



*Employee Benefits Compliance:
2026 Regulatory Reset*

February 19, 2026

Today's Speaker



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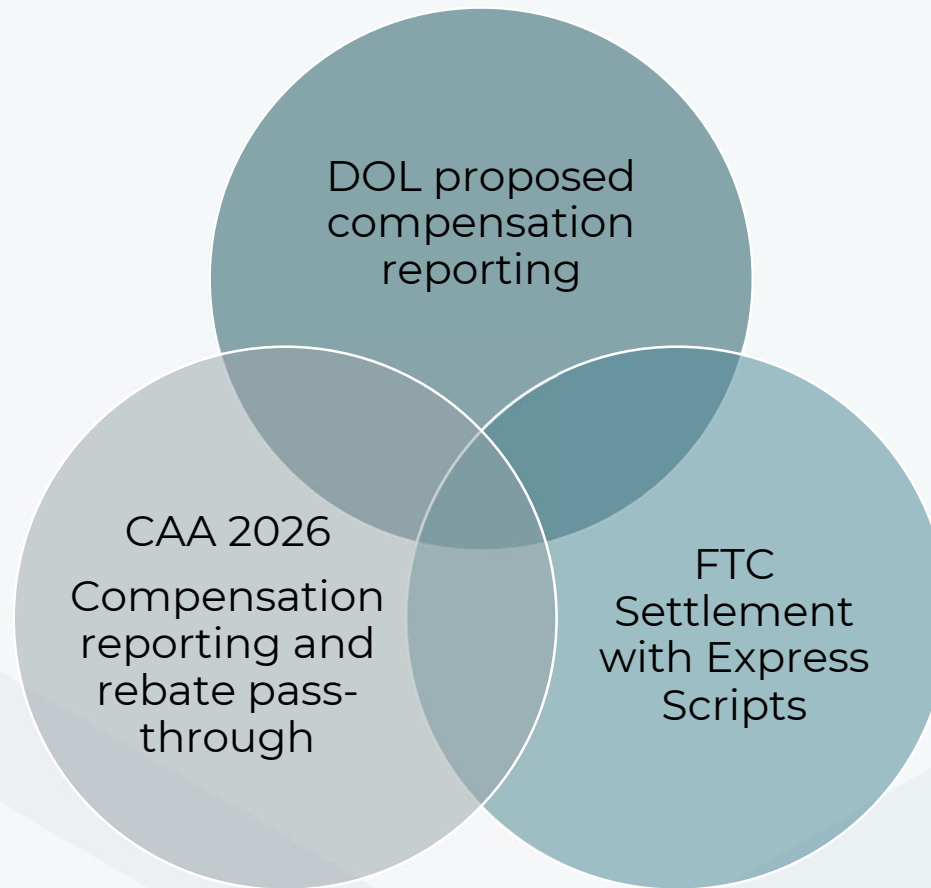


January was a long year...



Pharmacy Benefits

Interrelated Changes for PBMs



DOL Proposed Expansion of 408(b)(2)

- CAA 2021– Broker and consultant disclosure of sources of income in connection with group health plan to ERISA plan sponsors
 - Did not clearly apply to TPAs or PBMs
- January 29, 2026 DOL proposed regulations– Applies to ERISA plans
 - Includes providers of PBM services as covered service providers subject to compensation disclosure
 - Initial prospective disclosure reasonably in advance of entering/extending/renewing contract and then semiannually
 - Semiannual disclosure also requires a description and explanation of any overages if, in the aggregate, the compensation materially exceeds the quarterly estimate. “Materially” is defined as 5% or more, or a lower percentage or dollar amount if agreed to by the fiduciary in writing. The disclosure is required within 30 days after the end of each six-month period.
 - If finalized, effective for plan years beginning on or after July 1, 2026
 - With disclosure comes plan fiduciary obligation to review and determine whether compensation is reasonable



DOL Proposed Expansion of 408(b)(2)

- Disclosure includes:
 - Description of services provided by PBM
 - All direct compensation in the aggregate and by service reasonably expected to be received quarterly
 - Manufacturer payments for each drug on the formulary and in the aggregate plus whether amounts retained by the PBM or passed through
 - Spread compensation in the aggregate and for each drug on the formulary, quarterly
 - Copay claw-back compensation
 - Price protection agreements
 - Contract termination compensation
 - Formulary incentives
 - Net cost to the plan for each drug on the formulary, for each pharmacy channel
 - Other compensation not disclosed above
 - Fiduciary status and conflicts of interest
- Plan sponsor audit right



CAA 2026 Rx Provisions

- Ban on spread pricing for Medicare plans
- Full rebate pass-through to plan for ERISA plans
 - PBM must remit 100% of “rebates, fees, alternative discounts and other renumeration” *
 - Effective for plan years beginning on or after the date that is 30 months after the date of enactment (August 2028)
- Expansion of 408(b)(2) compensation reporting for ERISA plans
 - Similar but not the same as DOL proposed regulation*
 - PBMs and TPAs



* Likely to be clarified in subsequent regulations



FTC and PBMs

- In 2022, FTC requested data and documents of business practices of the 6 largest PBMs
- Spring of 2023, FTC ordered data from three additional PBMs
- July 2024, FTC issued a report alleging lack of cooperation from PBMs and anticompetitive practices
- September 2024 FTC filed administrative complaint against three largest PBMs (Caremark Rx, Express Scripts and OptumRx)
- January 2025, FTC issued second interim report on PBM practices



FTC Settlement with Express Scripts

- Changes to “Standard Formulary” and “Standard Offering”
 - However, can offer different calculations, offerings and terms to self-funded plans in response to written request
- By January 1, 2027:
 - Non-discrimination against lower-cost version of same drugs on the formulary
 - Compensation received from drug manufacturers will not be based on list price of drug or related benchmark
 - Allow members to receive the benefit of direct-to-consumer pricing through the TrumpRx platform, counting member payments through platform toward deductible and OOP maximum
 - Full access to members purchasing Insulin products through the Patient Assistance Program



FTC Settlement with Express Scripts

- By January 1, 2028:
 - No spread pricing (charging plan different price than pharmacy paid for a prescription drug)
 - No guarantee of predetermined amount of compensation to plan sponsor
 - Pass-through of rebates or discounts to members at point-of-sale
 - Additional transparency on drug product cost, pharmacy claim-level reporting, and broker compensation to plan sponsors
 - Compensation of retail community pharmacies based on acquisition cost plus dispensing fee

https://www.ftc.gov/system/files/ftc_gov/pdf/d09437caremarkproporder-esiresps.pdf



TrumpRx Launched

- February 5, 2026
- Government portal for access to drug manufacturer programs for specific drugs
 - Similar to GoodRx
- “Most favored nation pricing”
 - Coupons for 43 drugs, ranging from 33 to 93% off the list price
 - Some have noted that prices with coupons may not be lower than prices through insurance
 - Some of the medications aren’t well covered by insurance — such as weight loss and in vitro fertilization drugs



Other Developments

Section 530A “Trump Accounts”

- Authorized under Section 530A of the OBBBA
- Eligible: child who has not turned age 18 before the end of the calendar year in which the election is made and has valid SSN
- Annual contribution limit of \$5,000 per year in 2026 and 2027
 - Indexed to inflation thereafter
- Employer may contribute to an employee’s or the employee’s dependent’s account up to \$2,500 per year (which counts against the \$5,000 annual limit) and the contribution will not count toward the employee’s taxable income.
- Pilot program government contribution of \$1,000 for children born between Jan. 1, 2025, and Dec. 31, 2028, and who are U.S. citizens with a valid Social Security number.



Section 530A “Trump Accounts”

- Account funds must be invested in certain mutual funds or exchange-traded funds that track the S&P 500 or another index of primarily American equities
- Funds generally cannot be withdrawn before January 1st of the calendar year in which the child turns 18 years old
 - Account generally is treated as a traditional IRA and generally is subject to the same rules as other traditional IRAs, including those governing withdrawals
- Contributions can be made beginning July 4, 2026
- Use IRS Form 4547 or an online portal to open account
 - IRS draft form 4547 and draft instructions can be found at <https://www.irs.gov/pub/irs-dft/f4547--dft.pdf> and <https://www.irs.gov/pub/irs-dft/i4547--dft.pdf>.
- Awaiting final regulations/forms



Expansion of DFVCP

- Annual requirement for ERISA plans to file Form 5500 with EBSA
- Plans that report late (without an extension) or fail to report face stiff penalties from DOL and IRS (up to \$2,739/day with no upper limit.)
- Employers that self-report and remedy delinquent filings through Delinquent Filer Voluntary Correction Program (DFVCP) can cap penalties to \$10/day with a maximum of \$2,000/year (higher limits for multiple Form 5500s)
- DFVCP now available to MEWAs for their filings





Expansion of DFVCP

- MEWA is a multiple employer welfare arrangement in which the employees of two or more unrelated employers (less than 80%) common interest participate
- In addition to filing Form 5500, MEWAs file Form M-1:
 - 30 days before operating in any state
 - 30 days before operating in a new state
 - Upon merger with another MEWA
 - When there is a 50% increase in covered employees compared to prior calendar year
 - Annually by March 1
- DVFVC now available to MEWAs for M-1 delinquent filings



Expansion of DFVCP

- Entities claiming exemption (ECEs) from MEWA status also required to file M-1 if claiming exemption based on collective bargaining:
 - Within 30 days of merging with another ECE
 - When the number of employees under the ECE is 50% greater than last calendar year
 - While operating in a new state not indicated on prior M-1
 - Upon material changes
- DFVCP now available to ECEs for their delinquent filings
- 2025 penalty for delinquent/incomplete M-1 was \$1992/day
- Employers in MEWAs should make sure M-1 has been filed timely. If not, use DFVCP



HIPAA Notice of Privacy Practices (NPP)

- Recent changes to HIPAA Privacy Rule require covered entities make changes to NPP by February 16, 2026, including:
 - Notice of Rights concerning Substance Use Disorder (SUD) Records
 - Statement explaining that SUD records cannot be used or disclosed in investigations or court proceedings without written consent, court order or subpoena
 - Statement adequate to put the individual on notice of the potential for information to be redisclosure by the recipient and no longer protected by the Privacy Rule
- Model language released on February 13, 2026, can be found at [Model Notices of Privacy Practices | HHS.gov](#)
 - Templates that require or suggest input of information from the plan



HIPAA Notice of Privacy Practices (NPP)

Action Items for Employers

- Fully insured plan sponsors can typically rely on their insurance carrier to handle the NPP requirement
- Self-funded plan sponsor should use model template to update NPP
 - Must disclose updated NPP to plan members by April 14, 2026 (subject to electronic disclosure rules)
- Don't delay—
 - On February 13, 2026, HHS Office for Civil Rights (OCR) announced new program to implement and enforce requirements to protect confidentiality of SUD patient records
 - Beginning February 16, 2026, accepting complaints alleging violations and notifications of breaches of SUD records



California

San Francisco HCSO

- City & County of San Francisco Health Care Security Ordinance Poster 2026 is available
 - Display prominently at all workplaces where covered employees work
 - FAQs for more details on posting requirement
- Self-Insured Top-Off Payments deadline is February 28, 2026
 - For employers whose 2025 expenditures fell short of the required rate
- Annual Reporting Form due to Office of Labor Standards (OLSE) on April 30, 2026





City & County of San Francisco Health Care Security Ordinance

Covered Employers Must Post Where Employees Can Read Easily

OFFICIAL NOTICE 2026

You may be entitled to employer health care spending.

Most workers in San Francisco are entitled to employer health care spending, if you:

- Work at least **8 hours** per week in San Francisco
- Have been employed by your employer for about **3 months (90 days)**
- Work for a business that has **20 or more workers** worldwide or a non-profit with **50 or more workers** worldwide

Employer size	Required rate
20-99 workers worldwide (or nonprofits with 50-99 workers)	\$2.74 / hour
100 or more workers worldwide	\$4.11 / hour

Your employer may choose how they spend the money. For example, your employer may pay for health, dental, or vision insurance, make payments to the SF City Option program, etc.

The City may investigate possible violations of the law, and can order employers who violate the law to pay penalties and make payments to workers. Employers may not punish employees who file a complaint or who cooperate with an investigation.

If you have any questions, please contact your employer or the San Francisco Office of Labor Standards Enforcement at (415) 554-7892 or HCSO@sfgov.org. You can also visit the OLSE website at www.sf.gov/olse-hcso.

A/ISO OFICIAL 2026 · Ordenanza de Seguridad del Cuidado de la Salud (HCSO)

Es posible que tenga derecho a los gastos de atención médica del empleador.

La mayoría de los trabajadores en San Francisco tienen derecho a los gastos de atención médica del empleador, si usted:

- Trabaja por lo menos **8 horas** a la semana en San Francisco
- Ha estado trabajando por su empleador durante aproximadamente unos **3 meses (90 días)**
- Trabaja para una empresa que tiene **20 o más trabajadores** en todo el mundo o una organización sin fines de lucro con **50 o más trabajadores** en todo el mundo

Tamaño de la empresa	Tasa obligatoria
20-99 trabajadores en todo el mundo (o entidades sin fines de lucro con 50-99 trabajadores)	\$2.74 / hora
100 o más trabajadores en todo el mundo	\$4.11 / hora

Su empleador puede elegir cómo gastar el dinero. Por ejemplo, su empleador puede pagar un seguro médico, dental o de visión, hacer pagos al programa SF City Option, etc.

La Ciudad podría investigar los posibles incumplimientos de la ley, y puede ordenar a los empleadores que violen la ley que paguen multas y realicen pagos a los trabajadores. Los empleadores no deben castigar a los empleados que presenten una queja o que cooperen con una investigación.

Si usted tiene alguna pregunta, comuníquese con su empleador o con la Oficina de Normas Laborales de San Francisco en (415) 554-7892 ó HCSO@sfgov.org. También puede visitar el sitio web de OLSE en: www.sf.gov/olse-hcso

Fertility Benefits: SB 729

- Effective for fully insured plans only on January 1, 2026
- DMHC all-plan letter released December 30, 2025 List of covered treatments:
 - To diagnose infertility
 - List of covered treatments to treat infertility
 - For both, including any services consistent with established medical practices and the most current professional guidelines published by ASRM
 - Donors, donor material and surrogate services
- Rules regarding coverage of cryopreservation of sperm, oocytes and embryos
- Coverage for surrogacy
- Fertility preservation services



Fertility Benefits: SB 729

- Donors, material and surrogate services include: labs and imaging, infectious disease and genetic testing and screening, medication to induce ovulation, retrieval of donor gametes, gamete and embryo transfer
- Surrogacy:
 - If an enrollee is using a surrogate to treat the infertility of the enrollee, the enrollee's health plan shall cover medically necessary health testing of the surrogate for each attempt collect eggs or sperm or to create embryos, and for each attempt to achieve a pregnancy with that material.
 - The enrollee's health plan not responsible for health care costs of the surrogate after the embryo transfer procedure, including maternity services, except as required under the terms of the surrogate's health plan contract.
- [https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL25-021-ImplementationofSenateBill729\(2024\)-REVISED\(2_19_2026\).pdf?ver=ONG383MMauhJGzelfP6sMg%3d%3d](https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL25-021-ImplementationofSenateBill729(2024)-REVISED(2_19_2026).pdf?ver=ONG383MMauhJGzelfP6sMg%3d%3d)





PBM Regulation: SB 41

- Effective January 1, 2026
 - 100% rebate pass-through
 - nondiscrimination against non-affiliated pharmacies
 - limitations on member cost-sharing
 - New spread pricing terms in contracts (existing provisions void after January 1, 2029)
- Apply to PBM contracts with insurance carriers and impact appears to be limited to fully insured plans
- Fiduciary duty to both self-insured employer plans and health insurance clients



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You are advised to follow up with your own legal counsel and/or tax advisor to discuss how this information affects you.

Questions





Thank you!