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To: Health and Welfare Trust Fund Clients

From: Saltzman & Johnson

Date: February 3, 2025

Re: Compliance Updates

This memorandum concerns legal updates that apply to health and welfare trust fund clients. A brief summary of the changes, effective dates and the potential future action by the Trump Administration is below.

Legislative or Regulatory Change	**Effective Date of Changes**	**Trump Administration Outlook**
Mental Health Parity and Addiction Equity Act – New Final Regulations Outlines requirements for NQTL Comparative Analysis	Some changes are effective January 1, 2025, while others are effective January 1, 2026.	Final rule may be withdrawn or revised by Departments under Trump Administration
ACA 1557 –Nondiscrimination in Health Benefits New Final Regulations Changes to discrimination in health care and language accessibility	Various effective dates for different provisions from 2024 to 2025.	Likely to be withdrawn or revised by Departments under Trump Administration. Precursor of the new final rule previously revised during Trump 1.0 Administration.
Support Reproductive Health Care Privacy Sets requirements for privacy regarding reproductive health	Generally effective December 23, 2024. New Notice of Privacy Practices due February 16, 2026.	Likely to be withdrawn or revised by Departments under Trump Administration.

1. Mental Health Parity and Addiction Equity Act – New Final Regulations

The Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") prevents group health plans that provide mental health and substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical coverage. The 2013 Final Regulations set parity standards for quantitative treatment limits (financial and treatment

limitations) and parity with respect to non-quantitative treatment limits (e.g., prior authorization, medical management). Plans are not required to cover mental health or substance abuse benefits, but if covered, plans must cover in every classification where medical/surgical benefits are provided.

The Consolidated Appropriations Act, 2021 ("CAA") was signed into law on December 27, 2020. As part of CAA, group health plans are required to perform and document comparative analyses of the design and application of nonquantitative treatment limitations (NQTLS). Plans were required to be prepared to make these comparative analyses available to the DOL upon request by February 10, 2021 (45-days after the enactment of the CAA).

On September 23, 2024, the Departments issued final regulations ("Final Rule") concerning the content on comparative analyses of the design and application of NQTLs. Below is brief summary of new requirements under the Final Rule.

The Final Rule provides:

- List of non-exhaustive examples of NQTLS[1]:
    - Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether treatment is experimental or investigational;
    - Formulary design for prescription drugs;
    - For plans with multiple network tiers, network tier design;
    - Methods for determining out-of-network rates;
    - Step-therapy;
    - Failure to complete a course of treatment exclusions;
    - Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage;
    - Network composition, including:
        - Standards for provider and facility admission to participate in a network or for continued network participation
        - Methods for determining reimbursement rates
        - Credentialing standards
        - Procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan
- List of NQTLs – plans must have a list of NQTLs applicable under the plan, which can be requested by the DOL or HHS.[2]

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1 29 CFR 2590.712(c)(4)(ii).
2 29 CFR 2590.712-1(c).

- Data Collection – plans and issuers must collect and evaluate data and take reasonable action, as necessary, to address material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, where the relevant data suggest that the NQTL contributes to material differences in access.[3] The Departments may issue guidance on the collection and evaluation of data required.[4]
- Meaningful benefit requirement – New requirement to provide core treatments with respect to mental health and substance abuse benefits in classifications where Medical/Surgical benefits are provided.[5]
- Prohibition on discriminatory factors and evidentiary standards: Prohibit plans and issuers from using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to mental health and substance use disorder benefits when designing NQTLs.[6]
- Certification by Fiduciary: New requirement to have fiduciary certification in writing to prudent selection and monitoring of one or more qualified service providers to perform and document a NQTL analysis.[7]
- Plan Document – NQTL Comparative Analysis is an instrument of the plan, which can be requested by participants and beneficiaries of the plan.[8]
- Deadlines for DOL Requests –
    - 10 Business Days to respond to an initial request.[9]
    - 10 Business Days when an initial response is found insufficient and DOL requests supplemental information.[10]
    - 7 days to notify participants and beneficiaries when a final determination of noncompliance is issued. [11]
- **Effective Date:**
    - Rules apply to Plans first day of first plan year starting on or after January 1, 2025.[12]
    - Meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data and collection evaluation requirements, and the related requirements in the provisions for comparative analyses, which

3 29 CFR 2590.712(c)(4)(iii).
4 *Id*.
5 29 CFR 2590.712(c)(2)(ii)(A).
6 29 CFR 2590.712(c)(4)(i)(B).
7 29 CFR 2590.712-1(c)(6)(vi).
8 29 CFR 2590.712-1(e).
9 29 CFR 2590.712-1(d).
10 29 CFR 2590.712-1(d).
11 29 CFR 2590.712-1(d).
12 29 CFR 2590.712(i)(1)(i).

apply on the first day of the first day of the first plan year beginning on or after January 1, 2026.[13]

New Administration and Updates

The Consolidated Appropriations Act of 2021 was passed with bipartisan support during Trump's first term. However, this regulation may be changed or revoked in a Trump administration. On January 20, 2025, President Trump issued an Executive Order for all federal agencies to not propose or issue any rules until a Trump appointee reviews and approves the rule.

On January 17, 2025, the ERISA Industry Committee (ERIC) today filed a Complaint against the Departments, seeking to invalidate the Final Rule issued under MHPAEA and the Consolidated CAA. ERIC's lawsuit alleges that the Final Rule is unlawful in numerous respects. The Final Rule exceeds the Departments' authority under the MHPAEA and CAA, violates the Due Process Clause of the Fifth Amendment, is arbitrary and capricious, and otherwise violates the Administrative Procedure Act. ERIC's lawsuit also alleges that the January 1, 2025, effective date for many of the Final Rule's provisions is arbitrary and capricious because it did not leave enough time for plans to come into compliance with the entirely new, vaguely worded regulations.

2. Affordable Care Act Section 1557 – Nondiscrimination in Health Benefits

On April 24, 2024, the Office of Civil Rights ("OCR") issued a new final regulation under Section 1557 of the Affordable Care Act (ACA) concerning protections against discrimination in health care.

Rule:

- Prohibits an individual from discriminating on the basis of race, color, national origin, sex, age, disability, or any combination thereof, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.[14]
- Effective for plan years beginning on or after January 1, 2025, health plans cannot exclude, or limit services related to gender affirming-care (gender dysphoria).[15]

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[13] 29 CFR 2590.712(i)(1)(i).
[14] 42 CFR Part 92.101.
[15] 42 CFR Part 92.206. The enforcement of this provision has been stayed nationwide by district court case: *Tennessee v. Becerra* 2024 U.S. Dist. LEXIS 119525 (S.D. Miss. Jul. 3, 2024).

Covered Entity:

- Applies to every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Federal government, namely Retiree Drug Subsidies ("RDS") from Medicare.[16]

Policies and Procedures: Covered entities must have policies and procedures to:

- Section 1557 Coordinator[17]
- Written policies and procedures[18]
- Training[19]
- Notice of nondiscrimination –
    - must be provided annually and upon request to participants, beneficiaries, enrollees, and applicants
    - Must be available on website in conspicuous location
    - May be combined with other civil rights notices[20]
- Notice of availability of language assistance and auxiliary aids and services[21]
- Accessibility requirements for disability and languages
- Notice must be provided in English and at least 15 languages most commonly spoken by individuals with limited English proficiency of the relevant states in which a covered entity operates and must be provided in alternate formats for individuals with a disability who require auxiliary aids.
- Must be included in most other plan notices.[22]

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[16] 42 CFR Parts 92.1(a) and 92.2.
[17] 42 CFR Part 92.7.
[18] 42 CFR Part 92.8.
[19] 42 CFR Part 92.9.
[20] 42 CFR Part 92.10.
[21] 42 CFR Part 92.11.
[22] 42 CFR Part 92.11(c)(5). The Notice of Availability must be provided in the following electronic and written communications when these forms are provided by a covered entity:

(i) Notice of nondiscrimination required by § 92.10;
(ii) Notice of privacy practices required by 45 CFR 164.520;
(iii) Application and intake forms;
(iv) Notices of denial or termination of eligibility, benefits or services, including Explanations of Benefits, and notices of appeal and grievance rights;
(v) Communications related to an individual's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;
(vi) Communications related to a public health emergency;
(vii) Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);
(viii) Discharge papers;
(ix) Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B-6 of the Public Health Service Act;

- Individuals can opt out of receiving this notice.
- No more "taglines" from prior rule.

Effective Date:

- General Effective Date: July 5, 2024
- Designate 1557 Coordinator: November 2, 2024.
- Health Benefit Changes, including treatment for gender dysphoria: First day of plan year beginning on or after January 1, 2025.
- Implement Policies and Procedures: July 5, 2025.
- Training: No later than 30 days following implementation of procedures, and no later than May 1, 2025.
- Notice of Availability (Language Assistance and Auxiliary Aids and Services): July 5, 2025.[23]

New Administration

This regulation may be changed or revoked in a Trump administration. On January 20, 2025, President Trump issued an Executive Order for all federal agencies to not propose or issue any rules until a Trump appointee reviews and approves the rule.

3. HIPAA Privacy Rule Update

On April 22, 2024, the HHS Office of Civil Rights (OCR) published a HIPAA Privacy Rule to Support Reproductive Health Care Privacy ("Rule"). The Rule prohibits the use or disclosure of protected health information (PHI) related to lawful reproductive health care in certain circumstances.

The Rule requires a health plan to obtain a signed attestation that certain requests for PHI potentially related to reproductive health care are not for purpose of investigate or impose liability on individuals, health care providers or others who seek to obtain, provide or facilitate law reproductive care. [24] Plans will need to update their HIPAA Policies, Training and Notice of Privacy Practices.[25]

(x) Complaint forms; and
(xi) Patient and member handbooks.

[23] 42 CFR Part 92.1(b).
[24] 45 CFR Part 164.502(a)(5) and 164.509.
[25] 45 CFR Part 164.520.

Effective date:

- Generally effective December 23, 2024.
- New Notice of Privacy Practices due February 16, 2026.[26]

New Administration

This regulation may be changed or revoked in a Trump administration. On January 20, 2025, President Trump issued an Executive Order for all federal agencies to not propose or issue any rules until a Trump appointee reviews and approves the rule.

In *Purl v. United States Department of Health and Human Services,* 2024 WL 5202497, (N.D. Tex. 2024), a district court in Texas issued a preliminary injunction from enforcing the Reproductive Health Privacy Rule against the health providers who brought this lawsuit. In that case, the federal judge determined that Dr. Purl has at least a "reasonably probable chance" of prevailing in her lawsuit alleging that HHS exceeded its statutory authority under HIPAA when it published the 2024 Reproductive Privacy Rule.

4. Consolidated Appropriations Act of 2021 – No Surprises Act and Transparency in Coverage

a. Texas case – Challenge to use of Qualifying Payment Amount in Independent Dispute Resolution

As a reminder, effective January 1, 2022, the No Surprises Act ("Act") prohibits out-of-network providers from balance billing patients in cases of surprise out-of-network bills (limited to services provided by emergency room, air ambulance, and out-of-network providers at in-network facilities). Health plans must treat these out-of-network services as if they were in-network when calculating patient cost-sharing. The No Surprises Act also requires a new binding independent dispute resolution ("IDR") process to determine how much health plans must pay out-of-network providers for these surprise bills. If an out-of-network provider disagrees with a health plan's payment, it can initiate IDR.

The IDR process is a "baseball-style" arbitration. The provider and insurer each submits a proposed payment amount and explanation to the arbitrator.[27] The arbitrator must select one of the two proposed payment amounts "taking into account considerations specified in the [Act]."[28] The Act provides that the arbitrator shall consider:

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[26] https://www.federalregister.gov/d/2024-08503/p-5

[27] 42 U.S.C. § 300gg-111(c)(1)(B).

[28] 42 U.S.C. § 300gg-111(c)(5)(A).

- The Qualifying Payment Amount ("QPA"), which is generally the median of the contracted rates[29], for item or service provided in the same geographic area;
- The level of training, experience, and quality and outcomes measurements of the provider or facility;
- The market share held by non-participating provider or facility or that of the plan or issuer in the geographic area;
- The acuity or complexity of the individual receiving such item or service;
- The teaching status, case mix and scope of services of the nonparticipating facility; and
- Demonstrations of good faith made by the nonparticipating provide or facility or the plan or issuer to enter into network agreement between the provider and the facility and the plan or issuer during the previous 4 plan years.[30]

The arbitrator's selection of a payment amount is binding on the parties and is not subject to judicial review.[31] The Departments of Labor, Health and Human Services and the Treasury (the Departments") issued an interim final rule implementing the IDR process, which provided that the arbitrator must select the proposed payment amount closest to the QPA, unless the arbitrator determines that credible information submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.[32] The interim final rule effectively creates a "rebuttable presumption" that the payment amount closest to the QPA is the proper payment amount.[33]

A federal judge in Texas struck down certain parts of the interim final rule implementing the IDR process for determining the payment for services by out-of-network providers, finding that the regulations conflict with the language of the Act.[34] The judge found in favor of the Texas Medical Association, challenging that the IDR process should presume the QPA (median in-network rate) is the appropriate out-of-network rate.

In response to the district court's ruling, the Departments issued a memorandum clarifying that the Texas court decision did not affect any of the Departments' other rulemaking under the No Surprises Act. Therefore, consumers continue to be protected from surprise bills for out-of-network emergency services, out-of-network air ambulance services, and certain out-of-network services received at in-network facilities.[35] The Departments revised the interim final rule ("Final Rule") to take into consideration the court's ruling. On August 19, 2022, the Departments issued a final rule in response to the court's ruling, providing that arbitrators should

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29 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I)-(II).
30 42 U.S.C. § 300gg-111(c).
31 42 U.S.C. § 300gg-111(c)(5)(E).
32 45 CFR § 149.510(c)(4)(ii).
33 See 86 Fed. Reg. at 56, 56-61.
34 *Tex. Med. Ass'n v. United States HHS*, 587 F. Supp. 3d 528 (E.D. Tex. Feb. 23, 2022), *appeal dismissed* 2022 U.S. App. LEXIS 310150 (5th Cir. Oct. 24, 2022)(TMA I).
35 Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act/memorandum-regarding-continuing-surprise-billing-protections-for-consumers

start with the Qualifying Payment Amount, and then must review all additional permissible information submitted by each party to determine which offer best reflects the appropriate out-of-network rate.[36] The Final Rule was effective October 25, 2022.[37]

The Final Rule, among other things, sets out three procedures which arbitrators must follow in assessing which offer best reflects the value of the services at issue:[38]

1) The Arbitrator must consider the QPA and then consider information regarding the additional statutory factors.[39]
2) In considering additional evidence beyond the QPA, the arbitrator "should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount…or it is already account for by the [QPA].[40]
3) If the Arbitrator relies on information beyond the QPA, the arbitrator's written decision "must include an explanation of why the [arbitrator] concluded that this info was not already reflected in the [QPA].[41]

The Texas Medical Association challenged the above provisions of the Final Rule and alleged that the Departments lacked statutory authority to promulgate these three aspects of the arbitration process. [42] The district court ruled in favor of the Texas Medical Association, agreeing that the challenged portions of the Final Rule were unlawful and must be set aside. The Fifth Circuit affirmed the decision of the district court vacating provisions of the Final Rule.[43] The Appellate Court first explained that the Final Rule conflicts with the No Surprises Act as the Act did not give the Departments authority to weigh one factor or circumstance more heavily than the others nor does the Act authorize the Departments to superimpose regulatory rules on the clear statutory mandate only to establish an independent dispute resolution process. The Court further explained that the Departments exceeded their authority by infringing on arbitrators' discretion to balance the statutory factors as Congress has provided that it is not the Departments, but the arbitrator, who "shall consider" how to balance the factors under the statute.[44]

Further, the Fifth Circuit provided the below reasonings in reaching its decision that the Final Rule *exceeds* the Departments' authority as it overly imposed the above-mentioned three extra statutory requirements on the arbitrators:

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36 87 Fed. Reg. 52618.
37 *Id.*
38 *Id.*
39 87 Fed. Reg. 52627.
40 87 Fed. Reg. 52628; 52634.
41 87 Fed. Reg. 52632.
42 *Tex. Med. Ass'n v. United States HHS*, 654 F.Supp.3d 575 (E.D. Tex. Feb. 6, 2023)(TMA II).
43 *Tex. Med. Ass'n v. United States HHS*, 110 F.4th 762 (5th Cir. Aug. 2, 2024)(TMA II).
44 *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i)

(1) The Appellate Court explained that Congress gave no instruction to the arbitrator to consider the QPA first *before* other factors.[45] By requiring the arbitrators that they *must* consider the QPA before all other factors, the Departments place a thumb on the scale in favor of the insurer determined QPA in derogation of the other congressionally mandated factors. It would distort the statutory scheme for the Departments to impose such an extra statutory requirement here.[46]

(2) The No Suprises Act states that the arbitrators "shall consider" the "additional" factors and Congress did not soften this "mandatory duty" with any qualifying language.[47] The Final Rule mandates arbitrators to consider QPA *first* from the other factors distorting the judgment Congress directed the arbitrators to make. Congress imposed on the arbitrators a mandatory duty to consider all the factors listed in the statute which give preference to none.[48]

(3) The Final Rule violates the No Suprises Act by imposing an explanation requirement. The Final Rule states that if the arbitrator relies on information about the non-QPA factors in selecting an offer, the written decision must include an explanation of why the arbitrator concluded that this information was not already reflected in the QPA.[49] The Appellate Court explained that the arbitrator is under no obligation to explain why he/she chooses the QPA for reimbursement as this unequal burden tends to bias outcomes in favor of the offer closest to the QPA. Although Congress has required the Departments to report how often reimbursements exceed the QPAs, 42 USC 300gg-111(c)(7)(A)(v), B(iv), the reports *need not* explain why this is so, nor is there any requirement for the Departments' reports to reference explanations only when a non-QPA reimbursement is chosen.[50]

Based on the reasons foregoing above, the Fifth Circuit affirmed the District Court's judgment vacating the arbitration provisions at issue of the Final Rule.

In a third action the Texas Medical Association challenged the Department's regulations governing how insurers calculate the QPA, the sufficiency of disclosure requirements to review insurers' calculations. [51] In addition, air ambulance plaintiffs challenged the arbitration and payment procedures for air ambulances. [52] The court found in favor of the Texas Medical Association, finding that the certain challenged portions of the July 1, 2021 Rule and subsequent

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45 *Tex. Med. Ass'n v. United States HHS*, 2024 WL 3633795, pg. 9-10.
46 *Id*.
47 *Tex. Med. Ass'n v. United States HHS*, 2024 WL 3633795, pg. 10; *see* 42 U.S.C 300gg-111(c).
48 *Tex. Med. Ass'n v. United States HHS*, 2024 WL 3633795, pg. 10.
49 *Id.*, pg. 11.
50 *Id*.
51 *Tex. Med. Ass'n v. United States HHS*, 2023 U.S.Dist.LEXIS 149393 (E.D. Tex. Aug 24, 2023)(TMA III).
52 *Tex. Med. Ass'n v. United States HHS*, 2023 U.S.Dist.LEXIS 149393 (E.D. Tex. Aug 24, 2023)(TMA III).

guidance conflict with the No Surprises Act and must be set aside. [53] The district court vacated the following:

- Portions of the QPA methodology, including counting rates for all items and services regardless of the number of claims paid; using book of business rates instead of each plan's rates; rules governing calculation of QPA for providers in the same or similar specialty, exclusion of bonus, incentive and risk sharing payments, and exclusion of single case agreements.
- The "clean claim"[54] rule for air ambulance services, which states that the 30-day initial payment period starts when the plan has a clean claim.[55]

The district court held that the disclosure requirements were not arbitrary and capricious.

On appeal, the Fifth Circuit reversed the district court's vacatur of the QPA-calculation provisions, but affirmed the vacatur of the deadline provisions, and affirmed the district court's holding that the disclosure requirements are not arbitrary and capricious.[56]

New Administration

The No Surprises Act was passed with bipartisan support during Trump's first term. However, how out-of-network providers are reimbursed under the NSA may be changed in a Trump administration. On January 20, 2025, President Trump issued an Executive Order for all federal agencies to not propose or issue any rules until a Trump appointee reviews and approves the rule.

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53 *Tex. Med. Ass'n v. United States HHS*, 2023 U.S.Dist.LEXIS 149393 (E.D. Tex. Aug 24, 2023)(TMA III).

54 Clean claim rule refers to the practice that a claim is not considered final until the health plan receives the information necessary to decide a claim for payment for such services.

55 *Tex. Med. Ass'n v. United States HHS*, 2023 U.S.Dist.LEXIS 149393 (E.D. Tex. Aug 24, 2023)(TMA III).

56 *Tex. Med. Ass'n v. United States HHS*, 2024 U.S.App.LEXIS 27568 (5th Cir. Oct. 30, 2024)(TMA III).