Employee Benefits Compliance: Mid-Year Legislative Update June 12, 2025

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Today's Speaker

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Agenda

- Federal Compliance Update
- Potential Federal Changes
- State Compliance Update
- Federal Compliance Calendar for Q3-Q4

Federal Compliance Update

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Mental Health Parity

- May 15, 2025, tri-agencies released a statement that they would not enforce the 2024 Final Rule on MHPAEA
  - Reaction to ERISA Industry Committee (ERIC) suit filed in January that challenged the meaningful benefits requirement, outcomes data evaluations and fiduciary certifications
- STILL IN EFFECT:
  - MHPAEA, for financial limits, QTLs and NQTLs and 2013 Final Rule
  - CAA 2021 requirement that plans perform or obtain a written comparative analysis of NQTLs
  - April 2021 FAQs on NQTLs
    - https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/faqs-about-mental-health-parity-implementation-and-consolidated-appropriations-act-2021-part-45.pdf

Medicare Part D Creditable Coverage

- All Employer-sponsored plans are required to disclose to Medicare-eligible individuals whether the Rx coverage provides creditable or non-creditable coverage (must also report to CMS in first 60 days of plan year)
  - Rx coverage is creditable when the actuarial value of the coverage is at least equal to the actuarial value of Medicare Part D
- Plans use either Simplified Determination or actuarial determination
- CMS has revised the Simplified Determination
  - Old Simplified Determination can be used for plan years beginning in 2025 and 2026
  - Revised Simplified Determination must be used for plan years beginning after 2026

Medicare Part D Creditable Coverage

- Old Simplified Determination
  - The plan provides coverage for brand and generic prescriptions;
  - The plan provides reasonable access to retail providers;
  - The plan is designed to pay on average at least 60% of participants' prescription drug expenses; and
  - The plan satisfies at least one of the following:
    - The coverage has no annual benefit maximum or maximum annual benefit payable by the plan of at least $25,000;
    - The coverage has an actuarial expectation that the amount payable by the plan will be at least $2,000 annually per Medicare-eligible individual; or
    - For employer plan sponsors that have integrated prescription drug and health coverage, the integrated plan has no more than a $250 deductible per year, has no annual benefit maximum or a maximum annual benefit of at least $25,000, and has no less than a $1,000,000 lifetime combined benefit maximum.

Medicare Part D Creditable Coverage

- Revised Simplified Determination
  - Plan must meet all of the following standards:
    - Provides reasonable coverage for brand name and generic Rx and biological products
    - Provides reasonable access to retail pharmacies
    - Is designed to pay on average at least 72% of participants' Rx expenses.
- Actuarial Determination
  - Compares the actuarial value Part D to the actuarial value of the plan you are testing

Many employers that were "creditable" under the old Simplified Determination will be "non-creditable" under the Revised Simplified Determination.

Medicare Part D Creditable Coverage

Action Plan:

1. Consult with your carrier, TPA or PBM to see how they will assist with determining creditable status of Rx coverage.
2. Determine if status will change for next coverage year.
3. Determine if you will change Rx coverage to ensure status stays creditable.
4. Take extra care to communicate the change.
   - Make sure you notify Medicare-eligible individuals that their prescription drug plans no longer meet the standards for creditable coverage due to these new final instructions by delivering the non-creditable coverage notice to Medicare-eligible individuals.

PCORI Fee Due 7/31/2025

- Employers with self-insured group health plans (including level-funded plans and HRAs) must file Form 720 and pay before July 31, 2025
- Rate for plan years ending on or after October 1, 2024, and before October 1, 2025, is $3.47 per covered life (prior reference year is $3.22 per covered life)
- Three ways to determine # of covered lives: actual count, snapshot, or Form 5500 method
  - Use all three and ensure you are paying lowest amount
- Form 720 was revised at the end of May– https://www.irs.gov/pub/irs-pdf/f720.pdf

ACA Section 1557 Uncertainty

- “Covered entities” prohibited from denying or limiting or imposing additional cost-sharing for health coverage based on race, color, national origin, sex, age, or disability
- Bostock v. Clayton County (2020) U.S. Supreme Court interpreted Title VII protection against employment discrimination based on sex to extend to an individual’s sexual orientation or gender identity
  - In wake of Bostock, lower courts have found that benefit exclusions or limitations based on sex or transgender status violated the Equal Protection Clause, Title VII and §1557

ACA Section 1557 Uncertainty

- 2022 HHS Guidance stated that Section 1557 could be interpreted to prohibit "covered entities" from restricting access to gender-affirming care
- 2024 Final Rule on Section 1557 followed 2022 Guidance on gender-affirming care
  - Stayed nationwide
- Oral arguments in U.S. v. Skrmetti
- 2025 HHS rescinded 2022 guidance

Employers should proceed with caution!

- Considerations under state law, MHPAEA and ADA
- Litigation risk in limiting coverage based on gender identity

Potential Federal Changes

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House Budget Package Reconciliation Bill

- Passed House on May 22, 2025
- Only needs 51 votes in Senate – no filibuster
  - Only provisions that change spending or revenues can be included
  - Senate Parliamentarian role in enforcing the Byrd Rule
- Significant changes to Medicaid and changes to Medicare
- Also changes ACA and Health Savings Accounts (HSAs)
- Important EB priorities left out

House Reconciliation Bill: Proposed HSA Expansion

- If enacted, effective January 1, 2026
- Certain sport and fitness expenses treated as medical care– reimbursable
  - Capped at $500 for single filers/$1000 for joint filers
- Annual contributions double for 2026
  - From $4300/$8550 to $8600/$17,200
  - Phased out for individuals with AGI between $75,000 and $100,000 or joint filers with AGI between $150,000 and $200,000
- HSA contributions allowed even if spouse has an FSA
- 65 and older enrolled in Medicare Part A only can contribute to HSA
  - Individual may not use HSA distributions to pay for health insurance
  - Additional 20% tax on distributions not used for qualified medical expenses

House Reconciliation Bill: Proposed HSA Expansion

- Individual Market bronze and catastrophic plans treated as HSA-qualified HDHP that can be paired with an HSA
- Certain Direct Primary Care (DCP) arrangements will not be considered health plans
  - Allowing individuals covered by these arrangements to participate in HSAs
    - Only if fixed periodic fee for DCP is $150/month or less/individual or $300/month or less for family
    - Allows fees to be paid from HSA
- Allows HSA contributions even if employer provides on-site clinic
- Allows married couples over 55 to make individual catch-up contributions to same HSA
- Allows rollover of some FSA and HRA funds to HSA
- Allows payment of some medical expenses incurred before HSA established

House Reconciliation Bill: Proposed Changes to ACA

- Individual Market Changes
  - More difficult to get coverage/ subsidized coverage
    - Shorter Open Enrollment period
    - Ends low-income Special Enrollment Period (SEP)
    - Limits ability of federal and state marketplaces to provide SEPs based on poverty
    - Requires additional proof of eligibility
    - Ends marketplace coverage for DACA recipients and limits it for lawfully present immigrants
  - Easier to lose subsidy and/or coverage
    - New triggers for income verification and information attestation
    - Discontinues automatic re-enrollment
- Potential Impact
  - Marketplace enrollment has increased 113% over the last 5 years to 24.3 million
  - Potential 1/3 cut in Marketplace enrollment

House Reconciliation Bill: Proposed Changes to ACA

- ICHRAs 2.0 “CHOICE” arrangements
  - Codifies much of the 2019 Trump Administration rule that created ICHRAs
  - Allows employees with an ICHRA to use pre-tax dollars through a cafeteria plan to pay for ACA individual marketplace premiums
  - Small employer tax credit
- Group Market Change
  - Changes methodology of factor used in indexing the maximum annual limitation on cost-sharing, employer mandate penalties, and income thresholds for affordability exemptions)
    - Impact will be to pass more cost-sharing to employees over time, slow the growth of penalties
- Culture War Issues
  - no cost subsidy reduction for individual market plans that cover most abortion services
  - prohibits coverage of gender-affirming care as Essential Health Benefit
    - Potential impact for small group plans
    - Conflict with some state laws

House Reconciliation Bill Provisions Omitted

- NO telehealth fix for HDHPs
  - Does not appear to be a priority for Congress
- No PBM provisions that significantly impact employer-sponsored plans
- What PBM provisions are in the bill?
  - Prohibition on spread pricing in Medicaid (already prohibited in many states)
  - Medicare D transparency provisions
  - Prohibition on PBMs for Medicare D prescription drug plans from receiving income for services in any form other than a bona fide service fee

Trump Executive Order: Rx Pricing

- May 12, 2025, EO announcing price control policy on US and foreign drug manufacturers
- Directions to:
  - Secretary of Commerce and U.S. Trade Representative to take action re: foreign manufacturers
  - Secretary of HHS to facilitate “direct to consumer” purchasing programs that sell Rx at “most favored nation” pricing
  - Commissioner of FDA to review and modify or revoke approvals for drugs that may be unsafe, ineffective, or improperly marked

Trump Executive Order: Rx Pricing

- President alone has no power to dictate peacetime pricing to manufacturers
  - Likely swift litigation response if action taken
- Most likely to see action with regard to pricing in Medicare, Medicaid
- Signals potential shift in philosophy toward drug reimportation, biosimilars, 340(b), and government program negotiation has potential to impact pricing

Vaccine Coverage

- May 27, 2025, HHS Secretary Robert F. Kennedy, Jr. announced that “as of today” the COVID-19 vaccine has been removed from the CDC recommended immunization schedule for healthy children and healthy pregnant women
  - Directed the CDC to remove COVID-19 vaccines from its recommendations for these group
  - Usually, CDC develops recommended immunization schedule in consultation with the Advisory Committee on Immunization Practices (ACIP)
- June 9, 2025, Kennedy fired all 15 members of ACIP
- ACIP's next meeting is June 25-27, 2025
  - Meeting will proceed as planned, according to HHS; unknown if panel members will be replaced in interim

Vaccine Coverage

- Under the ACA, certain preventive services are required to be covered without cost-sharing under non-grandfathered health plans
  - Plans must provide coverage without cost-sharing for ACIP-recommended vaccines
    - When a new vaccine is added to ACIP's recommendations, plans must update their coverage once a new plan year starts following one year after the date when the CDC adopts that recommendation.
- Uncertainty as to what vaccines carriers will be required to cover

State Compliance Updates

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California– Changes Effective July 1, 2025?

SB 729– Infertility Coverage

- Requires fully insured plans for CA residents to provide coverage for infertility diagnosis and fertility treatment
- Effective July 1, 2025, BUT Governor Newsom's budget proposal includes 6-month delay of effective date
- Budget must be passed by June 15, 2025
- Update when bill signed

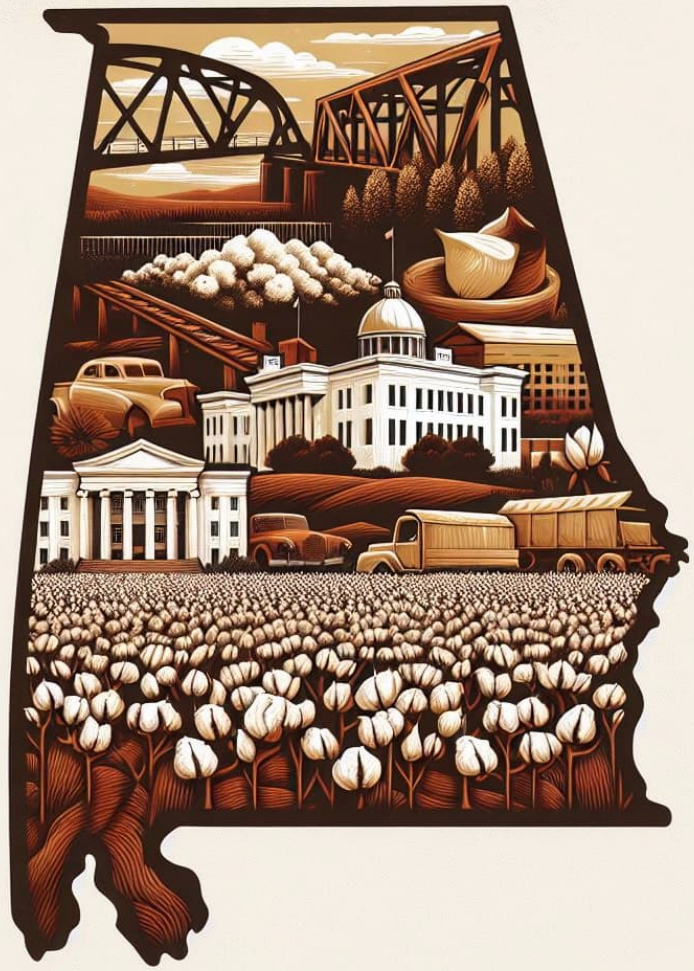
AB 2843– Coverage for Sexual Assault Victims

- Requires fully insured plans to provide coverage without cost-sharing for ER medical care and follow-up treatment for 9 months following rape or sexual assault
  - Does not require a police report
  - Does not require charges to be brought against assailant

FOR PLAN YEARS BEGINNING ON OR AFTER...

ENACTED PBM LEGISLATION

Alabama



- SB 252 effective October 1, 2025
- Broadly defines prohibited affiliate “steering”
- Prohibits spread pricing; requires 100% rebate pass-through unless health plan directs PBM to retain a portion of rebate as an administrative fee
- Establishes mandatory minimum reimbursement for “community pharmacies”
- Prohibits retroactive pharmacy reimbursement adjustments
- Applies to self-funded as well as fully insured

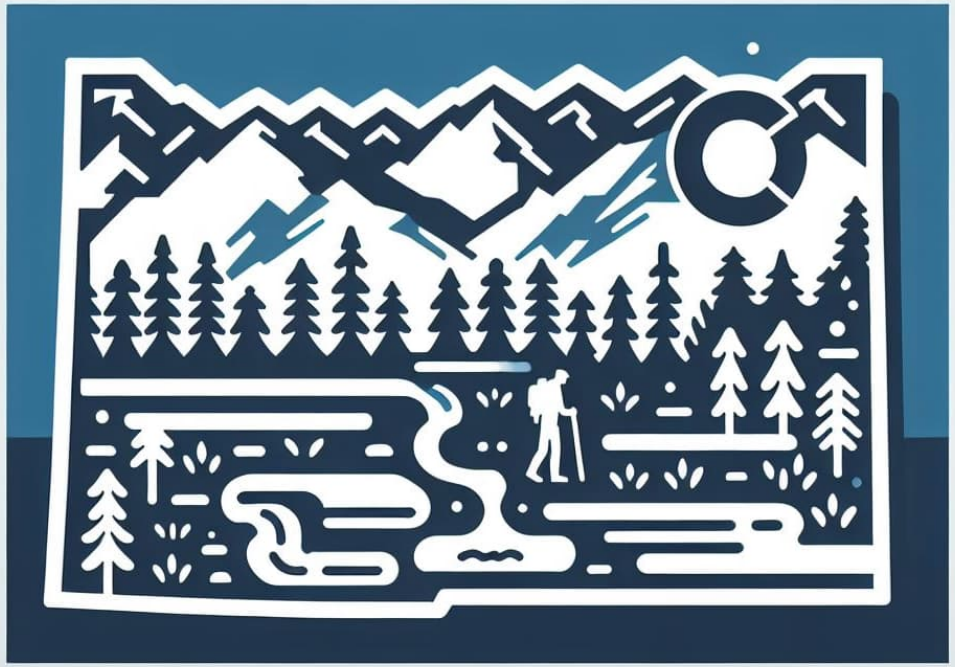
ENACTED PBM LEGISLATION

Arkansas

- HB 1150 effective January 1, 2026
- Prohibits PBMs from having a direct or indirect interest in a retail pharmacy licensed by State
- Prohibits spread pricing; requires 100% rebate pass-through unless health plan directs PBM to retain a portion of rebate as an administrative fee
- Applies to self-funded as well as fully insured

ENACTED PBM LEGISLATION

Colorado



- HB 1094 effective January 1, 2026
- Limits PBM compensation to “single, flat dollar service fee”
- Prohibits PBMs from favoring brand or biologic drugs over therapeutically equivalent generics or biosimilars
- Mandates pharmacy reimbursement at NADAC plus reasonable and adequate dispensing fee
- Impacts fully-insured plans

ENACTED PBM LEGISLATION

Indiana

- SB 3 effective July 1, 2025
  - Imposes fiduciary duty on PMBs and TPAs
  - Applies to self-funded as well as fully insured
- SB140 effective January 1, 2026
  - Establishes minimum pharmacy dispensing fees
  - Prohibits affiliate steering
  - Applies to self-funded as well as fully insured

ENACTED PBM LEGISLATION

Montana

- HB 740 effective October 1, 2025
- Establishes minimum pharmacy reimbursement mandate plus dispensing fee
- Prohibits affiliate steering
- Limitations on mandatory mail order
- Applies to self-funded as well as fully insured

ENACTED PBM LEGISLATION

North Dakota

- HB 1584 effective January 1, 2026
- Extends existing PBM legislation to self-funded ERISA plans

ENACTED PBM LEGISLATION

Oklahoma

- SB 789 effective January 1, 2026
- Modifies pharmacy audit law
- Prohibits effective rate pharmacy reimbursement contracts
- Applies to self-funded as well as fully insured

PBM Legislation– Pending

- California SB 41– Passed by Senate, sent to Assembly
  - Would ban spread pricing and require 100% rebate pass-through
  - Limits ability of PBM to negotiate exclusivity with manufacturers
  - Limits PBM compensation to fee for service and requires fee disclosure to health plans
  - Only exemption is for Taft-Hartley plans, so potential impact on self-funded plans
  - Similar to SB 966, vetoed by Governor Newsom (D) last year
- California budget trailer draft
  - Would establish PBM licensure under the state Department of Managed Health Care
  - Would require certain transparency reporting to DMHC

PBM Legislation– Pending

- Illinois– HB 1697 Sent to Governor Pritzker (D) on May 31, 2025
  - Would ban spread pricing and require 100% rebate pass-through
  - Prohibits steering
  - Transparency reporting
  - Limits classification of drugs as “specialty”
  - Exemption for self-funded plans
  - If signed, effective January 1, 2026
- Iowa SF 383 Sent to Governor Reynolds (R) on May 14, 2025
  - Prohibits spread pricing, affiliate steering, mandatory mail order and preferred networks
  - Requires 100% rebate pass-through
  - Limits classification of drugs as “specialty”
  - Prohibits copay accumulator programs
  - Sets mandatory minimum dispensing fees
  - Transparency reporting
  - Applies to self-funded as well as fully insured

Federal Compliance Calendar Q3-Q4

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Federal Compliance Calendar

Date	Requirement	Notes
June 1, 2025	RxDC	Due date for reporting data for the 2024 calendar year.
July 29, 2025	Last day to report a Summary of Material Modification (SMM) for the prior plan year for calendar year plans.	ERISA requires that a Summary of Material Modification (SMM) be issued any time there is a change in a plan provision that is "material" (but not a reduction) or any time there is a change in a plan provision that is required to be in the Summary Plan Description (SPD). The due date is 210 days after the end of the plan year to which the change applies. *NOTE: For a material reduction, an SMM is required within 60 days of the adoption of the change.*

Federal Compliance Calendar

Date	Requirement	Notes
July 31, 2025	PCORI fee	Patient-Centered Outcomes Research Institute (PCORI) fee is due for policy or plan years that ended in 2024. Fee is paid by carrier for fully insured plans. Self-funded plans, including HRAs, must calculate the fee and pay using IRS Form 720.
July 31, 2025	Form 5500 Filing for calendar year plans	Employers must file Form 5500s for plans with at least 100 participants (i.e., employees) at the start of the plan year. In addition, employers with plans that have fewer than 100 participants must file a 5500 if the plan is “funded” (i.e., the assets of the plan are segregated from the general assets of the plan sponsor through a trust).

Federal Compliance Calendar

Date	Requirement	Notes
September 30, 2025	Summary Annual Report (SAR) for calendar year plans	A summary annual report (SAR) is a summary of the Form 5500. A SAR is required to be distributed to participants in the plan for any plan subject to Form 5500 filing. It is due within 9 months of the close of the plan year.
September 30, 2025	Medical Loss Ratio (MLR) Rebates	Group health carriers are required to report prior year MLR data to HHS by July 31. If required MLRs were not met by the carrier, premium rebates must be provided to employers by the end of September.
October 14, 2025	Deadline for Medicare Part D Creditable Coverage Notices to Individuals	Employers offering prescription drug coverage must issue the Notice of Creditable/Non-creditable Coverage to individuals by October 14 (employers may provide the notice at any time during the 12 months preceding October 15 – e.g., during the previous open enrollment).

Federal Compliance Calendar

Date	Requirement	Notes
September 30, 2025	Summary Annual Report (SAR) for calendar year plans	A summary annual report (SAR) is a summary of the Form 5500. A SAR is required to be distributed to participants in the plan for any plan subject to Form 5500 filing. It is due within 9 months of the close of the plan year.
September 30, 2025	Medical Loss Ratio (MLR) Rebates	Group health carriers are required to report prior year MLR data to HHS by July 31. If required MLRs were not met by the carrier, premium rebates must be provided to employers by the end of September.

Federal Compliance Calendar

Date	Requirement	Notes
October 14, 2025	Deadline for Medicare Part D Creditable Coverage Notices to Individuals	Employers offering prescription drug coverage must issue the Notice of Creditable/Non-creditable Coverage to individuals by October 14 (employers may provide the notice at any time during the 12 months preceding October 15 – e.g., during the previous open enrollment).
October 15, 2025	5500 Filing Due Date with Extension (for calendar year plans)	Employers must file Form 5500s for plans with at least 100 participants (i.e., employees) at the start of the plan year. In addition, employers with plans that have fewer than 100 participants must file a 5500 if the plan is "funded" (i.e., the assets of the plan are segregated from the general assets of the plan sponsor through a trust).

Federal Compliance Calendar

Date	Requirement	Notes
December 29, 2025	Last day for employer to distribute portion of MLR rebate considered “plan assets”	Employers sponsoring fully-insured group health plans must distribute the portion of an MLR Rebate that is considered plan assets within 90 days of receipt (i.e., for rebates received September 30, by December 29). Otherwise, the employer may be subject to ERISA trust requirements.
December 31, 2025	Gag Clause Attestations	Employers and carriers must submit an attestation of compliance with the gag clause prohibition contained in the Consolidated Appropriations Act of 2021(CAA 2021).

Thank you!

Questions?

Thank you!