Compliance Insights

Alliant

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2024 Outlook: Compliance Hot Topics Now and on the Horizon

Introduction

Group health plan compliance moves quickly and includes an expansive landscape of requirements that can be difficult to track and prioritize. The Alliant Compliance team has put together an overview of key issues to consider and litigation to watch as many plans move into strategic planning for the next year. In this piece we cover certain pandemic provisions coming to an end, including telehealth and HSA flexibility, COVID-19 Testing and Treatment, and also outline updates to key benefit limits. We take a look at issues on the horizon, including final Mental Health Parity Addiction Equity Act (MHPAEA) regulations related to certain testing requirements, gender affirming care issues, new HIPAA rules that would require updates to HIPAA policies and procedures, ERISA fiduciary duties, and a group health plan litigation overview.

Hot Topics Now

Flexibility for Health Savings Account Compatible High Deductible Health Plans Ending

Telehealth

The Consolidated Appropriations Act of 2023 included a two-year extension of COVID-19 related telehealth flexibility for HSA compatible HDHPs. Under the extended relief, HDHPs have been allowed to provide first dollar coverage for telehealth or other remote care services below the plan's required minimum deductible for plan years beginning before January 1, 2025, without causing participants to lose HSA eligibility. Absent new legislation, this is the final year group health plans can extend this flexibility. For more information, see Compliance Alert 2022-07: The CAA of 2023 Includes a Two-Year Extension of Telehealth Flexibility for HSA Compatible HDHPs.

COVID-19 Testing and Treatment

Following the end of the Public Health Emergency on May 11, 2023, group health plans were no longer required to cover COVID-19 testing and related services without cost-sharing. However, due to flexibility provided to HSA compatible HDHPs, some group health plans chose to continue offering first dollar coverage of COVID-19 testing and/or treatment. IRS Notice 2023-37 ended this flexibility for HSA compatible HDHPs for plan years ending after December 31, 2024. This means that non-calendar year plans can only continue to offer COVID-19 testing and related treatment below the deductible of an HSA compatible HDHP for their final 2023 plan years, but not for plan years beginning in 2024. Calendar year plans that began on January 1, 2024, can continue to offer pre-deductible coverage for COVID testing or treatment through the end of the current plan year. Employers sponsoring HSA compatible HDHPs that chose to continue to cover COVID-19 testing after the expiration of the COVID-19 testing coverage mandate should work with Third Party Administrators (TPAs) on eliminating that coverage for plan years ending after December 31, 2024. For additional information, see Compliance Alert 2023-06: IRS Ends COVID-19 Testing and Treatment Flexibility for HSA Compatible HDHPs.

2024 Benefit Plan Limits

Throughout the year, the IRS releases various Revenue Procedures that adjust certain key tax and contribution limits for employer plans, including but not limited to, flexible spending account limits, health savings account (HSA) annual contribution limits, the out-of-pocket limits for high deductible health plans (HDHPs), the Affordable Care Act (ACA) affordability percentage, and pay or play penalty amounts. For a

detailed review of those limits, please see our Alliant Insight: IRS Employee Benefit Limits. In addition to the foregoing, each year the Department of Health & Human Services (HHS) releases updated Federal Poverty Levels (FPL). These levels are relevant for calculating the ACA pay or play FPL affordability safe harbor. The updated numbers for 2024 ($15,060 up from $14, 580 in 2023) will apply for purposes of calculating the ACA FPL affordability safe harbor for 2025 calendar year plans and non-calendar year plans beginning on or after August 1, 2024. Calculating ACA affordability under the FPL safe harbor requires a solid understanding of the relevant thresholds. For more information on that process, and the other ACA affordability safe harbors, see our Alliant Insight: An In-Depth Look at Affordability.

On the Horizon

New Mental Health Parity Rules

On July 25, 2023, the Agencies issued proposed rules that would expand a certain component of the Mental Health Parity and Addiction Equity Act (MHPAEA) compliance—specifically, the nonquantitative treatment limitation (NQTL) comparative analysis. By way of brief reminder, under longstanding Mental Health Parity rules, group health plans that cover Mental Health (MH) or Substance Use Disorder (SUD) benefits must ensure that, in addition to parity in certain financial requirements and quantitative treatment limits (visit limits), NQTLs applicable to MH/SUD benefits are not more restrictive than the requirements or limitations for Medical/Surgical (MS) benefits. Note that an NQTL is any provision that limits the scope or duration of benefits for treatment that is not a *quantitative* treatment limitation. Common examples of NQTLs include medical management standards, network access, and formulary design. The Consolidated Appropriations Act of 2021 (CAA) requires plans to complete an NQTL comparative analysis and, *upon request*, provide the analysis to the Department of Labor (DOL) (or appropriate Department), as well as relevant State authorities. The Departments later released sub-regulatory guidance setting forth what the comparative analysis must include, what documents plans should be prepared to make available upon request, practices to avoid, and a timeline for corrective action.

Notably, the proposed rules not only add new and complex elements to the NQTL comparative analysis, including quantitative testing, collection and evaluation of outcomes data and network adequacy to assess the impact of NQTLs on access to benefits, but they also state that plans should perform their NQTL comparative analysis proactively rather than wait for an agency request. The challenge for employer/plan sponsors is that the NQTL analysis generally requires an external vendor, is costly to conduct, requires significant engagement with third party administrators, and is only current for the existing plan year or until any plan changes are made. While the regulations remain proposed at this time, we expect the Agencies to finalize these rules in 2024. In preparation, plan sponsors should discuss what kind of support their TPA or carrier can provide, especially given that the proposed regulations specifically note the TPAs and carriers' role as a co-fiduciary of the plan. Depending on TPA/carrier support, plan sponsors may need to engage an outsourced vendor or law firm to complete the required analysis. For detailed information on the proposed rules, see Compliance Alert 2023-08: Agencies Issue Long Awaited Guidance on Mental Health Parity Compliance with New Requirements for Plan Sponsors.

Gender Affirming Care

The existing statutory and regulatory landscape can create questions for employer plan sponsors on the provision of gender affirming care. Applicable federal laws, as well as a developing state law landscape—where certain states prohibit the provision of gender affirming care to minors and other states affirmatively protect the provision of such care, can create confusion on the issue. We explore the key issues on gender affirming care below, noting specifically that treatment exclusions can raise issues under the Mental Health Parity and Addiction Equity Act (MHPAEA), Title VII of the Civil Rights Act, Section 1557 for certain entities, and has been the subject of recent litigation.

- **Mental Health Parity and Addiction Equity Act**. Under the MHPAEA, if a plan provides Mental Health (MH)/Substance Use Disorder (SUD) benefits in any of six coverage categories (inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs), it must provide MH/SUD benefits in every coverage category in which Medical Surgical (MS) benefits are also provided. For practical purposes this means that if a plan covers

gender dysphoria counseling or hormones it must also cover gender affirming surgeries. It is difficult, if not impossible, to screen topics addressed during counseling services or otherwise discern the reason certain hormones are prescribed. As a result, plans take on significant risk if they exclude all coverage of gender dysphoria (including gender affirming surgeries). In addition, placing limits on lifetime or annual limits on gender affirming surgeries are also problematic under MHP rules. The MHPAEA includes a somewhat complex 1/3 - 2/3 rule on lifetime or annual limits. Under that rule, if a plan does not include a lifetime or annual limit on any MS benefits or includes a lifetime or annual limit that applies to less than 1/3 of all MS benefits, it may not impose a lifetime or annual limit on MH/SUD benefits. If a plan includes a lifetime or annual limit on at least 2/3rds of MS benefits, it must either apply the same limit in a manner that does not distinguish between the MS and MH/SUD benefits or not include a limit on MH/SUD benefits that is less than the limit on MS benefits. However, since lifetime and annual limits are largely precluded by the ACA (with respect to Essential Health Benefits) they are generally no longer allowed for MH/SUD benefits because few plans meet the 2/3rds requirement. Finally, restricting coverage to participants 18 years old or older is likely problematic under the ACA uniformity rule that group health plans must cover dependents up to age 26 and that coverage, cannot vary based on age, except where the dependent is over age 26. See our note below on the applicability of state law prohibitions on gender affirming care for minors to self-funded plans. For additional information on this issue, see our Alliant Insight: Mental Health Parity It's Time for a Checkup.

- **Title VII.** Title VII of the Civil Rights act prohibits employment discrimination based on race, color, religion, sex and national origin. In June 2020, the U.S. Supreme Court held that Title VII prohibits employers from discriminating on the basis of an individual's sexual orientation or gender identity. Employment terms and conditions include employer-sponsored healthcare benefits. Therefore, a group health plan categorically excluding coverage of all gender affirmation surgeries could be challenged as discriminatory under Title VII or subject to plan participant litigation or enforcement action by the EEOC.

- **Section 1557.** Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in the "health programs and activities" of certain entities that receive federal funds. While Section 1557 is currently applicable only to entities "principally engaged in the business of providing healthcare" that receive federal financial assistance, new regulations may broaden the scope of entities to which Section 1557 applies. In addition, the current interpretation by HHS is that discrimination based on sex includes discrimination on the basis of sexual orientation and gender identity and forthcoming regulations are expected to confirm this interpretation. In addition to this regulatory guidance, in late December 2023, a federal district court judge in Washington declared that that Blue Cross Blue Shield of Illinois, acting as a third-party administrator (TPA) of a self-funded group health plan, violated ACA Section 1557 by discriminating on the basis of sex when it denied coverage for services for gender affirming care based on specific plan exclusions. As part of the decision, the Court issued a permanent injunction enjoining Blue Cross from "administering or enforcing exclusions and any policies or practices that wholly exclude or limit coverage of 'gender-affirming health care,' so long as it is a 'health program or activity' under the ACA's Section 1557." As a result, the TPA has advised clients it will not administer that exclusion. This decision is likely to be appealed, but could impact group health plan administration in the meantime.

- **State Law Developments.** There has been significant state law activity in the area of gender affirming care, including efforts to prohibit gender affirming care for minors, from the provision of certain hormones to surgical procedures, as well as certain state law efforts to protect access to such care. The state laws prohibiting access to care for minors include enforcement schemes that impose civil, criminal, or professional penalties on providers who perform the services. Self-funded group health plans are generally exempt from these state laws because the Employee Retirement Income Security Act (ERISA) preempts state laws that relate to benefits under a group health plan. ERISA does not, however, preempt criminal laws. As a result, self-funded group health plans that cover gender affirming care in states that impose criminal penalties should consult legal counsel about their risks. Alternatively, a self-funded plan seeking to exclude gender affirming care should be

aware of the risks under both federal and state law, and all group health plans should understand the legal landscape on this issue in the states in which they do business and have employees.

Watch for New HIPAA Prohibition on Disclosure of PHI Related to Reproductive Health Care

On April 17, 2023, with specific reference to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* and various state laws banning or restricting access to abortion, HHS proposed to modify the HIPAA Privacy Rule to include a new prohibition against the use or disclosure of PHI for the criminal, civil, or administrative investigation of or proceeding against an individual, regulated entity, or other person for seeking, obtaining, providing, or facilitating reproductive health care. This rule also prohibits disclosure for use in identifying any person or regulated entity for the purpose of initiating such an investigation or proceeding. This prohibition applies to "regulated entities" which includes health plans, heath care clearinghouses, most health care providers, and business associates. We expect HHS to finalize these regulations in 2024. Covered entities should be aware that these changes, once final, will require amendments to existing HIPAA policies and procedures and modifications to their processes in responding to requests for disclosure. Although anecdotally we have not yet seen plan sponsors receive requests for this type of information for this purpose, they may want to implement additional procedures to seek protective orders on behalf of participants in connection with any state court orders and/or subpoenas requesting medical records related to abortion and reproductive health care services. For additional information, see Compliance Alert 2023-04: Proposed HIPAA Amendments Protect Reproductive Healthcare Information.

ERISA Fiduciary Duties in a New Era of Risk

ERISA is comprehensive federal legislation that applies to non-federal governmental "employee benefits plans," including health and welfare and retirement plans. While the most common ERISA requirements are plan-related disclosures to participants (SPDs, SMMs) and governmental reporting (5500s), ERISA also imposes a strict fiduciary code of conduct for ERISA plan sponsors and plan administrators. A fiduciary duty is among the highest standards of care under law. ERISA fiduciary duties are not new, but employer plan sponsors of group health plans should revisit these duties in light of new transparency and disclosure requirements and the potential for class action litigation against group health plan fiduciaries for ERISA fiduciary duty violations. Specifically, disclosure rules that have been applicable to retirement plans for a number of years are now applicable to group health plans (known as 408(b)(2) disclosures), and it is evident by way of social media solicitations that several of the plaintiffs' attorney firms involved in retirement plans class action lawsuits are actively seeking potential class members for cases against health plan fiduciaries. In fact, within a week of this publication, a class action was filed against Johnson & Johnson's (J&J) group health plan and its plan fiduciaries in the United States District Court for the District of New Jersey, alleging several ERISA fiduciary violations related to J&J's prescription drug plan.

Given this new landscape, employer plan sponsors should understand their ERISA fiduciary duties, their compliance obligations, specifically the new transparency requirements, and how these rules apply to their decisions regarding the plan. Detailed information on this topic is available in Alliant Compliance Insight-ERISA Fiduciary Duties: The Impact of Transparency and How to Protect Your Plan, as well as our recorded webinar on this topic. In addition, Alliant's ERISA Fiduciary Toolkit, with practical implementation tools and guidance, is available to Alliant clients.

Benefit Plan Litigation to Watch

This overview is certainly not exhaustive of the ongoing group health plan-related litigation, but it focuses on those cases or issues likely to be impactful in 2024 and beyond. Note that there are certain cases pending in the Supreme Court that present somewhat esoteric legal questions, but depending on the Court's ruling, could subject certain regulations (ACA regulations in particular) applicable to group health plans to new litigation challenges.

Pharmacy Related Litigation

- **Copay Accumulators.** A District Court decision in the D.C. Circuit may have an impact on plans with a copay accumulator plan design. A copay accumulator provides that financial assistant that certain drug manufacturers offer participants who take those drugs does not have to be counted toward that

participant's and cost-sharing limits. HHS issued regulations confirming the permissibility of that approach, and offering that plans are permitted to count the manufacturer financial assistance toward out-of-pocket costs. Late last year, in *HIV and Hepatitis Policy Institution et al. v. United States Department of Health and Human Services,* the U.S. District Court for the District of Columbia vacated those HHS regulations and reverted to a prior rule that allows a copay accumulator only where a branded drug has a generic equivalent, limiting a plan's ability to manage costs in this way. **Takeaway**: This case is likely to be appealed and, in the meantime, plans with a copay accumulator program should work with carriers/TPAs/PBMs and counsel to determine a best path forward. If this decision is upheld on appeal, plan sponsors with this design should prepare to change their plan design and plan for the increased costs,

- **ERISA Preemption.** At this point, all 50 states have passed some form of law regulating pharmacy benefit managers (PBMs), largely in an attempt to manage costs and facilitate transparency in the prescription drug market. These laws take varying forms and have been the subject of litigation on the issue of whether those laws are pre-empted by ERISA, among certain other issues. This is an important concern for multistate employers attempting to administer a single pharmacy benefit plan consistently across its operations. Several years ago, one of those cases—*Rutledge v. Pharmaceutical Care Management Association*—made its way to the Supreme Court, where the Court concluded that ERISA did not preempt an Arkansas state law regulating PBMs. The Court noted, however, that its decision was fairly fact specific based on the provisions of that law, and that certain other statutory schemes may be preempted. As a result, the decision did not really settle the issue of whether state PBM laws apply to ERISA self-funded plans. With that background, last year the 10th Circuit decided in *Pharm. Care Mgmt. Ass'n v. Mulready,* that ERISA *did preempt* an Oklahoma law that imposed certain restrictions on PBMs. These restrictions included certain geographic "network restrictions", a prohibition against PBMs promoting in-network pharmacies using cost-sharing discounts, and a requirement that certain pharmacies must be allowed into a PBM's preferred network. This case is likely to be appealed to the Supreme Court in short order, but it is unclear whether the Supreme Court will reconsider this issue. **Takeaway**: State PBM-related laws come in many forms and are challenging for multistate plans to implement. This issue will continue to be litigated and plans should work with their PBMs and TPAs to determine the impact of and implementation approach for certain state PBM-related laws.

Reproductive Healthcare - Mifepristone Litigation. Litigation on the issue of reproductive health care continues in the wake of the Supreme Court decision in *Dobbs v. Jacksons Women's Health,* which overturned the prior decisions in *Roe v. Wade (and Planned Parenthood v. Casey*) that there was a Constitutional right to abortion. Specifically, plan sponsors should be aware that late last year, the Supreme Court agreed to hear a case out of the 5th Circuit where a federal district court ordered that mifepristone—the medication administered for non-surgical abortions—be removed from the marketplace. **Takeaway:** Pending this appeal to the Supreme Court, group health plans can continue to cover mifepristone without risk for now. Employer plan sponsors should, however, be aware that this case will be heard in 2024 and the outcome could impact whether and/or under what circumstances the medication can still be covered under the plan.

ERISA Fiduciary Litigation. In addition to the *Johnson & Johnson* case referenced above, we have generally seen increased litigation activity in this space, including a number of actions in recent years against plan sponsors for COBRA violations. In addition, both plaintiffs' attorneys and the Department of Labor (DOL) have focused their attention on third-party administrators (TPAs) acting in the capacity as an ERISA plan fiduciary, with both private litigants and the DOL alleging the TPAs breached those ERISA fiduciary duties in numerous circumstances and under several theories of liability. Limiting a plan's access to certain data is among those claims and theories of liability against TPAs. Plans sponsors should closely review their TPA agreements and be generally aware of the extent to which their TPA(s) might be limiting access to their own plan data.

Conclusion

Despite that Congress has not passed meaningful group health plan related legislation for some time, compliance obligations for employer plan sponsors continue to become more complex as a result of a host of factors—new regulations, including the implementation of certain transparency requirements, Supreme Court decisions, new and ongoing litigation, and ongoing agency oversight and enforcement. This trend is unlikely to wane, especially in an election year, and it is important that employer plan sponsors remain

informed of the shifting landscape, associated risks, and best practices. As always, we will continue to provide timely updates and practical guidance throughout the year via our Alerts, Friday Fast Facts, and Compliant with Alliant podcast. Please contact your Alliant representative with questions.

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