Compliance Recap | August 2024

Sept. 5, 2024

In August, the ban on non-compete agreements was struck down by a court stating that the FTC did not have the power to implement the ban and that its application was too broad. The FDA approved new and updated COVID-19 vaccines for adults and children as part of the preventive care mandate for group health plans. The Biden administration released its Unified Agenda, containing regulations impacting group health plans, and announced their anticipated release dates. New Hampshire announced an improved prior authorization process. The Johnson & Johnson breach of fiduciary duty lawsuit saw some movement and a similar suit was brought against Wells Fargo and its fiduciaries.

Federal Court Blocks FTC Non-Compete Ban Nationwide: Important Insights for Employers

On August 20, 2024, the U.S. District Court for the Northern District of Texas delivered a crucial ruling, effectively halting the Federal Trade Commission's (FTC) Rule prohibiting most non-compete agreements. The Rule, which was set to go into effect on September 4, 2024, was struck down by the court.

Background

The FTC's Rule aimed to ban the use of most non-compete clauses by employers, arguing that such clauses represent an unfair method of competition. The intent was to enhance employee mobility by eliminating barriers that could limit workers' ability to change jobs. However, businesses and trade associations, including the U.S. Chamber of Commerce, challenged the FTC's authority to impose such a ban. They argued that the FTC lacked the statutory power to create substantive rules governing unfair competition and could not retroactively invalidate existing contracts.

The Court's Decision

The court criticized the Rule's one-size-fits-all approach, because the FTC failed to adequately explain the rationale behind such a sweeping regulation. As a result, the court ruled it unenforceable and issued a permanent nationwide injunction against it, meaning the Rule will not take effect on September 4, 2024.

Key Considerations for Employers

This ruling carries significant implications for employers. First, it reaffirms the enforceability of well-drafted non-compete agreements tailored for the states where they are permitted.

Second, while the court's decision halts the near-total prohibition on non-competes, it does not guarantee that all non-competes will be enforceable. Employers should carefully review state laws governing restrictive covenants, as regulations vary widely across jurisdictions.

Employers should be aware that the FTC may still attempt to challenge non-competes through targeted enforcement actions. Keeping an inventory of all restrictive covenants, including those for former employees, could be beneficial for future compliance and tracking purposes, especially if the Rule is revived by an appeals court.

FDA Approves New and Updated COVID-19 Vaccines

The U.S. Food and Drug Administration (FDA) announced the approval of new COVID-19 vaccines for both adults and children for the 2024-2025 season.

Among these FDA approvals:

- COMIRNATY® vaccine for adults, developed by BioNTech and Pfizer
- A vaccine for children aged 6 months to 11 years, developed by Pfizer and BioNTech
- An updated SPIKEVAX™ vaccine for adults, developed by Moderna
- A new formula specifically designed for children aged 6 months to 11 months by Moderna

Emergency room visits for COVID-19 among working-age individuals (ages 18 to 64) hovers around 2%. The overall U.S. death rate remains 5% to 10% higher than pre-pandemic levels, influenced by both the direct impact of COVID-19 and its effects on routine healthcare and the broader healthcare system.

Employer Considerations

Employers offering fully funded health plans and self-insured employer-sponsored health plans are required by the Affordable Care Act to cover these vaccinations without any cost-sharing for patients.

Release Dates for Biden Administration Health Care Regulations

The Biden administration recently released its final Unified Agenda, a comprehensive list of regulations being developed by various federal departments, along with their anticipated release dates.

Key regulations to watch:

Mental Health Parity

Aimed at enhancing access to mental health and substance-use disorder benefits by tightening compliance with mental health parity requirements. Employers and insurance carriers have raised concerns about the challenges in meeting these new definitions and tests. The final regulations are expected to be released in September 2024.

Surprise Billing Requirements

These regulations include formalizing the open negotiation period, specifying details required on negotiation notices, and revising the use of service codes for batched claims. The release of these final regulations has been delayed until November 2024, with regulations on air ambulance services pushed to March 2025.

Advanced Explanation of Benefits

Federal agencies issued guidance in 2021 allowing self-insured plans and insurance carriers to send explanations of benefits (EOBs) without penalty until formal regulations on advanced EOBs are in place. After seeking input from stakeholders two years ago, proposed regulations are now expected in March 2025.

HIPAA Privacy and Cybersecurity

For the first time, federal departments are working on HIPAA regulations specifically aimed at enhancing cybersecurity measures for medical providers, health plans, and third parties that manage personal health information. The proposed regulations are scheduled for release in December 2024.

New Hampshire Pre-Approval Improvement

A new state law in New Hampshire is set to improve the process of prior authorizations, starting next year. This legislation establishes clear deadlines for insurers to respond to prior authorization requests: within 72 hours for urgent cases—or sooner if the patient's condition demands it—and within seven days for non-urgent procedures when requests are submitted electronically. If insurers fail to meet these deadlines, the requested procedure will be automatically approved. The law mandates that insurers use qualified medical experts to determine whether a procedure is medically necessary, ensuring that these decisions are grounded in evidence-based practices.

A 2023 survey by the health policy organization KFF highlighted the need for such reforms, with 16% of insured adults reporting that their insurance had been delayed or denied prior approval for treatment, services, or medications in the past year. This figure rose to 26% among those seeking mental health treatment.

AHIP, a national advocacy group for providers of healthcare coverage and services, supported the final version of the bill, noting that it would retain the benefits of prior authorization while encouraging more providers to submit requests electronically, ultimately improving the process for both doctors and patients.

While the new law does not apply to government insurers like Medicare and Medicaid, the federal Centers for Medicare and Medicaid Services (CMS) issued new rules in January that similarly require Medicare and Medicaid to process urgent prior authorization requests within 72 hours and all others within seven days.

Johnson & Johnson Litigation Update

The plaintiffs in litigation against Johnson & Johnson (JNJ) have alleged breaches of the Employee Retirement Income Security Act (ERISA) fiduciary duty rules in JNJ's administration of its prescription drug program.

JNJ filed a motion to dismiss the plaintiffs' initial complaint, questioning the plaintiffs' legal standing to pursue the claims, pointing out that the plaintiffs had not been denied any benefits and had not demonstrated that they were prescribed any of the medications they claimed were overpriced. Additionally, JNJ argued that the plaintiffs did not adequately allege that JNJ's selection process for a pharmaceutical benefit manager (PBM) was imprudent. The court has not yet ruled on the motion to dismiss.

Wells Fargo PBM and Fiduciary Duty Lawsuit

A lawsuit was filed in a Minnesota federal court accusing Wells Fargo and its plan fiduciaries of engaging in prohibited transactions and violating their fiduciary duties under the Employee Retirement Income Security Act (ERISA) concerning the Wells Fargo & Co. Health Plan (the "Plan") and its participants. The complaint mirrors many of the allegations made in a similar lawsuit against Johnson & Johnson (JNJ), with some sections being directly copied.

The plaintiffs allege that Wells Fargo mismanaged the Plan's prescription drug benefit program, leading to millions of dollars in increased premiums, out-of-pocket expenses, and reduced wages for participants. Unlike the JNJ case, this complaint includes specific drugs (although redacted) that the plaintiffs were prescribed and purchased, which are claimed to be among the overpriced medications.

A new aspect of the Wells Fargo complaint is the allegation that the Plan fiduciaries violated ERISA by causing the Plan to pay excessive and unreasonable administrative fees to its pharmaceutical benefit manager (PBM). ERISA generally prohibits transactions between a health plan and its service providers unless the terms are reasonable and necessary, with compensation being fair. The complaint asserts that the $25 million in administrative fees paid to Express Scripts in 2022 was significantly higher than what other comparable plans paid, making it an unreasonable and prohibited transaction. The complaint strengthens its argument by citing what similarly situated plans paid per participant in administrative fees, likely in response to the issues raised in the JNJ motion to dismiss.

The plaintiffs seek to recover losses to the Plan from Wells Fargo and its fiduciaries personally, request the removal of current Plan fiduciaries, the appointment of an independent fiduciary, and the replacement of Express Scripts as the Plan's PBM. They also seek any other equitable relief available.

Employer Action Items

- Create a committee dedicated to overseeing health and welfare benefits, adopt a charter, and delegate fiduciary responsibilities to this committee.
- Hire qualified prescription drug plan consultants to help compare PBMs and prescription drug arrangements, ensuring that these consultants have no conflicts of interest.
- Carefully review PBM agreements, fee structures, and formularies, and negotiate terms rather than accepting the PBM's standard agreement.
- Gather and analyze benchmark data from other plans and pharmacies to compare against current and potential vendor agreements.
- Consider whether all compensation arrangements are reasonable and free from conflicts of interest. Periodically subject PBMs and other vendors to competitive requests for proposals (RFPs).
- Thoroughly document all procedures for obtaining, reviewing, and monitoring proposals, agreements, and vendor performance to demonstrate procedural prudence.

Question of the Month

Q. Our client was advised in error to pay the PCORI fee for last year under the assumption the group's plan was self-funded. However, the group plan was, in fact, fully insured at the time. How should the client handle the over-payment?

A. If a plan sponsor overpaid the PCORI fee, it can file Form 720-X for an over-payment of a previously-filed PCORI liability. Form 720-X is available on IRS.gov.