EBEC EXPO2024

Proskauer's Perspective on Employee Benefits, Executive Compensation and ERISA Litigation

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Health Plans in the Hot Seat: Practical Advice on Navigating New Legislation, Regulation and Litigation

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Health Plans in the *Hot* Seat

- Plans wrestling with impact of legislation passed in the last few years
  - Transparency requirements and disclosures
  - No Surprises Act (and continued litigation regarding implementation)
- Increased regulatory activity
  - Mental health parity proposed regulations
  - Implementation of final rules on transparency
  - Agency focus on copayment assistance and copayment maximizer programs
- New litigation brought against plans and providers
  - Focus on ERISA fiduciary responsibility, service provider compensation

Overview of Topics

- Mental health parity
  - Proposed regulations
- Implementation of surprise billing rules
  - Overview of rules
  - Rocky implementation process
  - Initial impressions and suggestions
- Overview of trending health plan litigation

Mental Health Parity – Proposed Regulations

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Overview of MHPAEA Key Concepts

Requirement	Key Concepts
Annual or lifetime limits	• Need to apply the same (or higher) annual or lifetime dollar limit on MH/SUD benefits as medical benefits

Financial requirements and quantitative treatment limitations (QTLs)	• Cannot apply more restrictive quantitative treatment limits or financial requirements (QTLs) to MH/SUD benefits than to medical/surgical benefits
	• Mathematical test:
	  • If QTL does not apply to "substantially all" medical/surgical benefits in a classification, cannot be applied to MH/SUD benefits in that classification
	  • If QTL does apply to "substantially all" medical/surgical benefits in a classification, may be applied to MH/SUD benefits in that classification, but only if the restriction is not more restrictive than the "predominant level" applied to medical/surgical benefits

Nonquantitative treatment limitations (NQTLs) ***pending proposed regs***	• Cannot impose nonquantitative treatment limitations (NQTLs) on MH/SUD benefits unless the processes, strategies, evidentiary standards, and other factors used in applying them are comparable to, and applied no less stringently, than the same criteria as applied to medical/surgical benefits

MHPAEA Classifications

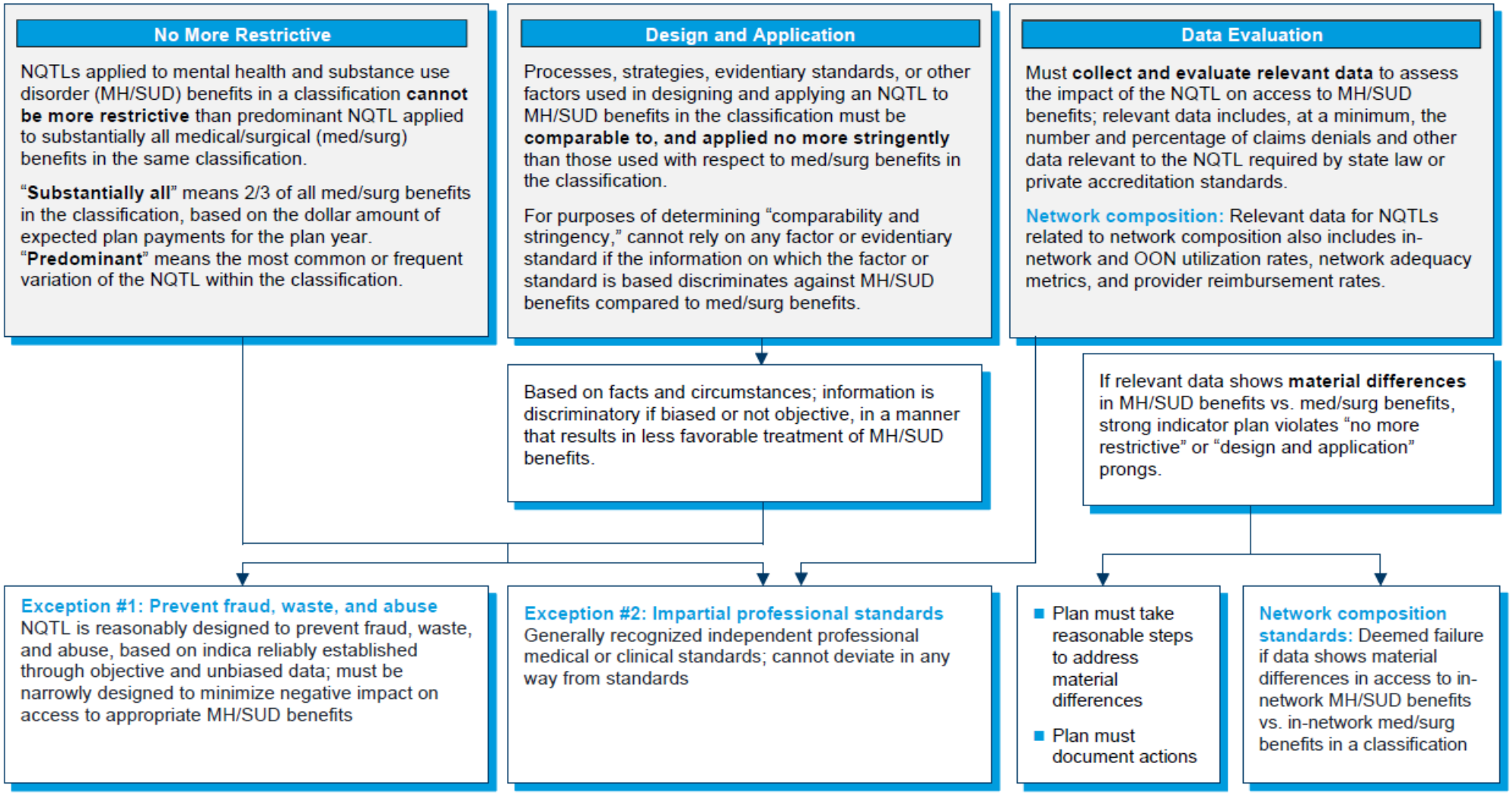
- MHPAEA works by comparing the treatment of medical/surgical benefits to MH/SUD benefits within separate classifications:

In-Network Inpatient	In-Network Outpatient *Sub-classification for office visits*	Emergency
OON Inpatient	OON Outpatient *Sub-classification for office visits*	Prescription Drug

MHPAEA – Current Rules v. Proposed Rules

2013 Rule and Guidance	Proposed Rules
NQTL assessment is process-oriented • Looks at whether NQTL is comparable and no more stringent, in writing and in operation, than NQTL applied on medical/surgical side	New NQTL 3-part test: • No more restrictive (math) • Design and application • Data evaluation (material difference=non-compliance; special rule for network composition NQTL)
If plan covers MH/SUD in benefit classification, must cover MH/SUD in all classifications	If plan covers MH/SUD condition in a benefit classification, must cover "meaningful benefits" for that condition in every classification, as compared to medical/surgical
NQTL comparative analysis content (ACA FAQs 45)	NQTL comparative analysis content, description of NQTLs • More elements • Fiduciary certification
If DOL makes final determination of non-compliance, notice to participants and listing in Report to Congress	If DOL makes final determination of non-compliance, notice to participants, listing in Report to Congress ***and*** DOL can order plan not to apply NQTL to MH/SUD benefits

NQTL – Proposed Three-Part Test



MHPAEA Data Evaluation - Network Composition for NQTLs

Required data collection

- Out-of-network utilization
- Percentage of in-network providers actively submitting claims
- Time and distance standards
- Reimbursement rates

Potential safe harbor *if* meet or exceed specific data-based standards

- Enforcement relief for two calendar years

MHPAEA Comparative Analysis Content Requirements

- Description of NQTL
- Identification and definition of the factors used to design or apply the NQTL
- Description of how factors are used in the design and application of the NQTL
- Demonstration of comparability and stringency as written
- Demonstration of comparability and stringency in operation
- Findings and conclusions
- For ERISA plans: ***Certification by named fiduciaries***

Implementation of Surprise Billing Requirements

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Surprise Billing Rules: Refresher

- The “No Surprises Act” was part of the Consol. Appropriations Act of 2021
  - DOL, Treasury, HHS and the Office of Personnel Management
- Designed to reduce “surprise” medical bills and balance billing
  - Prohibits balance billing of participants in specified circumstances
  - Adds notice requirements for plans, insurers, providers & facilities
  - Sets coverage, payment and dispute resolution requirements for plans
- Covers group health plans, health insurers, facilities & providers, and air ambulances
  - Includes grandfathered plans, HDHPs
  - Does not include HRAs, excepted benefits, retiree plans, ground ambulances, etc.

Surprise Billing Rules: Impact on Participants

- **Emergency Benefits:** If covered, OON emergency services must be covered without pre-authorization and as if in-network
- **Non-Emergency Benefits:** If covered, services by OON providers at in-network facility covered as if in-network, absent notice & consent
- **Air Ambulance:** If covered, OON air ambulances covered as if in-network
- **Cost Sharing:**
  - Same as in-network (as if total charged is the “recognized amount”)
  - Counts toward:
    - In-network deductibles
    - Out-of-pocket maximums
- **Balance Billing:** Prohibited

Surprise Billing Rules: Impact on Plans

- Initial updates to plan documents, SPDs, SBSs as necessary to reflect rules
- Participant cost sharing based on “Qualifying Payment Amount” (QPA)
  - Unless determined based on All-Payer Model Agreement under SSA 1115A or state law
  - Not based on whatever the plan ends up paying to the provider
- Determining QPA
  - Median contracted rate of the plan or issuer as of 1/31/19, as indexed
  - Must be for same market, same/similar items or services and facility type, same geographic region
  - Specific rules for determining QPA when there is insufficient information, non-fee-for-service arrangements, unit-based services, anesthesia, air ambulances

Surprise Billing Rules: Impact on Plans (Cont.)

- Must be able to timely identify and process No Surprises claims
  - Initial payment (or denial) due 30 calendar days after transmission of the bill
  - EOBs must contain required information, including QPA for each item or service, apply appropriate cost sharing, notify provider of 30-day negotiation period and IDR process
- Must establish initial payment amount
  - If not determined by All-Payer Model Agreement under SSA 1115A or state law, then payment amount must be agreed upon or determined through IDR
  - Plans have taken various approaches for initial payment amount
    - QPA
    - X% of Medicare
    - Other

Surprise Billing Rules: Impact on Plans (Cont.)

- Must sort out negotiation and dispute resolution processes
  - Work with TPAs or other entities to allocate responsibility and update applicable contracts
  - 30 business days to invoke negotiation period if unsatisfied with initial payment
  - 30-business day negotiation period for agree upon a payment amount
  - 4 business days after negotiation period for either party (generally provider) to negotiate the independent dispute resolution ("IDR") process (may continue negotiating)
  - Deadlines for selecting IDR entity
  - 10 business days for each party to submit proposed payment amount
  - 30 calendar days to make payment after IDR entity makes a determination
- Increased costs based on QPA payments and results of IDR

Surprise Billing Rules: Federal IDR Timeline

Submission of "Clean Claim" to Plan for Payment

30-Business Day Period to Commence "Open Negotiation:" Any party may initiate the "open negotiation" period during the 30-business day period beginning on the date that the provider or facility receives an initial payment or notice of denial of payment for an item or service. Must submit a written notice and supporting documentation to other party and Departments via the Federal IDR portal.

30-Calendar Day Period for Plan to Make Initial Payment or Notice of Denial of Payment: With either the initial payment or notice of denial of payment, the plan must provide sufficient information and contact details for the provider or facility to initiate open negotiations with the plan.

15 Business Days to Respond Open Negotiation Notice, during 30-Business Day "Open Negotiation" Period: The 30-business day open negotiation period starts on the day on which the open negotiation notice is first sent by a party. During the first 15 business days, the responding party must provide a response notice to the initiating party and the Departments, including supporting documentation. The parties will negotiate the out-of-network rate without the involvement of the Departments or a certified IDR entity during the open negotiation period. **Must exhaust** "open negotiation" period become commencing the federal IDR process.

4-Business Day Period to Initiate the Federal IDR Process: If the parties have not agreed on an out-of-network rate during the 30-business day open negotiation period, either party may initiate the federal IDR process during the 4-business day period beginning on the 31st business day after the start of the open negotiation period.

3-Business Day Period for the Parties to Select Certified IDR Entity: The parties may jointly select a certified IDR entity no later than 3 business days after the date of the federal IDR initiation. If the parties fail to agree upon a certified IDR entity, the parties must notify the Departments no later than 1 business day after the end of the 3-business day period (i.e., 4 business days after the federal IDR process is initiated).

6-Business Day Period for the Departments to Select Certified IDR Entity: If the parties do not jointly select a certified IDR entity, the Departments must select a certified IDR entity within 6 business days of the initiation of the IDR process. The initiating party has 2 business days to pay the administrative fee. If the fee is not timely paid, the matter will be closed. Once initially selected, the IDR entity has 3 business days to submit a conflict of interest attestation (if there is a conflict, another will be assigned).

3-Business Day Eligibility Review Period: After IDR entity is finalized, there is a 5-business day period for the IDR entity to review the submitted information and notify the parties and Departments whether or not the claim is eligible for the IDR process.

3-Business Day Period to Notify of Agreement Outside IDR Process: The parties may agree on an amount for a qualified IDR item or service after the federal IDR process is initiated, but prior to the determination by a certified IDR entity. In this instance, the parties must provide notice to the Departments and the certified IDR entity by electronically submitting notification of such agreement as soon as possible, but no later than 3 business days after the agreement.

10-Business Day Period to Submit Offer During IDR Process: Not later than 10 days after the selection of the certified IDR entity, each party must submit its proposed payment amount for the qualified IDR item or service to the certified IDR entity.

30-Business Day Period for Certified IDR Entity to Select Offer of Payment: The certified IDR entity must select one of the submitted payment offers no later than 30 business days after the selection of the certified IDR entity.

30-Calendar Day Period to Make Payment after Certified IDR Entity Selects Payment Amount: Once the certified IDR entity selects one of the submitted amounts, the plan must pay the amount within 30 calendar days after the agreement is reached.

30-Business Day Period to Refund the Certified IDR Entity Fee to Prevailing Party after Certified IDR Entity Selects Payment Amount: The certified IDR entity is required to refund the prevailing party's certified IDR entity fee 30 business days after the certified IDR entity selects the out-of-network rate amount.

90-Calendar Day "Cooling Off" Period: The party that submitted the initial Notice of IDR initiation **may not** submit a subsequent Notice of IDR Initiation involving the same other provider or facility with respect to a claim that is the same or similar to the item or service that was the subject of the initial determination.

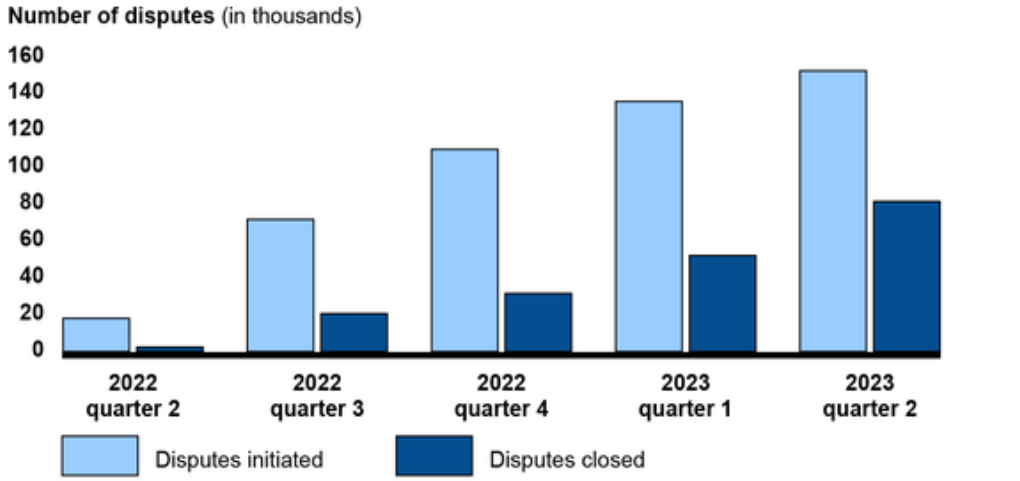
Surprise Billing Rules: A Rocky IDR Rollout

- "Baseball-style" arbitration, so the stakes are high
  - IDR entity selects one of the submitted amounts
  - Limited opportunity for explanation or responses
- Moving target on provider payment amounts
  - Court invalidated the regulatory presumption that QPA would be sufficient absent credible evidence clearly indicating it is materially different from what would be appropriate
    - Held that the presumption conflicted with the text of the No Surprises Act and HHS improperly bypassed certain regulatory processes
  - Now: IDR entities are to give equal weight to all required factors in determining appropriate amount. In addition to QPA, these include:
    - Training and experience level
    - Quality and outcomes measurement
    - Market share held by provider/facility or plan/issuer in the geographic region
    - Patient acuity and complexity of service
    - Good faith efforts (or lack of effort) to join the network and previously contracted rates

Surprise Billing Rules: A Rocky IDR Rollout (Cont.)

- Federal IDR process via an online portal
  - Limited opportunity for feedback
  - Limited ability to correct errors
  - Difficult to halt once started
  - No fee or recourse if submission is ineligible
  - Issues with incomplete information
    - Plan contact information
    - Amounts and deadlines in awards
- System overwhelmed – many more IDR submissions than anticipated (GAO)
  - IDR entities are dealing with backlog, handling high volumes (not necessarily carefully)
  - 490,000 disputes submitted from April 2022 through June 2023, with submission rates increasing
    - Had anticipated 22,000 for 2022
  - 61% of those cases were unresolved in June 2023 (reportedly due to complexity in evaluating eligibility)

INITIAL ROLLOUT



Source: Departments of Health and Human Services, Labor, and Treasury; Centers for Medicare & Medicaid Services. | GAO-24-106335

Surprise Billing Rules: Initial Impressions on Implementation

- Extensive litigation around QPA calculation and impact
  - *Texas Medical Association et al. v. HHS et al* ("TMA III")
    - Providers successfully challenged 2021 regulations outlining QPA calculation methodology
    - Can no longer use TPA's client base; calculation has to be plan-by-plan
    - Overhaul of QPA calculation processes needed, recognized by agencies in FAQ, enforcement discretion for items and services before May 1, 2024
    - Decision appealed to the Fifth Circuit
  - TMA III and TMA IV court orders temporarily halted new IDRs from Aug – Dec '23
  - TMA IV vacated increase in administration fee (from $50 to $350)
- Providers are winning, and winning big
  - Agencies released data indicating that providers won 77% of disputes in 2023 Q1 & Q2
  - Awards have averaged 322% of the QPA
  - Anecdotal accounts that IDR payments are or close to largest payments made by plans

Surprise Billing Rules: Initial Impressions on Implementation (Cont.)

- QPA does not appear to be a safe bet
  - Providers are supporting their proposals with information based on the other factors
  - Plans have limited opportunity to contest providers' rationale
  - TPAs typically are not submitting any additional information
- TPA issues
  - Have tended to minimize their role, even when they have agreed to manage the process
  - Communication issues (plans getting late notifications, lack of clarity on results and payment deadlines, difficulty getting access to IDR reports)
- Lack of consistency in determinations, lack of rationale
- Insurance companies reporting similar IDR experience for insured products
  - Potential premium increases?

Surprise Billing Rules: Potential Considerations

- Evaluate TPA agreements and performance
  - Do the agreements clearly delineate responsibilities and service standards?
  - Is the TPA living up to these standards and providing appropriate reporting?
  - If the process isn't working, what changes can be made?
- Re-thinking negotiations and payment proposals
  - What are your initial payment amounts?
    - Would an increase change provider behavior (maybe not, given IDR outcomes)?
  - What are you offering (or have authorized TPA to offer) during negotiations?
  - What amounts are being submitted to IDR entity?
    - For example, some only authorized up to QPA (often not enough)
    - What will TPA administer?
    - Is there any additional information that can/should be submitted as part of the process?

Health Plan Litigation

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Currently Trending . . . Health Plan Litigation

Category	Examples
Mental health parity	• Coverage of residential treatment • Coverage of wilderness therapy
Out-of-network, overlay arrangements	• In-network v. OON participant cost-sharing for repriced claims • Steerage towards OON providers
ACA Section 1557	• Coverage of gender affirming care (*also impacts mental health parity*) • Coverage of fertility services
ERISA fiduciary	• Retention of prescription drug rebates • Impact of service provider fees on participant cost-sharing • Imprudent structure and compensation paid to pharmacy benefit manager • Imprudent PBM compensation (pass-through v. spread pricing)

Observations and Practical Steps

Category	Key Details
Health and welfare plan fiduciary committee	• Formalization • Process • Records
Prudent selection and monitoring process	• Interaction with transparency limits • Access to claims information • Claims audits (impact of AI and other tools) • Think ahead — include in ASA, amendments
ERISA 408(b)(2) service provider disclosures	• Consultants, brokers • Other providers (impact on contracting)
Benchmarking of fees, costs, compensation	• PBM implications • RFP process

Bonus *Hot* Topic: Copayment Assistance

- Impact on out-of-pocket accumulators
  - ***2020 final rule***: Plans have discretion to count (or not count) copayment assistance towards plan accumulators for prescription drugs with medically appropriate generic equivalent
  - ***2021 final rule***: Plans have discretion to count (or not count) copayment assistance towards accumulators for prescription drugs regardless of availability of medically appropriate generic equivalent
  - ***HIV Institute v. Department of Health and Human Services (D.D.C. 2023)***: Vacated 2021 final rule, meaning 2020 final rule is now in effect pending future rulemaking
- Impact on high-deductible health plans
  - HDHP required to disregard discounts, manufacturer coupons towards minimum deductible (amounts must be paid by individual)
  - Potential conflict between reinstated 2020 final rule and HDHP requirements

Bonus *Hot* Topic: Copayment Maximizers

- Some maximizer programs keyed to reclassification of certain prescription drugs as non-EHBs
  - Copayment is increased to available assistance (enrolled participants pay $0 copayment)
  - Continued litigation between drug manufacturers and copayment maximizer programs under ERISA and state law theories
- Starting in 2025:
  - Prescription drugs in excess of state benchmark plan will be classified as EHBs for individual and small group market plans
  - Continued viability of copayment maximizer programs unclear under new rule
- Future rulemaking will extend same policy to large group market and self-insured plans (announced in ACA FAQs 66)

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