

A Flurry of Changes for Plan Sponsors, Prescription Drug Plans and Health Plan Vendors

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Agenda

- TrumpRx
- ESI Settlement
- CAA 2026 Changes
- Proposed PBM Disclosure Rules

TrumpRx



TrumpRx

- May 12, 2025: President Trump issues executive order “requiring” drug manufacturers to sell drugs in U.S. at prices no higher than other developed countries
 - Called “most favored nation” (“MFN”) pricing
- Backed by threat to impose tariffs if companies did not agree
- October 2025: Trump administration announced launch of “TrumpRx.gov”, government-operated website
 - To allow individuals to directly purchase certain medications from certain manufacturers (direct to consumer (“DTC”) model)
- November 2025: Five manufacturers agree to MFN pricing for certain drugs, resulting in tariff exemptions
 - Drugs include in vitro fertilization drugs and, perhaps most significantly, some GLP-1 weight loss drugs
 - Novo Nordisk’s Ozempic and Wegovy

TrumpRx

- At this point, many unknowns about TrumpRx.gov and its impact in the benefits industry
- **Will Lack of Law Matter?** No law provides for TrumpRx. “Foundation” seems to be President Trump’s tariff threats against prescription drug manufacturers
 - But that ability was recently reduced by U.S. Supreme Court (Learning Resources, Inc. v. Trump)
 - Will that cause drug manufacturers to limit future actions? No expansion of drugs at TrumpRx.gov?
 - Will Congress halt funding for TrumpRx.gov? (Who is paying for it?)
- Would future administration abandon it?

TrumpRx

- **What is Impact on Plan Sponsors / Employers?**

- Will employers have any “role”? Will they be encouraged to “steer” their employees / health plan enrollees to TrumpRx.gov?
 - Presumably not, at least initially
- Is availability of drugs through TrumpRx.gov “non-high-deductible plan” (“Non-HDHP”) coverage that makes a person ineligible to contribute to a health savings account (“HSA”)?
- If plan enrollees obtain drugs through TrumpRx.gov, will plan sponsors lose important data about prescriptions enrollees take?
- Is there a concern about harmful drug / drug or drug / disease interactions if TrumpRx.gov information is not available to pharmacy benefit managers, insurers, plans?

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - Can employer / plan sponsor reimburse for DTC-purchased drugs?
 - Yes, in some situations. But other situations pose legal concerns
 - Weight-loss program undertaken per a doctor's direction to treat a disease (like obesity, hypertension or heart disease) would usually be "medical care" and reimbursable on a tax-favored basis
 - E.g., through health reimbursement arrangement ("HRA") or health flexible spending account ("Health FSA"); consider HSA issues
 - IRS FAQs, Q9: Is the cost of a weight-loss program a medical expense that can be paid or reimbursed by an HSA, FSA, Archer MSA or HRA? (added March 17, 2023)
 - A9: Yes, but only if the program treats a specific disease diagnosed by a physician (such as obesity, diabetes, hypertension, or heart disease). Otherwise, the cost of a weight-loss program is not a medical expense
 - What if drug is for employee's "general health" or "appearance"?
 - IRS guidance (e.g., Revenue Ruling 2002-19; Publication 502) states that those are generally not medical care and, thus, difficult to reimburse on a tax-favored basis

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - If employers do get involved, will employers look to “pre-load” debit card to help enrollees with cash-flow issues (i.e., pay for drug directly, rather than wait for reimbursement)?
 - Will DTC and TrumpRx.gov impact plan sponsor’s relationship to its PBM? TPA? Insurer?
 - Contracts may require employer / plan sponsor to only use that vendor for prescription drug services. Will that prevent employer / plan sponsor interactions with TrumpRx.gov?
 - Given modest number of drugs expected at 2026 “launch”, unlikely to have any significant, immediate impact on plan sponsor’s relationship to PBM, TPA, insurer. Could that change over time? How many years?

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - Will health plans provide credits towards enrollee's deductible and maximum out-of-pocket ("MOOP") limits for DTC-purchased drugs?
 - Probably not, at least initially. Will plan enrollees "push" plan sponsors to provide credit towards deductible and MOOP for those DTC payments? How will plan sponsors react?
 - Curiously, FTC / ESI settlement addresses this
 - It says that ESI's "Standard Offering to Plan Sponsors shall ensure that Members receive the benefit of direct-to-consumer pricing through the TrumpRx platform"
 - And that the Standard Offering "shall count Member payments made through the TrumpRx platform toward Member deductibles and Out-of-Pocket Cost maximum accumulators

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - Seems to be a “roundabout way” of trying to have one type of DTC (only through TrumpRx) “count” towards deductibles / MOOP
 - Note, though, that coupons on TrumpRx seem to contain varying terms about whether submission through plans is ok (future slide)
 - If there are dozens of drugs and those terms can vary from day-to-day, who will monitor those terms and “track” that?
 - Will drug manufacturers expand from DTC to “direct-to-employer” (“DTE”) programs?
 - November 2025: Waltz Health announces agreement with Eli Lilly and Novo Nordisk for DTE program for obesity drugs
 - See here: <https://www.prnewswire.com/news-releases/waltz-health-launches-new-direct-to-employer-access-model-for-obesity-management-medications-302622533.html>

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**

- Waltz would perform typical PBM functions, such as confirming “medical appropriateness”, routing prescriptions to pharmacies with “reliable inventory,” “refill tracking” and “adherence tools”
- Will PBMs view “Waltz Health approach” as a threat and offer similar services?
- Will plan sponsors be interested in the DTE approach? Or view it as too “niche” -- because only a handful of drugs (albeit popular weight-loss drugs) are involved?
- Will brokers / benefit advisors “push” the DTE approach? Will they be compensated to do so?
- Would using DTE approach violate contract with PBM, TPA or insurer? Cause loss of other (all?) rebates? Trigger PBM’s right to renegotiate overall contract?

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - To obtain coupons on TrumpRx.gov, individual apparently must agree to certain terms and conditions
 - Some terms are ok with commercial insurance (e.g., Wegovy: “This offer is available to patients with commercial insurance....”)
 - Others are not. For drug Duavee, individual must agree that “Patients enrolled in commercial insurance plans may not submit any claims for reimbursement for prescriptions purchased as part of this Program”
 - If plan reimburses enrollee for cost of that drug, is plan causing patient to violate those terms? Is the plan “tortiously interfering with a contract”? Will plans “track” this? What if terms change over time?
 - See, e.g., *New England Carpenters Health and Welfare Fund v. Abbott Laboratories*, 2014 WL 4783833 (N.D. Ill. 2014)

TrumpRx

- **What is Impact on Plan Sponsors / Employers, continued?**
 - Employers / plan sponsors should consider fiduciary issues
 - Several recent lawsuits have claimed (with not-much success) that plan sponsors breached fiduciary duties under ERISA when certain drugs covered by plan were much-more-expensive than “cash price”, outside of plan
 - E.g., if Acme Co.’s prescription drug plan charges \$1,000 per month for Wegovy, but cash price is \$350 per month, could Acme Co. have fiduciary liability for “overcharging” the plan enrollees by \$650 per month?
 - This is the essence of recent Johnson & Johnson and Wells Fargo lawsuits
 - Should PBMs and plan sponsors discuss this issue now, prior to launch of TrumpRx.gov? Or is it too soon?

FTC Settlement with ESI

ESI Settlement

- “Big 3” PBMs (ESI, OptumRx and CVS) sued by Federal Trade Commission (“FTC”) over insulin pricing issues
- FTC and the three PBMs negotiated to determine if they could settle the matter
- About a month ago, ESI and FTC reached a proposed Settlement
- OptumRx and CVS still negotiating. Court filing from a few days ago notes that they are making progress on resolution
- Settlement only applies to ESI, but likely that OptumRx and CVS will reach similar terms

ESI Settlement

- ESI Settlement contains interesting terms – far beyond insulin pricing
- Federal government appears to have been trying to remake PBM industry, in essence, through this single leverage point
- ESI must provide “Standard Offering” to plan sponsors
 - Although plan sponsors can opt out; basically, “default” with better (?) terms for plan sponsors
- High-WAC versus Low-WAC drugs: When drug has wholesale acquisition cost (“WAC”), ESI cannot “offer or administer” a “Standard Formulary” favoring the High-WAC drug
- Seems to be an effort to force ESI to provide lower-cost drug, when there is an option

ESI Settlement

- Enrollee's out-of-pocket costs must be based on the "Net Unit Cost" of drug
- ESI must provide full access to programs (like patient assistance programs) that reduce costs
- As noted in prior slides, ESI must ensure that Standard Offering integrates TrumpRx.gov:
 - Member receives benefit of "direct-to-consumer pricing through the TrumpRx platform"
 - Member payments "made through the TrumpRx platform" must "count ... toward Member deductible and Out-of-Pocket Cost maximum accumulators"
 - How will PBMs, TPAs and plan sponsors track those payments?

ESI Settlement

- Rebates must be provided at point-of-sale to enrollees
 - May reduce rebates that plan sponsors receive later, in “bulk”
 - How will plan sponsors react? Will this increase premium costs that plan sponsors charge?
- No guarantee of compensation to plan sponsors (e.g., through rebates)
- No “spread pricing”
 - This one is effective “as soon as commercially feasible but no later than January 1, 2028”
 - Will ESI try to “make up” for lost revenue by increasing administrative fees? Other fees?

ESI Settlement

- ESI must provide “additional automated reporting for Plan Sponsors including an annual report disclosing each Drug Product costs and pharmacy claim-level reporting”
 - How will this “coordinate” with Proposed Regulations and CAA 2026 obligations?
- Plan must receive any data needed for Transparency in Coverage regulations
- ESI must disclose “compensation to consultants or brokers in connection with” pharmacy benefit. ESI must “fully disclose to each Plan Sponsor any such compensation paid or facilitated”
- Group purchasing organization onshoring by July 2028

ESI Settlement

- Group purchasing organization onshoring by July 2028
- Note that these have varying effective dates
- Are some (or all?) of these changes helpful to plan sponsors?
- Will plan sponsors who use ESI try to “accelerate” these changes and have them apply, e.g., in 2026? 1/1/2027?
- Will plan sponsors who use other PBMs (e.g., OptumRx and CVS) try to require, by contract, that they agree to similar terms?

Consolidated Appropriations Act (CAA) 2026 Changes

CAA 2026

- On February 3, 2026, President Trump signed into law the Consolidated Appropriations Act, 2026 (“CAA 2026”)
- CAA 2026 provides for many important changes for prescription drug plans, PBMs, plan sponsors, TPAs, brokers and others
- Two main pieces:
 - New restrictions on PBMs
 - New prohibited transaction rules that apply to a variety of health and welfare plan service providers (not just PBMs and TPAs)

CAA 2026: New Restrictions on PBMs

- PBMs have sometimes been criticized for opaque reimbursement models
- CAA 2026 is an apparent effort to change (eliminate?) that type of “opaque” reimbursement model
- But in a roundabout way: by prohibiting contracts between PBMs and plan sponsors / employers that contain certain terms
- Similar to CAA 2021’s Gag Clause Rule
- Little guidance under Gag Clause, so has led to uncertainty about how it is applied

CAA 2026: New Restrictions on PBMs

- Most new PBM restrictions apply for first plan year on or after 30 months from date CAA was enacted
 - **BUT, very important ERISA prohibited transaction change that may have taken effect immediately (February 3, 2026) (later)**
 - **AND may apply to MANY service providers (TPAs, brokers, etc.)**
- So, generally for plan years starting on or after August 1, 2028
- **New PBM Disclosure Report**
- Every 6 months (or, if plan agrees, every 3 months) PBM must provide to plan a “plain language”, “machine-readable” Report

CAA 2026: New Restrictions on PBMs

- Report must include various information
- Information required varies by whether the employer is a “specified large employer” or a “a specified large plan”
- **Drug List:** List of drugs “for which a claim was filed”
- **Compensation:** “Contracted compensation paid” by the plan for the drug to the PBM
- “Contracted compensation paid to the pharmacy” by PBM
 - And the difference between the two
 - E.g., if PBM charges \$100 for Drug ABC and only pays pharmacy \$60, the \$40 “spread” becomes “visible” now and is reported

CAA 2026: New Restrictions on PBMs

- **Drug Detail:** Name of drug, dosage unit
- Wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, “on the date such drug was dispensed”
- Total number of prescription claims
- **Drug Pricing Detail:** Net price per “course of treatment” or single fill “after rebates, fees, alternative discounts, or other remuneration received from applicable entities”
 - Will PBM know when the “course of treatment” is over?
 - Often takes months for rebates, etc., to be finalized. Will PBMs be able to timely include this information in the Report?

CAA 2026: New Restrictions on PBMs

- **Enrollee Spending:** Total amount of out-of-pocket spending by enrollees on the drug, “including spending through copayments, coinsurance, and deductibles”
 - But not including drugs excluded under the plan
- Total “net spending” on the drug
- **Plan Spending:** Total amount “received, or expected to be received, by the plan” from any “applicable entity in rebates, fees, alternative discounts or other remuneration”
 - This is basically “what the plan receives” in rebates, etc.
 - Will PBMs know this? Especially the “expected to be received”, which is an amount that has not yet been received?

CAA 2026: New Restrictions on PBMs

- **Rebates, etc. Received:** Total amount received, or expected to be received, by PBM “from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities”
 - This is basically “what the PBM receives” in rebates, etc.
- Also, PBM must disclose “to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, co-payment cards applied, or other discounts provided by each drug manufacturer ... to the participants and beneficiaries enrolled in such plan”

CAA 2026: New Restrictions on PBMs

- **Effect of Rebates on Drug Spending:** For each therapeutic class of drugs, certain spending information, including “total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities”
 - And “net spending” after such rebates, etc., are applied
 - And “total amount received, or expected to be received” by PBM from such rebates, etc.
- **Higher-Cost Drugs:** For higher-cost drugs (generally, that exceeds \$10,000 during the reporting period), list of other drugs in same therapeutic class and “rationale for the formulary placement of such drug”
 - Intent seems to be for PBM to explain why drug was placed in that formulary – e.g., because of cost and effectiveness, or due to rebates received

CAA 2026: New Restrictions on PBMs

- **Entities Related to PBM:** If the PBM has an “affiliated pharmacy”, it must disclose “mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing assistance incentives funded by” the PBM that:
 - Explain any benefit design parameters that encourage or require participants and beneficiaries to fill prescriptions at mail order, specialty, or retail pharmacies
 - And related information on those drugs (e.g., net acquisition cost per dosage unit and per 30-day / 90-day supply)

CAA 2026: New Restrictions on PBMs

- **Summary of Information to Plan Sponsor:** Summary document goes to group health plan from PBM with much of this information
- Goal is to provide plan sponsor with information that plan sponsor would find “useful ... for purposes of selecting [PBM] services, such as an estimated net price ..., a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary”
 - Will this information put plan sponsor in a difficult spot, from a fiduciary perspective, if it selects a PBM whose “estimated cost per participant” is HIGHER than what a different PBM is charging?

CAA 2026: New Restrictions on PBMs

- **Summary of Information to Plan Enrollee:** PBM must also include a “summary document for plans and issuers to provide to participants” that contains much of this information
 - And that states that they “may request specific, claims-level information required to be furnished” under CAA 2026 from the plan
 - Is this claims-level information specific to that one participant? Or all participants? If it’s “all” participants, will plaintiffs’ lawyers find one enrollee in a plan, then have them request a lot of data? Then “mine” that data to support claims / lawsuits?
 - Includes “total net spending by the plan or coverage for all such drugs”, along with “total amount received” in “rebates, fees, alternative discounts, or other remuneration”

CAA 2026: New Restrictions on PBMs

- **Disclosure of Compensation:** Report also includes “total net spending by the plan or coverage for all such drugs”, along with “total amount received” in “rebates, fees, alternative discounts, or other remuneration”
- And “amounts paid directly or indirectly in rebates, fees, or any other type of compensation” (as defined under ERISA Section 408)) to “brokerage firms, brokers, consultants, advisors, or any other individual or firm, for”:
 - Referral of plan’s “business to an entity providing” PBM services;
 - Consideration of the entity providing PBM services
 - As part of an RFP?
 - Retention of the entity (any type of “continued business” bonus)

CAA 2026: New Restrictions on PBMs

- Intent of Congress seems to be to “peel back” the layers of fees that may flow among various entities
- **Fiduciary Risk:** Is that a double-edged sword for plan sponsors?
 - Right now, difficult for plan sponsors to know all these details. Also difficult for plaintiffs’ lawyers too
 - Once details are known, will plan sponsors need to act on that information? Would it be “imprudent” under ERISA to not act, if fees are clearly higher? Or if broker, etc. is receiving fees that plan sponsor did not know about?
- Report from PBM must follow HIPAA Privacy Rules
 - Report generally must only contain “summary health information”, not “protected health information”

CAA 2026: New Restrictions on PBMs

- **HIPAA:** Plan sponsor must comply with HIPAA's restrictions at 45 CFR 164.504(f)
 - Related to plan sponsor's access to PHI (e.g., "firewall" for employees to receive the information) and summary health information
- **New Written Notice Requirement:** Each plan year, plan "shall provide to each participant or beneficiary written notice informing" them of requirement for PBM "to submit reports to group health plans"
 - "[M]ay include ... notification in plan documents provided to the participant ... or providing individual notification"
 - If can just include this notice in the SPD, most plan sponsors would want that (rather than an annual, individual notice)

CAA 2026: New Restrictions on PBMs

- **Disclosures to Business Associates:** Strange rule on limitations: Group health plan “receiving a report” under prior section “may disclose such information only to the entity from which the report was received or to that entity’s business associates ... or as permitted by the HIPAA privacy regulations”
 - First part does not make much sense
 - But second part arguably is broader and would allow plan sponsor to disclose the report to other business associates (e.g., to allow plan sponsor to provide PBM report to plan sponsor’s consultant or attorney)

CAA 2026: New Restrictions on PBMs

- **Restrictions on Public Disclosure:** Public disclosure of information: PBM may “plac[e] reasonable restrictions on the public disclosure of the information contained in a report described” above
- But plan cannot be restricted from disclosure to DOL / HHS / IRS or to plan participants (pursuant to above rules)
- Key term of “public” is not defined. Is “public” defined as “any random person on the Internet”? Or does it include plan vendors such as consultants?
- **DOL Guidance:** DOL to provide “standard format” for reports within 18 months (so, by about August 2027)
- And issue regulations at same time

CAA 2026: New Restrictions on PBMs

- **Other Disclosures From Plan to Enrollee:** Plan “shall provide” to enrollee:
 - (1) Summary document noted above;
 - (2) Certain claims-level information related to difference between “contracted compensation paid by the group health plan” to the PBM versus the “contracted compensation paid to the pharmacy” by the PBM
- **Enforcement:** Applies to both group health plans “and with respect to entities providing pharmacy benefit management services on behalf of such plans”
 - **Big development:** DOL / HHS / IRS officials have sometimes appealed to Congress for this authority (e.g., in MHPAEA cases)

CAA 2026: New Restrictions on PBMs

- **Civil Monetary Penalties, in General:** “\$10,000 for each day during which” plan fails to provide required information
 - Is that \$10,000 per day per enrollee? Or just \$10,000 total?
 - Does that apply only after enrollee requests information? What if plan has no process in place to provide information, but gets “lucky” and no one ever asks for the information?
- **False Information Penalties:** If PBM, health insurance issuer “or a third party administrator providing services on behalf of such issuer ... knowingly provides false information”, penalty is \$100,000 “for each item of false information”
 - Are “independent” TPAs excluded?
 - Is “each item” as broad as it sounds? Per enrollee?
 - Appears that penalties go to federal government
 - Penalties can be waived / reduced

CAA 2026: New Prohibited Transaction Rules

- CAA has special provisions for ERISA-covered plans
- Do not apply to non-ERISA plans (e.g., governmental plans)
 - Will those plans insist upon them? Or something similar?
- Modify ERISA prohibited transaction rules, require new terms
- In order for a “responsible plan fiduciary” to satisfy ERISA’s prohibited transaction rules, plan fiduciary must meet new terms for “covered service provider” (“CSP”) contract
- **Who is a CSP?** A “service provider that enters into a contract or arrangement with the covered plan and reasonably expects to receive \$1,000” (as adjusted)

CAA 2026: New Prohibited Transaction Rules

- For various services. Under CAA 2021, list was limited to “brokerage services” and “consulting services” linked to certain benefit plans (including prescription drug, medical, dental, vision)
- **Curiously, CAA 2026 seems to greatly expand the definition**
- Now it’s “Services (including brokerage services)” related to those activities
- And “Other services” (not just “consulting” services)

CAA 2026: New Prohibited Transaction Rules

- Services include:
 - Plan design
 - Insurance or insurance product selection (including dental and vision)
 - Recordkeeping
 - Medical management
 - Benefits administration selection (including vision and dental)
 - Stop-loss insurance
 - Pharmacy benefit management services
 - Wellness design and management services

CAA 2026: New Prohibited Transaction Rules

- Services include, continued:
 - Transparency tools
 - Group purchasing organization agreements and services
 - Would that apply even to non-health-plan related “group purchasing organizations”?
 - Participation in and services from preferred vendor panels
 - Disease management
 - Compliance services
 - Employee assistance programs
 - Third-party administration services
 - Consulting services related to any such services

CAA 2026: New Prohibited Transaction Rules

- Quite the long list!
- Also, quite a broad list. For example, suppose you ask your trusty Employee Benefits lawyer whether a particular “plan design” is ok (e.g., whether your plan can exclude weight-loss drugs and, if so, how). Your lawyer advises you and charges you \$1,000 or more. Is the lawyer subject to this rule?
- **Biggest issue:** When was this change effective? On February 3, 2026, when President Trump signed CAA 2026 into law?
 - No specific reference to a “next plan year after 30 months”
 - CAA 2026 says these are a “Clarification of Covered Service Provider”
- **If this rule applies now, significant compliance concerns and work to be done now**

CAA 2026: New Prohibited Transaction Rules

- Within 30 months of CAA 2026, generally, contract with service provider for pharmacy benefit manager services must contain certain terms in order to satisfy ERISA Section 408
- **Remit Rebates:** Remit 100% of “rebates, fees, alternative discounts, and other remuneration received from any applicable entity”
 - If related to utilization of drugs or drug spending under the plan. Does not seem to apply to “spread pricing” revenue, at this time
- 100% of rebates, fees, alternative discounts and other remuneration received under the contract related to utilization of drugs or drug spending “are remitted to the group health plan”
 - Must these amounts really go “to the group health plan”? Not the plan sponsor? Will that create “plan assets”? Cause plan to be “funded”? Result in new Form 5500 filing obligations? Handle similar to medical loss ratio rebates?

CAA 2026: New Prohibited Transaction Rules

- Must be remitted on a quarterly basis to the plan
 - If fully-insured, not later than 90 days after end of the quarter
- If there is an “underpayment” for a prior quarter, must be made “as soon as practicable, but not later than 90 days after notice of the underpayment is first given”
 - Who provides the “notice of the underpayment”?
- **Fully Disclose Rebates:** Must be “fully disclosed and enumerated to the group health plan”
 - How “granular” is “enumerated”? Show that \$x was received for Drug ABC?

CAA 2026: New Prohibited Transaction Rules

- Contract must require that if an excess payment is made to the plan sponsor, that it be returned back to the CSP
- DOL can issue regulations related to:
 - Procedures for remittance of rebates, fees, alternative discounts
 - Any audit
 - Timing, manner and content of disclosure of rebates, fees, alternative discounts
 - “[A]ny other information” the DOL “determines necessary for the responsible plan fiduciary to consider the reasonableness of the contract or arrangement” (but not PHI)
- **Audit Rules:** The “records of such rebates”, etc. “shall be available for audit by the plan (or the plan sponsor, issuer, or a third party designated by a plan sponsor) ... not less than once per year”

CAA 2026: New Prohibited Transaction Rules

- Rebate aggregator or other purchasing entity designed to aggregate rebates and an “applicable group purchasing organization” “shall remit such rebates” to the entity providing PBM services not later than 45 days after the end of each quarter
 - This is odd. This discusses a contract between the rebate aggregator and the PBM. But a plan / plan sponsor is not a party to that contract. So, how can the plan / plan sponsor enforce this requirement? Or know whether it’s being violated?
- TPA of a group health plan or CSP “shall make rebate contracts with rebate aggregators or drug manufacturers available for audit” by the plan

CAA 2026: New Prohibited Transaction Rules

- But, audit can require “reasonable restrictions” (as determined by the DOL) on confidentiality to prevent re-disclosure of such contracts or use of such information for unrelated purposes
- Audits carried out “shall be performed by an auditor selected by the responsible plan fiduciary”
 - May be a change for employers / plan sponsors. May need to formally document that they made their selection of the auditor as the “responsible plan fiduciary”

CAA 2026: New Prohibited Transaction Rules

- Payment for the audit cannot be made, directly or indirectly, by the entity providing PBM services
 - What if auditor and PBM routinely make payments to each other, for unrelated, other purposes?
- **Other Payments:** Contract can allow “reasonable payments” to PBMs for “bona fide services using a fee structure not described” above
 - IF fees are “transparent and quantifiable to [the] group health plan”
 - Appears designed to “tighten up” contracting process and make fees as “plain vanilla” as possible

CAA 2026: Wrap-Up

- CAA 2026 does not explicitly make PBMs or TPAs fiduciaries
- CAA 2026 does not mandate rebates at “point of sale”
- CAA 2026 does not eliminate “spread pricing”
 - Statute allows DOL to specify “other entity” in future regulation related to definition of “applicable entity”. Could DOL require all “spread pricing” revenue to be passed to plan?
- CAA 2026 does not prohibit use of related entities (e.g., PBM-owned mail order and specialty pharmacies)
- If CAA 2026 requires rebates, etc., to be provided back to plan sponsor (with no benefit to PBM) will PBM stop negotiating those?

CAA 2026: Wrap-Up

- Will plan sponsors request that their PBMs implement these disclosures early?
- What will plan sponsors do with all these new reports the PBM provides?
 - Increased fiduciary risk if plan sponsor “does nothing”?
- Expect contracts to be updated in 2028 (earlier?) for these rules
- Plan sponsors will likely ask PBMs for assistance with reports to plan enrollees
 - Put that into the contract
 - Will PBMs charge extra for those reports?
 - Will plan enrollee requests for claims-level data be sent to plan sponsor / employer? Or directly to PBM? If employer gets involved, will that lead to HIPAA / employment discrimination concerns?

Proposed PBM Disclosure Regulations



Proposed PBM Disclosure Regulations

- On January 30, 2026, the DOL released proposed regulations to increase disclosures made by PBMs
- Like CAA, regulation is based on ERISA's prohibited transaction rules
- "Covered Service Provider" ("CSP") contracts subject to proposed rule (similar to CAA 2026 CSP definition, above)
 - Term generally includes related "affiliate", "agent", "subcontractor"
- Must receive at least \$1,000 in compensation, directly or indirectly, and:
 - Provide pharmacy benefit management services or
 - Provide advice, recommendations or referrals regarding provision of pharmacy benefit management services

Proposed PBM Disclosure Regulations

- “Pharmacy benefit management services” means services necessary for the management or administration of a covered plan’s prescription drug benefits
 - Even if entity does not call itself a PBM
- Includes typical actions (e.g., processing and paying prescription drug claims)
 - Also, “Adjudicating appeals” and “performing regulatory compliance with respect to the covered plan’s prescription drug benefits under the service contract or arrangement” (e.g., medication adherence analysis)
- Also, “recordkeeping related to the covered plan’s prescription drug benefits”
 - Would that include an eligibility vendor?

Proposed PBM Disclosure Regulations

- List of information that must be provided by CSP to “a responsible plan fiduciary”
- Not later than date that is reasonably in advance of the date on which the service contract is entered into, and extended or renewed
 - 30 days in advance is deemed reasonable for extensions or renewals, but not for initial contract
 - So, how much time is needed, in advance, for initial contract?
- **(1) Services:** Description of services
- **(2) Direct Compensation** – On quarterly basis, payments from plan or plan sponsor on behalf of plan

Proposed PBM Disclosure Regulations

- **(3) Manufacturer Payments** – In aggregate and for each drug in formulary, reasonably expected “to be paid on a quarterly basis by the manufacturer or an aggregator to” CSP
- Must specify amount that will be passed on to plan / plan sponsor
 - And amount “that will be retained by” CSP
- **(4) Spread Compensation** – Describe quarterly amount expected to be received by CSP
 - Term means difference between negotiated rate expected to be paid by the plan to CSP and negotiated rate to be paid by it “for each drug on the formulary, and for each pharmacy channel (i.e., retail, mail order and specialty pharmacy)”

Proposed PBM Disclosure Regulations

- **(5) Copay Claw-Backs:** Quarterly amount of copay claw-back compensation expected to be recouped from pharmacy by the CSP
 - Term means dollar amount of difference between copayment / coinsurance amount paid to pharmacy by plan enrollee and the reimbursement to the pharmacy
 - E.g., suppose Ed's copayment for a generic drug is \$15. But PBM only pays pharmacy \$5 (less than Ed's copayment). PBM may "claw-back" from pharmacy the \$10 and keep it as additional compensation
- **(6) Price Protection Agreements:** Description of any inflation protection or price protection agreements that CSP has with drug manufacturer or other party
 - Specifying quarterly amount expected to be retained by CSP
 - And amount "that will be passed on to the plan and, if applicable, plan sponsor"

Proposed PBM Disclosure Regulations

- **(7) Compensation for Termination of Contract:** Describe any compensation that CSP expects to receive in connection with termination of contract
 - And how any prepaid amounts will be calculated and refunded upon termination
- **(8) Other Compensation:** If not covered above, describe “all compensation” CSP “expects to receive on a quarterly basis in connection with” contract
 - Identify payer of such compensation
 - Identify services for which compensation will be received
 - Describe arrangement between payer and CSP

Proposed PBM Disclosure Regulations

- **(9) Formulary Placement Incentives:** Describe any formulary placement incentives CSP has with drug manufacturers
 - And explain how incentives “affect services to and are aligned with the interest of the plan and / or its participants and beneficiaries”
 - What if those interests are NOT aligned?
 - For drugs on formulary where CSP “reasonably expects to receive any payment by the manufacturer or aggregator”, if \$ not passed through to plan, identify:
 - “Reasonably available therapeutically equivalent alternatives” and
 - Reason for omitting alternatives from the formulary
 - If CSP “retains authority to modify the formulary”, explain reasons for retaining such authority, expected frequency of changes
 - And that plan fiduciary “will be notified reasonably in advance” of modifications if change has “material impact” on CSP’s compensation
 - Means 5% or such other amount negotiated

Proposed PBM Disclosure Regulations

- **(10) Drug Pricing Methodology:** Net cost to plan of each drug on formulary, for each pharmacy channel, “expressed as a monetary amount”
- **(11) Statement of Fiduciary Status:** State whether CSP provides any services as a fiduciary
 - Disclose any activity or policy that “may create a conflict of interest”
 - E.g., if CSP “will benefit from drug substitution, from incentivizing use of affiliated pharmacies ... or from step therapy or ‘fail first’ protocols that require [plan enrollees] to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary”

Proposed PBM Disclosure Regulations

- **Brokers and Consultants:** DOL particularly concerned about “brokers and consultants” who “may receive payments from parties they are recommending”
 - Can create “high potential for conflicts of interest that warrant disclosure”
 - But is this limited to “affiliates” of CSPs (PBMs)? Apparently so
- DOL notes that brokers / consultants can be “CSPs” and be subject to these rules, including obligation to “disclose their compensation and to allow for an audit”
 - Again, though, is this only for “affiliates” of CSPs?
 - Will new expansion of CAA 2021, per CAA 2026, alter the regulation?
- **(12) Audit Rights:** State that plan has right to audit CSP

Proposed PBM Disclosure Regulations

- **Summary Report:** CSP must disclose to plan fiduciary, in writing, summary information on a semiannual basis
 - No later than 30 calendar days after end of each six-month period beginning on date contract is entered
- (1) All direct compensation, both “in the aggregate and by service”
- (2) All payments made by manufacturer or aggregator. Must include “amount passed on to the plan” (and plan sponsor) versus “amount retained by” CSP
- (3) Describe all “spread compensation” received on quarterly basis by CSP, in aggregate and for each drug on formulary, and for each channel (retail, mail order, specialty pharmacy)

Proposed PBM Disclosure Regulations

- (4) Copay claw-back compensation, on a quarterly basis, specifying the “total number of transactions”
- (5) Price protection compensation received
 - Include amount “passed on to the plan” and amount CSP retained
- (6) Other compensation, not covered above
- (7) Overage explanation: If compensation described above “materially exceeds the corresponding quarterly estimate”, identify the overage and reason for overage”
 - “Materially” means 5% or more (or lower amount under contract)

Proposed PBM Disclosure Regulations

- (8) State covered plan's right to audit
- (9) Catch-all: If requested in writing by plan fiduciary, CSP "must furnish any other information relating to the contract or arrangement that is required" for plan to comply with DOL rules (e.g., Form 5500 reporting)
- **Audit Rights:** At least once per year, CSP "shall allow for an audit" of CSP for "accuracy of any disclosure made to comply with" regulations
- Plan fiduciary "shall have the right to select the auditor"
 - CSPs cannot "select" auditor, but can they influence choice? State that auditors who work on commission basis are not allowed?

Proposed PBM Disclosure Regulations

- Information that must be produced on audit includes “contracts with retail pharmacies and drug manufacturers”
 - Subject to “reasonable confidentiality agreements to prevent redisclosure of information”
- Plan bears expenses related to selection and retention of auditor
- CSP must “confirm receipt of a request” for audit within 10 business days
- CSP cannot “impose conditions that would restrict” plan’s right to conduct an audit
 - Such as period of the audit, location of audit, number of records
 - But scope may be limited to period covered by disclosures under regulation

Proposed PBM Disclosure Regulations

- CSP is responsible for providing to auditor all records, data, etc., if owned or held by affiliate, agent, subcontractor
- **Manner of Disclosure:** Audit disclosures must be “clear and concise, free of misrepresentations” and have “sufficient specificity” to permit “evaluation of the reasonableness of” contract
 - Likely means need to define terms; no “generic industry terms” and no “jargon, or legalese”
 - Need “objectively determinable definitions, standards, or other similar guidelines” that are “publicly available” or will be provided free of charge to fiduciary

Proposed PBM Disclosure Regulations

- **Compensation Description:** Must be expressed as a monetary amount (e.g., \$1,000) and may be estimated if actual amount is not reasonably ascertainable
 - Must be “sufficient” to “permit evaluation of the reasonableness of the compensation received by” CSP
- If requested by plan fiduciary, must be provided in machine-readable file
 - Drugs “must be referred to using an industry standard name” and include “useful, non-proprietary identifier such as the National Drug Code”

Proposed PBM Disclosure Regulations

- **Confidentiality Agreements:** CSP “may not impose restrictions on the covered plan’s use of disclosures required under” regulations
 - Except, contract may require fiduciary to require third parties to whom it rediscloses such information to “execute reasonable confidentiality agreements preventing redisclosure”
- **Errors of CSP:** Must be corrected “as soon as practicable, but not later than 30 calendar days” from when CSP knows

Proposed PBM Disclosure Regulations

- **Exemption for Plan Fiduciary:** If CSP fails to meet regulation requirements, fiduciary is not liable IF:
 - (1) Fiduciary did not know about failure and fiduciary “reasonably believed” that requirements had been met
 - (2) Upon discovering error, fiduciary requests in writing that CSP correct the failure
 - (3) If CSP fails to comply within 90 calendar days of request, fiduciary notifies DOL of failure
- Notice to DOL: Include identifying information (plan name), description of error, date of correction and whether CSP is still providing services
 - Fiduciary risk to retain CSP if error occurs and report to DOL?

Proposed PBM Disclosure Regulations

- **Contract Termination:** If CSP fails to comply with written request to correct error within 90 days of notice, fiduciary “shall determine whether to terminate or continue” contract, consistent with ERISA’s prudence standard (Section 404)
 - Plan sponsors will likely build this “out” into their contract with CSP
- Will plan sponsors try to impose similar requirements on other health plan vendors (e.g., TPAs; brokers; consultants)?
 - How will they respond?
- Rules will require plan sponsors to identify who the plan’s “fiduciary” is and who should act

Proposed PBM Disclosure Regulations

- Consider creating procedures to follow
- Make sure that fiduciary is reviewing this information
 - With help of a vendor?
- And then acting upon it, if any “red flags”
- Lot of information going to plan fiduciary – but then fiduciary may need to “act” upon it, not “ignore” it
- Regulations seem to be on a “fast track”. Perhaps related to November 2026 election? Will this help prescription drug “affordability”?
- But will need to be harmonized with CAA 2026 (e.g., CSP definition just expanded in CAA 2026)
- Will July 1, 2026 effective date “slip”? Last week: Comment period date extended from 3/31/2026 to 4/15/2026

Questions?

THANK YOU!

This presentation provides information of a general nature. None of the information contained herein is intended as legal advice or opinion relative to specific matters, facts, situations or issues. Additional facts and information or future developments may affect the subjects addressed in this presentation. You should consult with a lawyer about your particular circumstances before acting on any of this information because it may not be applicable to you or your situation.