Today's webinar will begin shortly. We are waiting for attendees to log on.

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2022 Compliance Hot Topics: What Employers Need To Know

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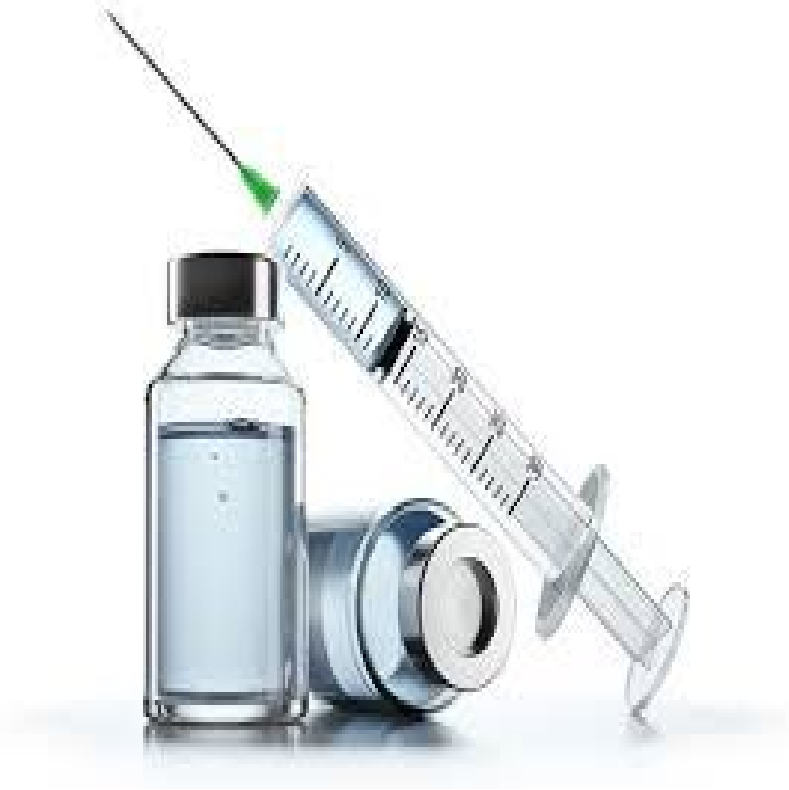
Agenda

This month's webinar will address compliance priorities for welfare benefit plan sponsors in the coming year. With penalties on the rise (again), and the agencies that monitor and enforce compliance ratcheting up their audit activity, it's more important than ever to ensure compliance with your benefit plan programs. We will specifically delve into:

- Details regarding new requirements for group health plans to cover at-home COVID-19 diagnostic tests.
- How the recent Supreme Court ruling regarding vaccine mandates will impact companies that require COVID-19 vaccinations.
- Relevant guidance governing COBRA deadlines and other COVID-related guidance during the ongoing national emergency.
- The steps employers must take now, and what they will need to be prepared to do throughout the year to grapple with the many new disclosure and communication rules in the No Surprises Act.
- The action items employer plan sponsors will need to take to understand the audit focus regarding Mental Health Parity and Addiction Equity Act non-quantitative treatment limitations and explain how employers can be prepared to answer new questions the DOL will raise on audit.
- Additional items such as ACA filings under new IRS guidance regarding enforcement and higher penalties for routine compliance violations.

Federal Vaccine Mandates

- OSHA's Vaccine/Testing/Face Covering ETS
- Federal Contractor Mandate
- CMS Mandate



OSHA's ETS

- Temporarily enjoined by the U.S. Supreme Court on January 13, pending Sixth Circuit Review
- OSHA announced its withdrawal of the ETS on January 25
- OSHA is not withdrawing the ETS to the extent that it serves as a proposed rule under section 6(c)(3) of the Act, as a proposed rule.
- OSHA to tailor the rule to a narrower group of employers by targeting specific industries, likely healthcare employers
- OSHA NEP still active
- General Duty Clause

OSHA's ETS - State-Plan States

- In states where the federal government does not have jurisdiction over workplaces safety, the state agencies were required to adopt the ETS or "just-as-effective measures" within 15 to 30 days.
- Minnesota and Illinois had formally adopted the federal OSHA ETS as part of their State Plans.
- Although these states were not required to take any action based on OSHA's announcement, both Minnesota and Illinois have announced that they had stayed enforcement of their State ETS following the Supreme Court's decision.

Policies and Procedures: What Should You Do?

- **Adopt Procedures for Determining Employees' Vaccination Status**
  - Maintain confidential records of employee vaccination status.
  - EEOC has indicated it is lawful to ask employees about COVID-19 vaccination status, but this should end your inquiry.
  - Collect proof of vaccination or create a confidential list of vaccinated workers.
  - Review state laws regarding confidentiality and privacy of medical records.

Policies and Procedures: What Should You Do?

- **Determine if you will mandate the vaccine or allow unvaccinated employees to be tested weekly.**
  - For some employers, collecting and tracking weekly test results may burden them such that they decide to adopt a mandatory vaccination policy.
  - If planning for weekly testing, think through the logistics:
    - Onsite or through designated vendors?
    - Payment for testing
    - Payment of time for testing

Policies and Procedures: What Should You Do?

- **Have a plan for tracking test results.**
  - You should have a plan in place for collecting and tracking test results.
  - Who is going to collect the results?
  - When will the test results need to be collected?
  - How will you track the results?

Policies and Procedures: What Should You Do?

- **Have a plan for addressing noncompliance by employees.**
  - What happens to an employee who does not get tested?
  - What happens to an employee who refuses to get vaccinated?

Policies and Procedures: What Should You Do?

- **Develop a plan for handling accommodation requests.**
  - Employees may request accommodations for disabilities or for religious reasons under federal or state laws.
  - Develop a robust and clear reasonable accommodation policy to address religious and disability issues.
  - Communicate and administer the accommodation process thoughtfully, emphasizing individualized, confidential consideration of each request.
  - Be prepared for employees to also request an accommodation from the weekly testing requirement, not just vaccination.

Federal Contractor Mandate

- Mandatory inclusion of a flow-down clause requiring compliance with the Safer Federal Workforce Task Force guidance
- Vaccine mandate requiring full vaccination for employees of covered federal contractors by December 8, then January 18, with limited exceptions for those legally entitled to an accommodation
  - Prior COVID-19 infection or antibody tests are not accepted as substitutes
  - No testing option
- Mask and physical distancing requirements at covered contractor worksites (including for employees, visitors and others)
- Contractors must designate a person or persons to coordinate COVID-19 workplace safety efforts at their workplaces

Federal Contractor Mandate - Coverage

- Contract in question (or a "contract-like" instrument that is not a grant) must be performed in the U.S., in whole or in part, and must be a:
  - Procurement contract for construction covered by the Davis Bacon Act (DBA);
  - Contract for services under the Service Contract Act (SCA);
  - Concessions contract under the SCA; or
  - Contract in connection with federal contracts or land offering services to federal employees, their dependents, or the general public.

Federal Contractor Mandate - Compliance

- Must receive a new contract or modification to fall within the mandate
- Court in Georgia granted an injunction that blocks Federal Contractor Mandate
- Preparation still recommended

CMS Vaccine Mandate

- Temporarily enjoined, but then allowed to be enforced by the U.S. Supreme Court on January 13
- CMS requires all employees of healthcare facilities participating in Medicare and Medicaid to be fully vaccinated
- CMS establishes and oversees health and safety standards, known as “Conditions” or “Requirements for Coverage,” for 21 types of healthcare organizations receiving federal funding through Medicare or Medicaid (“Participants”)

CMS Vaccine Mandate

- The Rule does not apply to physician offices, assisted living facilities, group homes, and community-based services or entities that do not provide services pursuant to contracts regulated by CMS.

- CMS has announced it will exercise some discretion in enforcing deadline based on states. Compliance dates of January 27th, February 14th, and February 22nd (for Texas) depending on your state for deadlines for first dose of vaccine.

OTC AT-HOME COVID-19 TEST MANDATE

COVID Test Requirement

- Families First Coronavirus Relief Act (FFCRA) required free COVID-19 test coverage as of 3/18/20 for duration of public health emergency
  - No cost sharing
  - No prior authorization
  - No medical management techniques
- CARES Act (3/27/20) set reimbursement rates to providers for free COVID testing
  - At negotiated rate
  - If none - at the test rate posted on the provider's website
  - Providers are required to post rates or face fines and penalties

Prior Agency Interpretations

- Affordable Care Act (ACA) FAQs Part 43 (6/23/20)
  - Free COVID diagnostic testing includes FDA approved (EUA) at-home tests ***if ordered by an attending health care provider***
  - At the time no home tests had FDA approval – EUA or otherwise
  - Must be medically appropriate
  - Does not include testing required for surveillance or employment purposes
  - No limit on tests covered

Biden-Harris Expansion

- ACA FAQs Part 51 issued 1/10/22 with an effective date of 1/15/22
  - Eliminates requirement that health care provider order test
  - Limited to 8 tests per covered person per month (unless ordered by health care provider) under safe harbor
  - Not for employment purposes
  - Incentivizes free tests at point of sale (Safe Harbor)
    - If free at point of sale (e.g., pharmacy network, retail or mail order), out-of-network costs may not exceed $12 per test (e.g., $24 per two-pack test); costs include reasonable shipping and sales tax
    - Requires “adequate access” to tests at point of sale to enforce payment cap; facts and circumstances

Biden-Harris Expansion

- ACA FAQs Part 51 issued 1/10/22 with an effective date of 1/15/22
  - Failure to meet Point of Sale Safe Harbor
    - Must reimburse actual cost of test ***with no cap***
  - Employers permitted to address fraud and abuse
    - May require attestation that tests are for personal use, will not otherwise be reimbursed, are not for employment purposes
      - Must be "brief"
      - Cannot request "multiple" documents or require "numerous" steps to show proof
    - May require proof of purchase, including UPC code and receipt documenting date and price

Clarifying Guidance

- ACA FAQs Part 52 issued 2/4/22 with an effective date of 2/4/22
  - Direct-to-consumer shipping
    - Adequate access is facts and circumstances test
    - ***Available through at least one direct-to-consumer shipping method and one in-person method***
  - Direct coverage
    - Direct-to-consumer shipping (online or telephone)
    - Pharmacy network
    - Non-pharmacy retailers (including coupons)
    - Alternative distribution (drive-through or walk-up)
    - Provide info on which tests are available through which method
  - Direct-to-consumer can be through same outlet as in-person; reasonable shipping costs must be covered similar to mail order items or products under plan.

Clarifying Guidance

- ACA FAQs Part 52 issued 2/4/22 with an effective date of 2/4/22
  - In-person availability
    - Adequate access is facts and circumstances test
      - Locality of participants
      - Current utilization of plan's pharmacy network
      - How participants are notified about locations and tests available
      - Departments can ask for copies of info provided
      - Not all possible available tests must be covered
  - Temporary supply shortages will not cause an otherwise compliant plan to be non-compliant
  - Reasonable to limit coverage to tests purchased from established retailers that would typically be expected to sell kits; can disallow resellers and online auction sites as well as individual sellers
    - Can require attestation that individual will not have test reimbursed from another source including resale.

Clarifying Guidance

- ACA FAQs Part 52 issued 2/4/22 with an effective date of 2/4/22
  - Does not apply to tests that require medical provider involvement
  - Still covered under original COVID-19 guidance
  - Be careful not to have individuals get tests reimbursed or paif for by plan and also seek reimbursement from HFSA, HRA or HSA

Next Steps

- Confirm how claims will process - pharmacy or medical or both *(caution regarding coordination of claims)*
- Coordinate point of sale coverage if using safe harbor
  - Until free at point of sale must pay full cost for test regardless where purchased
- Amend plan docs
- Prepare Employee Communications
  - Employees can order free tests from post office (COVIDtests.gov website)
  - False claims/attestations can result in discipline up to termination of employment

MENTAL HEALTH PARITY – NQTL ANALYSIS

Non-Quantitative Treatment Limitations

- A NQTL is generally a limitation on the scope or duration of benefits for treatment that is unrelated to a dollar or numerical limitation
- MHPAEA regulations prohibit a plan or an issuer from imposing NQTLs on MH/SUD benefits in any classification unless, under the terms of the plan or coverage **as written and in operation**, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, those used in applying the limitation with respect to M/S benefits in the same classification

Illustrations of Non-Quantitative Treatment Limitations

- Agency Examples of NQTLs:
  - Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
  - Formulary design for prescription drugs;
  - Standards for provider admission to participate in a network, including reimbursement rates;
  - Plan methods for determining usual, customary, and reasonable charges;
  - Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);
  - Exclusions based on failure to complete a course of treatment;
  - Standards for access to out-of-network providers
  - Network tier design, for plans with multiple network tiers (such as preferred providers and participating providers); and
  - 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

Non-Compliant Non-Quantitative Treatment Limitations

- Examples of NQTLs that do not comply with parity laws:
  - Requirement for prior authorization for MH/SUD benefits
  - Requirement for in-person utilization review for MH/SUD benefits
  - “Fail-First” requirement for inpatient treatment of SUD due to lack of geographical access
  - Exclusion of all court-ordered treatment for substance use disorder benefits
  - Developmental disability exclusion limitation

Enforcement Focus NQTLs

- 2022 DOL focus:
  - Prior authorization requirements for in-network and out-of-network inpatient services
  - Concurrent review for in-network and out-of-network inpatient and outpatient services
  - Standards for provider admission to in-network, including reimbursement rates
  - Out-of-network reimbursement rates, including plan methods for determining usual, customary, and reasonable charges

CAA Overview

- The Consolidated Appropriations Act, 2021 (CAA):
  - provided additional funding for mental health and substance abuse services
  - imposed public reporting requirements on DOL/IRS/HHS regarding compliance of group health plans and insurers with NQTLs
  - expressly required group health plans and health insurance issuers offering group or individual health insurance coverage that offer both M/S benefits and MH/SUD benefits and that impose NQTLs on MH/SUD benefits to perform and document a comparative analysis of the design and application of NQTLs
  - beginning February 10, 2021, dictated the comparative analysis be made available to the Agencies or applicable State authorities upon request
  - required Agencies to create a complaint process for MHPAEA violations

Comparative Analysis

The comparative analysis must contain the following:

i. The specific plan terms or other relevant terms regarding the NQTLs and a description of all MH or SUD and medical or surgical benefits to which each such term applies in each respective benefits classification;

ii. The factors used to determine that the NQTLs will apply to MH or SUD or substance use disorder benefits and medical or surgical benefits;

iii. The evidentiary standards used for the factors identified in clause (ii), when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits;

iv. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification; and

v. A disclosure of the specific findings and conclusions reached by the group health plan, including any results of the analyses described in the above, that indicate that the plan is or is not in compliance with the MHPAEA.

When is the Comparative Analysis due?

- Went into effect in 2021, so plans and issuers should now be prepared to make their comparative analyses available upon request.
- The Agencies must request comparative analyses from plans with potential violations or complaints regarding non-compliance, or other circumstances as determined appropriate by the Agencies or State.
- Agencies will be required to request no fewer than 20 of these comparative analyses per year.

Requests by States and Participants

- For plans subject to ERISA and the ACA claims procedures, the Agencies take the view that ERISA plan participants, beneficiaries, and their authorized representatives are entitled to:
  - Comparative information on medical necessity criteria for M/S and MH/SUD benefits.
  - The process, strategies, evidentiary standards, and other factors used to apply NQTLs concerning M/S and MH/SUD benefits.
- This means that any comparative analyses performed under the plan and other applicable information under the CAA must be made available to participants and beneficiaries on request.
- Plans and health insurers also must make available their comparative analyses and related information to state authorities on request.

Next Steps

- Fully-Insured: confirm your carrier is in compliance with the CAA's comparative analysis requirements
- Self-Insured: coordinate with TPA to ensure that comparative analyses in compliance with CAA are being conducted in a sufficient manner (e.g., no refusal to provide analyses based on proprietary data)
- Review contract language to properly delegate responsibility for future preparation of comparative analysis and compliance with participant/State disclosure requests
- If TPA refuses to prepare comparative analysis, take steps to demonstrate good faith attempt at compliance using DOL guidelines in Self-Compliance Tool and FAQ, Part 45 https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf
- Follow MHPAEA lawsuits and enforcement efforts to stay apprised of new developments

Preparing the Comparative Analysis DOL Guidelines in FAQ, Part 45 (2021)

At a minimum, sufficient comparative analyses must include a robust discussion of all elements listed below:

- A clear description of the specific NQTL, plan terms, and policies at issue.
- Clear statement identifying the specific MH/SUD and M/S benefits to which the NQTL applies within each benefit classification.
- Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in the determination of which benefits are subject to the NQTL.
  - Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.
- To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.
- The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and M/S benefits and, if so, describe the process and factors used for establishing that variation.

Preparing the Comparative Analysis DOL Guidelines in FAQ, Part 45 (2021)

At a minimum, sufficient comparative analyses must include a robust discussion of all elements listed below:

- If the application of the NQTL turns on specific administrative decisions, the plan or issuer should identify
  - the nature of the decisions,
  - the decision maker(s),
  - the timing of the decisions, and
  - the qualifications of the decision maker(s).
- If the plan's or issuer's analyses rely upon any experts, the analyses should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and M/S benefits.
- A reasoned discussion of the plan's or insurer's findings/conclusions concerning the comparability of the above-referenced processes, strategies, evidentiary standards, factors, and sources for each classification—including their relative stringency (as written and applied). This topic should include:
  - citations to any specific evidence considered; and
  - any conclusions of an analysis indicating that the plan or coverage is (or is not) MHPAEA-compliant..
- The date of the analyses and the name, title, and position of the person or persons who performed or participated in the comparative analyses

Preparing the Comparative Analysis Supporting Documents

The 2020 MHPAEA Self- Compliance Tool highlights the following types of documents and relevant information that a plan or issuer should have available to support its NQTL comparative analyses.

- Records documenting NQTL processes and detailing how the NQTLs are being applied to both M/S and MH/SUD benefits to ensure the plan or issuer can demonstrate compliance with the law, including any materials that may have been prepared for compliance with any applicable reporting requirements under State law.

- Any documentation, including any guidelines, claims processing policies and procedures, or other standards that the plan or issuer has relied upon to determine that the NQTLs apply no more stringently to MH/SUD benefits than to M/S benefits. Plans and issuers should include any available details as to how the standards were applied, and any internal testing, review, or analysis done by the plan or issuer to support its rationale.

- Samples of covered and denied MH/SUD and M/S benefit claims.

- Documents related to MHPAEA compliance with respect to service providers (if a plan delegates management of some or all MH/SUD benefits to another entity).

The precise information needed to support an NQTL analysis will vary depending on the type of NQTL

No Surprises Act

No Surprises Act

- Legislation Requires Additional Disclosures
  - Machine readable files for medical services with in-network and out-of-network costs updated monthly and published on website (July 1, 2022)
  - Machine readable files for prescription drug coverage (Delayed indefinitely)
  - Provider directories updated regularly (good faith standard)
  - ID cards contain in-network and out-of-network deductibles, out-of-pocket maximums and website addresses and telephone numbers for getting support and network information (good faith standard)
  - Continuity of care for up to 90 days after provider switches to out-of-network (good faith standard)
  - Public price comparison tool (January 1, 2023 pending final regulations)
  - Advanced explanations of benefits (Delayed indefinitely)
  - Ban on balance billing (January 1, 2022 and good faith and reasonable interpretation apply until final rules issued)

COBRA Election & Payment Deadlines

Department Guidance

- COBRA deadlines clarified
  - Guidance issued May 2020 that extended election and premium payment deadlines under COBRA during the national emergency declared in the face of the COVID-19 global pandemic
    - Extensions applied from March 1, 2020 through earlier of 60 days after end of national emergency or maximum period of one year
  - Guidance clarifies that election and payment deadlines are concurrent
  - Initial election must be made within earlier one year and 60 days from election notice or end of outbreak period
  - If election made within original election period, first premium due one year and 45 days after election
  - If election made outside initial 60-day period, first premium due within one year and 105 days from date election notice provided
  - No election due before November 1, 2021 if initial premium made within one year and 45 days after COBRA election.
  - Ongoing premiums extended by one year plus any applicable grace period

ACA Reporting

ACA Reporting: Extra Cautious This Cycle

- 2021 individual statements due by March 2, 2022 under extension regulation published in December; Forms 1094/1095 due to IRS February 28, 2022 (paper) or March 31, 2022 (electronic)
- IRS announced last year that it would not be granting automatic extension for individual statements this cycle but later made extended due date permanent
- Also announced no longer considering good faith effort for filing errors or inaccuracies

DOL Increased Non-compliance Penalties

Violation	2021 Penalty	2022 Penalty
Failure to file Form 5500	$2,259/day	$2,400/day
Failure to file Form M-1 (multiple employer welfare arrangement annual report)	$1,644/day	$1746/day
Failure to provide DOL with requested documents within 30 days	$161/day ($1,613 max/request)	$171/day ($1,713 max/request
Failure to provide summary of benefits and coverage (SBC)	$1,190/failure	$1,264/failure
Failure to meet Children's Health Insurance Program (CHIP) notice requirement, Genetic Information Nondiscrimination restrictions	$120/day	$127/day
Minimum penalty for de minimis genetic information failure uncorrected before DOL notice	$3,005	$3,192
Minimum penalty for non-de minimis genetic information failure uncorrected before DOL notice	$18,035	$19,157

Final Questions

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Thank You

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