Weight Loss Drugs (GLP-1 Drugs)—Legal Issues to Consider About Health Plan Coverage of These Drugs

Date: January 28, 2025

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Overview

- Why are we discussing this?
- Basic description of GLP-1 drugs
- Applicable rules
- Possible plan designs
- Recent lawsuits

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Why Are We Talking About This?

- Plan sponsors are evaluating whether to cover the cost of these drugs under their group health plans for the treatment of obesity—and employees are asking about this
- One study found that there was a 700% increase in the number of patients without diabetes that used GLP-1s from 2019 to 2023
- Another study estimated that 9% of the US population (i.e., 30 million people) could be on a GLP-1 for weight loss by 2030
- Because of their increased use and high price, these drugs are becoming a large expense for plans that cover this drug for obesity treatment

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Why Are We Talking About This?

- When group health plans do cover this drug for the treatment of obesity, plan sponsors have noted the high costs their pharmacy benefit managers (PBMs) charge to the plans for these drugs
- For many group health plans, the PBMs are charging the plan sponsor approximately $1,200 per script, even though the PBM reimburses the dispensing pharmacy at a much lower price
- For example, the PBM charges the group health plan $1,200 for Ozempic, but reimburses the dispensing pharmacy $400
    - The $800 differential is retained by the PBM as profit from the transaction—generally referred to as "spread compensation"
- Employees may be able to obtain certain GLP-1 drugs through direct-to-consumer programs for a cost closer to $500
    - We will discuss this later in the webinar

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Why Are We Talking About This?

- According to one study, GLP-1s made up 8.4% of group health plans' pharmacy spending in 2023, an increase from 6.4% in 2022
- Some employers claim GLP-1 coverage will increase annual costs by more than 10%
- Plan sponsors are weighing the costs of covering these drugs for the treatment of obesity versus the potential long-term health benefits these drugs may offer to certain employees
- This webinar discusses possible plan designs for covering these drugs for obesity treatment

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BASIC DESCRIPTION OF GLP-1s

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What are GLP-1s?

- GLP-1s are a class of medications that help treat type-2 diabetes
- Popular GLP-1s include Ozempic, Zepbound, Mounjaro, and Wegovy
- These drugs help the body release more insulin and control blood sugar levels
- They also reduce hunger and cause an individual to feel full for a longer period of time, which is why they can be effective for weight loss
- Studies have shown that GLP-1s can help people lose up to 15% of their body weight and can minimize side effects of obesity, such as heart and kidney problems

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GLP-1 Coverage

- For this webinar, we're focusing on coverage of GLP-1s with respect to obesity treatment, not diabetes
  - Most plans already cover some GLP-1s for treating diabetes
  - Far fewer plans cover them for treating obesity or other conditions

- Some studies show that these drugs, when used for the treatment of obesity, don't decrease plan costs over the life of the plan
  - This may be due, in part, to movement of employees between employers
  - However, GLP-1s for the treatment of obesity have been shown in some studies to have a positive impact on long-term health

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GLP-1 Coverage

- We are not advocating that plans cover these drugs for obesity treatment, and we are not providing any information on the effectiveness of these drugs for treating obesity (we are not doctors)

- This webinar is to provide plan sponsors with information to think about when considering whether their group health plan should cover these drugs for treating obesity

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APPLICABLE RULES

Applicable Rules

- Before we can discuss possible plan designs, we need to review some of the relevant rules, including:
  - Definition of "Medical Care"
  - Essential Health Benefits
  - High-Deductible Health Plans (HDHPs)
  - Preventive Care
  - Health Reimbursement Accounts (HRAs)
  - Excepted Benefits

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Medical Care

- Group health plans can only cover/reimburse “medical care” on a non-taxable basis (IRC Section 213(d))

- Weight-loss programs will qualify if recommended by a medical practitioner to treat a specific medical condition (such as obesity, heart disease, or diabetes) and not simply to improve general health
  - **This is KEY!!! A weight loss drug that just assists with losing weight but not for the treatment of a medical condition, such as obesity—is not considered medical care**

- To show that the expense is primarily for medical care, a note from a medical practitioner recommending it to treat a specific medical condition is normally required to substantiate that the claim is for medical care

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Medical Care

IRS Frequently asked questions about medical expenses related to nutrition, wellness and general health contains the following:

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.

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Essential Health Benefits

- Under the Affordable Care Act ("ACA"), a group health plan cannot impose lifetime dollar limits or annual dollar limits on Essential Health Benefits ("EHBs")

- The Departments of Labor, Treasury and Health and Human Services (the "Departments") have informally stated that day or visit limits combined with specific dollar limits would be impermissible

- Sub-regulatory guidance issued by HHS notes that non-dollar limits on EHBs are permissible, so long as such limits are consistent with other applicable guidance and statutory provisions. (FAQs on Essential Health Benefits Bulletin, Q/A-10)

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Essential Health Benefits

- In addition, the ACA market reform rules require group health plans to have an out-of-pocket maximum (“OOPM”) that limits overall out-of-pocket costs (“cost-sharing”) on EHBs
- In general, cost-sharing under the ACA includes deductibles, coinsurance, copayments, or similar charges, and any other required expenditure that is a qualified medical expense with respect to EHBs covered under a group health plan
- The cost-sharing limit rules in the ACA do not apply to non-EHBs

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Essential Health Benefits

- What prescription drugs are EHBs?

- Affordable Care Act Section 1302(b): "… the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories … Prescription drugs."

- HHS Bulletin December 16, 2011: HHS intends to propose that essential health benefits are defined using a benchmark approach. Under the department's intended approach announced, states would have the flexibility to select a benchmark plan that reflects the scope of services offered by a "typical employer plan."

- 45 CFR 156.122(a): "A health plan does not provide essential health benefits unless it…covers at least the greater of: (i) one drug in every United States Pharmacopeia (USP) category and class; or (ii) the same number of prescription drugs in each category and class as the EHB-benchmark plan."

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Essential Health Benefits

- Group health plans have a lot of discretion to determine which drugs are EHBs

- Possible change to the EHB rules in the future is that all drugs on the formulary will be considered EHBs for large group health plans. (We question whether this will be the direction taken by the Trump Administration.)

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Essential Health Benefits

Proposed Notice of Benefit and Payment Parameters for 2025 and FAQ Part 66

The FAQ states, “In the proposed HHS Notice of Benefit and Payment Parameters (NBPP) for 2025 (proposed 2025 NBPP), HHS proposed to amend 45 CFR 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB…comments received in response to the EHB Request for Information issued in 2022 included a significant number of requests from interested parties to clarify the applicability of this policy in rulemaking, particularly as it relates to some plans in the individual, small group, and large group markets that have developed programs to provide coverage of some drugs as ‘non-EHB,’ outside of the terms of the rest of the coverage. After consideration of comments on the proposed 2025 NBPP, HHS is finalizing the amendment to 45 CFR 156.122 in the final HHS NBPP for 2025 (final 2025 NBPP) with respect to issuers of non-grandfathered individual and small group market plans that are subject to the requirement to provide EHB.”

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High Deductible Health Plans (HDHPs) and Health Savings Accounts (HSAs)

- To be an eligible individual for HSA purposes, an individual must be covered by a qualifying HDHP and have no other impermissible coverage
- An HDHP is a health plan that meets the statutory requirements for annual deductibles and out-of-pocket expenses and provides significant benefits
- To be eligible to make or receive HSA contributions, an individual generally cannot have health coverage other than HDHP coverage—meaning that the individual cannot be covered by any health plan that provides coverage below the statutory minimum HDHP deductible
- There are several exceptions, such as for preventive care and excepted benefits

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Preventive Care

- There are 2 sets of rules for preventive care
- The first one is under the ACA and it dictates benefits that must be offered under a group health plan at no cost
- The second one is a tax rule in the Internal Revenue Code that relates to HDHPs/HSAs

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Preventive Care—the ACA Rules

- Under the ACA market reform rules, group health plans must provide certain preventive services without imposing any cost-sharing
- This means that deductibles, copays, coinsurance, or other cost-sharing may not be imposed on these services
- There are specific statutory and regulatory guidance on what is considered preventive care for the ACA
- Mandatory preventive care does not include weight-loss drugs for the treatment of obesity

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Preventive Care—HDHP/HSA Rules

- A plan that applies no deductible to its coverage of preventive care does not fail to qualify as an eligible HDHP (Internal Revenue Code §223)
- Preventive care for this rule includes all of the preventive care mandated by the ACA market reform rules plus other items listed in IRS guidance
- Of importance to this webinar, drugs for the treatment of obesity that are offered as part of a weight-loss program may be considered preventive care, if the applicable rules are met
- This guidance opens the door for plans to cover weight-loss drugs for the treatment of obesity prior to meeting the deductible of a HDHP

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Preventive Care—HDHP/HSA Rules

IRS Notice IRS Notice 2004-50 states the following:

Q-27. To what extent do drugs or medications come within the safe-harbor for preventive care services under section 223(c)(2)(C)?

A-27. Notice 2004-23 sets out a preventive care deductible safe harbor for HDHPs under section 223(c)(2)(C). Solely for this purpose, drugs or medications are preventive care when taken by a person who has developed risk factors for a disease that has not yet manifested itself or not yet become clinically apparent (i.e., asymptomatic), or to prevent the reoccurrence of a disease from which a person has recovered…In addition, drugs or medications used as part of procedures providing preventive care services specified in Notice 2004-23, including obesity weight-loss and tobacco cessation programs, are also preventive care. However, the preventive care safe harbor under section 223(c)(2)(C) does not include any service or benefit intended to treat an existing illness, injury, or condition, including drugs or medications used to treat an existing illness, injury or condition.

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Stand-Alone HRAs

- In general, employees cannot be enrolled in a stand-alone HRA, because on their own, HRAs cannot meet the market reform requirements of the ACA (such as no lifetime limits or covering all mandated preventive care at no cost)
- There are some exceptions to this rule such as retiree-only HRAs or ICHRAs (individual coverage HRAs)
  - We do not discuss the requirements applicable to these exceptions in this webinar
- An HRA can be exempt from the ACA market reform rules if it is an excepted benefit
- Alternatively, an HRA can meet the requirements of the ACA market reform rules if it is considered "integrated" with a major medical plan that provides minimum value

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Excepted Benefit HRAs

- An HRA structured to provide only HIPAA-excepted benefits may be exempt from compliance with the ACA market reform rules

- This includes health plans that provide only:
  - limited-scope dental benefits;
  - limited-scope vision benefits;
  - benefits for long-term care, nursing-home care, home care, or community-based care; and
  - other similar, limited benefits specified in the regulations

- HHS has stated that an HRA that covers prescription drugs is not an excepted benefit and a 2015 federal court decision agreed with HHS. (*Seabrook v. Obama*, (S.D.N.Y. 2015))

- We believe that an HRA that only covers prescription weight-loss drugs for the treatment of obesity cannot be considered an excepted benefit

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Integrated HRAs

- An "integrated" HRA can meet the ACA market reform rules

- Basic rules for an integrated HRA (Treas. Reg. §54.9815-2711(d)):
  - **(A)** The plan sponsor offers a group health plan (other than an HRA or other account-based group health plan) to the employee that provides minimum value;
  - **(B)** The employee receiving the HRA is actually enrolled in a group health plan, regardless of whether the plan is offered by the plan sponsor of the HRA (such as the group health plan of the spouse);
  - **(C)** The HRA is available only to employes who are actually enrolled in non-HRA minimum value group coverage; and
  - **(D)** Under the terms of the HRA, an employee is permitted to permanently opt out of and waive future reimbursements from the HRA at least annually, and, upon termination of employment, either the remaining amounts in the HRA are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA

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POSSIBLE PLAN DESIGNS

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Option #1—Limit Coverage to Type-2 Diabetes

- A group health plan could limit covering GLP-1 drugs to treatment of type-2 diabetes only
- It could include strict prior authorization requirements (such as periodic blood tests) and audits to ensure that these requirements are met
- This is the most restrictive plan design
- Consider if this is a violation of nondiscrimination laws
  - We will discuss this issue later in the webinar
  - The short answer is that it is not clear

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Option #2—Permit Coverage With Limitations

- A group health plan could cover GLP-1s for the treatment of obesity, but add limitations such as the following:
  - Require prior authorization where certain criteria must be met before the plan will cover the GLP-1 drugs for the treatment of obesity (e.g., working with a comprehensive weight management program for 6 months)
  - Only covering GLP-1 drugs indicated by the FDA for "weight loss without diabetes" (i.e., covering Zepbound and Wegovy, but not Ozempic and Mounjaro)
  - Requiring the participant to participate in the employer's lifestyle management programs in tandem with getting the GLP-1 medication for obesity

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Option #2—Permit Coverage With Limitations

- If GLP-1s for the treatment of obesity are not considered EHBs, then additional limitations can apply, because the ACA cost-sharing limits do not apply
- This means that a plan could provide that it would only pay 50% of the drug, and the other 50% must be paid by the participant—and those amounts paid by the participant never accumulate to the OOPM
- It also seems that a plan could provide that weight-loss drugs for the treatment of obesity are only covered for a period of time (like 1 year) or if a person has a BMI over 35

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Option #3—HRA for Weight-Loss Drugs Only

- For employees (and their dependents) who are also covered under a group health plan, the employer could offer an HRA that only reimburses weight-loss drugs for the treatment of obesity
- This design should be permitted under the integration rule described earlier
- These reimbursements could be provided prior to meeting the deductible if the weight loss drugs to treat obesity meet the requirements for preventive care under the HDHP rules

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Option #4—HRA for Weight-Loss Drugs Only—DTC Programs

- Could an HRA just reimburse the cost of weight-loss drugs for the treatment of obesity that are received directly by the participant from a pharmaceutical company?
- Eli Lilly has launched a direct-to-consumer (DTC) program for certain weight-loss drugs
- The Eli Lilly online platform offers Zepbound to treat obesity
  - It is coupled with a telehealth program to connect users with healthcare professionals who can prescribe medications that can be delivered to the home
- This program cuts out the PBMs and in general, the drugs costs over 50% less than what is being charged by PBMs for this same drug

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Option #4—HRA for Weight-Loss Drugs Only—DTC Programs

Some Cautions:

- #1 – Almost all PBM agreements contain an exclusivity provision—meaning that the employer agrees that its health plans will only cover drugs that are provided through the PBM
    - If this provision is violated, the PBM can renege on all of the price guarantees in the agreement
- #2 – Most PBM agreements also contain a provision that if certain drugs are removed from the formulary, the PBM has the right to renegotiate all of the drug pricing provisions in the agreement

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Option #4—HRA for Weight-Loss Drugs Only—DTC Programs

- If an employer wants to remove GLP-1s for the treatment of obesity from its formulary, it will likely only be able to do so during an RFP
- It is possible that the PBMs will increase the “spread compensation” on other drugs to make up for the loss of revenue on these drugs

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Side Note

- Will drug companies offer more DTC programs? If so, how will this impact group health plans?

- Right now, the DTC programs are only being offered for a limited number of drugs
  - We assume that this is being done because the drug companies do not want to get crosswise with the PBMs, who could remove their other drugs from the formulary

- It will be interesting to see if the PBMs take any actions against drug companies for offering these DTC programs

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RECENT LITIGATION

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Recent Litigation—ACA Section 1557

- Two cases have been filed against insurance carriers/third-party administrators for excluding coverage of weight loss drugs that treat obesity in health plans—when those same plans cover those drugs for the treatment of diabetes

- The claims in the cases are based on Section 1557 of the Affordable Care Act

- The next few slides provide an overview of how Section 1557 could apply to a group health plan

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ACA Section 1557

- Section 1557 is the ACA's primary anti-discrimination provision
- It prohibits health programs or activities that receive federal funds from discriminating based on race, color, national origin, age, disability, or sex
- An individual cannot be excluded from participation in, denied the benefits of, or subjected to discrimination on these bases

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ACA Section 1557

- Section 1557 incorporates existing federal civil rights laws and applies them to federally funded health programs. The prohibited grounds for discrimination are specified by:
  - Title VI of the Civil Rights Act of 1964 (“Title VI”) with respect to race, color, national origin
  - Title IX of the Education Amendments of 1972 (“Title IX”) with respect to sex
  - The Age Discrimination Act of 1975 (“Age Act”) with respect to age, and
  - Section 504 of the Rehabilitation Act of 1973 (“Section 504”) with respect to disability

- The statute incorporates the enforcement mechanisms under those laws for purposes of violations under Section 1557

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ACA Section 1557

- Section 1557 does not apply to self-insured ERISA group health plans so long as (or to the extent) they do not receive funding from HHS

- However, other entities that contract with a group health plan may be covered by Section 1557 (i.e., third-party administrators)

- This was discussed in *C.P. v. Blue Cross Blue Shield of Ill., 2022 WL 17788148 (W.D. Wash. 2022)*

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ACA Section 1557

- The preamble of the April 2024 final rule provides the following guidance on the scope and application of the rule:
  - Scope of the Rule. "A recipient of Federal financial assistance that is principally engaged in the provision or administration of health insurance coverage is covered under this rule for **all of its operations…**This position is also supported by a decision of the District Court for the Western District of Washington, which held that third party administrators operated by health insurance issuers are subject to section 1557 even if the third-party administrators do not receive Federal financial assistance."

- TH Comment—Assume that XX insurance carrier is subject to Section 1557 because it sells Medicare supplemental coverage and receives Federal financial assistance. The third-party administrator (TPA) arm of XX insurance company is also subject to Section 1557

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ACA Section 1557

- The preamble also discusses how this works when the TPA is covered by Section 1557, but the employer is not:
  - “When analyzing a claim against a covered third party administrator, OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the third party administrator, group health plan, or the plan sponsor.”

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ACA Section 1557

"Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, OCR will process the complaint against the covered third party administrator because it is the entity responsible for the decision or other action being challenged. For example, if a covered third party administrator applies a plan's neutral, nondiscriminatory utilization management guidelines in a discriminatory way against an enrollee, OCR will proceed against the covered third party administrator as the entity responsible for the decision. In addition, OCR will pursue claims against a covered third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer."

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ACA Section 1557

- "Where the alleged discrimination relates to the benefit design of self-insured group health plan coverage that did not originate with the covered third party administrator, but rather with the plan sponsor or the group health plan, and where the third party administrator played no role in the development of the plan's benefit design, OCR will refer the complaint to the EEOC or DOJ for potential investigation."

- TH Comment: If the employer-sponsored plan has nondiscriminatory provisions, but it is administered in a discriminatory manner, that Section 1557 claim will be against the TPA. If the TPA gave the plan sponsor a plan provision that was discriminatory, and the TPA was responsible for the design feature, that Section 1557 claim will be against the TPA. If it's the employer's fault (i.e., the employer included a discriminatory design in the health plan), OCR will refer that to the EEOC as a potential claim.

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ACA Section 1557—The Complaints: *Whittemore v. CIGNA*

- A class action lawsuit was filed in a federal district court alleging that CIGNA engaged in disability discrimination in violation of Section 1557 for failing to cover GLP-1s for obesity treatment under certain health plans it administered. *Whittemore v. CIGNA* (June 4, 2024)
  - The complaint was filed in the United States District Court for the District of Maine

- The plaintiff in this case was a participant in an employer-sponsored health plan administered by CIGNA
  - The plaintiff was diagnosed with obesity by her doctor, and was prescribed Zepbound
  - The request to cover her Zepbound treatment was denied because the drug was not covered by the plan for obesity treatment
  - The plan excluded coverage for all "medical and surgical services intended primarily for the treatment or control of obesity"
  - The complaint refers to this as the "Obesity Exclusion"

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ACA Section 1557—The Complaints: *Whittemore v. CIGNA*

- Although these GLP-1s were covered under certain other plans administered by CIGNA for the treatment of various diseases, they were excluded under the plaintiff's plan for the treatment of obesity
- The complaint alleged that obesity is a disability under Section 1557 and that CIGNA's exclusion of GLP-1s for obesity treatment constituted disability discrimination
- The plaintiff alleges that because the drugs are excluded only if prescribed for obesity but are covered when used for another condition (namely diabetes), the plan violates Section 1557 by treating one disease or disability differently from another
- A motion to dismiss was filed, which is currently pending

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ACA Section 1557—The Complaints: *Holland v. Elevance Health, Inc.*

- A similar class action lawsuit was filed several months later against Elevance Health (Anthem). *Holland v. Elevance Health, Inc.* (Sept. 20, 2024)
  - This complaint was also filed in the United States District Court for the District of Maine
- The complaint alleged that Anthem's exclusion of GLP-1s for treating obesity—when the drug was covered for the treatment of other diseases—was disability discrimination under Section 1557
- A motion to dismiss is currently pending

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ACA Section 1557—The Complaints

- It is unclear whether obesity will be considered a disability under Section 1557
  - Courts are mixed on whether obesity is a disability under the Americans with Disabilities Act (ADA)
  - Most federal courts have held that obesity is not a disability under the ADA unless it is caused by an underlying health condition (such as diabetes)
  - However, some federal district courts have held that obesity is a disability even absent evidence of an underlying health condition

- If the exclusion of GLP-1s for the treatment of obesity—when covered for type-2 diabetes—is considered a violation of Section 1557, we will likely see the insurance carriers and TPAs require plan sponsors to either: (1) cover these drugs for both type-2 diabetes and obesity; or (2) not cover the drugs for any disease

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Action Items

- If the plan sponsor wants to cover GLP-1s for the treatment of obesity, evaluate the increased cost to the plan of covering those drugs
- Consider possible plan designs that could limit the costs and ensure that the drugs are used for the treatment of obesity—and not general weight loss
- If considering the direct-to-consumer HRA design, review the PBM contract to understand the impact of offering that product
- Watch for updates on how the Section 1557 cases are resolved

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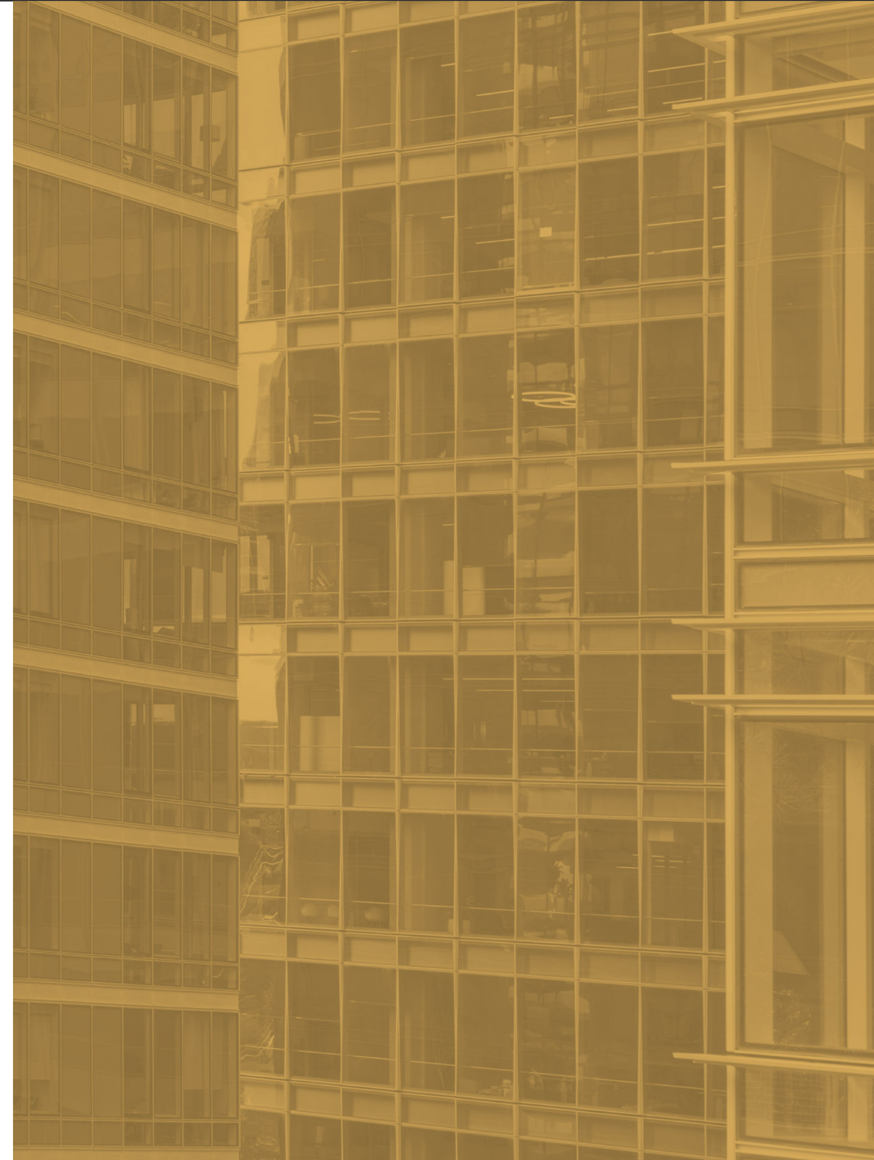

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