2023 NCCMP Interim Annual Conference

Healthcare Legal & Regulatory Update

September 13, 2023 / Meghan Horn, Vice President & Senior Consultant

Segal

Agenda

Inflation Reduction Act of 2022

No Surprises Act/Transparency in Coverage Rule

ACA Preventive Services

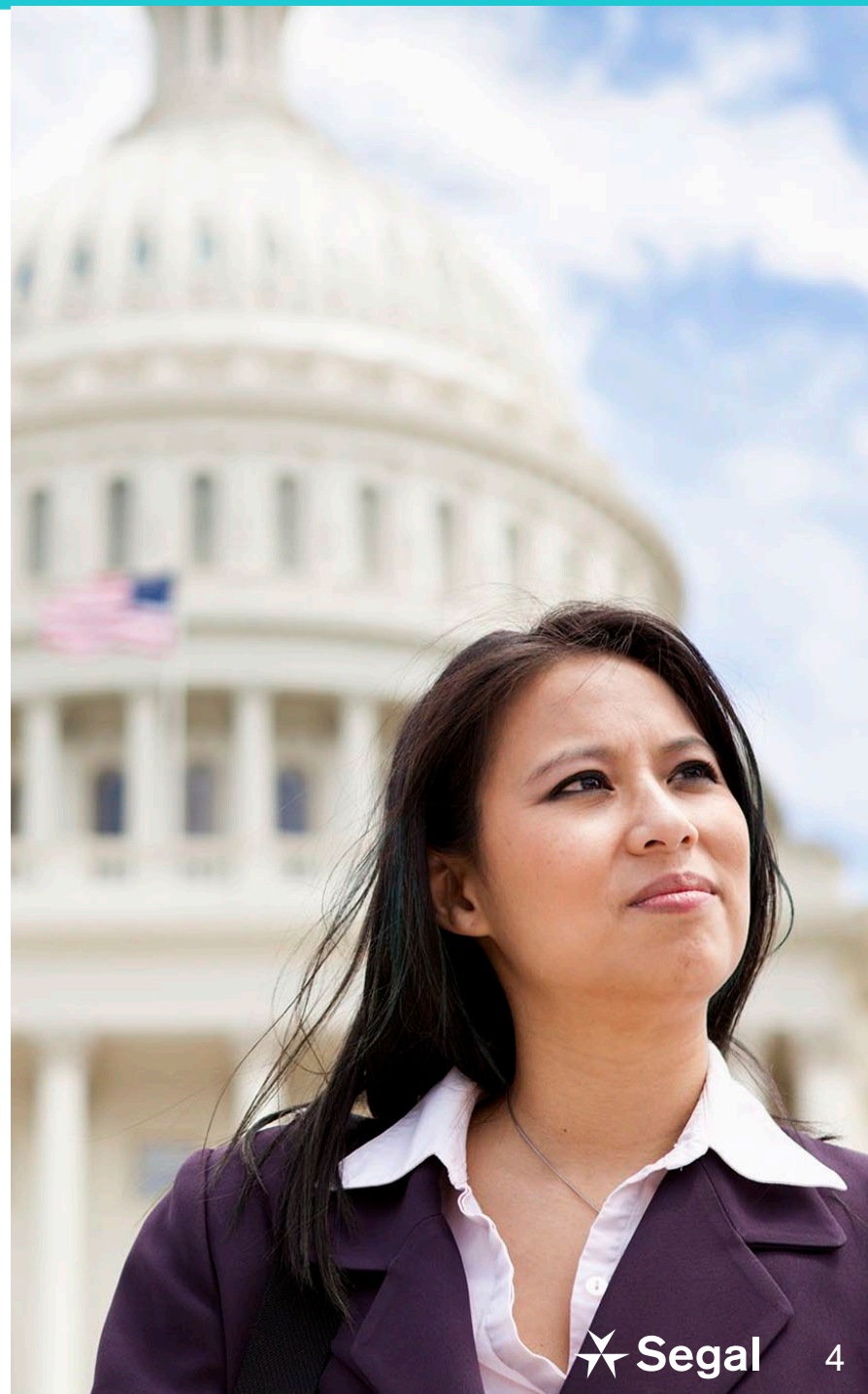
Post-Dobbs

1557 Regulation

Inflation Reduction Act of 2022

Inflation Reduction Act

- Enacted August 16, 2022, the Act significantly changes Medicare coverage
  - Medicare will negotiate prices for certain prescription drugs
  - Medicare will receive inflation rebates from manufacturers
  - Part D coverage changes significantly
  - Additional Medicare coverage for vaccines and insulin
- Passed using the “budget reconciliation process”



What Wasn't Included

- No expansion of Medicare to cover vision, dental or hearing
- Medicare eligibility age not lowered
- No federal paid leave program

The Build Back Better Act would have made substantial changes to Medicare and other programs but was not enacted. Its provisions were scaled back into the Inflation Reduction Act

Insulin Coverage

Medicare changes

- During plan years 2023, 2024, and 2025: Medicare beneficiaries cannot be required to pay more than $35 for a 30-day supply of insulin
- During plan year 2026 and subsequent years: changed to the lesser of
  - $35,
  - 25% of the maximum fair price established for the insulin, or
  - 25% of the negotiated price under the plan

Insulin Coverage

HSA/HDHP changes

- In 2023 and thereafter, HSA-qualified HDHPs may cover insulin before the deductible is met

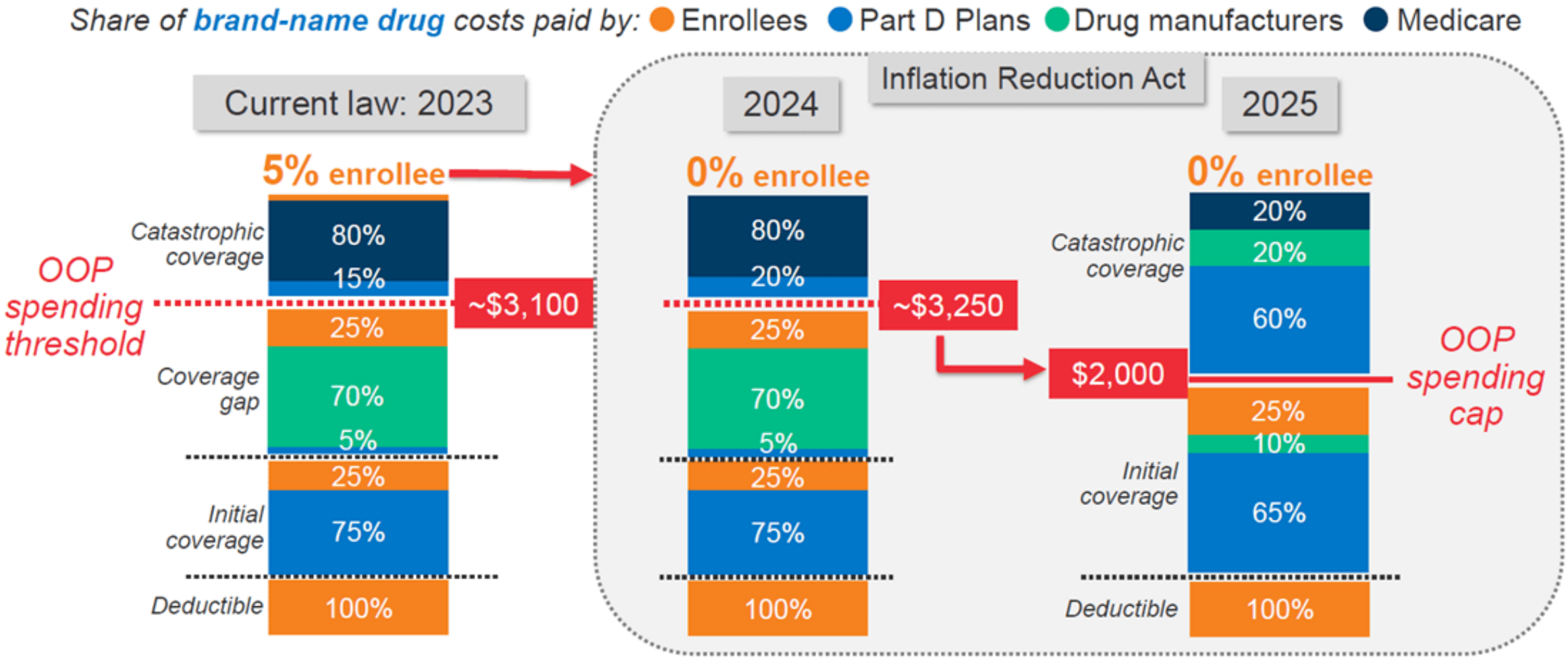
Group health plan changes

- NOTE: The cap on insulin copayments does not apply to group health plans or employer-sponsored plans
- The cap also does not apply to a retiree plan that gets the Retiree Drug Subsidy

Part D Benefit Changes

- Medicare Part D coverage significantly modified to eliminate participant coinsurance during the catastrophic payment period, and change who pays during that period
- By 2025, annual out-of-pocket maximum of $2,000 (smoothing permitted to allow beneficiaries to pay monthly)
- Part D premiums: increases limited to six percent per year from 2024–2029
- Manufacturer discount program changed
- Expanded income eligibility for Low Income Subsidy

Changes to Medicare Part D for Brand-Name Drug Costs



NOTE: OOP is out-of-pocket. The out-of-pocket spending threshold will be $7,400 in 2023 and is projected to be $7,750 in 2024 and $8,100 in 2025, including what beneficiaries pay directly out of pocket and the value of the manufacturer discount on brand-name drugs in the coverage gap phase. These amounts translate to out-of-pocket spending of approximately $3,100, $3,250, and $3,400 (based on brand-name drug use only).

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Medicare Negotiations

- On August 29, 2023, CMS announced the first 10 drugs covered by Medicare Part D selected for negotiation
  - Chosen from list of 50 highest-spending, brand-name drugs covered by Medicare Part D
  - Negotiated prices will be available starting in 2026
- Medicare will choose and negotiate 15 more Part D drugs for 2027, 15 more Part B or Part D drugs for 2028, and 20 more Part B or Part D drugs for each year after that

No Surprises Act Transparency in Coverage

No Surprises Act & Transparency Rule

- Effective for plan years beginning on or after January 1, 2022
- Multiple regulatory initiatives
  - Gag clause attestation
  - Independent Dispute Resolution

Gag Clause Prohibition under the NSA

Effective December 27, 2020, health plans and insurance issuers 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/data with a business associate

Attestation FAQ

- Departments published FAQ 57 on gag clause attestation requirement
- 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

Independent Dispute Resolution Process

1

The Qualifying Payment Amount (QPA) must be used to calculate **participant cost-sharing** for Emergency Services at an Out-of-Network provider or facility, Non-Emergency Services at certain In-Network Facilities, and Non-Network Air Ambulance Services

If the plan sends the provider/facility an **initial payment or notice of denial**, it must tell them what the QPA is for that service

2

3

IDR **MUST** consider: QPA; quality and outcomes measurements of the provider/facility; market share; complexity of case; teaching status, case mix, and scope of services of facility; good faith efforts to enter into network agreements; additional credible information
MAY NOT consider: UCR, billed amount, public payer rates

Litigation Over IDR Process

- On August 24, 2023, in Texas Medical Association, et al. v. United States Department of Health and Human Services (TMA III), 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 and related guidance
- IDR is paused pending further guidance from HHS

Federal IDR Process Status Update

- Between April 15, 2022, and March 31, 2023:
  - 334,828 disputes initiated through the IDR Portal
    - 14x more than expected
  - 42,158 disputes resulted in payment determinations
    - Party initiating IDR prevailed in 71% of disputes
    - Providers generally initiate IDR
  - 39,890 disputes found to be ineligible for IDR

IDR Process Backlogged

How Much Will IDR Cost?

- Effective January 1, 2023, IDR Administrative Fee increasing from $50 to $350
  - This increase was vacated by an August 3, 2023 opinion by the District Court for the Eastern District of Texas in Texas Medical Association, et al., v. Department of Health and Human Services (TMA IV)
- IDR Entity fees will range from $200-$700 for single determinations and $268-$938 for batched determinations
- Fees increasing because of backlog and new pre-eligibility review process by government and its contractors

Awaiting Guidance…

- Air ambulance data reporting for 2022 and 2023 (proposed rule published September 16, 2021)
  - Reporting not expected to begin until 2024
- Advanced Explanation of Benefits (EOB) and Good Faith Estimate (Request for Information published September 16, 2022)

How do Legislative Transparency Proposals Differ from TiC Rule?

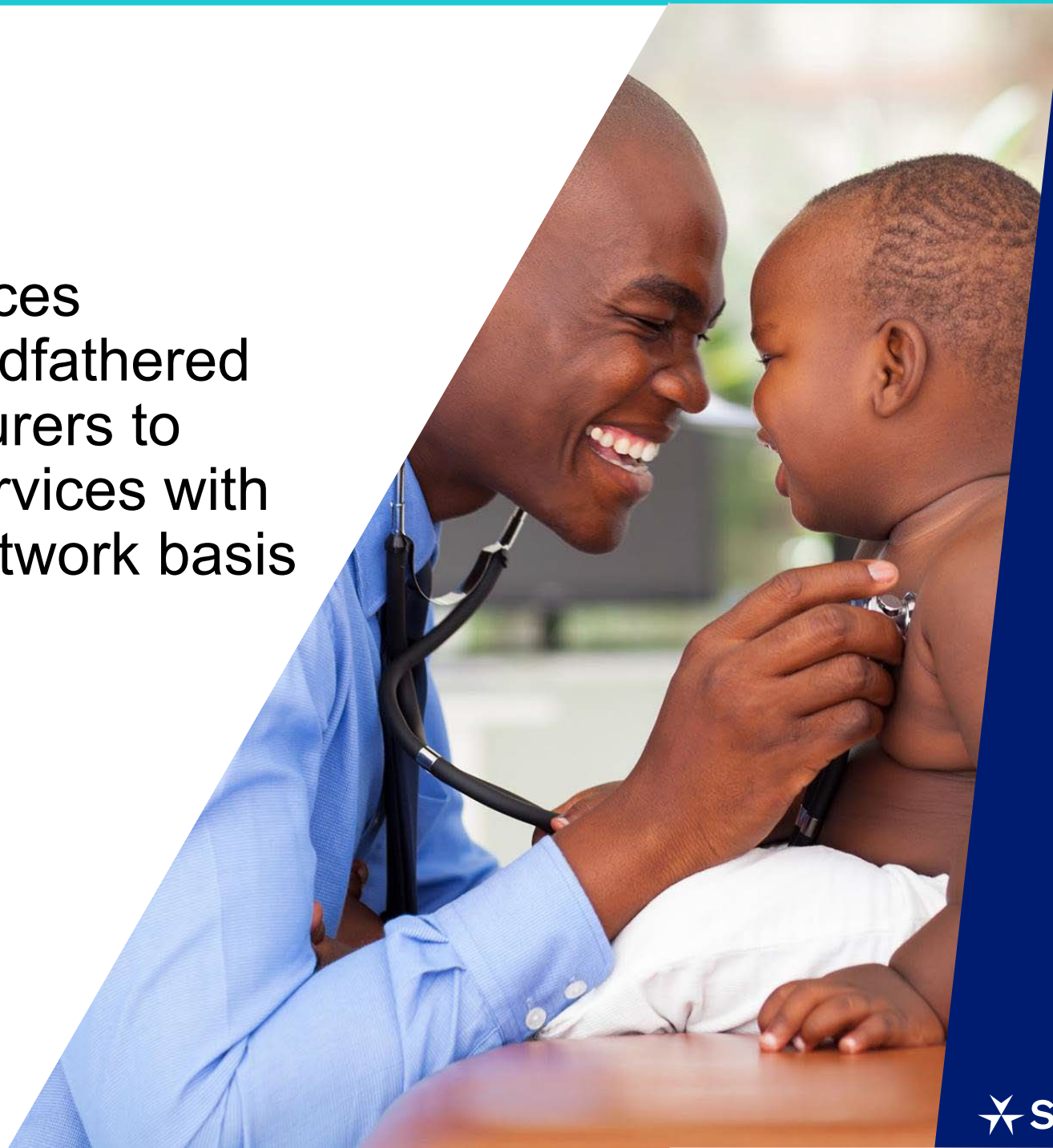
Bills include:

- PBMs would be required to report plan-specific data to plan sponsors, including information about rebates, wholesale prices, and claims filled by pharmacies owned by the PBM
- PBMs would be required to report to FTC on payments from plans and fees charged to pharmacies
- PBMs would be required to report detailed information about rebates and clawbacks to HHS
- PBMs would be required to publish negotiated prices for covered drugs in a member-friendly format
- New point-of-sale disclosures

ACA Preventive Services

Background

- 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



ACA Preventive Services Litigation

- 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 preventive care coverage requirements on or after March 23, 2010
- Plan sponsors do not need to take any action in response to this decision and may be best served by monitoring the response by the federal government and higher courts

The Decision

- The recent case, *Braidwood Management Inc. v. Becerra*, was brought by plaintiffs who challenged the legality of the ACA's preventive services mandate on several grounds, including that it violates the Constitution because members of the United States Preventive Services Task Force (USPSTF) have not been appointed in a manner consistent with Article II's Appointments Clause
- The court ordered that the preventive care requirements issued based on the USPSTF are vacated and the federal government is enjoined from implementing or enforcing them

The Decision

- The court's order is complex—in part because:
  - The USPSTF recommends "A" or "B" ratings for specific evidence-based items and services for all patient demographics
  - The Health Resources and Services Administration (HRSA) issues guidance regarding preventive care and screening for infants, children, adolescents and women
  - The Advisory Committee on Immunization Practices (ACIP) recommends certain immunizations
- Because both ACIP and HRSA are ultimately subject to the "supervision and direction" of the Secretary of Health and Human Services, the court's order does not appear to extend to ACA-mandated preventive care recommended by the ACIP or the HRSA, including contraceptive coverage and vaccines

> . . . the Departments strongly encourage plans and issuers to continue to cover such items and services without cost sharing. Preventive services help people avoid acute illness, identify and treat chronic conditions, reduce the risk of cancer or facilitate early detection, and improve health.

FAQ 59

The Case Continues…

- The Administration has appealed the decision
- On June 13, 2023, the Fifth Circuit Court of Appeals issued a stay. Consequently, the preventive services requirements remain in place until further action from the courts
  - Provider groups agreed not to oppose agencies' motion to stay lower court's decision
  - Agencies agreed not to seek penalties or enforcement for periods before case is resolved
- Dozens of patient advocacy groups have asked to file amicus briefs in support of the ACA requirement
  - Groups argue that the decision will lead to an uptick in preventable deaths, especially among people who otherwise could not afford health care

Post Dobbs

State of the States Following Dobbs

- Approximately 16 states have some type of protection for abortion in place
- Abortion is currently illegal or heavily restricted in 17 states
- Some states have ongoing lawsuits over the interpretation and application of state law - six states currently have abortion bans on hold that were blocked by courts
- More bans expected as lawmakers in other states have proposed new laws to restrict abortion access

ERISA Preemption

- Generally, ERISA preempts state laws that relate to an employee benefit plan
- Consequently, self-insured group health plans can continue to design benefits without complying with state insurance law
  - However, state insurance law would generally apply to fully-insured group health plans
- Criminal laws are not generally preempted by ERISA, but the issue will depend on how the law is written and applied
- ERISA preemption application in the state abortion law area has not yet been litigated

Medication Abortion

- Medication abortion is FDA-approved for use up to 10 weeks of pregnancy and in 2020 accounted for 54% of US abortions
- FDA-approved medication abortion regimen involves:
  - Mifepristone
  - Misoprostol (taken 24-48 hours after mifepristone)
- In December 2021, permanently lifted the “in-person” requirement, allowing mifepristone to be dispensed by pharmacies and mailed directly to patients
- Medication abortion versus emergency contraception
  - Different drugs

Medication Abortion Litigation

- April 7, 2023
  - *Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.*
    - Texas District Court stayed the FDA's 2000 approval of mifepristone
  - *State of Washington, et al. v. U.S. Food and Drug Administration, et al.*
    - Washington District Court ruled in favor of 17 states and Washington, D.C., requiring FDA to keep mifepristone available in those jurisdictions
- April 21, 2023
  - Supreme Court issued a stay of the April 7 order pending disposition of the appeal in the Fifth Circuit and the disposition of a writ of certiorari, if sought

Fifth Circuit Ruling on Mifepristone

- 5th Circuit Court of Appeals, August 16, 2023, holding in *Alliance for Hippocratic Medicine v FDA:*
  - Upheld FDA's 2000 approval of mifepristone
  - Held that FDA failed to take into account safety concerns when it loosened access to mifepristone in 2016 and 2021
    - 2016 and 2021 changes would be rolled back, such as the ability to take the drug 10 weeks into pregnancy (instead of 7 weeks) and the ability to receive the drug by mail
  - Upheld the FDA's 2019 approval of generic mifepristone
- Supreme Court appeal is expected
- Ruling does not affect current availability of mifepristone, pending Supreme Court's final ruling

Contraceptive Coverage

- Affordable Care Act requires non-grandfathered group health plans and issuers to cover, without cost sharing, at least one form of contraceptive in each method for women currently identified by the U.S. Food and Drug Administration (FAQ 54)
  - https://www.fda.gov/consumers/free-publications-women/birth-control-chart
  - Plans must have medical exceptions process stated clearly in SPD and available without having to make an appeal
  - Free coverage may be limited to in-network
  - Coverage includes Plan B (emergency contraceptives)
- Secretaries Walsh, Becerra, and Yellen have announced an enforcement initiative

Executive Order on Contraceptives and Family Planning

- Executive Order #14104, Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services, June 23, 2023
- Directs Treasury, Labor, and HHS to issue guidance to improve Americans' ability to access low- or no-cost contraception
- Secretaries are directed to:
  - Ensure coverage of all contraceptives approved, granted or cleared by the FDA, without cost sharing
  - Streamline the process for patients and healthcare providers to request coverage, without cost sharing, of medically necessary contraception.
  - Promote increased access to affordable over-the-counter contraception, including emergency contraception.

1557 Proposed Rule

Gender Affirming Care Coverage

- Gender-affirming care includes care for transgender individuals that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition
- Exclusions of services because of an individual's sex assigned at birth, gender identity, or gender recorded could be challenged under:
  - Americans with Disabilities Act
  - ACA Section 1557
  - Title VII of the Civil Rights Act
    - The EEOC cites the Bostock decision as it continues to take the position that employment discrimination based on sexual orientation or transgender status constitutes discrimination prohibited by Title VII

1557 Proposed Rule Considerations

- Rule proposed August 4, 2022, comments due October 3, 2022
- Would expand scope of covered entities
- Would reinstate notification obligations concerning language assistance
- Would require disability accommodation in benefits
- Plans could not deny or limit health coverage to individuals based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded
- Would require written policies and procedures

Questions?