PPI BENEFIT SOLUTIONS

SELF-INSURED GROUP HEALTH PLAN COMPLIANCE CONSIDERATIONS: A GUIDE FOR EMPLOYERS

Sponsors of fully insured group health plans seeking greater control over their healthcare expenses and more flexibility with their plan design may consider self-insuring plan benefits. Self-insuring offers the potential for significant long-term cost savings and more customized benefits by giving sponsors a more direct role in managing financial exposure and tailoring plan coverage options.

Self-insuring also provides an opportunity to enhance plan governance and administration because the sponsor as plan administrator will be primarily responsible for implementing the plan and fulfilling applicable fiduciary and compliance obligations. ERISA self-insured plan administrators have heightened fiduciary responsibilities, since they assume duties previously fulfilled by the insurance carrier. Self-insuring also expands the sponsor's compliance role with respect to various group health plan laws, including the ACA, COBRA, HIPAA, and transparency laws, and introduces new obligations, such as compliance with IRC Section 105 nondiscrimination rules. Although service providers can assist with many daily plan functions, plan sponsors remain accountable, so strong contracting and vendor monitoring are essential.

The move to self-insuring can enhance plan design flexibility and cost controls while giving employers a more direct role in fulfilling benefits compliance and fiduciary obligations.

Accordingly, employers evaluating whether to self-insure their major medical plan should understand the key differences, particularly from a compliance perspective, between fully insured and self-insured plans. Note that health FSAs, HRAs, and many point solution programs (not discussed in this guide) are also self-insured plans and often have compliance obligations similar to self-insured medical plans.

Employers should consult with their legal counsel and tax advisors for legal or tax advice specific to their plan(s) and circumstances.

At a Glance:

1. The Decision to Self-Insure

While the potential for long-term cost-savings and greater control over plan design often drives the move to self-insurance, employers considering this change must carefully evaluate their financial risk tolerance, cash flow dynamics, and administrative capacity. Stop-loss coverage can mitigate cost exposure but does not eliminate the employer's ultimate responsibility for claims. Self-insuring requires greater administrative involvement and coordination among internal teams and external vendors to support ongoing plan operations, including compliance with numerous federal – and some states' – group health benefit laws.

2. Compliance Considerations When Self-Insuring

A. The Plan Sponsor's Role

- *ERISA Fiduciary Duties*
  - *Fiduciary Functions.* Self-insuring expands plan sponsor responsibilities, which are no longer shared with an insurer. Self-insured plan sponsors, as plan administrators, must ensure their plans comply with all applicable laws. When performing fiduciary functions (e.g., plan implementation and operations, the selection and monitoring of service providers, claims adjudication), plan sponsors must act solely in participants' interests.
  - *Selecting and Monitoring Plan Service Providers.* Plan sponsors must prudently select plan service providers (e.g., TPAs and PBMs) and continuously monitor their performance, documenting the process to show ongoing and reasoned oversight. This oversight includes reviewing contractual terms, performance, fees, and expenses. Self-insured plan sponsors typically delegate day-to-day administration to a TPA or insurer acting under an administrative services only (ASO) arrangement, but plan sponsors remain ultimately responsible for plan compliance and operations.
  - *Claim Adjudication and Appeals.* Self-insured plan sponsors should carefully consider their role in the claims review and appeals process. Sponsors typically delegate claim adjudication authority to a TPA, and the contract with the TPA should specify the TPA's role and fiduciary status with respect to claim appeals. If a plan sponsor wishes to play a direct role in the appeals process, they must have a prudent process in place to review claim appeals, apply plan terms, comply with regulatory requirements (including timeframes and notices), and consult with medical experts as necessary.
  - *Plan Assets.* Under ERISA, fiduciary duties apply to "plan assets," including participant contributions and the portion of refunds or rebates attributable to participant contributions, which must be used in accordance with DOL guidance. Although ERISA generally requires plan assets to be held in a trust, the DOL does not enforce this requirement for group health plans if participant contributions are promptly applied to premiums or claims, so most self-insured plans operate on an "unfunded" basis using general assets.

B. Plan Design

- *ERISA Preemption of State Insurance Laws.* Fully insured group health plans must comply with applicable state insurance mandates, which can limit plan design flexibility and increase costs. In contrast, ERISA generally preempts (i.e., sets aside) state insurance laws for self-insured plans, allowing sponsors greater discretion to tailor eligibility and benefits to their workforce and budget. This flexibility can also support uniform plan design across states but requires careful coordination with the plan's TPA and vendors.

  Governmental plans and certain church plans are not subject to ERISA, meaning ERISA fiduciary duties and preemption do not apply. However, these plans may be subject to state laws, including fiduciary standards similar to ERISA, as well as other federal group health plan requirements.
- *ACA Requirements.* Like fully insured plans, self-insured plans must comply with many ACA requirements, including coverage of dependent children to age 26, summary of benefits and coverage (SBC) distribution, coverage of preventive services without cost-sharing, and annual maximum limits.
  - *Prohibitions on Annual and Lifetime Dollar Limits.* Self-insured plans are not required to cover essential health benefits (EHBs), but they may not impose annual or lifetime dollar limits on any EHBs they do cover. The definition of EHBs is based on a benchmark plan selected by the plan sponsor from any state benchmark, providing greater control over plan design. Sponsors should formally document their benchmark selection and coordinate with TPAs to ensure proper administration.
- *MHPAEA.* Self-insured plans that offer mental health and substance use disorder (MH/SUD) benefits must do so on par with medical and surgical (MED/SURG) benefits. Plan exclusions or limitations affecting MH/SUD benefits require careful scrutiny.
  - *NQTL Comparative Analysis Requirement.* Self-insured plan sponsors must prepare and maintain a written comparative analysis demonstrating parity in the design and application of nonquantitative treatment limitations (NQTLs) such as

coverage exclusions, prior authorization requirements, medical necessity criteria, or network limitations. This requires engaging in a prudent process to select and monitor qualified service providers (e.g., TPAs, PBMs, or specialized vendors) to complete the plan's comparative analysis.

- *Section 105 Nondiscrimination*. Self-insured plans must satisfy IRC Section 105 nondiscrimination rules to preserve tax-free treatment of benefits, ensuring that eligibility, contributions, and benefits do not favor highly compensated employees (HCEs). Permissible distinctions may be based on bona fide employee classifications, and designs that disproportionately benefit HCEs are problematic. Ongoing nondiscrimination testing is critical, as failures result in adverse tax consequences for HCEs that cannot be easily corrected after the plan year ends.
- *HIPAA Nondiscrimination*. HIPAA prohibits group health plans from discriminating based on health factors with respect to eligibility, premiums, or benefits. While plans may limit or exclude coverage for specific conditions or diseases, for certain types of treatments or drugs, or for treatments determined to be experimental or not medically necessary, they may not target individuals based on a health factor or incentivize high-cost claimants to drop group coverage.

C. Plan Implementation

- *Determining the Premium Equivalent*. Self-insured plan sponsors must estimate the cost of coverage for the upcoming plan year to determine participant cost-sharing and, if subject to COBRA, the COBRA "applicable premium." The IRS permits sponsors to estimate self-insured plan costs using either a past-cost method or a more precise actuarial method. The past-cost method relies on prior year costs adjusted for inflation but may be less accurate, while the actuarial method incorporates claims trends, demographics, and other variables to produce a forward-looking cost projection.
- *COBRA Rates*. COBRA premiums for self-insured plans are typically set using tiered rates that correspond to the coverage options available to active employees, with an additional 2% administrative surcharge permitted. As ERISA fiduciaries, sponsors must ensure COBRA rates reasonably reflect expected plan costs and are not set higher than calculated under the past-cost method or actuarial method.
- *HIPAA Privacy and Security Obligations*. When transitioning to self-insurance, sponsors assume expanded responsibilities under the HIPAA Privacy and Security Rules due to increased access to protected health information (PHI). Self-insured sponsors must appoint a privacy officer, adopt written policies and procedures, maintain and distribute a Notice of Privacy Practices, train workforce members, implement safeguards for electronic PHI, manage business associate relationships, perform risk assessments, and respond to security incidents, often with support from HIPAA compliance vendors or legal counsel.

D. Plan Disclosure and Reporting Requirements

- *ERISA*
  - *Written Plan Document*. All ERISA plans must maintain a written plan document, but self-insured plans require a more comprehensive document in the absence of an insurance policy that describes coverage. The plan document must clearly describe eligibility, benefits, exclusions, claims procedures, handling of plan assets, and HIPAA provisions for handling PHI. Sponsors must ensure consistency across the plan document, summary plan description (SPD), SBC, and enrollment materials and coordinate terms with stop-loss coverage to avoid gaps and disputes. Self-insured plan sponsors are directly responsible for responding to participant requests for plan documents, including SPDs. To avoid penalties, sponsors should establish processes with TPAs to ensure timely and complete responses.
  - *Form 5500*. ERISA group health plans with 100 or more participants (enrolled employees, but not dependents) at the beginning of the plan year, or plans funded through a trust, must file Form 5500 annually. Self-insured plans generally do not file Schedule A unless wrapped with insured benefits, and Schedule C applies only if plan assets are held in trust.
  - *Summary Annual Report*. Plans required to file a Form 5500 must generally distribute a Summary Annual Report (SAR) to participants. However, self-insured health plans funded from general assets are exempt unless the plan is wrapped with insured benefits for Form 5500 purposes. In that case, a SAR must be distributed for the wrapped plan.
- *ACA*
  - *Employer Mandate Reporting.* Self-insured plan sponsors are responsible for ACA reporting using Forms 1094 and

1095. Section 6055 reporting identifies months of minimum essential coverage for covered individuals. Notably, for all self-insured plans, the employer is responsible for Section 6055 reporting, regardless of size. Section 6056 reporting applies to applicable large employers (ALEs), i.e., those with 50 or more full-time employees in the prior year, and reflects offers of coverage to full-time employees. Self-insured ALEs may combine Sections 6055 and 6056 reporting using Forms 1094-C and 1095-C. While many employers rely on vendors to assist with completing Forms 1094 and 1095, employers should carefully review all forms prior to filing to ensure they accurately reflect all offers of coverage and to avoid penalties for reporting failures.

Several states impose individual mandate reporting requirements that are separate from federal ACA reporting. For self-insured plans, employers are typically responsible for furnishing coverage statements to employees and filing reports with the state, based on employees' state of residence.

- *PCOR Fee*. Self-insured plan sponsors must file IRS Form 720 and pay the annual PCOR fee by July 31 of the calendar year following the end of the plan year. While the fee applies to both insured and self-insured plans, responsibility shifts from the carrier to the employer when a plan becomes self-insured. The fee must be paid using employer funds, not participant contributions, as the latter amounts are plan assets.

- *Medicare Part D*. Group health plans with prescription drug coverage must disclose whether that coverage is "creditable," meaning whether it is expected to pay at least as much as Medicare Part D coverage. In fully insured plans, the insurer typically confirms creditability, but in self-insured plans the employer (sometimes with TPA assistance) must determine creditability status to ensure accurate, timely disclosures.
- *CAA 2021 and Transparency in Coverage*. The Consolidated Appropriations Act, 2021 (CAA 2021) and Transparency in Coverage final rule impose significant reporting and disclosure obligations on group health plans and insurers. While fully insured plans may allocate many responsibilities to carriers, self-insured plan sponsors remain ultimately responsible for compliance. Sponsors typically rely on TPAs and vendors to assist but must prudently oversee their performance.
  - *CAA 2021, Title I, No Surprises Act*. The No Surprises Act (NSA) establishes federal protections to limit participants' exposure to unexpected bills for certain out-of-network services, including emergency care, air ambulance services, and certain nonemergency services received at in-network (INN) facilities. Self-insured plan sponsors must ensure the required surprise billing notice is posted on a public website, monitor participant complaints, and confirm that TPAs will handle the independent dispute resolution process on the plan's behalf.
  - *CAA 2021, Title II, Transparency*. CAA 2021 transparency provisions require plans to satisfy multiple compliance obligations, including filing gag clause prohibition compliance attestations, reviewing service provider compensation disclosures, reporting specific prescription drug data, and maintaining a MHPAEA NQTL comparative analysis. Plan sponsors typically rely on TPAs to handle many of these obligations but remain responsible for monitoring compliance.
  - *Transparency in Coverage Final Rule*. The Transparency in Coverage final rule requires plans to publicly disclose pricing information in machine-readable files and to provide participants with a self-service tool showing personalized cost-sharing estimates. These disclosures are intended to increase price transparency and enable plan sponsors and participants to better compare healthcare costs. Compliance is an enforcement priority and typically requires coordination with TPAs and vendors.

3. Summary

Self-insuring can give employers more control over health plan costs and design, with potential long-term savings, but it also shifts claims risk and requires planning (e.g., for cash-flow volatility, incurred but not yet reported (IBNR) reserves, and stop-loss coverage). Transitioning to self-insurance increases ERISA fiduciary responsibilities, requiring strong governance and prudent vendor selection and monitoring. While ERISA preemption can expand plan design flexibility, sponsors of self-insured plans must still meet key federal requirements, new requirements (e.g., Section 105 nondiscrimination, ACA reporting), and expanded HIPAA Privacy/Security and Transparency/NSA obligations. With the right governance and well-structured vendor support, sponsors can manage these responsibilities effectively and implement self-insuring successfully.

4. Resources

1. THE DECISION TO SELF-INSURE

Comparing Fully Insured and Self-Insured Plan Costs

Employers with fully insured plans pay a fixed monthly premium to the insurer to assume the financial obligations for all plan claims and administrative costs. In contrast, employers with self-insured plans are responsible for paying participants' claims, which are variable, and the related administrative expenses.

Self-insuring removes the employer from the insurer's risk pool, allowing the employer's financial risk to be assessed based on the characteristics of its own employee population. Certain expenses, such as state premium taxes and the insurer's profits, which are factored into the fully insured plan premium, are eliminated by self-insuring. Self-insured plan sponsors may also reduce costs by modifying their plan design (e.g., limiting or excluding certain benefits), carving out programs (e.g., pharmacy benefits), and adopting clinical management strategies to increase efficiencies and improve patient outcomes. However, self-insuring will add some new costs, such as stop-loss insurance premiums and fees for TPAs and other service providers.

Projecting Self-Insured Plan Costs

An estimate of the future costs of self-insuring normally considers the projected cost of plan claims (based on historical claims, if available), administrative expenses, and stop-loss premiums, among other items. Underwriters and analytics teams can normally provide projections for employers considering self-insuring. If claims experience is not available, actuaries and analytics teams rely on carrier information such as manuals and fully insured rates to guide a client and help create a self-insured plan budget.

Employers often engage an actuary to review the plan's historical information, including claims costs (e.g., over a three-year period, if available from the carrier), plan design, and demographic changes to provide a more customized future cost projection that incorporates anticipated changes in addition to expected trends in healthcare costs and utilization, among other items. These actuarial estimates can help the employer determine if, over the long-term, self-insuring will be more or less expensive than continuing to pay premiums to an insurance carrier.

Risk Tolerance and Cash Flow Dynamics

An employer must also consider its financial position, risk tolerance, size, ability to obtain reinsurance, and cash flow dynamics, among other factors, when evaluating whether self-insuring is a viable and appropriate option.

The key distinction of a self-insured plan (as compared to a fully insured plan) is the lack of insurance to shift financial risks from the sponsor to an unrelated third party (e.g., an insurance carrier). Therefore, employers must recognize this risk and assess their financial ability to pay participant claims, which may exceed actuarial estimates and fluctuate from month to month. Volatility is typically greater for smaller plans, where one or two high-cost claims can materially affect costs; larger plans can better absorb such variability.

Our Observation	When a plan initially self-insures, the sponsoring employer may be pleasantly surprised to find that there are few medical claims payable in the first few months. However, this experience is simply due to the delay between when medical claims are incurred and when they later become payable. Accordingly, the employer must manage their cash flow and be prepared to pay incurred claims when required to do so. Employers typically establish a reserve to fund claims incurred but not yet reported (IBNR). Ongoing tracking and budgeting for the plan's IBNR claims is an important part of the sponsor's cash flow management.

Role of Stop-Loss Coverage

Self-insured plan sponsors normally secure reinsurance (typically in the form of stop-loss coverage) to provide some financial protection against the risk of higher than anticipated claims. However, the employer, and not the stop-loss carrier, remains ultimately responsible for ensuring participant claims are paid.

Stop-loss insurance is typically a contract between the plan sponsor and the stop-loss carrier, although in some cases the plan itself purchases the policy. Generally, employers can purchase their own (i.e., stand-alone) policy unless, based on the size of the participant population, the TPA requires the stop-loss policy to be built into their service agreement. Under a standard stop-loss policy, the carrier agrees to reimburse the employer (or plan) for claims paid in excess of a stated "attachment point," which can be a per-participant amount or an aggregate amount (for plan-wide claims), or both, for the applicable stop-loss coverage period.

Stop-loss policies vary widely. Employers comparing stop-loss policies should thoroughly review the specific policy details to avoid unexpected coverage gaps that can create financial exposure. For example, employers should understand the covered benefits and coverage period (i.e., when claims must be incurred or paid to count toward attachment points and qualify for reimbursement). Attention should be paid to any coverage exclusions (e.g., a stop-loss carrier may add exclusions to the policy or impose a higher specific attachment point called a "laser" for individuals it considers likely to incur high claims). Of course, pricing and the insurer's reputation and financial rating are also important.

Additionally, employers should carefully reconcile their stop-loss policy with their plan document terms, particularly with respect to plan coverage and eligibility requirements. Many stop-loss carriers have a "mirroring" policy that states the underlying plan documents will be used to determine eligible claims and individuals. Therefore, it is critical for employers to have a documented leave policy, consistent with the plan terms, that addresses how long an employee can remain on the plan while not actively at work. Moreover, employers must monitor plan eligibility to ensure the plan is operated in accordance with the plan terms and benefits are provided only to eligible individuals. (TPAs normally do not assume this obligation.)

Our Observation	Employers may occasionally wish to make an exception and provide coverage for a benefit (e.g., specialty drug) or to an individual (e.g., an employee on extended medical leave) not covered by the plan terms. Employers should generally avoid making such one-off exceptions, which not only violate ERISA fiduciary duties but may result in the stop-loss carrier investigating and denying reimbursement, especially if a high-cost claimant or catastrophic claim is involved. Therefore, employers should always communicate directly with the stop-loss carrier regarding any special situations (e.g., exceptions to eligibility requirements or standard operating procedures) or contemplated plan amendments to obtain approval and determine if and how their stop-loss coverage will be impacted.

Finally, it is advisable for plan sponsors to have legal counsel review stop-loss agreements when coverage is first obtained, at renewal, or when changing carriers. A carrier change requires careful coordination of both policies to minimize coverage gaps (e.g., if claim payments are significantly delayed due to multiple levels of appeals). However, certain stop-loss policy terms are set by state regulators and therefore are not subject to negotiation.

Stop-loss consultants can help employers effectively screen, evaluate, and compare stop-loss carriers.

Administrative Aspects

Both the initial decision to self-insure and the ongoing self-insured plan design and administrative issues normally require review and input from the employer's internal teams (e.g., human resources and benefits, finance, risk management, legal, tax, and payroll) and outside service providers (e.g., TPAs, actuaries, brokers, consultants, attorneys, accountants). Accordingly, employers considering self-insuring should be prepared to assemble the appropriate internal and external resources to properly address plan issues.

Alternative Funding/Level-Funding

An employer, particularly a small or midsize one, that sponsors a fully insured plan may wish to consider alternative funding arrangements, including level-funding. With level-funding, the employer pays a fixed monthly amount to a TPA. The fee typically covers claims funding, the stop-loss premium, and administrative costs. Depending on the arrangement, the employer may be responsible for claims costs up to a stated maximum and may receive a refund if claims are favorable.

An analysis of alternative funding arrangements, including level-funded plans, is beyond the scope of this guide. However, and importantly, level-funded plans are considered self-insured plans for benefits compliance purposes and therefore generally must comply with the self-insured plan obligations outlined in this guide.

Employer Checklist (1: The Decision to Self-Insure)

- ☐ Compare fully insured premiums vs. projected self-insured costs (claims, administrative expenses, stop-loss premiums, and vendor fees).
- ☐ Obtain credible projections (underwriter/analytics and, if needed, an actuarial evaluation using multiyear claims and demographic trends).
- ☐ Assess financial readiness: risk tolerance, month-to-month cash flow volatility, and need for IBNR reserves.
- ☐ Evaluate stop-loss strategy (specific/aggregate attachment points, contract terms, exclusions/lasers, coverage period/run-in/run-out) and coordinate stop-loss terms with the plan document and eligibility rules.
- ☐ Identify internal owners (HR/benefits, finance, risk, legal, tax, payroll) and external service providers (TPA, broker, actuary, counsel) needed to properly administer the self-insured plan.
- ☐ Recognize that level-funded plans are considered self-insured plans for benefits compliance purposes.

2. COMPLIANCE CONSIDERATIONS WHEN SELF-INSURING

A. The Plan Sponsor's Role

Self-insuring significantly expands an employer's group health plan role, since obligations are no longer shared with a carrier. The self-insured plan sponsor is ultimately responsible for the plan's compliance with all applicable laws.

ERISA Fiduciary Duties

Most private group health plans are subject to ERISA, a federal law that imposes fiduciary, reporting, and disclosure obligations on employers as plan administrators. Employers, as plan fiduciaries, must adhere to duties of prudence and loyalty to the plan and participants, maintain and follow the terms of a written plan document, and abide by specific claim and appeals rules.

Fiduciary Functions

Importantly, employers should identify when they are performing fiduciary functions (e.g., plan implementation and operations, selection and monitoring of service providers, claims adjudication) and must act solely in the interests of plan participants. In contrast, when employers are performing business (aka "settlor") functions (e.g., plan establishment, design decisions, risk management), they can act in their own best interest. To the extent possible, fiduciary decisions should be made separately from settlor decisions.

Our Observation	When making fiduciary decisions, employers should engage in a prudent process (e.g., by gathering relevant information, consulting experts as needed, deliberating carefully, and documenting the decision). Although not required, employers that transition to self-insuring may want to consider establishing an employee benefits committee to facilitate and document a prudent decision-making process. A prudent process can also protect employers from potential liability in the event of litigation. For further information, see the PPI publication **ERISA Fiduciary Governance: A Guide for Employers**.

Selecting and Monitoring Plan Service Providers

A core fiduciary duty of a self-insured plan sponsor is the prudent selection and monitoring of plan service providers, including TPAs and PBMs. Recently, class action lawsuits have targeted employers for allegedly failing to fulfill this fiduciary duty.

When selecting a service provider, employers should carefully evaluate the candidates' qualifications, services, and total compensation and should document the selection process (whether conducted via a formal request for proposal process or

otherwise). Before contracting for ERISA group health plan services, employers should ensure they receive and review the service provider's 408(b)(2) disclosure of direct and indirect compensation. The service provider's performance, fees, and compensation should be monitored at regular intervals throughout the relationship.

Our Observation	**TPA vs. ASO Arrangement** Self-insured plan sponsors typically delegate many plan administrative responsibilities to a medical TPA or an insurer acting under an administrative services only (ASO) arrangement that has no insurance element. A TPA is generally viewed as independent of an insurer and thus able to work with different provider networks to tailor benefits, although this type of arrangement may require greater coordination among the various parties to process claims. An ASO arrangement is normally affiliated with one insurer and is able to provide streamlined services since the various parties (e.g., claims review, provider networks) are under one umbrella, though custom options may be more limited. Employers may want to consider both options to determine the appropriate choice for their plan's administration. Since the services provided by a TPA or ASO arrangement are similar, both are referred to as a "TPA" for purposes of this publication.

Claim Adjudication and Appeals

Under ERISA, a self-insured plan sponsor has a fiduciary duty to ensure claims are processed in accordance with the plan terms and applicable regulations. This role includes maintaining compliant claims procedures, providing a "full and fair review" of denied claims, and furnishing proper notices to participants. The extent to which this role is delegated to the TPA is normally specified in the administrative services agreement (ASA), which should be reviewed carefully.

The plan sponsor may be able to designate the TPA as claims fiduciary with final decision-making authority over appeals of denied claims, though additional fees may apply. However, some TPAs refuse to acknowledge their fiduciary status in the ASA. In such case, the sponsor may consider outsourcing the final internal appeal level (e.g., the second level, if the plan has two levels of internal appeal). Alternatively, the TPA may offer only one internal appeal level before a denied claim is routed to an external independent review organization (IRO), as required by the ACA. The sponsor should verify that the ASA addresses the external review process, which requires the availability of three IROs and a randomized process for routing an appealed claim to one of these organizations to ensure the review process is fair and impartial.

Importantly, a self-insured plan sponsor must determine whether to participate directly in internal appeals to exercise control over the process. However, a sponsor wishing to play a more hands-on role with claim appeals must understand they will be held to the fiduciary standard of a prudent expert regarding their decisions.

Our Observation	Employers should deliberate carefully before assuming a direct role in the appeals process for their self-insured major medical plan. Many employers may not be equipped to make medical necessity determinations (which require a medical professional's judgment), adhere to ERISA appeals procedures, or address claims within the requisite timeframes (e.g., 24 hours for urgent care claims). In such cases, employers should instead work with legal counsel to ensure the ASA reflects their TPA's fiduciary status with respect to claim appeals and the employer's right to access and audit plan data to monitor the TPA's performance.

Employers that decide to play an active role with respect to claim appeals should have a prudent and documented process in place to thoroughly and independently review claim appeals, apply plan terms, comply with regulatory requirements (including timeframes and notices), and consult with medical experts, as necessary. The employer may want to set up an appeals committee for this purpose.

For more information, see the PPI *Compliance Corner* article Handle with Care: A Self-Insured Employer's Role in Health Plan Appeals.

Plan Assets

Under ERISA, certain fiduciary duties attach to "plan assets," which include participant contributions to premiums or benefits, amounts attributable to plan assets (e.g., the portion of plan rebates due to participant contributions), and funds held in a separate plan account or trust to pay benefits. Generally, plan assets must be used for the exclusive benefit of plan participants.

"Funded" vs. "Unfunded" Plans

ERISA requires plan assets to be held in a trust. But in the group health plan context, the DOL does not enforce this requirement with respect to participant contributions, provided the employer timely forwards these amounts to the carrier or TPA for the payment of plan premiums or benefits. "Timely" for this purpose generally means as soon as the amounts can be segregated from the employer's general assets. As a result, most plans, whether fully insured or self-insured, pay benefits from the employer's general assets ("unfunded" plans) rather than via a trust ("funded" plans), especially since trust funding brings additional compliance obligations (e.g., a trust document, appointment of trustees, accountant's opinion of plan finances).

However, the sponsor of an unfunded plan should be careful not to inadvertently trigger the trust requirements, such as by maintaining participant contributions outside of the employer's general assets (e.g., in a separate account in the plan name) before applying these amounts to pay claims.

Plan Refunds and Rebates

An ERISA plan sponsor must handle plan refunds or rebates consistent with applicable guidance, including DOL Technical Release 2011-04, and the specific terms of the plan document or policy. If the plan document and policy are silent, the sponsor generally must allocate the plan asset portion of the refund back to participants in some manner (e.g., an offset to their future contributions, cash refund, or benefit enhancement) within 90 days. For further information, see the PPI publication **ERISA Compliance Considerations for Health and Welfare Benefit Plans: A Guide for Employers**.

Employer Checklist (2A: The Plan Sponsor's Role)

- ☐ Recognize the expanded ERISA fiduciary role of a self-insured plan administrator, identify fiduciary vs. settlor duties, and establish a prudent fiduciary decision-making process.
- ☐ Select and monitor TPAs/PBMs and other vendors using a documented process; obtain and review ERISA 408(b)(2) compensation disclosures from covered service providers and periodically benchmark for reasonableness of costs.
- ☐ Review ASAs carefully for scope of delegated duties, fiduciary acknowledgments (if any), data access, audit rights, and external review requirements.
- ☐ Define and document the plan's claims and appeals governance (including who decides appeals). Carefully evaluate whether to play a hands-on role in the appeals process.
- ☐ Establish controls around plan assets (participant contributions, rebates/refunds) and avoid inadvertently triggering trust requirements.

B. Plan Design

Sponsors of group health plans transitioning to self-insuring normally work with their TPA and consultants to design their plan benefits. Subject to budgetary and administrative constraints, sponsors generally have flexibility to tailor the benefits to suit their organization's needs. However, as explained below, sponsors should be aware of how certain group benefit and tax laws may influence their decisions.

ERISA Preemption of State Insurance Laws

Fully insured group health plans must cover benefits mandated by state insurance laws. Some states have enacted extensive mandates that require coverage of certain types of healthcare (e.g., chiropractic care), items and services (e.g., hearing aids, genetic testing), and/or individuals (e.g., parents who qualify as dependents) that extend beyond any federal requirements. Although the state mandates are often designed to address perceived gaps in federally mandated benefits, the additional coverage requirements can restrict a fully insured plan sponsor's benefit choices and increase premium costs.

In contrast, ERISA self-insured plans are not required to comply with state insurance mandates because ERISA, as federal law, preempts (i.e., sets aside) state insurance laws as applied to self-insured plans (except for multiple employer welfare arrangements).

Example: A large fully insured plan sitused in New York must comply with the state's fertility benefit mandate, which has specific in vitro fertilization (IVF) coverage requirements. However, a self-insured plan sponsored by an employer based in New York does not need to comply with this state IVF coverage mandate.

Our Observation	Because state insurance mandates do not apply to ERISA self-insured plans, plan sponsors have discretion to establish plan rules (e.g., eligibility requirements) and covered benefits (including any limitations or exclusions) tailored to their workforce and budget. Additionally, self-insured sponsors operating in multiple states can have uniformity in plan benefits, if desired, throughout their locations. However, as a practical matter, plan sponsors need to work with their TPA and other service providers to ensure their preferred plan design can be administered. Particularly with smaller self-insured (including level-funded) plans, customization options may be more limited.

One notable exception to ERISA's preemption of state laws is Hawaii's Prepaid Health Care Act (PHCA), which predates ERISA and is not preempted. Hawaii's PHCA requires state-approved coverage and imposes employee cost-sharing contribution limits, including with respect to self-insured plans.

Other State Laws

Although ERISA generally preempts state insurance laws for ERISA self-insured plans, other types of state laws are not subject to preemption and thus would still apply. For example, self-insured plans may be subject to state criminal laws (e.g., abortion prohibitions), Medicaid recovery laws (to recoup benefits for a participant also covered by Medicaid), and smoker discrimination laws.

PBM Laws

Whether a state pharmacy benefit manager (PBM) law is preempted by ERISA depends on the specific law and is often a matter of debate (and litigation). Generally, a state PBM law that interferes with a central matter of plan administration is more likely to be preempted. However, a state law that only increases ERISA plan costs without mandating a particular benefit structure is less likely to be preempted. For example, in *Rutledge v. Pharmaceutical Care Management Assn.*, the U.S. Supreme Court ruled that an Arkansas law that required PBMs to reimburse pharmacies at a price equal to or greater than wholesale cost was not preempted by ERISA. Accordingly, some state PBM laws may impact self-insured plans, including by imposing certain reporting and disclosure obligations. Therefore, plan sponsors should clarify at the outset of their relationship with their PBM what state-level filings, reporting, or disclosures may apply and how the PBM will support compliance.

Surcharge Laws

Some state laws apply surcharges to payments for care (e.g., New York's Health Care Reform Act surcharge on certain hospital services, which applies if a plan sponsor does not elect to pay a covered lives assessment rate to the state). These state laws are generally not preempted by ERISA and therefore can apply to self-insured plans, even if the employer is located in another state. Self-insured plan sponsors should work with TPAs to ensure all applicable state surcharge-related obligations are satisfied since these will no longer be addressed by the insurance carriers.

Non-ERISA Plans

Certain group health plans, such as those offered by governmental entities or churches, are not subject to ERISA. So, ERISA fiduciary duties and preemption would not apply. Thus, non-ERISA plans and their sponsors may be subject to state laws, including laws regulating fiduciaries that are similar to ERISA.

Self-insured plan sponsors should consult with legal counsel if guidance is needed regarding the application of state laws to their specific plans.

Additionally, self-insured plans must still comply with other federal group health plan laws, as discussed in the following sections.

ACA Requirements

Like fully insured plans, self-insured plans must comply with many ACA mandates. For example, self-insured plan sponsors must ensure their plan covers dependent children until age 26 and must provide a summary of benefits and coverage (SBC) to participants. Self-insured plans must also provide in-network (INN) coverage for recommended preventive services (e.g., cancer screenings, certain vaccines) without cost-sharing and adhere to annual maximum limits on INN cost-sharing. However, as illustrated below, there are distinctions regarding how certain ACA provisions apply to self-insured plans.

Prohibitions on Annual and Lifetime Dollar Limits

The ACA restricts lifetime and annual dollar limits on essential health benefits (EHBs) provided under group health plans. EHBs are comprised of items and services in ten general categories, which include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, and prescription drugs.

For fully insured plans in the individual and small group markets, HHS regulations set the standards for the EHBs that must be provided. The actual EHB package is determined by a benchmark plan designated by each state (or by HHS, in the absence of state action), based on the largest insurance products sold in the state.

Self-insured group health plans are not required to cover EHBs. However, these plans are prohibited from imposing annual and lifetime dollar limits on any EHBs they do offer. For example, if kidney dialysis benefits are covered as an EHB under a self-insured plan, annual or lifetime dollar limits cannot apply to such benefits.

Importantly, a self-insured plan's EHBs are defined by the state benchmark plan selected by the plan sponsor. Under HHS guidance, a sponsor may select from any of the 51 state or District of Columbia base-benchmark plans. The HHS/CMS website provides Information on Essential Health Benefits Benchmark Plans of each state. Thus, a plan sponsor in New York could choose the Utah base-benchmark plan to define the plan's EHBs that could not be subject to annual or lifetime dollar limits.

Our Observation	Self-insured plan sponsors should carefully consider their selection of a benchmark plan. Many sponsors choose Utah as a benchmark plan because they believe it is one of the less restrictive plans with respect to EHBs. However, as a practical matter, the sponsor's choices may be limited by their TPA's ability to administer a particular state's benchmark plan. Accordingly, it is important for the sponsor to discuss and coordinate the choice of an EHB benchmark plan with their TPA. Additionally, the selection should be formally documented by the plan sponsor.

MHPAEA

The Mental Health Parity and Addiction Equity Act (MHPAEA) requires group health plans, including self-insured plans, that offer mental health and substance use disorder (MH/SUD) benefits to do so on par with medical and surgical (MED/SURG) benefits. More specifically, group health plans with annual or lifetime dollar limits for MED/SURG benefits generally must apply those same (or higher) dollar limits for MH/SUD benefits. Plans also cannot impose more restrictive financial requirements, such as deductibles, copays, coinsurance, or out-of-pocket maximums; quantitative treatment limitations (QTLs), such as limits on covered days, visits, or treatments; or nonquantitative treatment limitations (NQTLs), such as coverage exclusions, prior authorization requirements, medical necessity criteria, or network limitations, on MH/SUD benefits as compared to those applied to MED/SURG benefits. Sponsors should inquire if a potential TPA will provide a QTL analysis based on their plan's claims data.

Our Observation	Self-insured plan sponsors should ensure their plan design (and operation) complies with MHPAEA's requirements, especially with respect to any exclusions or limitations on MH/SUD benefits. Exclusions and limitations are typically set by the TPA in their standard plan design. Plan sponsors should carefully review the TPA's standard plan design for potential MHPAEA issues ahead of time and request any needed modifications before adopting. For example, excluding ABA therapy as an experimental treatment for autism spectrum disorder (despite clinical evidence of its effectiveness) or placing greater restrictions on MH/SUD residential treatment benefits than on comparable MED/SURG benefits, are common red flags that signal MHPAEA noncompliance. For a list of common plan terms that signal MHPAEA noncompliance, see the PPI publication **MHPAEA Compliance: Red Flag NQTLs**. Consultation with legal counsel is advisable before adding any restriction or limitation on MH/SUD benefits.

NQTL Comparative Analysis

The Consolidated Appropriations Act, 2021 (CAA 2021) included an amendment to MHPAEA requiring that group health plans and insurers document compliance with the law, specifically on NQTLs. Employers sponsoring self-insured group health plans serve as fiduciaries responsible for plan administration, which includes completing the NQTL comparative analysis. While there is no annual submission requirement, employers must be prepared to provide the NQTL comparative analysis upon request by regulators, state agencies, or plan participants. (Note that although QTLs and financial requirements are not subject to the comparative analysis requirement, they must maintain parity.) For additional guidance on completing the analysis, including action items for self-insured plan sponsors, see the PPI publication **MHPAEA NQTL Comparative Analysis: A Guide for Employers**.

Our Observation	The comparative analysis is not straightforward. Simply identifying NQTLs to analyze requires a sophisticated understanding of plan design and administration. Federal regulators have indicated they expect a plan's TPA or similar service provider to provide the comparative analysis, rather than create a new industry of MHPAEA vendors. As a result, MHPAEA compliance should be addressed in TPA agreements. Ideally, the TPA will complete the comparative analysis for NQTLs in the TPA's standard plan design such as exclusions, coverage guidelines and restrictions, prior authorization requirements, network composition, and reimbursement rates designed by the TPA. Importantly, even where a TPA performs the comparative analysis, a self-insured plan sponsor remains responsible for the plan's compliance with MHPAEA and needs to monitor the TPA's work.

Section 105 Nondiscrimination

Self-insured group health plans must satisfy Section 105 nondiscrimination rules in order for qualified medical expenses to be excluded from employees' income. Generally, these rules are designed to prohibit discrimination in plan eligibility, contributions, and benefits that disproportionately favor highly compensated employees (HCEs). (The Section 105 rules currently are not enforced with respect to fully insured plans.)

HCE Definition

For this purpose, HCEs are defined to include the employer's five highest-paid officers, a more than 10% owner or shareholder, and those among the highest-paid 25% of all employees of the employer, as defined on a controlled group basis. Thus, every employer will have HCEs, regardless of their compensation level.

Permitted and Prohibited Variances

The Section 105 rules permit variances in benefits based on bona fide classifications of employees (e.g., by job category, geographic location, business line, membership in a collective bargaining agreement), provided the result does not favor HCEs. However, these rules specifically prohibit variances in maximum benefits or employer contributions based upon age, salary, or years of service, and variances in waiting periods. Additionally, plan designs in which employer contribution levels or the types and amounts of reimbursable medical expenses favor HCEs, such as members of an executive class, are generally problematic.

Our Observation	Despite Section 105's explicit prohibitions, cost-sharing that is inversely related to a percentage of salary, such as a contribution structure that requires HCEs to pay more of the premium costs than non-HCEs, would seem to be permissible. In addition, many industry experts believe that disparate waiting periods are allowed, so long as the result doesn't intentionally or unintentionally favor HCEs.

Section 105 Nondiscrimination Testing

To ensure their plan does not violate the Section 105 rules, self-insured group health plan sponsors should conduct nondiscrimination testing throughout the plan year. The component Section 105 nondiscrimination tests focus upon discrimination in eligibility and benefits in both plan design and operations. Most sponsors engage an experienced vendor to assist with the testing process. Failed tests result in adverse tax consequences for HCEs, with the amount determined by the specific failure. Corrections are not possible once the plan year has ended.

COBRA Subsidies

Sponsors should also be mindful of the Section 105 rules when offering COBRA subsidies (e.g., as part of severance benefits or during extended non-protected leaves). The Section 105 rules generally prohibit COBRA subsidies that are available in greater amounts or longer duration for HCEs as compared to non-HCEs.

Our Observation	Most sponsors of group health plans, whether fully insured or self-insured, are already familiar with the Section 125 nondiscrimination rules, which apply if the employer allows employees to make pre-tax salary reduction contributions through a cafeteria plan to pay for their share of the cost of health plan coverage (and often other benefits). The Section 125 rules must be satisfied so that employees' contributions are excludable from their taxable income and the employer and employee are not subject to payroll taxes on these amounts. A self-insured plan that allows for premiums to be paid on a pre-tax basis must comply with both the Sections 105 and 125 nondiscrimination rules and tests; passing one set of tests does not guarantee passage of the other set. For additional details on Sections 105 and 125 nondiscrimination rules, see the PPI publication **Sections 105 and 125 Nondiscrimination Rules: A Guide for Employers**.

HIPAA Nondiscrimination

The HIPAA nondiscrimination rules prohibit group health plans and insurers from discriminating against individuals regarding eligibility, premiums, or coverage based on health factors. Health factors include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability, or disability.

Therefore, a plan may not exclude an individual from plan eligibility or require them to pay more in premiums or contributions than a similarly situated individual if the difference is based on a health factor. Nor can the employer try to incentivize an individual to drop the group health plan coverage based on a health factor.

PPI Observation	While HIPAA nondiscrimination rules apply to fully insured and self-insured plans alike, sponsors of self-insured plans need to be particularly careful not to violate these requirements. Since self-insured plan sponsors assume the financial risks for all plan claims and sometimes have difficulty obtaining affordable stop-loss coverage due to high claimants, sponsors may be tempted to try to incentivize high claimants to drop the plan coverage. Sponsors should be particularly wary of vendors offering solutions to specifically remove high claimants from the plan, which would violate HIPAA's nondiscrimination rules and likely other federal laws too.

However, a plan may limit or exclude coverage for specific conditions or diseases, for certain types of treatments or drugs, or based on a determination that the benefits are experimental or not medically necessary, if the limitation or exclusion is not designed to target the coverage of an individual participant, directly or indirectly, based on a health factor.

Additionally, the HIPAA nondiscrimination rules generally allow the group health plan and employer to obtain information from covered individuals about their claims experience and health history (other than genetic information) if the information is used for underwriting purposes to determine the aggregate health status or premium of the group. For example, it is permissible for a stop-loss insurer to request medical questionnaires as part of the underwriting process to determine the stop-loss premium and for an employer to ask their employees to complete the questionnaires. But since the stop-loss carrier is generally not considered a covered entity under the HIPAA privacy rule, it is advisable for the plan to have a confidentiality and nondisclosure agreement with the stop-loss carrier to limit its use and disclosure of an individual's health information.

Numerous other nondiscrimination laws, including employment-based laws, could affect aspects of the group health plan but are beyond the scope of this guide.

Employer Checklist (2B: Plan Design)

- ☐ Recognize that state insurance mandates do not apply to self-insured plans due to ERISA preemption, allowing for plan design flexibility.
- ☐ Identify non-preempted state laws that may still apply (e.g., criminal laws, surcharge laws, and possibly PBM laws); assign responsibility for compliance support (TPA/PBM vs. employer).
- ☐ In consultation with TPA, carefully select ACA EHB benchmark plan for purposes of defining covered benefits not subject to annual/lifetime dollar limits, and document selection.
- ☐ Address MHPAEA parity in design and operation; ensure contractually that TPA provides NQTL comparative analysis for the employer's review and carved-out vendors provide support.
- ☐ Evaluate Section 105 nondiscrimination implications of eligibility, contributions, benefits, and COBRA subsidies; conduct nondiscrimination testing throughout the plan year.
- ☐ Confirm HIPAA nondiscrimination compliance and avoid practices (or vendors) aimed at steering high claimants off coverage.

C. Plan Implementation

After designing the plan, the sponsor as plan fiduciary must implement and administer the plan in ongoing compliance with ERISA, the ACA, MHPAEA, the IRC, and HIPAA nondiscrimination rules. In addition, the sponsor will need to determine the premium equivalent and COBRA rates and adopt HIPAA Privacy and Security policies to safeguard participants' protected health information (PHI).

Determining the Premium Equivalent

With fully insured group health plans, the monthly premium rate is determined by the carrier through an underwriting process and is expected to cover the insurer's total costs of providing coverage, including plan claims and expenses. With self-insured plans, the "premium equivalent" represents the total monthly cost to operate the plan. It is the self-insured plan's version of a monthly premium rate.

However, the cost of providing coverage under a self-insured plan cannot be determined precisely for a plan year because many factors are not known beforehand, including the extent to which participants will use the coverage during that period. Therefore, estimating a plan's expected costs for a year typically involves looking at the plan's prior costs and adjusting these amounts for anticipated variances in the next period.

The IRS has provided two basic methods that can be used to estimate a self-insured plan's costs for the upcoming plan year. These methods are generally used to calculate both the premium equivalent (upon which active participant cost-sharing is based) and the COBRA applicable premium (as explained below).

Past-Cost Method

Under the first "past-cost" method, the total cost for a plan year is estimated by reviewing the total plan cost for the immediately preceding plan year (including claims, administrative expenses, stop-loss premiums, and stop-loss reimbursements) and adjusting this cost by the percentage increase (or decrease) in the cost of living. Notably, the past-cost method may be used only if there is no significant change in the coverage being offered or in the number of employees covered under the plan from one determination period to the next.

The past-cost method does not consider utilization trends, costs of complying with new legal requirements, and, significantly, healthcare cost increases, which may exceed general cost-of-living increases. Accordingly, the past-cost method may not yield a very accurate cost estimate.

Actuarial Method

Alternatively, a more precise estimate can be obtained through an actuarial evaluation of the plan's expected costs for the coming year. This method involves engaging an actuary to analyze the plan's actual costs over a prior period and then factor in expected changes in participant demographics and healthcare costs for the coming year. The actuary will need certain information to provide the estimate, including all of the following:

- The plan year for which costs are being estimated (for COBRA rates, this is known as the COBRA determination period)
- Plan claims data (both incurred and paid) for a prior "review" period (e.g., twelve months)
- Information about administrative costs, stop-loss premiums, and stop-loss reimbursements
- An estimate of the average number of covered lives (participants, spouses, dependents, COBRA-qualified beneficiaries, etc.) for each month of the plan year

After determining the claims cost for the prior review period, the actuary will apply a trend factor that projects changes in the unit cost of claims and utilization rates (i.e., the number and types of services expected to be used by participants) and considers the geographic region, type of plan (e.g., HMO, PPO), and numerous other items. The application of the trend factor produces the estimated claims costs for the upcoming plan year.

In addition to estimated claims costs, plan administrative expenses and stop-loss premium costs (if any and the sponsor chooses to include these) would factor into the determination of the premium equivalent (and COBRA applicable premium). The actuary will normally provide an average cost projection "per employee per month" (PEPM) for each applicable coverage tier (e.g., employee plus spouse, employee plus family) for the upcoming plan year. The employer could then use the PEPM to set contribution rates for active participants, taking into account any cost-sharing considerations.

For further information on setting participant rates and cost-sharing, see the PPI publication **Cost-Share Contribution Models: A Guide for Employers**.

COBRA Rates

Additionally, employers subject to federal COBRA requirements will need to determine the COBRA "applicable premium" rate for COBRA beneficiaries. Federal COBRA continuation coverage generally applies to group health plans maintained by private employers with 20 or more employees on typical business days in the prior calendar year, or by state and local governments.

As explained above, the two methods (past-cost method and actuarial method) used to determine the premium equivalent rate are also used to set the COBRA rates. In fact, absent guidance specific to self-insured plans, for COBRA purposes, most plans use a multi-rate structure that corresponds to the "tiers" of coverage offered under the plan to active employees and their dependents. For COBRA, an additional 2% surcharge may be added to the cost of the continuation coverage to offset COBRA administrative expenses. Notably, the COBRA rates generally must remain constant for a 12-month determination period.

Our Observation	Importantly, the sponsor as plan fiduciary should keep in mind that under ERISA's exclusive benefit rule, participant contributions are considered plan assets that may only be used to pay plan benefits or reasonable plan administrative costs. Accordingly, sponsors should not violate their fiduciary obligations, such as by setting COBRA rates for the plan year higher than determined under the actuarial method to avoid a potential cash shortfall if claims exceed expectations. Additionally, including stop-loss premium costs in rate calculations (particularly the COBRA applicable premium) can increase the risk that the stop-loss reimbursements are considered plan assets. Although not a universal view, courts can interpret "plan assets" broadly. Given this gray area, employers should consult with legal counsel if stop-loss costs affect COBRA rates.

State Continuation Coverage

Due to ERISA preemption, self-insured plans are not subject to state insurance laws and thus are generally not subject to state continuation coverage (aka mini-COBRA) laws. While some states (notably, Vermont and Louisiana) have passed mini-COBRA laws that attempt to reach self-insured (including level-funded) plans, a reviewing court could find the law is preempted by ERISA. Because of this uncertainty, sponsors of small, self-insured plans should confirm whether their stop-loss carrier interprets the applicable state mini-COBRA law as applying to their self-insured plan.

Our Observation	Because state insurance laws are generally preempted by ERISA and federal COBRA does not apply to employers with fewer than 20 employees on average in the prior calendar year, some small self-insured plans are not required to provide any coverage continuation rights to participants. In such cases, the sponsor should be careful not to convey otherwise. A sponsor wishing to optionally offer some type of continuation coverage could inquire with their TPA regarding the possibility and related costs and seek approval from the stop-loss carrier. However, the sponsor would need to consider the additional administrative obligations and financial risks involved with offering such COBRA-like coverage.

For further information on COBRA, see the PPI publication **COBRA: A Guide for Employers**.

HIPAA Privacy and Security Obligations

Sponsors of group health plans that transition to self-insuring should prepare to assume expanded compliance obligations under the HIPAA Privacy Rule and HIPAA Security Rule.

The HIPAA Privacy Rule protects the use and disclosure of PHI by covered entities, which include health plans, insurers, and healthcare providers. The HIPAA Security Rule establishes standards to protect the confidentiality, integrity, and security of electronic PHI (ePHI).

Many fully insured major medical plans are "hands-off" with respect to PHI, meaning they receive only enrollment, disenrollment, and summary health information. In such cases, the plan sponsor's obligations are limited and the health insurer assumes primary responsibility for complying with most of the privacy and security requirements.

In contrast and by definition, self-insured plan sponsors are "hands-on" with respect to PHI and must comply with all HIPAA Privacy Rule and HIPAA Security Rule requirements. As such, the self-insured plan sponsor is responsible for all of the following:

- Appointing a Privacy Officer
- Creating and maintaining written privacy policies and procedures that describe the plan's HIPAA compliance
- Training workforce members on the policies and procedures
- Implementing administrative, physical, and technical safeguards for ePHI as required by the Security Rule. This includes conducting a risk analysis with internal IT to determine if there are any areas (administrative, physical, or technical) where PHI could be inadvertently exposed
- Recognizing security incidents, performing risk assessments, and providing proper notifications in accordance with breach notification requirements
- Educating workforce members (particularly the HR/benefits employees) on the boundaries of permissible PHI access and usage
- Adopting a general policy of not retaliating against workers for exercising their HIPAA rights
- Requesting HIPAA authorizations from employees that contact HR with plan-related questions and assistance; although information provided by the employees is not PHI, information received back from the insurer in response may be PHI
- Maintaining and distributing a Notice of Privacy Practices
- Entering business associate agreements (BAAs) with vendors and other parties that will be handling PHI on behalf of the plan

For further details on the comparison between fully insured and self-insured HIPAA Privacy and Security compliance, see Appendix A of the PPI publication **HIPAA Privacy and Security for Group Health Plans: A Guide for Employers**.

In most cases, plan sponsors rely on HIPAA compliance vendors and legal counsel to assist them with satisfying the requirements unless they have HIPAA privacy and security experts on staff.

Our Observation	For most self-insured plan sponsors, engaging a HIPAA vendor is often critical to the establishment and maintenance of effective privacy and security policies tailored to their circumstances. Vendors can also assist sponsors in fulfilling other ongoing HIPAA compliance obligations, such as conducting regular risk assessments and employee training. Additionally, since self-insured plans have broader access to PHI than fully insured plans, the potential risk of privacy breaches, regulatory exposure, and fines increases. While not all risks can be eliminated, demonstrating serious HIPAA compliance efforts may help to mitigate regulatory penalties.

Employer Checklist (2C: Plan Implementation)

- ☐ Implement the plan in alignment with written terms and establish operational controls to maintain ongoing compliance (ERISA, ACA, MHPAEA, IRC, and HIPAA nondiscrimination).
- ☐ Set the COBRA rate using an appropriate method (past-cost or actuarial) and retain documentation supporting assumptions.
- ☐ Establish COBRA applicable premiums (by tier), confirm the 12-month determination period approach, and avoid setting rates above the calculated amount solely to create a cushion.
- ☐ Confirm whether state continuation coverage could be asserted (particularly for smaller plans) and align communications to participants with actual continuation rights.

- ☐ Build HIPAA Privacy and Security compliance infrastructure appropriate to the plan's PHI access (privacy officer, policies/procedures, workforce training, risk analysis, safeguards, incident response, BAAs, and required notices). Consider engaging a HIPAA vendor.

D. Plan Disclosure and Reporting Requirements

Generally, the same disclosure and notice obligations under the ACA, COBRA, ERISA, HIPAA, Medicare, Transparency in Coverage, CAA 2021, and other benefits compliance laws apply to both fully insured and self-insured group health plans. For more information on these requirements, see the PPI publications **Required Group Health Plan Notices Overview** and **Required Group Health Plan Notices Chart**.

However, the sponsor of a self-insured plan is ultimately responsible for ensuring that all disclosures (e.g., SBCs, HIPAA Notice of Privacy Practices) are accurate and satisfy applicable content and delivery requirements, even if the sponsor has engaged a TPA or other service provider to help draft or distribute the disclosures. Similarly, the self-insured plan sponsor is responsible for timely satisfying the plan's reporting and filing obligations, including those previously addressed by the carrier when the plan was fully insured. Since self-insured plan sponsors typically rely heavily on their TPA, PBM, and other service providers for compliance support, they should ensure the applicable service agreements clearly spell out which disclosures, reports, and filings the service provider will complete and the timing for completion and any related fees.

Despite the broad application of many group health plan laws, as explained below, there are distinctions regarding how certain requirements under ERISA, the ACA, and transparency laws apply to self-insured vs. fully insured plans.

ERISA

Written Plan Document

Sponsors of ERISA plans, whether fully insured or self-insured, and regardless of size, have a fiduciary obligation to maintain a written plan document.

With fully insured plans, the coverage details are normally set forth in insurance policies, which are supplemented by a document containing ERISA-required provisions. Often, the sponsor will choose to "wrap" various benefits into one ERISA plan and document for disclosure and Form 5500 reporting purposes, if applicable.

With self-insured plans, there are no insurance policies that describe the coverage. Accordingly, a self-insured plan document is typically comprehensive and must set forth the plan terms (e.g., eligibility rules, covered benefits, exclusions, claims and governance procedures, handling of plan assets). Additionally, for a self-insured health plan sponsor to receive PHI for plan administration purposes (e.g., to monitor plan service providers, adjudicate claim appeals), the plan document must include provisions in which the employer agrees to comply with applicable HIPAA restrictions. Since state insurance law generally does not govern a self-insured plan's coordination of benefits terms (which determine the order of benefit payments when a participant is covered by more than one health plan) and subrogation and reimbursement rights (which let the plan recover medical expenses it paid from a third party or a participant), the sponsor may set these terms.

Our Observation	Although self-insured plan sponsors normally depend on a vendor, TPA, or legal counsel to draft the plan document, sponsors should review the content carefully and must administer the plan according to the written terms. Sponsors should also verify the plan document terms are consistent with other plan materials required to be provided to participants, particularly the plan's summary plan description (SPD), SBC, and participant enrollment materials. Inconsistencies among these documents can lead to participant confusion and lawsuits. As noted earlier, the plan document terms, particularly those related to eligibility, benefits, and related limitations, should be carefully coordinated with the stop-loss carrier to avoid unexpected gaps and coverage disputes.

Self-insured plan sponsors generally hold direct responsibility to respond to participant requests for plan information, which may include the SPD, a Form 5500, or, broadly, any contract or other instrument under which the plan is established or operated (e.g., administrative services agreements, medical necessity guidelines, or other claim review criteria). Failure to furnish documents within 30 days of a participant request can lead to penalties of $110 per day, with no cap. Because some claim administration documents are maintained by a TPA, plan sponsors should coordinate a process with TPAs to respond to participant document requests quickly and completely.

Form 5500

Each ERISA group health plan, whether fully insured or self-insured, that has 100 or more participants (i.e., enrolled employees, but not dependents) at the beginning of the plan year or that is funded through a trust, must file an annual report with the DOL via Form 5500. In contrast with a fully insured medical plan, a self-insured medical plan does not receive Schedule A, which reports "insurance contracts information." However, if the plan sponsor uses a wrap document that wraps the self-insured medical plan and other fully insured benefits into one ERISA plan, the Schedule A's would apply to the wrapped fully insured policies and thus would be included in any required Form 5500 filing. Additionally, if self-insured plan assets are held in a trust (which is rare), Schedule C, used to provide information about service providers' compensation, would apply.

For further information on Form 5500 reporting requirements, see the PPI publication **Form 5500: A Guide for Employers**.

Summary Annual Report

Generally, if an ERISA plan is required to file a Form 5500, the sponsor is required to distribute to plan participants a corresponding Summary Annual Report (SAR), which summarizes the Form 5500 information.

Self-insured group health plans that are funded from the employer's general assets are not subject to the SAR requirement. But if the employer wraps the self-insured medical plan with fully insured benefits into one ERISA plan for Form 5500 filing purposes, a SAR must be distributed for that wrapped plan.

For further information on ERISA obligations generally, including reporting and disclosure requirements, see the PPI publication **ERISA Compliance Considerations for Health and Welfare Plans**.

ACA

Employer Mandate Reporting

All self-insured plan sponsors are responsible for satisfying certain ACA reporting requirements using IRS Form 1094 and 1095. There are two separate ACA reporting obligations under IRC Sections 6055 and 6066.

Section 6055

The purpose of Section 6055 reporting is to report the months in which an individual is enrolled in minimum essential health coverage. With fully insured plans, the insurer completes the Section 6055 reporting. However, employers that sponsor self-insured plans, including level-funded plans, are responsible for the Section 6055 reporting, regardless of the employer's size.

Section 6055 reporting may be reported on Forms 1094-B and 1095-B (for a small employer) or on Forms 1094-C and 1095-C for an applicable large employer (ALE), i.e., an employer with 50 or more full-time or equivalent employees in the prior year. The forms must be filed with the IRS and furnished to individuals.

Our Observation	There is a risk that employers might overlook the Section 6055 reporting requirement when they initially self-insure their group health plan, since this obligation was previously handled by the carrier. With level-funded plans, the plan vendor will sometimes handle the reporting on the plan sponsor's behalf, but most often the employer will need to complete the reporting. Small employers that newly sponsor self-insured plans should ensure they fulfill this obligation, since penalties apply for reporting failures, as explained further below.

Section 6056

Section 6056 reflects the months in which an ALE makes an offer of health coverage to its full-time employees. Section 6056 reporting must be reported on Forms 1094-C and 1095-C. Employers that are subject to both Sections 6055 and 6056 (i.e., self-insured ALEs) may combine their reporting and use only Forms 1094-C and 1095-C to report both the offer of coverage and enrollment in coverage. Notably, Form 1095-C is divided into two sections to facilitate combined reporting for employers that are both large and sponsor self-insured plans.

Penalties for Reporting Failures

Penalties apply for Sections 6055 and 6056 reporting failures. For failures with respect to 2025 reporting forms that must be filed and furnished in 2026, the penalty amount is $340 per failure. For example, if an employer fails to file a correct form with the IRS and furnish such form to an individual, the penalty would be $680 for that one individual. Accordingly, penalties can be significant if the failure involves numerous individuals.

For further information about ACA reporting responsibilities, see the PPI publication **ACA: Employer Mandate Reporting Requirements**.

State Individual Mandate Reporting Requirements

Employers should not overlook state individual mandate reporting obligations, which currently are in effect in California, the District of Columbia, Massachusetts, New Jersey, Rhode Island, and Vermont. These state individual mandates generally require distributing coverage statements to resident employees and submitting annual reports to the state. Most states (except for Massachusetts and Vermont) accept Form 1095 as a coverage statement. With fully insured plans, it is generally the carrier's obligation to provide the coverage statement to the state. However, for self-insured plans, it is generally the employer's obligation.

Our Observation	Beginning in 2025, changes to federal ACA reporting requirements permit employers and health insurance carriers to furnish Forms 1095-B and 1095-C to employees upon request (with adequate notice of the opportunity to request the applicable form) instead of automatically distributing these coverage statements. However, each state's individual mandate still generally requires employers to automatically distribute coverage statements to employees (regardless of any request) and to submit reports to state agencies by specific annual deadlines. Importantly, the state reporting requirements are generally based on an employee's home address for any portion of the reporting year, regardless of the location of the employer's headquarters or the situs state of the healthcare contract.

For further information about state-specific reporting details, see the PPI publication **State Individual Mandate Reporting Requirements**.

Patient-Centered Outcomes Research Institute (PCOR) Fee

A self-insured plan sponsor must also file and pay the annual PCOR fee mandated by the ACA to help fund research on the comparative effectiveness of medical treatments. The fee is reported on IRS Form 720, Quarterly Federal Excise Tax Return, and is due by July 31 of the calendar year following the close of the plan year. The fee is calculated based on the average number of lives covered by the plan and the applicable rate announced by the IRS for the period. The annual requirement currently applies to plan years ending before October 1, 2029.

The PCOR fee applies to both fully insured and self-insured plans. However, fully insured plan sponsors typically pay the PCOR fee indirectly in the form of an increased premium rate paid to the insurer, which pays the PCOR fee to the IRS and files the Form 720. For self-insured plans, the plan sponsor is directly responsible for calculating and paying the PCOR fee and filing the Form 720. Therefore, a plan sponsor switching to self-insuring should add this obligation to their compliance calendars to avoid penalties for late or missed filings or payments.

Our Observation	The IRS has specified that the plan sponsor is the party responsible for paying the fee for a self-insured plan; therefore, the sponsor as ERISA plan fiduciary should not be using participant contributions, which are plan assets, to pay the fee.

For additional information about PCOR fee reporting obligations, see the PPI publication **PCOR Fees: A Guide for Employers**.

Medicare Part D

Group health plans that offer prescription drug coverage must disclose to CMS and individuals whether the coverage is "creditable" (i.e., is expected to pay on average at least as much as a standard Medicare Part D plan). For fully insured plans, the creditable status of the prescription drug coverage is generally confirmed by the insurer. For self-insured plans, the employer may be responsible for making the creditable coverage determination unless their TPA has agreed to assist. The determination may be made using a non-actuarial or actuarial method, depending on the prescription drug plan design specifics. Accordingly, sponsors switching to self-insuring should discuss with plan service providers how this creditability determination will be made and must ensure disclosure requirements are met on an accurate and timely basis.

For further information about Medicare Part D disclosure requirements, see the PPI publication **Medicare Part D Creditability Disclosures: A Guide for Employers**.

CAA 2021 and Transparency in Coverage

More recently, federal transparency provisions under the CAA 2021 and Transparency in Coverage final rule have imposed significant reporting and disclosure obligations on group health plans and insurers.

For fully insured plans, generally both the plan sponsor and the insurer are responsible for compliance with transparency laws, and the sponsor can enter into a written agreement with the insurer to fulfill many of these obligations on the plan's behalf. In contrast, a self-insured plan sponsor is ultimately responsible for compliance with the transparency laws.

Our Observation	Typically, self-insured plan sponsors depend on their TPA and other service providers to assist with satisfying most transparency requirements. Since sponsors have a fiduciary obligation to prudently select and monitor appropriate service providers, they should understand the core transparency requirements and ensure contracts with service providers clearly specify the scope of transparency services to be provided, deadlines, and all related service provider fees and compensation. Since implementation of transparency laws is ongoing, the contract should address both current requirements and any obligations regulators may begin enforcing during the contract term.

CAA 2021, Title I, The No Surprises Act

The CAA 2021 No Surprises Act (NSA) prohibits the surprise billing of participants for certain out-of-network (OON) healthcare services, including emergency services, air ambulance services, and nonemergency services received at INN facilities. NSA enforcement is a regulatory priority; sponsors should monitor participant complaints and their TPA's processes.

For fully insured plans, a state surprise billing law may apply before the NSA provisions. For self-insured ERISA plans, the NSA typically applies directly because state insurance laws are preempted. Both fully insured and self-insured plan sponsors should ensure the required surprise billing notice for their plan is posted on a public website, accessible to participants, and included in each Explanation of Benefits for NSA-protected services.

Plans must also abide by the NSA's independent dispute resolution (IDR) process if it is initiated to resolve a payment dispute with an OON healthcare provider. For fully insured plans, the insurer will normally engage in the IDR process. Self-insured plan sponsors should verify if their TPA will manage the IDR process (directly or via a subcontractor), understand how any additional IDR service fees will be assessed, request periodic updates on the status of disputes, and monitor the impact on plan costs.

CAA 2021, Title II, Transparency

The CAA Transparency provisions include several important requirements:

- ***Gag Clause Prohibition Compliance Attestation —*** Plan sponsors and insurers must attest annually (by December 31) that they have not entered network agreements with "gag clauses" that restrict their access to provider-specific cost and de-identified claims data or their ability to share this information with a business associate.

Our Observation	The gag clause prohibition is designed to ensure that plan sponsors, particularly self-insured plan sponsors, have access to data they need to effectively review plan pricing and monitor service providers. Despite the prohibition, some TPA and PBM service agreements still contain gag clauses. Often, these provisions restrict the sponsor from auditing plan claims to verify compliance with the plan terms and service agreement. Accordingly, sponsors should carefully review the service agreement language prior to execution and request written confirmation from the service provider that they have not entered any network agreements with prohibited gag clauses.

- ***Service Provider Compensation Disclosures —*** Plan sponsors as fiduciaries must ensure they receive and review a compensation disclosure from each group health plan service provider (including a TPA or PBM), determine if the service provider's compensation is reasonable, and document the process.
- ***RxDC Reporting —*** Plan sponsors and insurers must annually report (by June 1) specific prescription drug data from the prior calendar year to HHS for analysis and compilation in public reports on drug pricing trends.

Our Observation	Typically, the RxDC reporting is completed by the insurer for a fully insured plan or the TPA and/or PBM for a self-insured plan. However, with a self-insured plan, the TPA or PBM may request permission to report for the sponsor. Plan sponsors should respond promptly to requests from service providers for information needed to timely complete the reporting. Additionally, the sponsor of a plan that just transitioned to self-insuring should confirm their prior carrier will complete the RxDC reporting for a terminated group. For further details, see the PPI publication **Prescription Drug Data Collection Reporting: A Guide for Employers**.

- ***MHPAEA NQTL Comparative Analysis Requirement —*** As described in the above section regarding MHPAEA compliance considerations in plan design, plan sponsors and insurers must demonstrate parity through a detailed written analysis, known as a comparative analysis, of the design and application of NQTLs imposed on MH/SUD benefits in comparison to NQTLs imposed upon MED/SURG benefits. This requirement has been a particular challenge for sponsors of self-insured plans, who should confirm their TPA will contractually agree to provide a comparative analysis for the sponsor's review and should discuss how any carved-out benefits (e.g., pharmacy, behavioral health) will be addressed. For further information, see the PPI publication **MHPAEA NQTL Comparative Analysis: A Guide for Employers**.

Transparency in Coverage Final Rule

The Transparency in Coverage final rule has two basic requirements applicable to non-grandfathered health plans and policies.

- ***Public Disclosure of Plan Pricing —*** Plans and insurers must disclose INN rates, historical OON-allowed amounts, and (when implemented) prescription drug negotiated rates and historical net prices in machine-readable files (MRFs) posted on a public website. The MRF data is intended for access by data analytics firms to compile the data into price comparison tools that plan sponsors can (and should) use to shop for competitive healthcare coverage. Self-insured plans should verify their TPAs are timely updating and posting these files since the sponsor is ultimately liable for a compliance failure.
- ***Participant Self-Service Tool —*** Plans and insurers must make an internet self-service tool available to participants that provides personalized cost-sharing information for covered services. Sponsors should ensure the tool can be used effectively by participants to compare healthcare costs.

For further information regarding transparency obligations, see the PPI publication **Transparency and CAA 2021 Obligations of Group Health Plans**.

Employer Checklist (2D: Plan Disclosure and Reporting Requirements)

- ☐ Follow an annual compliance calendar covering disclosures/notices and reporting across ERISA, ACA, COBRA, HIPAA, Medicare, Transparency in Coverage, and CAA 2021 requirements; contractually confirm level of support from vendors to satisfy requirements.
- ☐ Ensure participant disclosures are accurate and delivered correctly (even when drafted by vendors) and retain proof of distribution where appropriate.
- ☐ Confirm ERISA documentation is complete and consistent (written plan document, SPD/SBC alignment).
- ☐ Adopt a process to respond timely to participant document requests (coordinate with TPAs for documents they maintain) to mitigate ERISA penalty risk.
- ☐ Determine whether Form 5500 filing (100+ participants or trust funding) and SAR distribution obligations apply.
- ☐ Address ACA reporting responsibilities for self-insured plans (Section 6055 for self-insured sponsors of all sizes; Section 6056 for ALEs); implement quality controls to minimize penalty exposure.
- ☐ Identify and comply with any state individual mandate reporting requirements tied to employees' home addresses.
- ☐ Pay and file PCOR fees via Form 720 on time (and ensure the fee is paid by the sponsor as required, not from participant plan assets).
- ☐ Confirm Medicare Part D creditable coverage determination ownership and ensure timely CMS/participant disclosures.
- ☐ Operationalize CAA 2021 and transparency duties: remove/avoid gag clauses, collect and review service provider compensation disclosures, coordinate RxDC reporting, maintain MHPAEA comparative analyses, and confirm MRFs and participant price tools are posted/functional.

3. SUMMARY

Self-insuring can provide employers with greater control over their group health plan costs and design, with potential long-term savings. But self-insuring also shifts claims risk to the employer and requires planning for cash-flow volatility, including reserves for IBNR claims, and effective stop-loss protection.

Key Takeaways

Key compliance takeaways on transitioning to self-insuring:

- Fiduciary accountability increases under ERISA (prudent process, governance, and vendor selection/monitoring).
- Plan design flexibility increases due to ERISA preemption of most state insurance mandates, but certain non-preempted state laws may still apply.
- Self-insured plan sponsors must address additional federal requirements, including Section 105 nondiscrimination and ACA reporting responsibilities.
- Self-insured plans must comply with expanded HIPAA Privacy and Security compliance obligations.
- Transparency and NSA obligations remain with the sponsor even when a TPA or other vendor performs the operational work; contracts should clearly allocate duties and fees.

Service providers can address many day-to-day plan functions, but the plan sponsor remains ultimately accountable. Strong contracting, data access, and ongoing oversight are essential.

Sponsors that understand these financial and compliance requirements – and build effective governance practices and vendor support systems – are best positioned to implement self-insuring successfully.

4. RESOURCES

DOL Technical Release 2011-04

Information on Essential Health Benefits Benchmark Plans

PPI BENEFIT SOLUTIONS