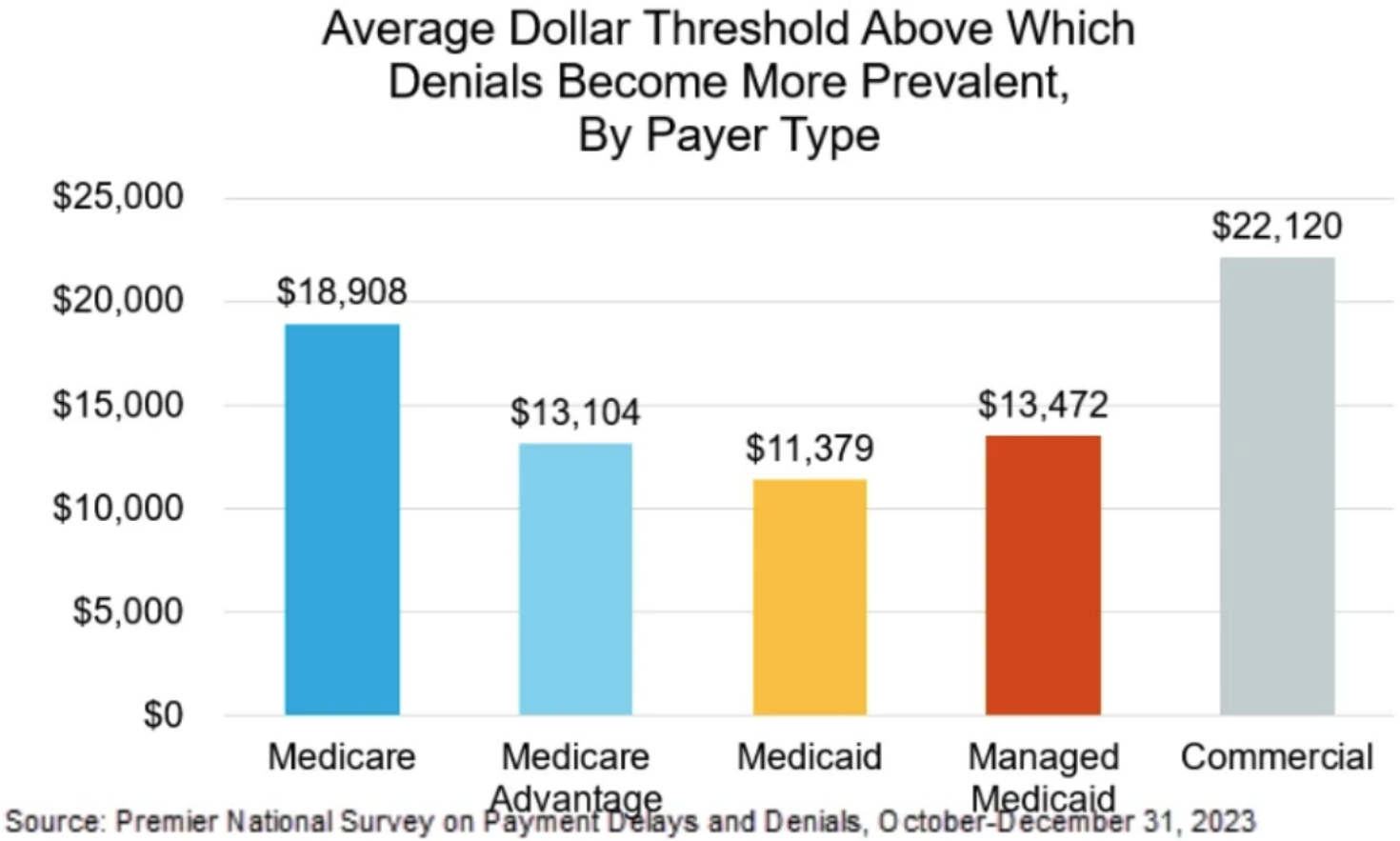
Analysis: Health insurance claim denials are on the rise, to the detriment of patients

Health May 28, 2023 9:00 AM EDT





Source: Premier National Survey on Payment Delays and Denials, October-December 31, 2023


Average Dollar Threshold Above Which Denials Become More Prevalent, By Payer Type
$25,000
$20,000
$15,000
$10,000
$5,000
$0
$18,908
$13,104
$11,379
$13,472
$22,120
Medicare
Medicare Advantage
Medicaid
Managed Medicaid
Commercial
Source: Premier National Survey on Payment Delays and Denials, October-December 31, 2023

Claim Denials: Stats Summary

~15%

Estimated annual claim denial rate***; data is uncertain but experts est. ~10-20% overall

Sources: KFF (ACA/MA), Premier, Cal. Nurses Ass'n, Vermont

<1%

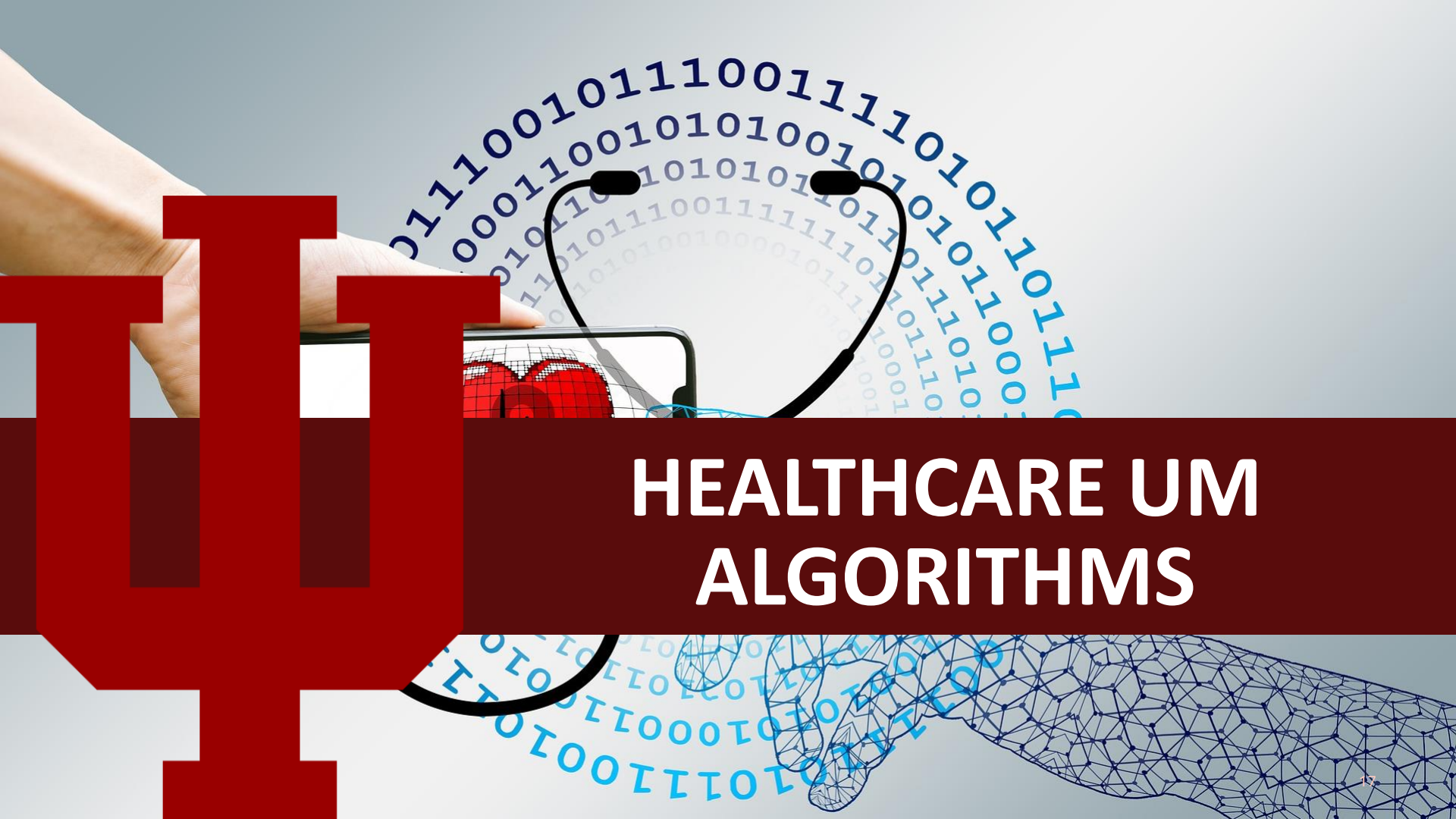
Est. rate at which patients appeal claim denials

Sources: CMS, KFF, Premier (Hospital Survey)

~50%

Est. rate at which claim denials are overturned on appeal

Sources: KFF, Premier



HEALTHCARE UM ALGORITHMS

“Humans’ natural inclination to rely on algorithmic decision support tools to summarize information and save time is amplified when adherence to AI-derived predictions aligns with economic and professional pressures.”

– Michelle M. Mello & Sherri Rose, *Denial—Artificial Intelligence Tools and Health Insurance Coverage Decisions*, 5 JAMA HEALTH F. 1, 2 (Mar. 7, 2024)

The Rise of Automated UM Tools

- As insurers escalated the number of treatments/services subject to PA and other UM processes, the manual performance of those voluminous reviews became increasingly time-and-resource intensive
- Manual reviews also lead to increasingly lengthy treatment delays
- They further suffered from lack of standardization and human error
- As a result, insurers turned to automated UM processes
- UM algorithms can perform claims reviews at a rapid clip with little human oversight

UM Software Litigation

- Various class action lawsuits have been filed over the previous two years challenging the use of UM software tools
- Claims include state unfair trade practices acts, breach of contract, unjust enrichment, breach of the implied covenant of good faith and fair dealing, et.

GOVERNANCE & POLICY

Health Insurance Regulation: Overview

- As a general rule, states lead on insurance regulation with a federal fallback for most protections BUT
- ERISA limits the application of state law to certain employer-sponsored plans
- The federal government regulates federal health insurance plans (e.g., Medicare, VA healthcare, DoD/Tricare, et.)
- Federal regulation of private health coverage can differ based on the marker/source of coverage
- Special exceptions in regulations allow certain types of private coverage (e.g., church plans, ACA grandfathered plans, et.) to avoid having to meet many insurance protections

Federal Oversight: Employer-Sponsored Insurance

- The U.S. Department of Labor (DOL) regulates employer-sponsored health plans pursuant to the Employee Retirement Income Security Act of 1974 (ERISA)
- ERISA specifically and broadly pre-empts or prevents state law from applying to most self-insured employer group health plans
- Will ERISA pre-empt state law reforms aimed at automated UM processes?

ERISA Preemption: "Relate to" Clause

- **"Relate to" clause**: ERISA supersedes state laws that "relate to" any employee benefit plan
- *Travelers* Factors:
  - Does the state law mandate employee benefit structures or their administration?
  - Does the state law bind employers or plan administrators to particular choices or preclude uniform administrative practice?
  - Does the state law provide an alternative enforcement mechanism to ERISA?

ERISA Preemption: Savings & Deemer Clauses

- **Savings clause**: A state law that regulates *insurance*, banking, or securities is not preempted
- (*Miller* Test) A state law regulates insurance if
  - (1) it is specifically directed toward the insurance industry; and
  - (2) substantially affects the risk pooling arrangement between the insurer and insured
- **Deemer clause**: No *self-funded ERISA plan* "shall be deemed to be an insurance company or other insurer"

Federal Oversight: ACA & Other Group Plans

The U.S. Department of Health and Human Services (HHS) regulates non-group marketplace plans and other group plans

This gives the federal government fairly expansive powers when combined with its ERISA authority BUT several of the ACA standards only apply to individual and small group market plans and not ERISA-covered large group plans

As already mentioned, the ACA exempts plans that existed prior to ACA enactment (‘grandfathered plans’) from many of the ACA’s insurance requirements

Federal Oversight: Medicare Advantage Insurers

- The U.S. Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) regulates Medicare Advantage (MA) insurers pursuant to the Social Security Act (Medicare statute).
- In response to complaints about MA insurer use of UM algorithms to process claims, the HHS Office of the Inspector General (OIG) conducted a study of MA claims denials in 2022.
- OIG examined a one-week random sample of 430 claims denials and estimated that 13% of PA claim denials and 18% of post-acute care claim denials ran afoul of the MA rules and should have been approved. The OIG recommended several UM reforms to CMS.

State Oversight of UM Algorithms

- States have the authority to regulate UM algorithms but cannot regulate certain healthcare insurers
- They cannot regulate federal healthcare insurers (e.g., Medicare, VA, DoD, et.)
- They generally cannot regulate self-funded employer group plans (ERISA)
- There are ERISA limitations on the extent that they can regulate fully-funded employer group plans
- They cannot regulate insurers over which they have no jurisdiction (e.g., those that do not operate in-state and do not provide insurance products to their residents)

REFORMS & CHALLENGES

CMS Rule #1: Use of UM Algorithms

- CMS took the HHS OIG report regarding MA claims denials seriously and issued two new rules
- First rule: Apr. 12, 2023 (issued); Jan. 1, 2024 (effective)
- MA plans can use UM algorithms but
- (1) UM medical necessity decisions must be based on the specific patient's individual circumstances (general criteria is insufficient);
- (2) Those decisions must be reviewed by a physician/other appropriate healthcare professional; and
- (3) MA plans must make the use of any algorithmic products and their internal coverage determination criteria publicly available.

Rule #1 Considerations

- What does “account for individual circumstances” actually entail? Do the patient’s social determinants of health and/or social supports constitute “individual circumstances”?
- What does “reviewed by a human” mean? How much freedom does that human have to overrule the algorithm? Does that human have to understand how the algorithm works?
- Are the plans required to disclose the prediction algorithm’s list of data proxies/weights/predictors (or just its “use”)?
- The rule neither makes any attempt to limit the application of UM to particular treatments or services nor require UM algorithms to adapt as medical knowledge, efficacy, and costs evolve.

CMS Rule #2: Streamlining PA Processes

- Second rule: Feb. 8, 2023 (issued); Apr. 8, 2024 (effective)
- Applies to various government healthcare programs, including Medicare Advantage, Medicaid, Children's Health Insurance programs, and Qualified Health Plans that are on the federally facilitated ACA marketplaces. It mandates that health plans:
- (1) develop and implement electronic exchanges where patients, providers, and insurers can share information;
- (2) send notices to providers that detail the specific reason for any claim denial as well as respond to prior authorization requests within specified timelines; and
- (3) publicly report various metrics concerning their prior authorization determinations to promote enhanced transparency.

Rule #2 Considerations

- Application is limited to a very specific set of government health insurance programs. It does not, for example, apply to employer-sponsored plans (which cover 60.4% of people under 64 in the US)
- Application is limited to a very specific sub-set of benefits offered by those government programs. It does not, for example, apply to government healthcare prescription drug benefits.
- The rule's provisions that aim to speed up/expedite prior authorization decision-making may further incentivize reliance on automated UM tools/less human oversight.
- Much like Rule #1, it does nothing to address the ongoing lack of external pre- and post-market vetting and secrecy that applies to UM algorithms

State Reform & Challenges

- According to NCSL at least 45 states, Puerto Rico, the Virgin Islands, and Washington, D.C. introduced AI bills in just 2024.
- Very few of these measures are aimed specifically at healthcare insurers and virtually no bills that are aimed at healthcare insurers have yet to be enacted.
- As mentioned numerous times, the states cannot regulate all health insurers.
- None of the state measures propose pre- or even post-market vetting of UM algorithms for accuracy and validity.
- It will be difficult for insurers that operate across jurisdictions to comply with potentially 50-plus state and federal laws and regulations.

Uniform National Solution: Proposal

- The FDA has the authority to regulate software, including healthcare algorithms, under its medical device authority (SaMD authority)
- The FDA, therefore, has the obligation to vet UM algorithms for accuracy and validity before they go to market and are used to generate coverage decisions. The FDA also has post-market oversight of such devices.
- Upshot #1: stakeholders can have enhanced confidence that UM tools do (and will continue to do) what they are purported to do: make accurate and valid coverage determinations.
- Upshot #2: this reform would provide a uniform national solution that gets around the disparate maze of federal-state health insurance regulation and relieve insurers from having to following 50-plus different rules.
- Upshot #3: FDA pre-emption/liability-reduction

Uniform National Solution: Challenges

- The FDA SaMD scheme may not apply to healthcare coverage algorithms because they may not satisfy the statutory definition of “medical device.”
- The argument is that healthcare coverage algorithms are exempt from FDA oversight because they:
- (1) are used outside the clinical care context and
- (2) merely assist the insurer in generating coverage decision (e.g., they do not generate treatment decisions)
- Even if it does apply, the FDA SaMD scheme has been critiqued as insufficient, particularly given that Congress restricted FDA’s authority over medical software devices in the 21st Century Cures Act in 2016.

THANK YOU!

BRING ON TOMORROW