NORTHEAST
BUSINESS GROUP ON HEALTH

2022 Employer Compliance Reboot: The Buck Stops with You!

Tuesday, January 18, 2022
12:00 - 1:00 PM

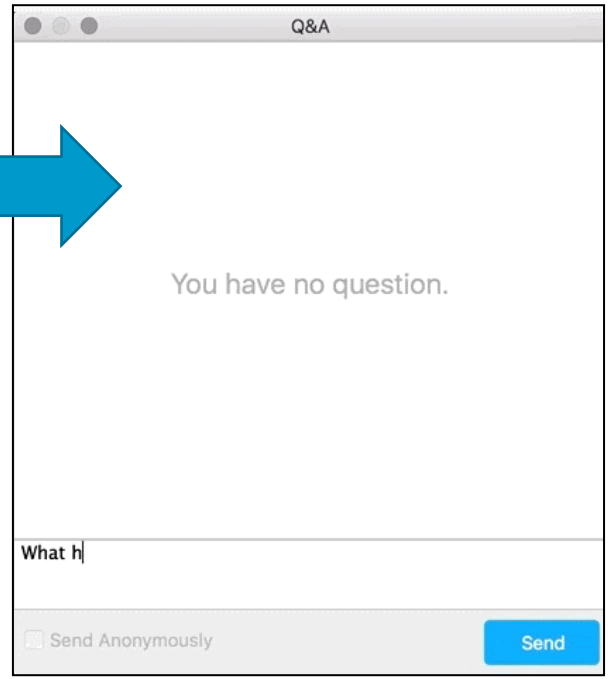
Webinar Procedures

All lines will be muted

Please submit all questions using the “Q&A” dialog box

Email Diane Engel at dengel@nebgh.org with any issues during this webinar

The recording and a PDF of the slides will be shared



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2022 Employer Compliance Reboot

Disclosure Requirements under the Consolidated Appropriations Act, 2021

January 18, 2022

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Agenda

1. Overview of the No Surprises Act (“NSA”)
2. Removal of Gag Clauses
3. Vendor Compensation Disclosure
4. Prescription Drug Pricing Disclosure
5. Mental Health Parity
6. Questions

Overview of the No Surprises Act ("NSA")

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NSA Protections/Requirements

OVERVIEW

- The law took effect January 1, 2022
- Protects enrollees of **Group** and **Individual market** and **Federal Employees Health Benefits** ("**FEHB**") plans from surprise billing for
  - **Emergency services** provided by a non-participating provider and/or non-participating emergency facility
  - **Non-emergency services** provided by a non-participating provider at a participating health care facility
- Imposes certain payment and dispute requirements on plans and issuers and on providers and facilities that furnish protected services to covered enrollees on an out of network basis
- Requires certain surprise billing-related **disclosures** to patients by providers/facilities and plans/issuers
  - General billing rights disclosures
  - Good faith estimates
  - Advanced Evidence of Benefits
- Imposes transparency requirements including with respect to
  - Provider Directories
  - ID Cards
  - Prohibiting information blocking/gag clauses
  - Broker/Consultant Compensation for to Plan Fiduciaries
  - Agent/Broker Fees to Individual Market Plan enrollees

NSA Disclosure and Transparency Requirements

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NSA Transparency and Disclosure Requirements

NO GAG CLAUSES

- Individual and Group plans and issuers may not enter into an agreement with a provider(s), TPA or other entity offering access to a network of providers that would ***directly or indirectly restrict*** the plan from:
  - Providing provider-specific cost or quality information, through a consumer engagement tool or other means, to referring providers, the plan sponsor, enrollees or those eligible to enroll
  - Sharing information (or directing that the data be shared) with a business associate
  - Electronically accessing de-identified claims and encounter data for each enrollee, upon request and consistent with HIPAA, GINA, and the ADA, including—
    - Financial information, such as the allowed amount or any other claim-related financial obligation in the provider-contract
    - Provider information, including name and clinical designation
    - Service codes, or
    - Any other data element included in the claim or encounter transactions.

NSA Transparency and Disclosure Requirements

NO GAG CLAUSES

- Health care providers, networks or associations of providers, or other service providers are ***not prohibited from placing reasonable restrictions*** on the public disclosure of the information described

- All commercial plans or issuers must ***annually submit*** to the relevant Department an ***attestation of compliance*** with these requirements
  - Guidance explaining how plans and issuers should submit their attestations is forthcoming
  - The Departments do ***not intend to conduct rulemaking*** on this requirement as it is "self-implementing"
  - The Departments anticipate collecting attestations starting in 2022

IMPLEMENTATION REQUIRED USING GOOD FAITH, REASONABLE INTERPRETATION OF THE LAW

NSA Transparency and Disclosure Requirements

GROUP HEALTH MARKET DISCLOSURE REQUIREMENTS

- ERISA generally prohibits the furnishing of goods or services between a plan and a party in interest to the plan
- To be exempted, providers of brokerage or consulting services ("covered service providers") may instead disclose certain information to plan fiduciaries
  - Such disclosure is to provide the fiduciaries with sufficient information to assess the reasonableness of the compensation and potential conflicts of interest that may exist from a covered service provider's receipt of indirect compensation from sources other than the group health plan or the plan sponsor.
- Covered service providers are those that enter into a contract or arrangement with a covered plan, under which they reasonably expect to earn $1,000 or more in (direct or indirect) compensation
  - Direct compensation means compensation received directly from a covered plan.
  - Indirect compensation means compensation received from any source other than a covered plan, the plan sponsor, the covered service provider, or an affiliate.

NSA Transparency and Disclosure Requirements

GROUP HEALTH MARKET DISCLOSURE REQUIREMENTS, cont.

Examples of the types of brokerage and consulting services provided by covered service providers are

BROKERAGE SERVICES	CONSULTING SERVICES
• Selection of insurance products • Recordkeeping services • Medical management vendor • Benefits administration • Stop-loss insurance • Pharmacy benefit management services • Wellness services • Group purchasing organization preferred vendor panels • Disease management vendors and products • Employee assistance programs, or • Third party administration services.	• The development or implementation of plan design • Insurance or insurance product selection • Recordkeeping • Medical management • Benefits administration selection • Stop-loss insurance • Pharmacy benefit management services • Wellness design and management services • Group purchasing organization agreements and services • Participation in and services from preferred vendor panels • Disease management • Employee assistance programs, or • Third party administration services.

NSA Transparency and Disclosure Requirements

GROUP HEALTH MARKET DISCLOSURE REQUIREMENTS, cont.

- The Department of Labor has not yet issued regulations or specific guidance on this disclosure obligation but did issue a Temporary Enforcement Policy, DOL Field Assistance Bulletin 2022-03, stating that,

  > [w]hen analyzing a covered service provider's efforts to comply with the requirements, [DOL EBSA] will consider whether the provider's disclosure of information is reasonably designed and implemented to provide the required information and transparency

  as well as the provider's "good faith and reasonable interpretation of the law"

- For insight on compliance expectations for the new disclosure provisions, the Temporary Enforcement Policy directs stakeholders to DOL's regulations regarding fee disclosures for pension plans
- Of note is that disclosure obligations are ongoing, meaning that any changes that occur with respect to the information previously disclosed must be submitted as soon as practicable but no later than 30 days from the date on which the covered service provider discovers the error or omission

NSA Transparency and Disclosure Requirements

GROUP HEALTH MARKET DISCLOSURE REQUIREMENTS, cont.

- Pursuant to the referenced regulations, the Disclosure must be
  - made **no later than a reasonable time in advance of the date on which the contract or arrangement is entered into (or extended or renewed)**
  - Made in writing and must contain:

- A description of the services to be provided
- A statement (if applicable) that the covered service provider or its affiliates or subcontractors will provide services as a fiduciary
- A description of all direct and indirect compensation that the covered service provider or its affiliates or subcontractors reasonably expect to receive in connection with the services described
- A description of the arrangement between the payer and the covered service provider or its affiliates or subcontractor pursuant to which any indirect compensation is paid
- A list identifying the services for which the indirect compensation will be received.
- A list identifying the payers of the indirect compensation
- A description of any compensation that will be paid among the covered service provider and its affiliates or subcontractors, if paid on a transaction basis, including a list identifying the services for which such compensation will be paid and a list identifying the payers and recipients of such compensation, regardless of whether such compensation also is disclosed under another provision.
- A description of any compensation that K Health or its affiliates or subcontractors reasonably expect to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

NSA Transparency and Disclosure Requirements

PRESCRIPTION DRUG AND HEALTH CARE SPENDING TRANSPARENCY

- Requires data submission by group health plans and health insurance issuers offering group or individual health insurance coverage, including grandfathered, non-federal governmental, student, church plans and Federal Employee Health Benefit Plans
- Does not apply to health reimbursement arrangements (HRAs) or other account-based group health plans that make reimbursements subject to a maximum fixed dollar amount for a period, or to short term limited duration or excepted benefit plans
- Data will
  - Inform required **Report to Congress**

    > on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated in such a way as no drug or plan specific information will be made public.

    86 Fed. Reg. 66682
  - Facilitate compliance with **E.O. 14036**, directing the federal government to ‘‘**enforce the antitrust laws** to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony.’’

NSA Transparency and Disclosure Requirements

PRESCRIPTION DRUG AND HEALTH CARE SPENDING TRANSPARENCY, cont.

- Submission will be by calendar year to ensure uniformity and increase usability of data (regardless of timing of plan year), for the year immediately preceding the calendar year of submission
  - The Departments are exercising enforcement discretion to defer enforcement on the submission of the 2020 and 2021-related data until December 27, 2022
- Data on total annual spending for prescription drugs must be submitted separately for prescription drugs covered under the medical benefit from those covered under the pharmacy benefit
  - Due to compliance burden, currently only requiring submission of more specific data elements for prescription drugs under the pharmacy benefit
- Plans and issuers must separately report data on total annual spending for health care services by the plan or coverage from total annual spending by participants, beneficiaries and enrollees
- The majority of the information must be submitted on an aggregate basis by state and market segment
  - Will allow the Departments to assess market trends, capture drug rebate data, protect PHI, and lessen burden

NSA Transparency and Disclosure Requirements

PRESCRIPTION DRUG AND HEALTH CARE SPENDING TRANSPARENCY, cont.

- Draft Reporting Instructions for 2020 reference year submissions are under Paperwork Reduction Act review by the Office of Management and Budget and are posted on the CMS website at https://www.cms.gov/files/zip/cms-10788.zip
- Data will be submitted through CMS' Health Insurance and Oversight System (HIOS) which will allow multiple reporting entities to submit different subsets of the required information with respect to the same plan or issuer.
- Required data elements include (for each state and market segment)

  - The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug
  - The 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug
  - The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding that addressed in the report, and, for each, the change in amounts expended by the plan or coverage in each such plan year;
  - Total annual spending on health care services by plan or coverage, broken down by the type of costs (including hospital, health care provider & clinical service, prescription drugs; and other medical costs)
  - Prescription drug spending and utilization by health plan or coverage and by enrollees
  - The average monthly premium amounts paid by employers on behalf of enrollees and paid by enrollees;
  - Prescription drug rebates, fees and other remuneration
  - Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration.

Mental Health Parity

Recent Pivots in Enforcement and Compliance

- **Model Parity Act**
  - Requires state licensed insurers to submit very granular "step-wise" compliance analyses for NQTLs to state DOI on an annual basis
    - Also applies to Medicaid MCOs in some states
  - Requires state regulators to report to state legislature on enforcement efforts
  - In most states does not create financial penalties
  - Adopted in 17+ states and counting, reporting deadlines vary by state
- **Consolidated Appropriations Act of 2021**
  - Creates new federal requirement for step-wise NQTL compliance analyses
  - Enforced through investigations only—no annual reporting
  - Creates new authority for DOL to enforce parity with regard to insurance issuers
  - "Naming and shaming" required for violations

Litigation Risks

Lawsuits involving MHPAEA filed on a nearly daily basis, including an increasing number of class actions, with sometimes unpredictable results

Medical necessity criteria and UM

- *Wit v. United Behavioral Health* requiring United to reprocess 67,000+ claims
- *Meridian Treatment Centers v. UBH* presents same facts on behalf of a nationwide class of providers, asserting $9 billion in affected claims

Provider reimbursement strategies

- *O'Dowd v. Anthem* – recently settled, plaintiffs alleged disparities in reimbursement strategies
- *Smith v. United Healthcare* – plaintiffs recently survived a motion to dismiss

Residential treatment and wilderness therapy: Highest volume of litigation—plaintiffs challenge coverage exclusions, provider network exclusions, and medical necessity criteria

Few cases filed to date regarding pharmacy benefits – Greatest risks likely involve complaints from manufacturers seeking more advantageous coverage for their products

Walsh v. United Behavioral Health

- Groundbreaking lawsuit filed by DOL alleging MHPAEA violations
- The settlements in the case include:
  - $2.5 million to resolve claims brought by the U.S. Department of Labor
  - $1.1 million for claims brought by the New York Attorney General
  - $2 million for New York state penalties
  - $10 million for restitution to members with denied claims
- Substantive complaints include:
  - Differential approaches to utilization management
  - Parity reporting and disclosures were inadequate for failing to specifically address these UM strategies

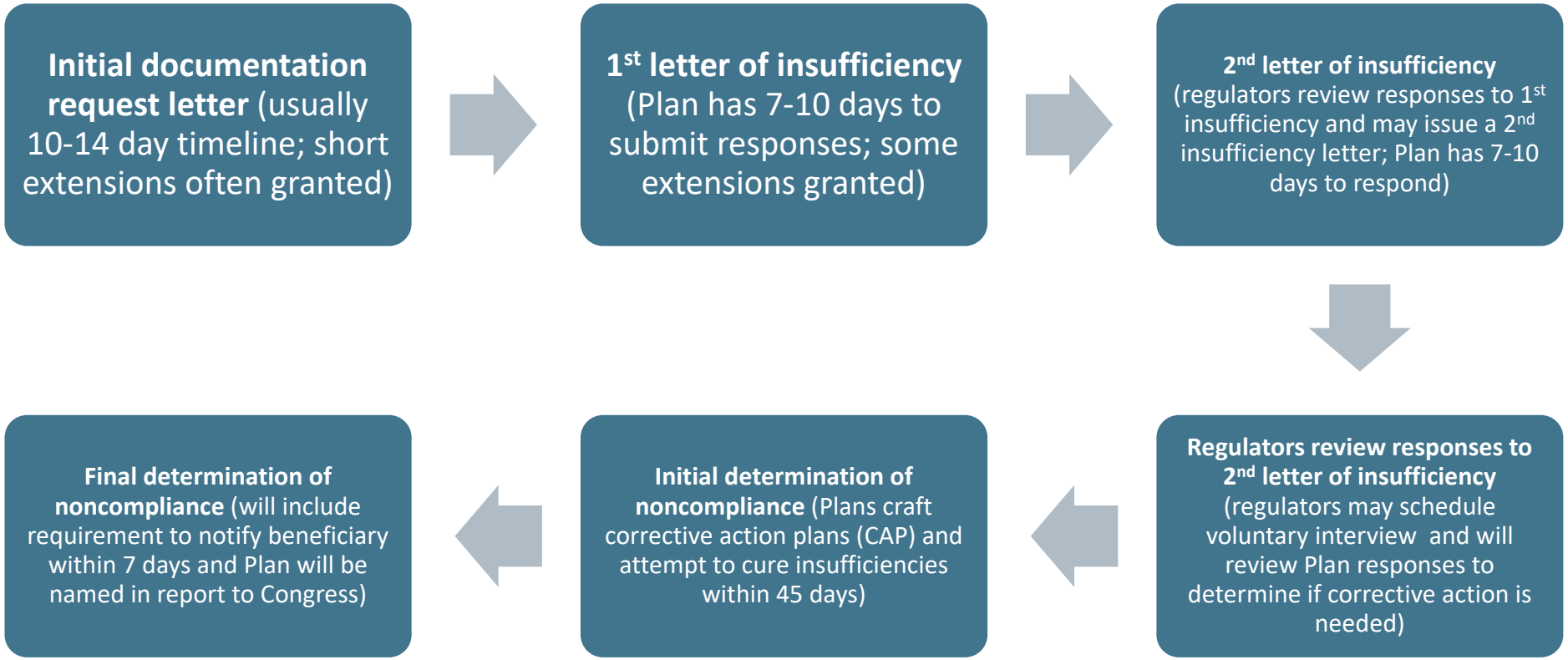
"The Secretary of Labor views [mental health parity] as probably our top health enforcement priority for EBSA"

– Ali Khawar, Acting Assistant Secretary, Employee Benefits Security Administration (EBSA)

DOL/CMS regulatory enforcement

- Large number of current open investigations
  - DOL FAQ language suggests a focus on inpatient and outpatient benefits, however, investigations have also included significant scrutiny of prescription drug benefits
  - Regulatory enforcement tends to focus on specific NQTLs including prior authorization, concurrent review, reimbursement (in and out-of-network), network adequacy standards, and prescription drug NQTLs (e.g. step therapy)
  - Investigators are requiring justification for any language in the summary plan description or benefit booklet to suggest exclusions or other limits
- Tri-Department report to Congress on enforcement was due 12/27 (*report has not been issued to date*)
  - Anticipate that the report will list plans who DOL has closed investigations with and has issued final notices of non-compliance

DOL/CCIIO Process for Parity Investigations



Best Practices When Responding to a MH Parity Audit Request

- Considerations during the investigative process:
  - Consider the scope of the investigation.
    - What type of documents are being requested?
    - Is the investigation focused on particular lines of business, geographic areas, specific entities, or specific NQTL types?
  - Identify and collect documents requested by the investigator (consider the scope, time period under review, and priority of documents for production)
    - DOL routinely asks for additional documentation after the initial document request (e.g. through subsequent sufficiency letters)
  - For any interviews that occur during the investigation, communicate with the investigator about the topics to be asked so the appropriate individuals are present
  - Draft responses to insufficiencies raised by the investigator
    - Update NQTLs where comparative analyses are deemed insufficient, provide operations metrics data as requested, clarify plan documents, prepare cover letter explaining key issues)

Best Practices When Responding to a MH Parity Audit Request

- Design and Implement a comprehensive parity compliance program
  - Conduct a parity risk assessment
    - Analyze existing parity documentation (e.g. medical coverage and UM policies, PBM/vendor oversight, provider contracting and reimbursement)
  - Develop formal P&Ps that govern parity compliance
  - Designate key personnel responsible for ongoing compliance and governance
  - Train personnel on parity requirements
    - Train on key parity requirements and documentation (NQTLs and QTL/FRs)
    - Explain ongoing personnel roles in advancing parity compliance
  - Develop an internal auditing and monitoring program
    - Program should address the 5-step analysis and identify timelines for updating operations measures and the resulting analysis for each NQTL
  - Identify areas of concern and implement appropriate corrective action
    - Including internal communication related to complaints, issues identified by regulators, trends in enforcement

QUESTIONS?

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- **Jan. 24 –** Monday COVID-19 Update w/ Dr. Mark
- **Feb. 10 –** Software to Treat Disease: Prescription Digital Therapeutics