HEALTHCARE LEGAL AND REGULATORY UPDATE

ULA Advanced ERISA Seminar

September 26, 2024/Kathryn Bakich and David Fusco

Segal

No Surprises Act and Transparency in Coverage Rule Roundup

Litigation Update: IDR Process and TMA III

- On August 24, 2023, in *Texas Medical Association, et al. v. United States Department of Health and Human Services*, the U.S. District Court for the Eastern District of Texas issued a judgment and order vacating certain portions of the Departments' August 2022 final rules (TMA III)
- IDR was paused, and then reopened October 6, 2023, for certain single and batched disputes but continued to pause air ambulance disputes

TMA III Holding

- The district court vacated:
  - Portions of the QPA methodology, including counting rates for all items and services regardless of the number of claims paid; using book of business rates instead of each plan's rates; rules governing calculation of QPA for providers in the same or similar specialty; exclusion of bonus, incentive and risk sharing payments, and exclusion of single case agreements
  - The "clean claim" rule for air ambulance services, which states that the 30-day initial payment period starts when the plan has a clean claim
- The ruling will likely require changes to plan administrators' QPA methodology calculations and cause disruption
- Departments appealed

Departments Respond in FAQ 62

- FAQ 62 issued FAQs in response to the TMA III decision
- Plans must calculate QPAs consistent with the rules that remain in effect after TMA III using a good faith, reasonable interpretation
- The Departments will exercise enforcement discretion for plan QPA calculation in accordance with the July 2021 IFR in effect before TMA III for items and services furnished before May 1, 2024
- In FAQ 67, the Departments extended the enforcement discretion to November 1, 2024
- Plans must still disclose the QPA to providers and participants, and should disclose which methodology is used

Final Rule IDR Fees for 2024

- On December 21, 2023, the Departments published a final rule establishing IDR fees effective for disputes initiated on or after the later of the rule effective date or January 22, 2024
- Nonrefundable Administrative Fee: $115 per party per dispute
  - Departments proposed flexibility to modify the fee with notice and comment rulemaking rather than annually to account for program needs
- Entity Fees (refunded to the prevailing party):
  - Single Determinations: $200 to $840
  - Batched Determinations: $268 to $1,173; Batched Determinations with more than 25 line Items: $75 to $250 for every additional 25 line items within a batched dispute beginning with the 26th line item

Gag Clause Prohibition Under the NSA

- Effective 12/27/20, health plans and insurers may not enter into contracts that would restrict the plan from:
  - Disclosing provider-specific cost or quality of care information
  - Electronically accessing de-identified claims and encounter information or data consistent with HIPAA, GINA, and ADA
  - Sharing this information/data with a business associate.

Gag Clause Attestation—FAQ 57

- Plans must complete attestation that they do not have gag clauses in contracts by December 31, 2023
  - Subsequent attestations due each December 31
- Online forms available
- Determine who will complete the attestation on behalf of the plan
- Legal counsel should review relevant contracts
- Treasury Department stated 10/18/23 that they do not expect to issue additional guidance

Gender Affirming Care and Section 1557

ACA Section 1557 (Nondiscrimination in Health Benefits)

- April 26, 2024, HHS released new final 1557 regulation (published May 6, 2024)
- Entities that receive federal financial assistance from HHS cannot discriminate on the basis of race, color, national origin, sex, age or disability with regard to health programs
- Appears to only affect those plans that receive the Retiree Drug Subsidy
- However, insurers and ASO/TPA that are covered entities because of insurance payments (e.g., on the ACA exchange) may ask clients to comply with the rules

Requirements for 1557 Covered Entities

- Effective for plan years beginning on or after 1-1-25, cannot exclude or limit services related to gender-affirming care
- Must have policies and procedures:
  - Section 1557 coordinator
  - Written policies and procedures
  - Training
  - Notice of nondiscrimination
  - Notice of availability of language assistance and auxiliary aids and services
- Accessibility requirements for disability and languages
- Various effective dates

Section 1557 Litigation

- In *Tennessee v. Becerra*, a Mississippi District Court ruled there was a substantial likelihood that HHS exceeded its statutory authority when it interpreted the phrase "on the basis of sex" in Title IX
  - The Court stayed the effective date of the regulation nationwide as to certain provisions, in so far as they extend "discrimination on the basis of sex" to include gender identity
  - It also enjoyed HHS on a nationwide basis from implementing or enforcing the provisions as to gender identity
- In *Texas v. Becerra*, a Texas District Court stayed the entire final regulation in Texas and Montana
- In *Florida v. Becerra*, a Florida District Court enjoined HHS from enforcing the entire final rule in Florida

Transgender Care Litigation

- *Kadel v. Folwell* , No. 22-1721 (4th Cir. 4/29/24).
- In an 8-6 ruling, an *en banc* appeals panel of the Fourth Circuit Court of Appeals held that the North Carolina state health plan for teachers and employees violated the 14th Amendment's Equal Protection Clause by refusing to pay for medically necessary treatments for gender dysphoria treatments
- Defendants' request for Certiorari to US Supreme Court is pending

Mifepristone Litigation and EMTALA

Mifepristone Litigation and EMTALA

- *FDA v. Alliance for Hippocratic Medicine*
  - Plaintiffs did not have standing to challenge FDA approval of Mifepristone
- *Idaho v. United States*
  - US sued Idaho arguing their abortion ban conflicted with EMTALA. Supreme Court dismissed the case without ruling on the merits

ERISA Preemption, Prescription Drugs, and Fiduciaries

Mulready v. PCMA

- In *PCMA v. Glen Mulready,* August 15, 2023, the Tenth Circuit Court of Appeals found ERISA preempted state pharmacy benefit regulation
- The court rejected the argument that the Oklahoma Act escapes preemption because it regulates PBMs (not health plans)
- Held that ERISA preempts four provisions of the Oklahoma Act that interfere with central matters of plan structure and administration
- Petition for rehearing filed, but denied on December 12th.
- Oklahoma petitioned for Certiorari to the US Supreme Court

Lewandowski v Johnson & Johnson and *Navarro v Wells Fargo & Co*

- Plan participants filed class actions against plan and its fiduciaries alleging breach of fiduciary duty and other violations under ERISA related to the plan's prescription drug benefit

FTC v. The Big Three

- FTC published a report on Pharmacy Benefit Mangers in July 2024
- On September 17, 2024, Express Scripts filed a lawsuit demanding that FTC retract the report
- On September 20, 2024, FTC filed an administrative complaint against Caremark, ESI, and OptumRx alleging that they accepted money from drugmakers in exchange for keeping lower cost insulin off their formulary lists

Preventive Services Lawsuit

Preventive Services Update

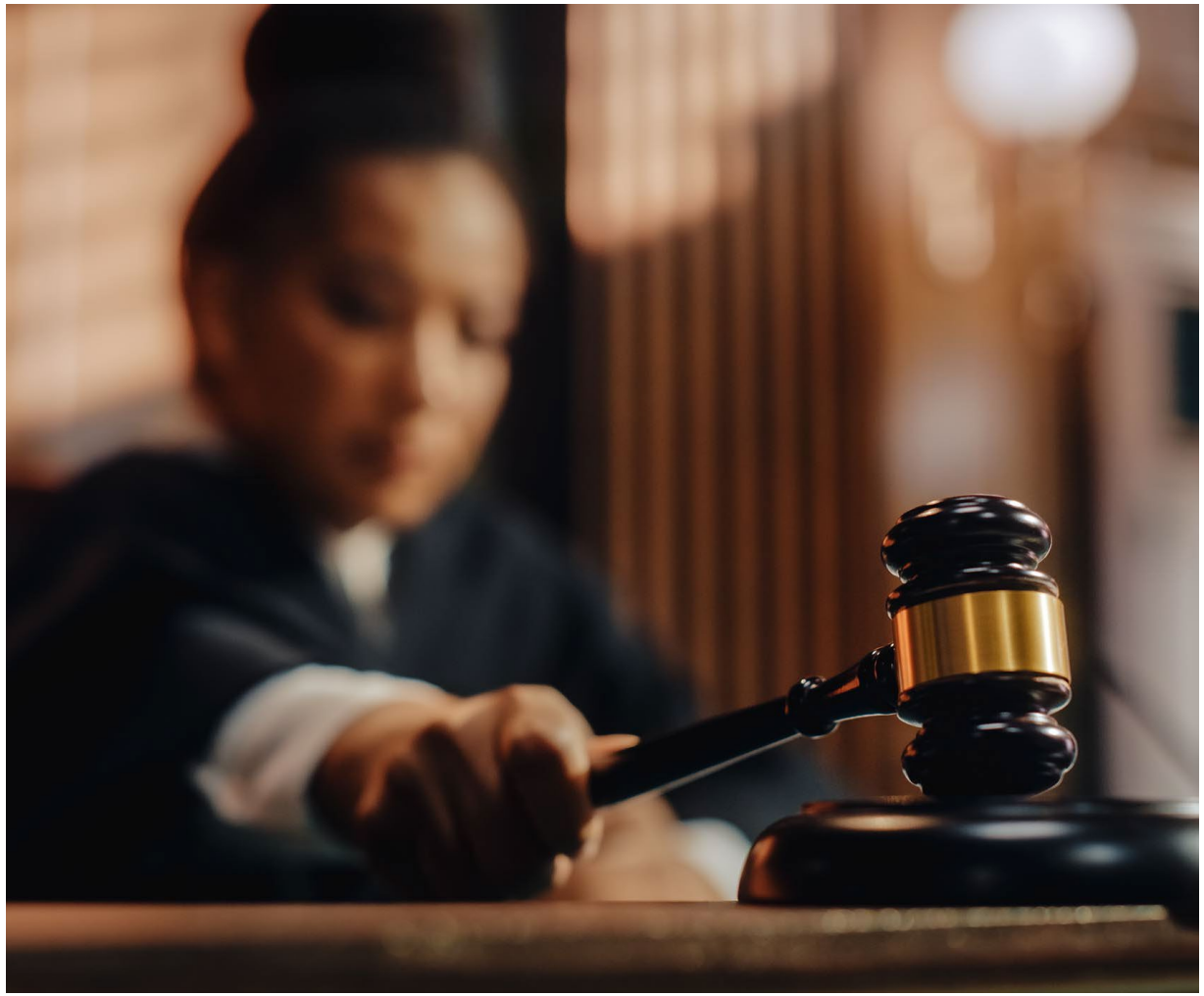
- The ACA's preventive services mandate requires non-grandfathered group health plans and insurers to cover certain preventive services with no cost sharing on an in-network basis

No Cost Sharing Preventive Services

- The following preventive services are covered:
  - The USPSTF recommends "A" or "B" ratings[1] for specific evidence-based items and services for all patient demographics
  - The Health Resources and Services Administration (HRSA[2]) issues guidance regarding preventive care and screening for infants, children, adolescents and women
  - The Advisory Committee on Immunization Practices (ACIP[3]) recommends certain immunizations

1 https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations
2 https://www.hrsa.gov/
3 https://www.cdc.gov/vaccines/acip/index.html

Litigation Update: Braidwood Management Inc. v. Becerra



- On March 30, 2023, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas ruled that part of that mandate violates the Constitution and vacated all agency action taken to implement or enforce the USPSTF "A" or "B" preventive care recommendations on or after March 23, 2010

The Case Continues . . .

- June 13, 2023: Fifth Circuit Court of Appeals stayed the lower court's order
  - Provider groups agreed not to oppose agencies' motion to stay the lower court's decision
  - Agencies agreed not to seek penalties or enforcement for periods before the case is resolved
- June 21, 2024: Fifth Circuit affirmed district court decision but limited remedy to plaintiffs, and remanded case for further consideration

Copay Accumulator Programs

Litigation update: Copay Accumulator Programs

- These programs allow patients to use a manufacturer coupon to pay for medications, but the value of the coupon is not credited toward the participant's deductibles or cost-sharing for purposes of reaching the out-of-pocket maximum

Copay Accumulator Programs and the ACA

- Background: The ACA requires non-grandfathered group health plans to have an out-of-pocket maximum for essential health benefits
- Under current guidance, plans may decide whether or not to count the coupon toward a participant's ACA out-of-pocket maximum

Copay Accumulator Programs Challenged

- In 2022, the HIV and Hepatitis Policy Institute, the Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council, as well as several individuals, sued HHS
- Plaintiffs alleged that due to their carrier's copay accumulator, manufacturer assistance was not credited toward their out-of-pocket maximum and they were required to pay additional money out of pocket before reaching the maximum
- On September 29, 2023, the U.S. District Court for the District of Columbia overturned existing agency guidance and remanded the issue for further review by HHS

Next Steps

HHS intends to issue rulemaking to address whether financial assistance provided to patients by drug manufacturers qualifies as "cost sharing" under the ACA

Pending the issuance of a new final rule, HHS does not intend to take any enforcement action

No immediate action is required in response to this ruling or HHS dropping its appeal – but plans should examine current coupon programs to determine whether they could be affected

ACA Transitional Reinsurance Fee Settlement

ACA Transitional Reinsurance Fee

- In *Electrical Welfare Trust Fund v. United States*, Case No. 19-353C, plaintiffs filed a class action challenging assessment of the transitional reinsurance fee (ACA) against self-administered, self-insured health plans during the 2014 benefit year
- A class action settlement should be paid in fall 2024
- The “takings” case for the fee for the years 2014-2016 is still pending

Fertility Benefits Litigation

Fertility Benefits Litigation

- Cases challenge denial of fertility treatment benefits based on discriminatory policies, such as sexual orientation and different rules for heterosexual individuals v LGBTQ+ individuals

Insulin Class Actions

Insulin Class Action

- Plaintiffs claimed Caremark leveraged its market power to negotiate unfavorable contracts with insulin manufacturers resulting in artificially inflated prices to consumers

Loper-Bright and *Cogdell v Reliance Standard Life Ins.*

Cogdell v. Reliance Standard Life Ins.

- Plaintiff sought disability benefits from Reliance Standard Life Insurance Co. with a diagnosis of long COVID
- Reliance argued that the claims and appeals regulation's 45-day deadline for benefit plan administrators to respond to appeals of denied claims was invalid, citing *Loper-Bright*
- The court found that the regulation merely sets a time limit for claim exhaustion, it did not mandate or direct the courts to apply a particular standard of review and *Loper-Bright* challenge failed

Loper-Bright and HIPAA Reproductive Health PHI Rule

HIPAA Reproductive Health PHI rule challenge

- On September 4, 2024, Texas sued HHS seeking declaratory and injunctive relief against enforcement of ***both*** the 2000 privacy rule and the 2024 reproductive rule, alleging that the rules lack statutory authority and are arbitrary and capricious
- Texas alleges that no text in HIPAA authorizes HHS to limit the documents that medical providers may produce to a State law enforcement agency

Thank You