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HEALTH & WELFARE PLAN LUNCH GROUP

November 6, 2025

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1. Health & Welfare Benefits Monthly Update Presentation

















November 2025 Agenda

- Compliance Corner: Litigation Mitigation
- PBM Update
- Fertility/Preventive Services Updates
- Litigation Update
- Compliance Grab Bag

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Compliance
Corner: Litigation
Mitigation



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Anti-Assignment Clause

- Provision: The Plan does not recognize and does not allow assignments of rights to third parties
- O.k. to direct payment to provider
- Prevents transfer of all other rights that participant may have

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Authorized Representatives

- Provision: Require use of plan/claims administrator to authorize a third party to file claims and appeals
- ERISA grants covered individuals the right to authorize a third party to file claims/appeals
- You can establish a process for authorizing third parties, including use of a form.

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Exhaustion of Remedies

- Provision: Require participants to exhaust internal claims and appeals.
- Courts routinely dismiss suits for failure to exhaust.
- Must be clearly stated in both the plan and SPD.

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Venue Selection Clause

- Provision: Designate a specific federal court for disputes.
- Courts uphold venue clauses if clearly stated.
- Helps avoid forum shopping and inconsistent rulings.

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Statute of Limitations Clause

- Provision: Set a contractual time limit for filing lawsuits.
- Courts enforce reasonable limitations periods (e.g., 1–3 years).
- Must be unambiguous and disclosed in the SPD.

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Subrogation and Reimbursement Rights

- Provision: Preserve the plan's right to recover from third-party recoveries.
- ERISA plans can assert equitable liens on third-party settlements.
- Language must be specific and consistent across documents.

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Employer Contribution Provisions

- Provision: Clarify employer discretion over contributions.
- Prevents implied promises of continued funding.
- Supports plan flexibility and termination rights.

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Right to Amend or Terminate

- Provision: Reserve broad rights to amend or terminate the plan.
- Courts uphold clear reservation of rights.
- Protects against claims of vested benefits.

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"Microsoft Clause" and "no employment rights"

Provision:

- Microsoft language -- Clarify that plan determines eligibility based on assigned employment classification (even if court later reclassifies employment status);
- Additional language specifies that participation does not create employment rights.
- Prevents claims of implied employment or benefit guarantees.
- Named after litigation involving Microsoft's contingent workers.

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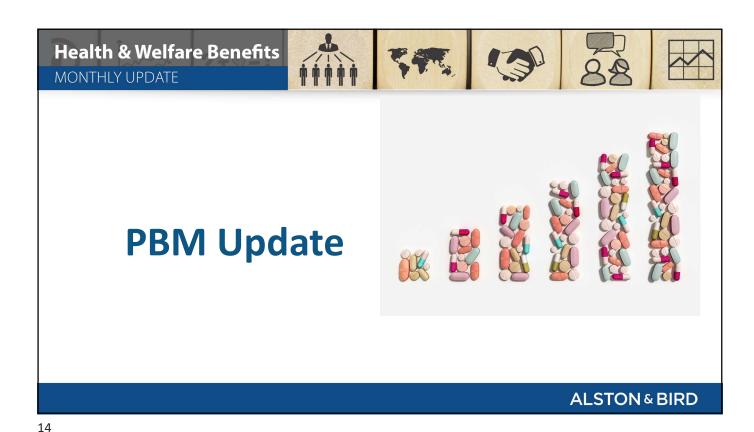




SPD Drafting Best Practices

- Use plain language and highlight limitations.
- Ensure consistency with plan documents.
- Include required disclosures (COBRA, HIPAA, subrogation).
- Review regularly for compliance and clarity.

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Arkansas

- PBM Ownership Law (2025 Act 624, HB 1150)
 - Bars PBMs from owning pharmacies in Arkansas (effective Jan. 1, 2026).
 - Preliminary injunction issued; challengers likely to succeed (Commerce Clause, Supremacy Clause).
- **PBM Pharmacy Compensation Data Reporting (Rule 128)**
 - Does it apply to self-funded ERISA plans?
 - Court dismissed plaintiffs' ERISA preemption challenge in Cent. States v. McClain (N.D. III., Sept.
 - Notice of appeal filed on September 30, 2025.
 - Next reporting deadline is due March 1, 2026.

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California SB 41

- Key Provisions:
 - PBM Licensing: Required by Jan 1, 2027; DMHC oversight and financial reporting.
 - Pricing & Rebates: Spread pricing banned; mandatory passthrough model; 100% of manufacturer rebates must offset participant cost sharing.
 - Network Protections: Nonaffiliated pharmacies must have equal network access; anti-steering and non-discrimination rules.
 - Cost-Sharing: Cannot exceed actual plan-paid or PBM net price.
 - Transparency: Quarterly reporting of pricing, rebates, and fees; 30-day notice for contract changes.
- Applicability:
 - Express exemption for Taft-Hartley
 - Imposes fiduciary duties on PBMs serving self-insured employer plans and health plan clients. The fiduciary duty includes
 acting in the best interests of the plan, avoiding conflicts, and performing duties with care, skill, prudence, and diligence.
- Effective January 1, 2026

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Iowa - SF 383

- In July a court ordered a preliminary injunction on several provisions (ERISA preemption, First Amendment grounds) (*Iowa Ass'n of Bus. & Indus. v. Ommen*, (S.D. Iowa July 21, 2025)):
 - Anti-discrimination, any-willing-provider, specialty drug designation.
 - Cost-sharing, mail-order pharmacy rules.
 - Third-party financial assistance, contract terms.
 - Pharmacy enforcement rights.
 - Referral prohibitions, compelled disclosures.
- Provisions left intact:
 - 100% rebate pass-through.
 - NADAC reimbursement rates.
 - Limits on steering, accreditation, reporting, appeals.

- Dispensing fee invalidated.
 - July injunction applies only to named plaintiffs and their contractors/agents.
- Iowa appealed to 8th Cir. on October 1, 2025.
- lowa issued enforcement guidance for non-plaintiffs (Bulletin 25-06).
- <u>Update:</u> On October 29, 2025, another district court stipulated to the same relief for Wellmark and their contractors/agents (*Wellmark Inc. v. Ommen*, (S.D. Iowa Oct. 29, 2025)), which will stay in place until the courts resolve either *Wellmark*'s lawsuit or the pending appeal in the ABI case.

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Illinois - Prescription Drug Affordability Act (HB 1697)

- PBM requirements:
 - No participant payment above lowest available price.
 - No spread pricing.
 - No steering to affiliated pharmacies.
 - 100% rebate pass-through.
 - No specialty drug access limits.
 - \$15 per-enrollee annual fee for Prescription Drug Affordability Fund.
 - Annual audit and reporting requirements.
- Application to self-funded ERISA plans is unclear.
 - Defines health benefit plans to include "self-funded employee welfare benefit plans except for self-funded multiemployer plans that are nonfederal government plans [i.e., union plans]."
 - The terms health insurer and insurer explicitly exclude a "plan sponsor of a self-funded, single-employer employee welfare plan or self-funded multiemployer plan subject to 29 U.S.C. 1144 [the preemption portion of ERISA]."
- Effective Jan. 1, 2026.

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North Carolina – SCRIPT Act (SB 479)

Supporting Community Retail Pharmacies and Improving Transparency (SCRIPT)

- PBM restrictions:
 - Pharmacy reimbursements ≥ acquisition cost for independents/deserts.
 - Network adequacy: Medicare Part D standards.
 - Duty of good faith and fair dealing.
 - Anti-affiliate: parity in reimbursements.
 - Rebates: 90% pass-through at point of sale.
 - Annual transparency reporting.
- SB 479 uses the existing statutory definition of a PBM (i.e., an "entity contracting with a pharmacy on behalf of an insurer or third-party administrator"). There is no express exemption for PBMs servicing selffunded ERISA plans.
- Effective Oct. 1, 2025.

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Tennessee

- Tennessee's PBM restrictions as applied to self-funded group health plans governed by ERISA were overturned by the U.S. District Court in the E.D. Tennessee in McKee Foods Corporation v. BFP, Inc. d/b/a Thrifty Med Plus Pharmacy, et al. (No. 1:21-cv-279; E.D. Tennessee, 3/31/25):
 - the any willing provider requirements in Tenn. Code Ann. §§ 56-7-2359, 3120(b)(1), 3121(a)-(b) and
 - the incentive and disincentive provisions for network and preferred pharmacies in Tenn. Code Ann. §§ 56-7-3120(a); (b)(2); and 3121(c).
- Tennessee filed an appeal to the 6th Circuit with oral arguments scheduled for December.
- The court agreed with the 10th Circuit in *Mulready* that the scope of a plan's pharmacy network is a key aspect of how the plan structures and designs benefits and that Tennessee's restrictions "require providers to structure benefit plans in particular ways."

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Fertility/Preventive Services



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ACA Implementation FAQs – Part 72 (Oct. 2025)

- ACA FAQs Part 72: Clarify how stand-alone fertility benefits can be structured as "excepted benefits" under existing law if certain
 conditions are met.
 - Does <u>NOT</u> change existing law.
- **Excepted benefits** are types of coverage not subject to ACA group health plan requirements:
 - Non-health coverage (e.g., auto, liability, workers' comp, accident/disability income) always excepted.
 - Limited excepted benefits (e.g., vision, dental, long-term care, certain HRAs/EAPs).
 - Independent, noncoordinated excepted benefits (e.g., specified disease/illness policies, hospital indemnity).
 - Supplemental excepted benefits (e.g., Medigap, CHAMPVA/Tricare supplements).
- Self-Funded Arrangements: Currently, self-funded arrangements cannot qualify as independent, noncoordinated excepted benefits. The
 Departments intend to address this in future rulemaking.
- Supplemental Coverage Standards: The Departments are considering changes to the limitation-on-value safe harbor for supplemental
 coverage, which could impact how supplemental fertility benefits are structured.
- Note: Clarification and expansion of the types of fertility services and treatment that qualify as a Code Section 213(d) medical expense
 would also be welcome.

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Stand-alone Fertility Benefits: Current Pathways

Independent, Noncoordinated Excepted Benefits

- Must be provided under a separate insurance policy, certificate, or contract.
- No coordination with any group health plan exclusions.
- Benefits paid regardless of group health plan enrollment.
- Cannot be self-funded by the employer—must be insured.
- Compatible with Health Savings Accounts (HSAs).

Limited Excepted Benefits (EBHRAs)

- Must not be an integral part of the main health plan (other group health coverage must be available).
- Annual benefit cap applies (\$2,150 for 2025).
- Cannot reimburse major medical premiums (except for excepted benefits).
- Must be uniformly available to all similarly situated employees.
- Reimbursements limited to IRS Code Section 213(d) medical expenses.

Employee Assistance Programs (EAPs)

- Must not provide significant medical care.
- No coordination with other group health plans.
- No employee premiums, contributions, or cost sharing.

BUT REMEMBER.....

- Not all fertility treatments qualify under 213(d):
 - Treatments and services for a surrogate who is not a covered person under the plan.
- Some may qualify: if preparatory to a procedure performed on a participant/spouse, or other person whose expenses are eligible for tax-free reimbursement as medical care:
 - Egg donor fees and expenses
 - Infertility treatments (e.g.: IVF, surgery, shots, treatments)
- Others are even more uncertain:
 - Fees for "temporary" storage of eggs, sperm, and embryo storage
 - Legal expenses that bear "a direct or proximate relationship to the provision of medical care to the taxpayer" (e.g., medical care that requires legal assistance)

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Pennsylvania v. Trump (2025): ACA Preventive Services Exemptions – Current Status

- The ACA requires most health plans to cover preventive services, including contraception, without costsharing, subject to federal rules for "Religious" and "Moral" Exemptions.
- 2020: Supreme Court upheld agencies' authority to create exemptions but left open whether the rules were "arbitrary and capricious."
- In mid-August 2025, the District Court found both the Religious and Moral Exemption Rules to be arbitrary and capricious under the Administrative Procedure Act (APA) and vacated them in full.
 - Employers can no longer rely on these broad exemptions to avoid ACA preventive service mandates.
 - The pre-2017 framework applies: Only a narrow exemption for certain religious organizations remains.
 - No general exemption for employers with moral objections.
- Agencies may revisit rulemaking, but as of now, the expanded exemptions are not in effect.
- Notice of Appeal Filed in late August
 - Government shutdown has complicated deadlines for briefings.

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Litigation Update



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11th Circuit: Inland Seafood ERISA Litigation

Bolton et al. v. Inland Fresh Seafood Corp. of America, Inc. (11th Cir. 2025)

Background:

- Inland Fresh established an Employee Stock Ownership Plan (ESOP) in 2016, using a \$92 million loan to buy all company stock from directors/officers.
- Plaintiffs (former employees) alleged fiduciary breaches: plan overpaid for stock due to inflated valuations and misrepresented sales/inventory, harming participants' retirement benefits.
- Plaintiffs sought restoration of plan losses and disgorgement of ill-gotten gains.

Court's Ruling:

- Dismissal Affirmed: Plaintiffs failed to exhaust the plan's administrative remedies before filing suit.
- Strict Exhaustion Rule: In the 11th Circuit, all ERISA claims—including breach of fiduciary duty/statutory claims—require
 exhaustion of internal plan procedures before litigation.
- No Valid Excuse: Plaintiffs' arguments for futility, inadequate forum, or plan language exceptions were rejected.
- Remand: District court to clarify if dismissal is with or without prejudice (affects ability to refile after exhaustion).

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Inland Seafood (Continued)

How the 11th Circuit Differs:

- Majority of Circuits: Most federal circuits do not require exhaustion for ERISA statutory violation or fiduciary breach claims—only for benefit claims. (E.g., 3rd, 4th, 5th, 6th, 9th, 10th, D.C. Circuits).
- 11th Circuit: Stands alone in requiring exhaustion for all ERISA claims, including statutory/fiduciary breach claims.
- Potential Change: Recent concurring opinions urge the full 11th Circuit to reconsider this rule; Supreme Court review is possible.

Action Steps :

- Review and Communicate Claims Procedures: Ensure plan documents clearly outline administrative remedies.
- **Enforce Exhaustion:** Require participants to complete all internal appeals before litigation; document all steps. Failure to exhaust is a procedural defense that can be used to seek early dismissal of ERISA claims.
- Monitor Circuit Developments: The 11th Circuit's rule is stricter than most—future *en banc* or Supreme Court review could change the landscape.

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Portions of ACA 1557 Vacated

State of Tennessee, et al. v. Kennedy, et al., No. 1:24-cv-161-LG-BWR (S.D. Miss. Oct. 22, 2025)

- Court Order Vacating Parts of Section 1557 Final Rule (Oct. 2025)
- Background:
 - Section 1557 of the ACA prohibits discrimination "on the basis of sex" in health programs receiving federal funds.
 - HHS's 2024 Final Rule expanded "sex discrimination" to include "gender identity" and "gender-affirming care."
- Court's Decision:
 - The district court ruled HHS exceeded its authority by interpreting "sex" to include "gender identity."
 - Key portions of the 2024 Rule relating to gender identity and gender-affirming care are vacated.
- Implications for Plan Sponsors:
 - Plans subject to Section 1557 are not required, under the vacated provisions, to treat gender identity discrimination as sex discrimination. Section 1557's definition of "sex discrimination" does not currently include "gender identity" or require coverage for gender-affirming care
 - The legal landscape may continue to evolve; ongoing monitoring is recommended.

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Tennessee v. Kennedy—further implications for MHPAEA?

- The court stated that HHS lacks authority to repeal or amend the Final Rule without engaging in Administrative Procedure Act (APA) rulemaking (including notice and comment).
- Court stated that it is "even questionable" whether HHS can postpone enforcement of a final rule absent statutory authority to stay enforcement; thus, informal "consideration" or reliance on executive orders does not suspend the Rule's effect.
- Court emphasized that an agency is bound by a duly promulgated legislative rule until it is amended or revoked through proper APA procedures, and that postponing enforcement likewise requires lawful authority.
- Consequences for plaintiffs under the APA:
 - If the case were dismissed, the preliminary injunction would dissolve automatically, leaving plaintiffs immediately subject to the Rule and its enforcement exposure.
 - The court found that because the Rule remains a final agency action and defendants provided no binding assurance of non-enforcement, plaintiffs face real compliance and enforcement risks—hardship that supports ripeness and warranted adjudication rather than waiting for an enforcement action.

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Litigation Update--4980H

- Faulk Company, Inc. v. United States Department of Health and Human Services et al., No. 4:24-cv-00609-P (N.D. Tex. Apr. 10, 2025)
- Issue: Can the IRS impose an employer mandate penalty under IRC § 4980H without a Section 1411 certification from HHS?
- Ruling: No. The court held that the IRS cannot assess § 4980H penalties unless the employer receives a valid 1411 certification from HHS confirming that an employee enrolled in Marketplace coverage and qualified for a premium tax credit.
 - The IRS lacks authority to issue its own substitute for the 1411 certification (e.g., Letter 226J).
 - Employers must receive a proper 1411 certification before any penalty is assessed.
 - The court ordered a refund of \$205,621.71 to Faulk Company due to the improper penalty.
- Action for Plan Sponsors:

If you've been assessed a § 4980H penalty without a 1411 certification, consider challenging the assessment based on this precedent.

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No Surprises Act: Guardian Flight

Guardian Flight v. Health Care Service Corp.

- Review: Air ambulance providers Guardian Flight and Med-Trans Corporation sued Health Care Service Corp (HCSC) for failing to pay 33 Independent Dispute Resolution (IDR) awards under the No Surprises Act (NSA). They also alleged violations under ERISA and Texas unjust enrichment law.
- Key Issue: Whether the NSA provides a private right of action for providers to enforce IDR payment awards in federal court.
- Fifth Circuit Ruling (June 2025):
 - No private right of action under the NSA to enforce IDR awards.
 - ERISA claims dismissed due to lack of standing—patients were not financially harmed due to NSA protections.
 - Quantum meruit claims rejected, as services benefited patients, not the insurer.
- Update:

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- Petition for Certiorari filed (October 2025).
- Petitioners argue that Congress intended IDR awards to be judicially enforceable, citing the NSA's mandate that insurers "shall" pay within 30 days.
- The Supreme Court has not yet granted or denied the petition

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Complaint: Barbich et al v. Northwestern University et al (N.D. III. 2025)

- Complaint file in June 2025
- ERISA Fiduciary Breach Allegations Self-Funded Plan PPO Menu
 - Defendants allegedly failed to prudently select and monitor the Plan's PPO medical insurance options.
 - The "Premier PPO" (low-deductible) option is financially dominated by the "Value PPO" (high-deductible) and "Select PPO" (mid-deductible) options.
 - All options provide the same coverage; differences are only in financial terms (premiums, deductibles, coinsurance, out-of-pocket max).
 - Premier PPO participants pay thousands more in premiums with no offsetting financial or medical benefit.
- Failure to Disclose
 - Defendants allegedly failed to inform participants that the Premier PPO is financially dominated, breaching ERISA's duty of loyalty and disclosure.
 Internal communications and actuarial analysis confirmed no scenario where Premier PPO is financially advantageous.
 - Misleading plan communications suggested Premier PPO could be the best choice.
- Impact:
 - Plan participants incurred excessive healthcare expenses and lost wages due to unnecessary premium payments.
 - Plaintiffs seek class-wide relief: monetary recovery, injunctive relief, and removal of imprudent options.

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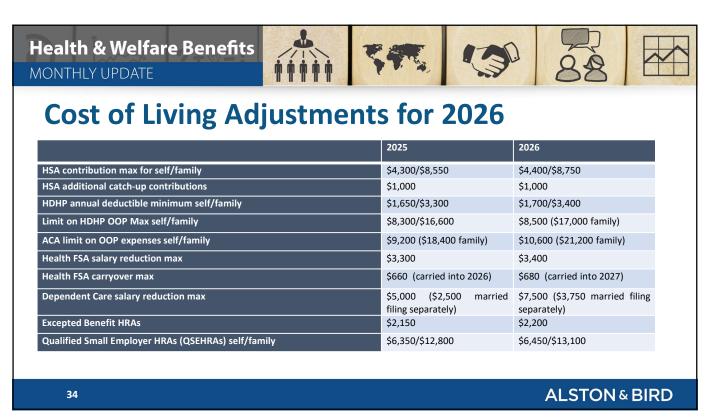


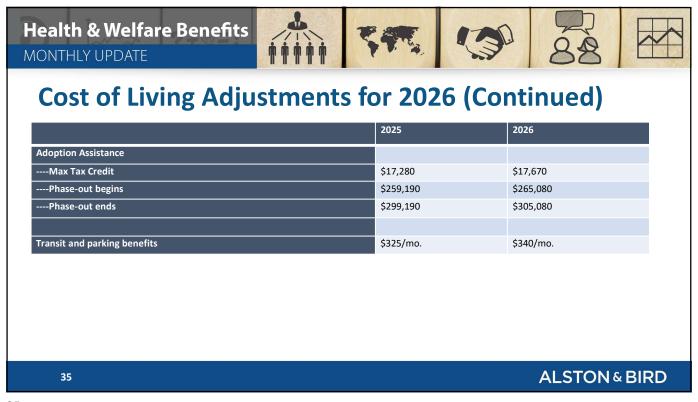


Grab Bag



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Gag Clause Attestation

- Deadline: December 31, 2025. Covers the period since the last attestation (typically the prior calendar year)
- Where to Submit: Submit electronically via the CMS Health Insurance Oversight System (HIOS) Portal on the CMS GCPCA Website.
- Who Must File
 - Fully Insured Plans: The issuer (carrier) typically submits on behalf of the plan
 - Self-Insured Plans: The plan sponsor is legally responsible (may delegate filing to a TPA via written agreement)
- What's New in 2025
 - Downstream Agreements: Must ensure TPAs or vendors do not enter into contracts with third parties that restrict access to cost, quality, or claims data
 - Discretionary Clauses: Agreements that allow data sharing

- only at the **discretion of TPAs or providers** are considered prohibited gag clauses
- Reporting Non-Compliance: If prohibited clauses remain, attestation must still be submitted, with details provided in the "Additional Information" section of the form.

Action Steps for Plan Sponsors

- Review contracts with TPAs, PBMs, and other vendors for prohibited gag clauses
- Confirm that no downstream agreements restrict data access
- Coordinate with TPAs or carriers to determine who will submit the attestation
- Document any efforts to remove prohibited clauses
- Submit attestation or ensure your TPA/carrier does so by Dec. 31, 2025

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Massachusetts HIRD Form

- Purpose of the HIRD Form:
 - Collects data on employer-sponsored insurance (ESI) offerings
 - Helps MassHealth identify members eligible for the Premium Assistance Program
- Filing window opens November 15; deadline is December 15.
- Who Must File
 - All employers (in-state or out-of-state) with 6 or more employees in Massachusetts during the past 12 months.
 - Includes full-time, part-time, and temporary employees
 - Employee count is based on quarterly wage reports submitted to the Department of Unemployment Assistance (DUA)
- No major changes reported for 2025
- Action Steps for Employers
 - Log in to your MassTaxConnect account
 - Gather plan details from your Summary of Benefits
 - Complete and submit the HIRD form by Dec. 15
 - Coordinate with payroll vendors if they assist with filing
 - Retain confirmation of submission for your records

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Updates: Health Resources and Services Administration (HRSA)

- Effective for New Plan years in 2026:
 - Additional imaging (e.g., MRI, ultrasound, mammography) or pathology required after initial screening.
 - Patient navigation services added: For breast and cervical cancer screening and follow-up, as relevant, to increase
 utilization of screening, based on patient's needs for navigation services. Patient navigation services involve person-toperson (e.g., in-person, virtual, hybrid models) contact with the patient.
- Notice of Proposed New Guideline:
 - HRSA Notice of Request for Comments on Draft Recommendations to Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Cervical Cancer. Comment Period ends 30 days after the date of publication in the F.R.
 - Women aged 30 to 65 years:
 - Primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not available, continue screening with cytology alone every 3 years.
 - Patient-collected hrHPV testing should be offered as an option for cervical cancer screening in women at average risk.
 - Women of all screening ages: If additional testing (e.g., cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services also are recommended.

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HIPAA Part 2: Notice of Privacy Practices (NPP)

- February 16, 2026: deadline to update NPP for HIPAA Part 2
 - In general, Part 2 protects Substance Use Disorder (SUD) information obtained by any federally assisted program.
- What updates need to be made to the HIPAA NPP for HIPAA Part 2?
 - A statement that such records (or related testimony) cannot be used in legal proceedings against
 the patient without written consent or a court order with notice and opportunity to be heard.
 - If used for fundraising, individuals must be given a clear opt-out option.
- HHS promised model language, which has not yet been issued.

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