NCCMP Lawyers and Administrators Meeting
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Health and Welfare Litigation Update

1. No Surprises Act

Most group health plans and health insurers are subject to the No Surprises Act for plan years beginning on or after January 1, 2022. The No Surprises Act prevents surprise billing of patients who receive emergency services in the emergency department of a hospital, at an independent freestanding emergency department and from air ambulances. In addition, the law protects patients who receive certain non-emergency services from an out-of-network provider at an in-network facility.

Part I of the Interim Final Regulation (IFR) on the No Surprises Act, which was released in July 2021, addressed patient rights and how to calculate the Qualifying Payment Amount (QPA), generally defined as the plan's median in-network contracted rate. Part II of the IFR issued in November 2021 covers what happens after the participant's cost-sharing is complete and they are protected from balance billing and how the plan resolves its claim with the out-of-network provider or facility though an Independent Dispute Resolution (IDR) process.

The Administration has promulgated additional regulations and sub-regulatory guidance through FAQs on the IDR process, method for calculating the QPA, etc. Three decisions issued in the Eastern District of Texas have vacated portions of these regulations and guidance. As a result of the decisions, IDR operations were paused several times in 2022 and 2023, but are reopened at this time.

a. TMA I – IV

i. *Texas Medical Association v. Department of Health and Human Services (TMA I)*, 587 F. Supp. 3d 528 (E.D. Tex. 2022), appeal dismissed, 2022 WL 15174345 (5th Cir. Oct. 24, 2022).

Plaintiffs alleged that the agencies unlawfully required Independent Dispute Resolution Entities to "rebuttably presume" that the offer closest to the qualifying payment amount (QPA) was the appropriate out-of-network rate. Plaintiffs also argued that the interim rule was issued without the required notice and comment under the Administrative Procedure Act (APA).

TMA won in District Court, which held that the Act unambiguously requires IDR Entities to consider several factors when selecting the proper payment amount—and does not instruct them to weigh any one factor or circumstance more heavily than the others. The court concluded that the interim rule conflicted with the Act because it improperly restricted IDR Entities' discretion and directed them to consider one factor – the QPA – as more important than the others. Also held that the Departments

violated the APA by failing to provide the required notice and comment. Departments appealed and voluntarily dismissed case.

ii. *Texas Medical Association v. Department of Health and Human Services (TMA II)*, No. 6:2022cv00372 (E.D. Tex. 2023), affirmed, Case No. No. 23-40217 (5th Circuit August 2, 2024).

On February 6, 2023, the District Court vacated certain portions of technical guidance issued under the Final Rule relating to the Federal IDR process. The Departments revised the Federal IDR portal and Federal IDR process guidance documents to adhere to this decision.

iii. *Texas Medical Association v. Department of Health and Human Services (TMA III)*, 6:2022cv00450 (E.D. Tex. 2023), No. 23-40217 (5th Cir. 2024)

On August 24, 2023, the district court issued an opinion and order in TMA III vacating certain provisions of the July 2021 interim final rules as well as other portions of the Departments' No Surprises Act guidance. The district court in TMA III held that several provisions of the regulations and guidance are unlawful and vacated and remanded them for further consideration, including provisions related to the methodology for calculating the QPA. 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, and 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 Department of Justice partially appealed the district court's decision in TMA III, which remains pending before the United States Court of Appeals for the Fifth Circuit (oral argument was September 3, 2024).

On October 6, 2023, the Departments issued FAQs Part 62 stating that the Departments would exercise their enforcement discretion under the relevant No Surprises Act provisions for any plan or issuer, or party to a payment dispute in the Federal IDR process, that uses a QPA calculated in accordance with the methodology under the July 2021 interim final rules and guidance in effect immediately before the decision in TMA III, for items and services furnished before May 1, 2024. In FAQ 67 that enforcement discretion was extended to November 1, 2024.

iv. *Texas Medical Association v. Department of Health and Human Services*, 6:2023cv00059 (E.D. Tex. 2023)

Plaintiffs allege that the increased administrative fee constitutes a material limitation on provider access to the IDR process, and therefore requires a notice-and-comment period under the APA. Held that the fee increase must be set aside as arbitrary and capricious under the APA

because it was not the product of reasoned decision-making. Final rules were published on December 21, 2023 modifying the administrative fee and certified IDR entity fee range.

b. Report on Status of Independent Dispute Resolution Program

i. Supplemental Background on Federal Independent Dispute Resolution Public Use Files; July 1, 2023 - December 31, 2023

ii. Between July 1, 2023, and December 31, 2023, disputing parties initiated 390,346 disputes through the Federal IDR portal, 35% more than the first six months of 2023 (288,810 disputes). This increase is particularly notable because dispute initiations were temporarily suspended for all dispute types for approximately 9 weeks in response to multiple court orders issued in August 2023. Overall, disputing parties initiated 679,156 disputes in 2023, more than three times the number of disputes initiated in 2022 (200,112 disputes).

iii. The majority of disputes were initiated by a small number of initiating parties or their representatives. The top ten initiating parties represented approximately 76% of all disputes initiated in the last six months of 2023. Many of the top initiating parties are (or are represented by) large practice management companies, medical practices, or revenue cycle management companies representing hundreds of individual practices, providers, or facilities. The top three initiating parties (Team Health, SCP Health, and Radiology Partners) represent thousands of clinicians across multiple states and accounted for approximately 58% of all disputes initiated in the last six months of 2023.

iv. Overall, certified IDR entities rendered 209,346 payment determinations in 2023, more than twelve times the number of payment determinations made in 2022 (16,238 determinations). Certified IDR entities closed 311,863 disputes in 2023, more than five times the number of disputes closed in 2022 (54,821 disputes).

v. Providers won approximately 82% of resolved cases, often receiving substantial awards.

2. Gender Affirming Care Litigation (Section 1557 Final Rules and Litigation)

a. 1557 Final Rule 89 Fed. Reg. 37522 May 6, 2024

i. *State of Tennessee v. Becerra*, (S.D. Miss. July 3, 2024)*:* Fifteen individual States filed a Complaint challenging the final rule in the United States District Court for the Southern District of Mississippi. Plaintiffs claimed that the rule violated the Administrative Procedure Act (APA) by (1) unlawfully defining "on the basis of sex"; (2) unlawfully regulating the practice of medicine; (3) because it is contrary to the Spending Clause, Nondelegation Doctrine, and the Eleventh Amendment of the United States Constitution; and (4) because it is arbitrary and capricious. The district court issued a nationwide stay of the effective date of several

provisions,[1] in so far as the final rule is intended to extend discrimination on the basis of sex to include discrimination on the basis of gender identity.

ii. *Texas and Montana v. Becerra*, No. 6:24-cv-211-JDK, 2024 BL 228454 (E.D. Tex. July 03, 2024). Texas and Montana sued HHS under the Administrative Procedure Act. The states claimed that neither Section 1557 nor Title IX permits these new rules. The United States District Court for the Eastern District of Texas granted a stay of the effective date of the final rule, stating that Montana and Texas would suffer irreparable harm and "are likely to lose billions of dollars in federal funding for their Medicaid and CHIP programs for refusing to comply." The stay applies to Texas and Montana.

iii. *State of Florida v. Department of Health and Human Services*, (8:24-cv-01080 (M.D. Fla. July 3, 2024)*:* Florida filed a motion for a preliminary injunction of the final rule. The United States District Court for the Middle District of Florida stayed the final rule in part, postponing the effective date of several of the regulations. The effect of the court order broadly limits any changes to Florida's laws. The Court also issued a preliminary injunction preventing HHS from enforcing the final rule under Section 1557. However, the order only applies in Florida.

b. Transgender care litigation

i. *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 state employee health plan violated the 14th Amendment's Equal Protection Clause by refusing to pay for medically necessary treatments for gender dysphoria treatments. The court cited *Bostock v Clayton County,* 140 S. Ct. 1731 (2020) which held that sex discrimination included discrimination on the basis of sexual stereotyping and gender identity. The case involved the North Carolina state health plan for teachers and state employees, and the West Virginia Medicaid program.

ii. On July 30, 2024, North Carolina and West Virginia filed a Petition for a Writ of Certiorari with the US Supreme Court (Case No. 24-99). Response is due October 28, 2024. Multiple Amicus curiae briefs have been filed.

iii. In June 2024, the US Supreme Court granted certiorari to decide whether states can outlaw gender-affirming care for minors. *United States v. Skrmetti,* (Case No. 23-477).

[1] 45 C.F.R. Sections 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301, 92.303, and 92.304.

3. Mifepristone Litigation and EMTALA Case

a. *Food and Drug Administration v. Alliance for Hippocratic Medicine*, No. 23-235, (U.S. June 13, 2024), consolidated with *Danco Laboratories v. Alliance for Hippocratic Medicine*, No. 23-236, 143 S. Ct. 1075 (2023)

i. The Alliance for Hippocratic Medicine contended that the FDA had insufficiently evaluated the risks linked to mifepristone, especially during the later stages of pregnancy. In response, the FDA asserted that the drug was both safe and effective when used as prescribed. The Supreme Court, in a unanimous decision, held that plaintiffs did not have standing.

b. *Idaho v. United States*, No. 23-727, 2024 WL 3569010 (U.S. June 27, 2024)

i. Idaho enacted a near-total abortion ban with limited exceptions, including to preserve the life of a pregnant individual. The US government sued Idaho, arguing that the ban conflicts with Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to provide emergency care to patients with stabilizing medical conditions. The district court granted a preliminary injunction blocking enforcement of the ban to the extent it conflicts with EMTALA. Idaho appealed to the Supreme Court, which granted certiorari to review the case. The Supreme Court dismissed the case without ruling on the merits, leaving in place the district court order temporarily blocking the state from enforcing its abortion ban.

4. ERISA Preemption of Pharmacy Benefit Manager State Laws

a. *Mulready v. Pharm. Care Mgmt. Ass'n*, 78 Fed. Fourth 1183 (10th Cir. 2023), petition for certiorari filed U.S., No. 23-1213, (2024)

i. The Supreme Court previously upheld an Arkansas law in *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020), which held that the Employee Retirement Income Security Act did not preempt the statute that regulated payments to pharmacies from PBMs.

ii. Oklahoma enacted the Patient's Right to Pharmacy Choice Act to regulate pharmacy benefit managers (PBMs). The Pharmaceutical Care Management Association (PCMA), representing PBMs, challenged the law arguing preemption by ERISA and Medicare Part D. The challenged provisions of the Act (1) require all pharmacy networks to meet certain brick and mortar geographic restrictions; (2) require inclusion of any willing pharmacy ("AWP") into a plan's preferred network; (3) prohibit use of cost-sharing discounts to incentivize use of particular pharmacies; and (4) forbid terminating a pharmacy's contract based on whether one of its pharmacists is on probation with the State Board of Pharmacy.

iii. The district court found ERISA did not preempt the Act but Medicare Part D preempted six provisions. PCMA appealed, and the Tenth Circuit

affirmed, finding the remaining provisions were also preempted by Medicare Part D.

iv. Oklahoma petitioned for certiorari to the Supreme Court, arguing the decision conflicts with the Supreme Court's Rutledge v. PCMA decision and creates a circuit split.

5. ERISA Fiduciary Litigation

a. *Lewandowski v. Johnson & Johnson*, D.N.J., No. 1:24-cv-00671 (2024), response filed 7/22/24.

i. Plaintiff alleges that Johnson and Johnson breached its fiduciary duties under ERISA by mismanaging the company's prescription drug benefit plan. The plaintiff contends that J&J paid exorbitant prices for prescription drugs (generics) through its PBM, failed to provide adequate information regarding the cost and factors associated with pricing decisions, and breached their fiduciary duties under ERISA by not ensuring employees received reasonable drug coverage. Defendants have challenged standing.

b. *Navarro v. Wells Fargo & Co.*, D. Minn., No. 0:24-cv-03043 (July 30, 2024).

i. Plaintiffs allege that defendant violated its fiduciary duty under ERISA by overpaying for drugs through its contract with Express Scripts, a pharmacy benefit manager. The plaintiffs allege that the plan administrative fees are not reasonable because they are higher than that paid by other employers, and that drug prices are higher than those for drugs bought outside the plan. Case is a proposed class action.

c. Segal publication: *How to be Sure Your PBM's Actions Align with Your Objectives* (August 26, 2024).

d. The FTC published a report in July 2024 on *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies.* On September 17, 2024, Express Scripts filed a lawsuit demanding that the FTC retract its report.

e. On September 20, 2024, the FTC filed a complaint in its administrative court alleging that CVS's Caremark, Cigna's Express Scripts and UnitedHealth's Optum Rx accepted money from drugmakers in exchange for keeping lower-cost insulin off their lists of approved drugs. The administrative court complaint has not yet been released.

6. Preventive Benefits Under the ACA

a. *Braidwood Mgmt., Inc. v. Becerra* , 5th Cir., No. 23-10326, (2024)

i. 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, On June 13, 2023, the 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 and the agencies agreed not to seek penalties or enforcement for periods before the case was resolved.

ii. On June 21, 2024, the Fifth Circuit affirmed the district court decision that members of the USPSTF were not properly appointed and that their coverage recommendations were invalid. In addition, they lifted a nationwide remedy and stated that the decision would apply only to the plaintiffs. The case was remanded for further consideration.

7. Copay Accumulator Program Litigation

a. *HIV & Hepatitis Policy Inst. v. U.S. Dep't of Health and Human Servs.*, Civ. A. No. 22-2604 (JDB), 2023 WL 6388932 (D.D.C. Sept 29, 2023)

i. The case challenged a 2021 HHS rule allowing health insurers to use "copay accumulators." These programs track patient out-of-pocket costs, but exclude manufacturer assistance, delaying the point at which insurers cover the full cost of medications. Plaintiffs argues this increased patient costs and hindered access to essential treatments. The court found the rule arbitrary and capricious, violating the Administrative Procedure Act. The decision struck down the rule, and instructed HHS to issue regulations definition cost sharing in this context.

ii. The parties moved to clarify the ruling. The court issued a ruling December 22, 2023, leaving in effect a 2020 Notice of Benefit and Payment Parameters rule that requires HHS governed health plans to count manufacturer copay assistance toward the annual limit on cost-sharing for drugs that do not have a medically appropriate generic equivalent.

iii. In January 2024, the government dropped its appeal of the lawsuit and stated that it intends to address through rulemaking whether financial assistance provided to patients by drug manufacturers qualifies as cost sharing under the ACA.

8. ACA Transitional Reinsurance Fee Settlement and Ongoing Litigation

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.

9. **Fertility Benefits Litigation**

   a. *Briskin v. City of New York*, S.D.N.Y., No. 1:24-cv-03557 (IVF for Same Sex Couples)

      i. This class-action lawsuit challenges the City's denial of In Vitro Fertilization (IVF) benefits to gay male employees and their partners. The plaintiffs argue that this policy discriminates against them based on their sexual orientation and violates the Equal Protection Clause of the Fourteenth Amendment.

   b. *Goidel v. Aetna Life Ins. Co.*, S.D.N.Y., No. 21-cv-7619, settlement 5/3/24. (Definition of Fertility for LGBTQ+ couples)

      i. This case is centered on the definition of infertility under Aetna's health insurance policy. The policy defined infertility as the inability to conceive after a certain period of unprotected sexual intercourse. The definition was challenged as discriminatory against heterosexual individuals who cannot conceive through heterosexual intercourse. The plaintiffs argues that Aetna's definition was discriminatory because it required LGBTQ+ couples to pay out-of-pocket for a year of treatment before qualifying for coverage, while heterosexual couples did not. Aetna countered that its policy was gender-neutral and did not discriminate based on sexual orientation. Ultimately, the parties reached a settlement in which Aetna agreed to revise its policy to provide equal coverage for fertility treatments to all eligible policyholders, regardless of sexual orientation or gender identity.

10. **Insulin Class Actions**

   a. *People of the State of California v. CaremarkPCS Health LLC*, 9th Cir., No. 23-55597, 8/13/24.

      i. This is a class-action lawsuit alleging that the defendant, a pharmacy benefit manager (PBM), engaged in unfair and deceptive business practices that contributed to the exorbitant cost of insulin. Specifically, the lawsuit claims that CaremarkPCS Health leveraged its market power to negotiate unfavorable contracts with insulin manufacturers, resulting in artificially inflated prices passed on to consumers. The state argues that these practices violate California's Unfair Competition Law and seek restitution for consumers who were overcharged.

11. ***Loper-Bright* Litigation**

   a. *Cogdell v. Reliance Standard Life Ins. Co.* , 2024 BL 321535, E.D. Va., No. 1:23-cv-01343, order docketed 9/12/24

      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 Enterprises v. Raimondo.* Reliance argued that the regulation's rule that a claim has been administratively exhausted if no appeal decision has been rendered within 45 days exceeded the Secretary's grant of statutory authority to promulgate regulations that ensure a full and fair review process.

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. Instead, the courts have determined whether the procedural violation means a plan administrator's decision is reviewed *de novo*, rather than for abuse of discretion. Therefore, *Loper-Bright* did not support an attack on the claims regulation.

12. **HIPAA Reproductive PHI Rule**

a. Texas v. U.S. Dep't of Health & Human Servs. , N.D. Tex., No. 24-cv-204, complaint filed 9/4/24. .

In April 2024, HHS published final rules under HIPAA that would protect reproductive health information from disclosure to law enforcement unless specific processes were met. The State of Texas filed a complaint on September 4, 2024, 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. Texas further alleges that HHS has not reasonable explained its reproductive PHI rule, and it is therefore arbitrary and capricious.