The Consolidated Appropriations Act (CAA) Post Election Webinar Toolkit

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Utilize Leapfrog's CAA Compliance Webinar Series resources by visiting:
https://www.leapfroggroup.org/employers-purchasers/caa-compliance-webinar-series

Explore these additional resources on the CAA from Winston & Strawn LLP:
https://www.winston.com/en/blogs-and-podcasts/benefits-blast/departments-release-final-mental-health-parity-rules

https://www.winston.com/en/blogs-and-podcasts/benefits-blast/benefits-bulletin-recent-cases-highlight-the-need-for-fiduciary-attention-to-health-plan-fees

https://www.winston.com/en/insights-news/amy-gordon-discusses-employer-lawsuits-against-health-plan-administrators-with-bloomberg-law

https://www.winston.com/en/blogs-and-podcasts/benefits-blast/notable-decisions-of-the-2024-us-supreme-court-term-impacting-group-health-plans

https://www.winston.com/en/blogs-and-podcasts/benefits-blast/the-internal-revenue-service-health-and-welfare-limits-for-2025

CAA and Quality

Leah Binder, President and CEO, The Leapfrog Group

December, 2024

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Consolidated Appropriations Act of 2021 (CAA)

- Employers and purchasers are responsible for ensuring cost-effective, high-quality health benefits.
- Health plans must provide quality-of-care data; participants should use this to find the best care at the best price.
- High-profile lawsuits and DOL investigations highlight the stakes.

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The Quality Factor

The Transparency in Coverage Rule – Issued by the DOL and Departments of Treasury and HHS:

- The quality of health care services provided under a group health plan is an important component of value.
- Plan sponsors need to demonstrate diligence in monitoring quality and disclosing comparative quality information to beneficiaries.
- Negotiating a good price for bad care does not fulfill the fiduciary obligations.

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Resources for Evaluating Quality: The Leapfrog Group

- Founded by employers whose vision anticipated the fiduciary standards in CAA.
- Deliver hospital and ASC comparisons on quality and safety that can easily be accessed in a variety of ways.
- Also provides plans and purchasers with a Value-Based Purchasing Program, a pay-for-performance initiative aimed at aligning payment to outcomes.

LEAPFROG HOSPITAL SURVEY

LEAPFROG ASC SURVEY

LEAPFROG HOSPITAL SAFETY GRADE

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Leapfrog's Vision

- **Measurable Achievement** of excellence and equity continually accelerate.
- **Patient Safety and outcomes** are the centerpiece of all payment contracts.
- **Transparency is the norm**, turbo-charging clinical effectiveness and competition within and among all types of delivery settings.

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A Historic Moment

Employers are under pressure to follow new ERISA regulations in the CAA

With a new administration and new Congress coming in January, Employers have unique opportunities and new challenges

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WINSTON & STRAWN LLP

AMY GORDON, WINSTON & STRAWN
DECEMBER 4, 2024

The Consolidated Appropriations Act (CAA) and Post Election Predictions

CAA Current Provisions

- No Surprise Medical Billing
- Independent Dispute Resolution (IDR)
- More Explicit Medical Identification cards
- Continuity of Care
- Updated Network Provider Directories
- Transparency and Disclosure
  - machine-readable files on a public site, cost comparison tools, advanced cost estimates, broker compensation, etc.
  - Website and Explanation of Benefits and Pricing Disclosures
  - GAG Clause Prohibition Compliance
- The Mental Health Parity and Addition Equity Act (MHPAEA)-Non-Quantitative Treatment Limitation (NQTL) Compliance
  - Audits, fiduciary certification, etc.

GAG Clause Prohibition Compliance Attestation

- The Gag Clause Prohibition Compliance Attestation is a yearly attestation that group health plans and health insurance issuers must submit to ensure compliance with the CAA
- These provisions prohibit group health plans and health insurance issuers offering group health insurance coverage from entering into an agreement with a health care provider, network or association of providers, third-party administrator (TPA), or other service provider offering access to a network of providers that would directly or indirectly restrict the release of certain health care information and fees
- Attestations are due by December 31 of each year

MHPAEA-NQTL

- United States Department of Labor (Department) audits of plans which require the plans to produce NQTL analysis for purpose of demonstrating compliance with the MHPAEA shall continue
- New guidance earlier this year [see https://www.winston.com/en/blogs-and-podcasts/benefits-blast/departments-release-final-mental-health-parity-rules] for more details
- New rules go generally go into effect January 1, 2025, with one year delay for certain requirements
- New Fiduciary Certification- Fiduciaries need to certify that they have engaged in a prudent process, including the selection and monitoring of any vendor who helped document the NQTL comparative analysis

Post Loper Bright Decision

- After the U.S. Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* overturning the *Chevron* doctrine, agency interpretations of ambiguous statutes are no longer afforded the same deference and are more vulnerable to legal challenges
- In this new regulatory environment, we can expect legal challenges to a number of the Department's as well as other regulator's rules
- The ERISA Industry Committee has already spoken out criticizing the Final MHPAEA NQTL rule (Final Rule) and said it would consider "all possibilities… up to and including litigation" to protect plan sponsors who may be negatively affected by the Final Rule

Litigation Trends

- Increased Plaintiffs' Bar Activity
  - New transparency/fee disclosure requirements create potential opportunities because more cost information is publicly available and certain service providers must provide direct and indirect compensation information to their plan clients
  - May be exploring cases alleging that service provider fees are unreasonable, borrowing from theories used in 401(k) excessive fee cases
- Recent class action cases
  - Challenges to prescription drug costs, fees, and Pharmacy Benefit Manager selection/oversight
  - Objection to company's use of prescription drug rebates
  - Allegations of plan mismanagement

Recent Health and Welfare Plan Litigation

- Johnson & Johnson (J&J) Sued Over Health Plan Drug Prices
  - Class action suit brought against Johnson & Johnson alleging breach of fiduciary duties by
    - Failing to ensure plan costs were reasonable
    - Failing to exercise prudence in selecting its pharmacy benefits manager (PBM)
    - Agreeing to unfavorable contract terms
  - Complaint alleges an average markup of 498% across all generic specialty drugs on the formulary managed by J&J's PBM for which there is publicly available data
- Navarro v. Wells Fargo: New Case with Similar Allegations
  - Alleged Wells Fargo paid excessive fees - cited fee information reported on Form 5500
    - Alleged failure to consider alternative PBMs and pricing models

Recent Win for MetLife

- MetLife Prevails in Suit About Use of Prescription Drug Rebates
  - Alleged MetLife breached its fiduciary duty by keeping drug rebates
  - District court found no injury to the plaintiffs – dismissed on standing grounds
  - Third Circuit upheld, but left the door open for participant excessive fee/plan mismanagement lawsuits
  - MetLife case cited in supplemental authority notice filed by Johnson & Johnson plaintiffs

Questions

ERIC | *Shaping benefit policies before they shape you.*

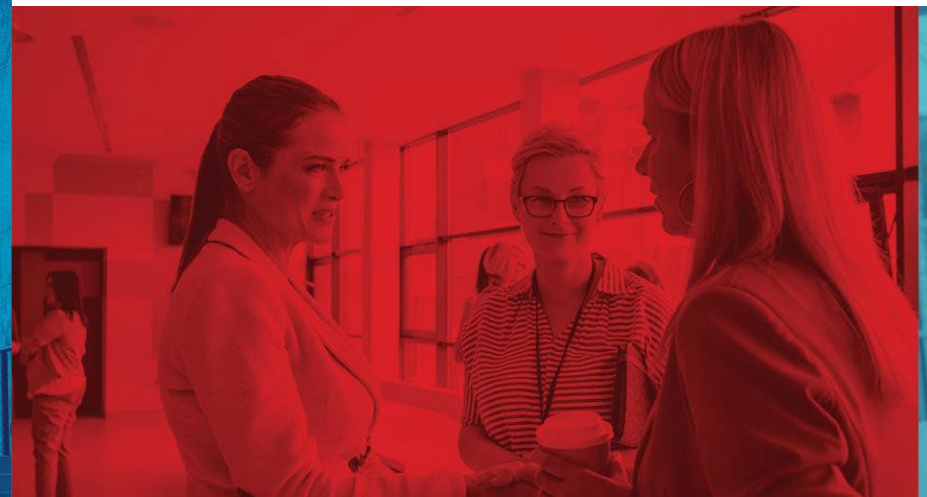
December 4, 2024

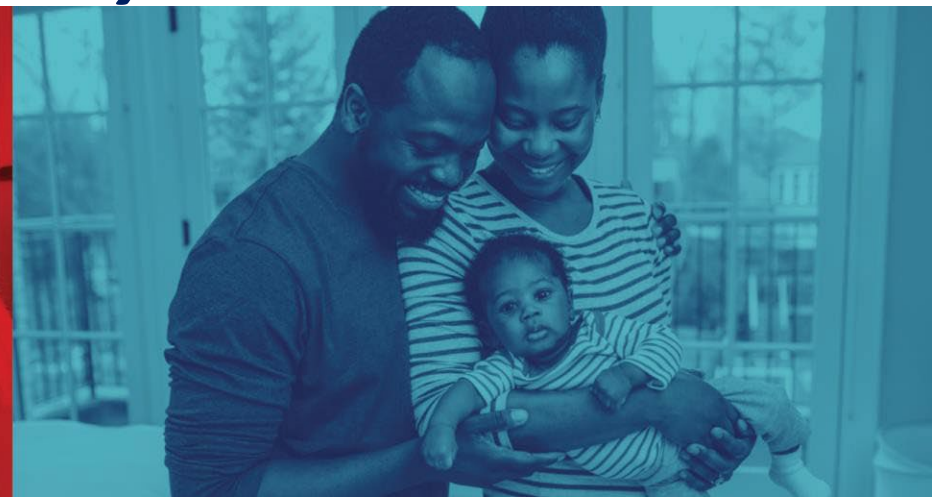
The Consolidated Appropriations Act (CAA) and Post Election Predictions

James Gelfand

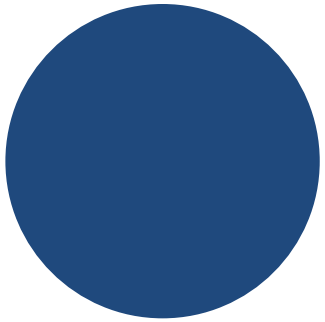
President and CEO

The ERISA Industry Committee

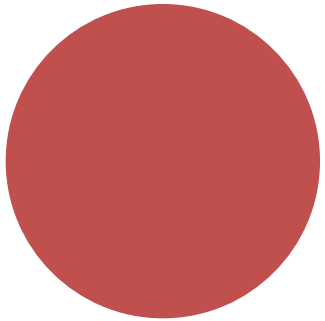




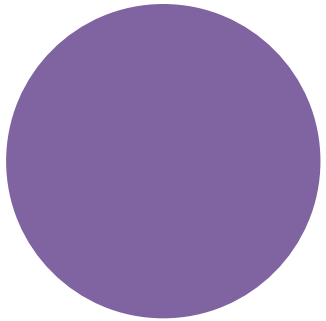
Lame Duck – Certain Health Policies/Programs Expiring after 12/31/24



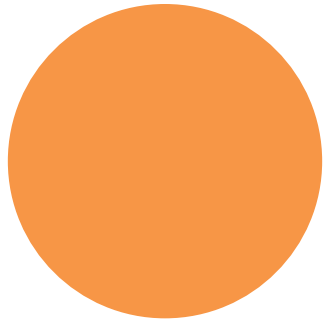
Medicare payments



Community Health Centers

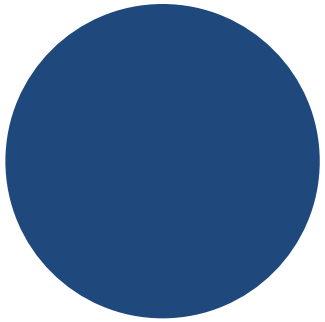


Telehealth

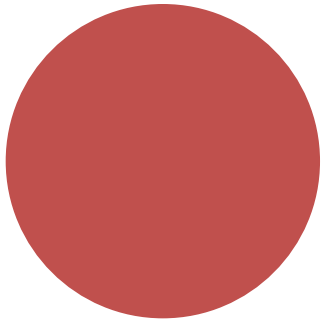


Medicaid/ Public Health Programs/ Certain Hospital Programs

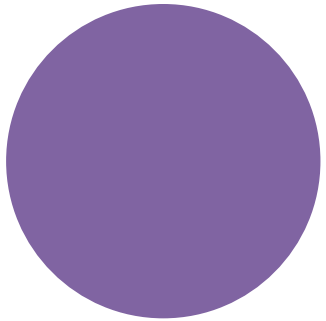
Lame Duck – What Additional Health Policies Could Congress Include?



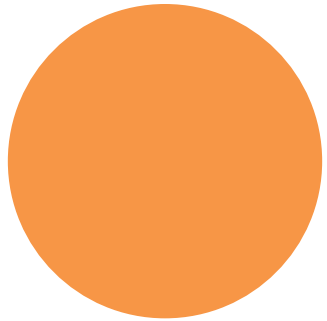
Transparency and PBM Reforms



Patent Reforms



HDHP/HSA Reforms



Fairness in Contracting/Honest Billing

TRANSPARENCY IN COVERAGE AND HOSPITAL TRANSPARENCY RULE

- Codifying the Hospital and TiC Rules will memorialize these very important requirements in statute, protecting them in the case of a likely court challenge in the wake of the elimination of Chevron deference

MENTAL HEALTH PARITY ACT

- This massive rule purportedly stems from minor NQTL documentation requirement from CAA

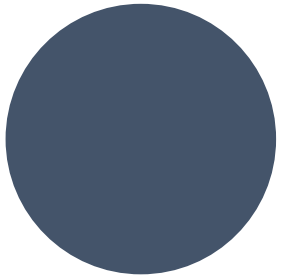
- The rule goes far beyond Congress's clear intent when it enacted the MHPAEA and the CAA and adds complexity for employers who choose to offer mental health benefits

GAG CLAUSE PROHIBITION COMPLIANCE ATTESTATION

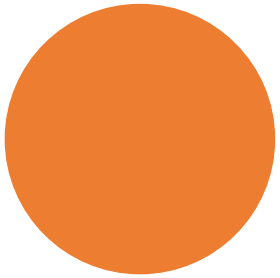
- Congress sees gaps in CAA gag clause prohibition as attestations near

- LCMT would fix the following gag clause loopholes
  - Congress needs to strengthen the "Gag Clause Prohibition" by imposing penalties on owners of the provider network that refuse to share complete and accurate health claims data with the plan administrator, especially in cases when a plan sponsor cannot rightfully "attest" that there are no restrictive "gag clauses" in their health plan's agreements
  - Congress must also allow plan sponsors to share their health claims data with service providers hired by the sponsor to assist in the administration of the health plan

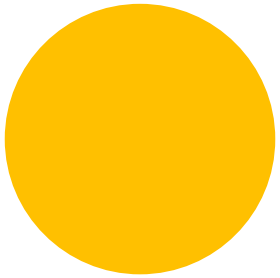
PBM REFORM



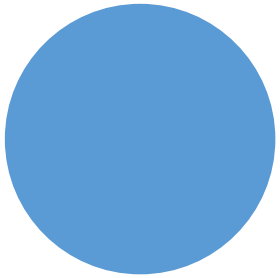
Ban spread pricing



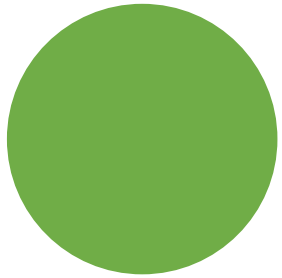
Require 100% pass-through to employer plan sponsors of rebates, discounts, fees, and other payments from drug manufacturers



More transparency into PBM-owned pharmacies and other entities in the supply chain under common ownership and/or control as a PBM



Policies to effectively de- link PBM profits from list prices for drugs



Hold PBMs accountable in the same way plan sponsors are held accountable

ISSUE BRIEF – PBM REFORM: DEEM PBMS A "FIDUCIARY" UNDER ERISA

- Since 2017, ERIC has been the leading employer group on PBM reform and transparency

- ERIC later called for applying fiduciary duties to PBMs, leading to the release of our recent issue brief

The Issue Brief:

Explains current law as it applies to an ERISA fiduciary, describing who is an ERISA fiduciary and who is not, and details ERISA's fiduciary duties and the consequences for breaching an ERISA fiduciary duty.

Pages 4-7

Illustrates what actions or inactions taken by an employer plan sponsor can result in claims of fiduciary breach filed against them, with additional illustrations of various PBM practices that could result in liability if the PBM was considered an ERISA fiduciary. These illustrations are intended to put into context how harmful PBM-related practices would be curbed if PBMs are subject to ERISA's fiduciary duties.

Pages 8-10

Provides information regarding how plan sponsors and PBMs could satisfy their ERISA fiduciary duties if they gave due consideration to reducing the cost of covered prescription drugs by including biosimilars in drug formularies made available to employer-sponsored health plans.

Page 11

Includes a case study comparing the cost of Humira® and Humira® biosimilars. It concludes by examining what Congress needs to do to apply ERISA's fiduciary duties to PBMs.

Pages 12-13

ERIC | THE ERISA INDUSTRY COMMITTEE


2024-2026 ISSUE
PREDICTIONS

RECONCILIATION

- The main focus of reconciliation will be extending the Tax Cuts & Jobs Act
- Senate Parliamentarian determines if bills are germane to the budget and are permissible
- Republican trifecta will start with reconciliation instruction to determine how much of the deficit can be financed
- Internal party negotiations will pit TCJA extenders against high price tags and Trump campaign promises

Elizabeth MacDonough
Parliamentarian

TAX REFORM

- Tax Cuts and Jobs Act 2.0
  - Corporate Tax
  - Caregivers Tax Credit
  - Concern = Employer Tax Exclusion

- HDHP/HSA Legislation Possibly included?
  - Worksite Health Centers
  - Direct Primary Care
  - Chronic Disease

THE FUTURE OF MAJOR HEALTH CARE LEGISLATION WE MAY SEE

- Health Transparency
- Tax Reform/HDHP/HSAs
- Hospital and Drug Prices
- ACA & Other Coverage Options
- Prescription Drug Costs

- Focused on reducing government intervention and increasing market competition, reducing costs
- Future efforts may build on these goals, focusing on deregulation and state-based reforms

EARLY INDICATORS OF MAKE AMERICA HEALTHY AGAIN AGENDA

"The corruption and the conflicts out of the regulatory agencies"

"Return the agencies to the gold standard, empirically-based, evidence-based agents in medicine that they were once famous for"

"End the chronic disease epidemic with measurable impacts on a diminishment of chronic disease within two years"

EXECUTIVE ACTION AND REGULATIONS

- Executive Orders and regulations could be doubled-down or reversed – returning to where the Trump Administration left off

Chronic Disease

OTC Birth Control

ICHRAs, AHPs, Short Term Insurance

Artificial Intelligence

Government Agency Reorganization (i.e. NIH, CDC, etc.)

MHP Rule?

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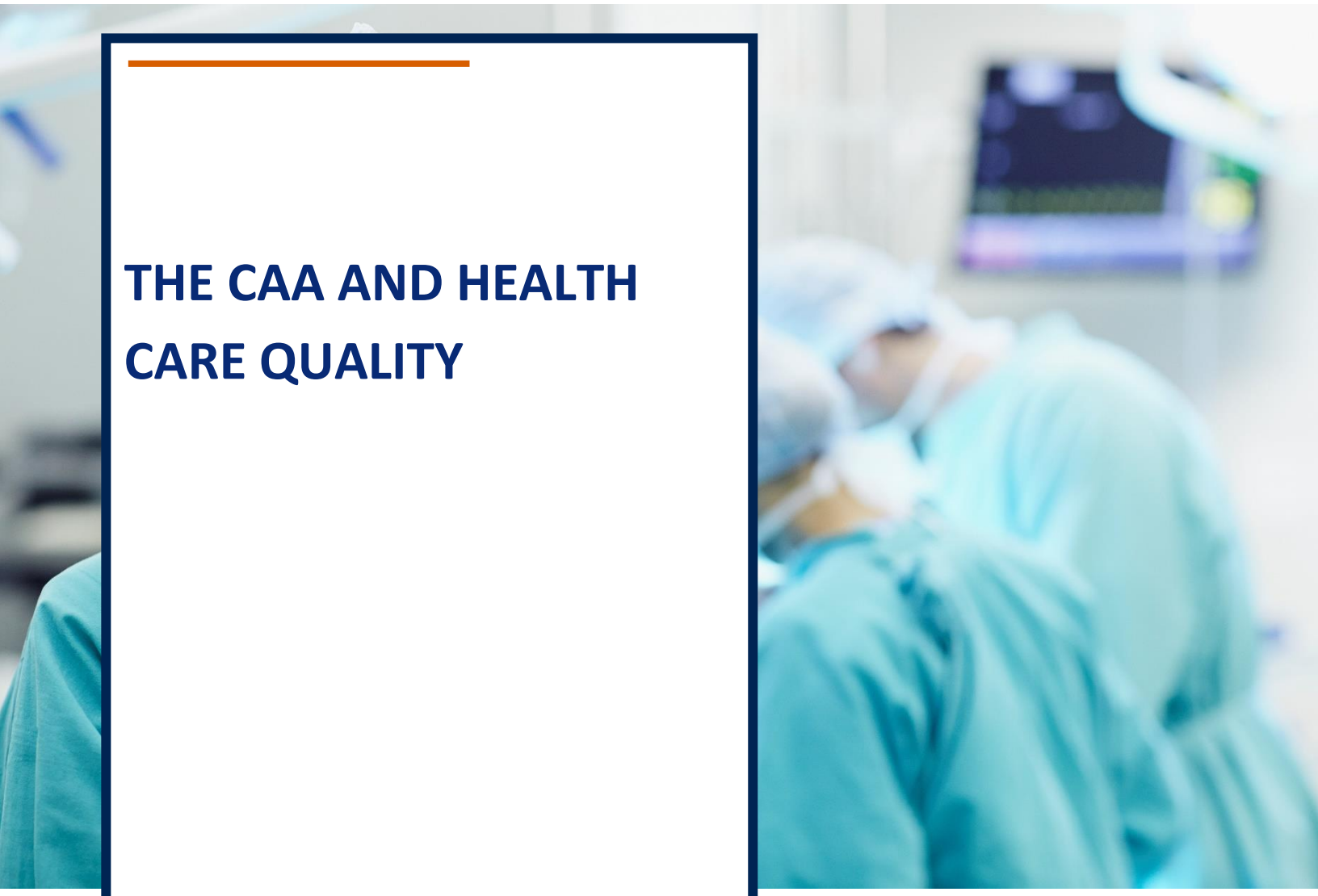
ERIC

Shaping benefit policies before they shape you.



THE CAA AND HEALTH CARE QUALITY

July 19, 2023

BERGER | MONTAGUE

THELEAPFROGGROUP
Giant Leaps for Patient Safety

FIDUCIARY IN A BOX

Leah Binder
Jamie Greenleaf
Karen L. Handorf
Julie S. Selesnick

INTRODUCTION

Since the 1940s, access to health insurance has largely been governed by employers and other group purchasers, such as "Taft-Hartley" plans run by unions. Approximately 50% of the American population is covered by group health coverage.[i] Health care is the second largest expense after payroll for most companies and is crucial to the overall recruitment and retention of employees, as well as to their health, safety, and productivity.

The federal government treats purchaser investment in health benefits as tax-free compensation and regulates it under a 1974 federal law called the Employee Retirement Income Security Act of 1974 (ERISA). A new law amending ERISA was signed in 2020 and is now in effect with broad implications for purchasers, employees, and the health care industry: The Consolidated Appropriations Act of 2021 (CAA). The CAA clarifies certain fiduciary obligations under ERISA, significantly enhancing existing employer accountability for cost-effectiveness, quality, and value of health benefits. This paper focuses on one of the critical issues for employer compliance with the new law: employer responsibility for the quality of health care services offered to plan participants. The actions employers take may have significant implications for the broader health care industry including direct providers of health services in the post-CAA world.

Health plans should provide access to quality-of-care data and participants should be incentivized to use that data to seek the best care available at the most reasonable price.

THE CAA CLARIFIES AND, IN SOME CASES, CHANGES HOW HEALTH BENEFITS ARE REGULATED

Small businesses typically offer employee health benefits by purchasing an insurance product and paying premiums to a health insurance company. This is called a fully insured health plan, under which the insurer assumes the risk of providing health benefits for eligible expenses. The majority of employers with 200 or more employees are "self-insured", meaning they offer self-funded health plans under which they assume all of the financial risks. Employers offering self-funded health benefits pay all eligible health care claims, typically contracting with a third-party administrator (TPA) to process and administer claims and issue payments to providers. In both cases, the investment in health benefits is tax-exempt compensation to employees.

Self-insured employer coverage is governed by ERISA, the same federal law that governs retirement benefits such as 401K plans and pension plans. ERISA sets minimum national standards for most voluntarily established retirement and health plans. ERISA requires that employers and other entities that administer plans and control plan assets, called "plan fiduciaries", act prudently and "solely in the interest of participants and their beneficiaries" and "for the exclusive purpose" of providing benefits and defraying reasonable plan expenses.[ii] ERISA also prohibits payments to service providers unless the fees are reasonable.[iii]

Over the decades, a large industry of service providers has emerged to support employers in carrying out their duties under ERISA. Unfortunately, when it comes to health benefits, too often those service providers do not disclose enough information to assure accountability to plan sponsors or allow for plan sponsors to effectively monitor their performance. Too often TPAs withhold from the employer the claims data generated when administering the plan, as well as the negotiated network rates and other cost and fee considerations. In addition, service providers often fail to disclose information reflecting their direct and indirect compensation, which could lead to a conflict of interest that negatively impacts the value of health benefits.

The new CAA language amends ERISA to solve these longstanding challenges and applies to fully insured and self-funded health plans. The CAA takes longstanding retirement plan compensation disclosure requirements[iv] and expands them to health benefits plans, requiring, among other things, health plan fiduciaries to ensure that service provider compensation disclosures have been made. The CAA also prohibits gag clauses in service provider contracts which have been used to limit the ability of plans to obtain their own claims information and requires a plan fiduciary to submit an attestation to the Department of Labor (DOL) that such clauses have been removed from all their contracts with service providers. In addition, plans are now required to provide cost-sharing information to participants and to disclose in-network provider rates, historical out-of-network allowed amounts and the associated billed charges, and the negotiated rates for prescription drugs. These provisions, together with recently issued hospital transparency regulations requiring hospitals to disclose their rates and other provisions contained in the CAA, the Transparency in Coverage Final Rule, and the provisions of the No Surprises Act (NSA), create the conditions for full transparency and better value from health benefits. Employers are directly accountable for evaluating their existing service provider contracts to determine whether they are being operated in the best interest of plan participants, which empowers them to require the information and tools they need from vendors. This paper will focus on one of the least discussed aspects of employer compliance with the new law: employer responsibility for impacting the quality of health care services plan participants' access.

ARE EMPLOYERS REQUIRED TO FOCUS ON QUALITY OF CARE UNDER THE CAA?

ERISA already imposes significant requirements on plan sponsors for addressing quality of care, and those standards have been strengthened with the passage of the CAA. The DOL, which enforces ERISA, stated more than 20 ago that quality of service is a factor in selecting and monitoring a health plan service provider and that "a plan fiduciary's failure to take quality of services into account in the selection process would constitute a breach of the fiduciary's duty under ERISA."[v] According to DOL, a responsible health plan fiduciary "must engage in an objective process designed to elicit information necessary to assess the qualifications of the provider, the quality of services offered, and the reasonableness of the fees charged in light of the services provided."[vi] This process includes an evaluation of (a) the qualifications of those who will be providing medical services; (b) ease of access to medical providers and information about the health care provider's operations; (c) the procedures

in place to timely consider and resolve patient questions and complaints; (d) the procedures for patient record confidentiality; and (e) enrollee satisfaction statistics. [vii]

DOL, in conjunction with the Departments of Treasury and Health and Human Services (HHS) (collectively, the Departments), recently reiterated that the quality of health care services provided under a group health plan is an important component of overall plan value when they jointly issued the new Transparency in Coverage rule at the same time the CAA was being negotiated by Congress. The Departments noted in the rule's preamble that government agencies and the private sector have been working to provide quality information to consumers and that "once pricing data is available through the final rules, existing quality data can be considered with pricing data to produce a more complete and accurate picture of total value." [viii]

While no court has yet had occasion to determine whether group health plan fiduciaries have a fiduciary duty under ERISA to provide information related to quality of care to health plan participants, DOL's repeated instruction to ERISA plans that quality of health care services is important, as well as the strong language in CAA heightening that standard (e.g., the CAA amended ERISA to add Section 724, which prohibits group health plans from entering into agreements that directly or indirectly restrict the plan from providing specific quality-of-care information about specific providers), suggest the time has come. Fiduciaries should make it a priority to facilitate informed decision-making for plan participants when it comes to accessing healthcare providers and facilities. At a minimum, even prior to enforcement or potential court actions, plan sponsors that demonstrate diligence in monitoring quality and disclosing comparative quality information to beneficiaries will likely minimize such risks.

Current regulatory guidance on specific standards for complying with the CAA is limited, but plan sponsors are still accountable and subject to the authority of DOL regulators as well as the courts for adhering to the spirit of the law. Plan sponsors seeking guidance should look to already-developed laws applicable to fiduciaries of retirement plans choosing investment options and service providers. It is well settled that retirement plan fiduciaries must have a prudent process in place for choosing investment options and service providers based on an evaluation of the costs, fees, risks, and investment performance, all of which have a direct impact on the amount of money available to employees upon retirement. Courts uniformly hold that fees paid for overpriced and poor performance are not reasonable and cannot meet the exclusive benefit requirement or the reasonableness requirement necessary to exempt compensation payments to service providers from the prohibited transaction rules. Retirement plan fiduciaries who do not pay close attention to investment options cost and performance are at substantial risk of litigation by unhappy plan participants and are personally liable for the losses resulting from their failure to do so.

Similarly, health plan fiduciaries must have a prudent process in place to evaluate the performance and costs of their health plan options, as well as a fiduciary process for retaining and monitoring service providers to those plans. Employers should establish management structures to run their health plans similar to the structures they have in place to run their retirement plans.

Like the benchmarks retirement plan fiduciaries establish to gauge whether plan investment options will provide enough retirement income for participants, health plan fiduciaries should establish measures to gauge whether their health plan is providing participants with valuable health care in terms of quality outcomes and cost-effectiveness. If they do not have the expertise to do so themselves, they must hire experts to advise them.

Still, in the past a fiduciary seeking to evaluate the value of a fee-for-service PPO was likely to encounter significant resistance from a TPA or other vendor asked to provide detailed information concerning the quality of care delivered by providers covered (or excluded from) the PPO network. Typically, insurers and TPAs providing access to networks do not emphasize the quality of network providers but instead, emphasize the breadth of the network and the price per unit of services they offer. The transparency requirements in the CAA support the position that non-disclosure of cost *and* quality information is outside the boundaries of the law and holds plan sponsors accountable for either acquiring the information or reporting failures to comply.

Due diligence by health plan fiduciaries requires that both price and quality be evaluated independently. Poor quality is one of the foremost "red flags" for a fiduciary standard because the absence of quality makes price irrelevant for patients and their loved ones. Negotiating a good price for bad health care does not fulfill the fiduciary obligations of prudence and loyalty. Moreover, quality—or its absence--is a major factor in determining the cost of care even if it is not correlated with the pricing of individual services. For instance, a hospital may offer lower prices, but if hospital-acquired infections are high, that will increase total patient costs by lengthening inpatient stays, necessitating new treatments, prompting readmissions, and requiring long-term follow-up care from community physicians.

Health equity is an additional aspect of quality of care, and one that is ripe for class action litigation in the future, so employers should seek out and report quality data that accounts for disparities in outcomes and/or other patient-level performance. Thousands of studies, as well as consensus reports from the National Academy of Medicine and others, have long established a high prevalence of inequity in health care quality.[ix]

Plan fiduciaries can and should ask their network service providers what methods they use to select and evaluate their providers as well as how often they evaluate them for quality including equity. They should consult experts and analyze for themselves whether these measures of quality are appropriate for their plan, what measures are in place to evaluate providers to ensure they meet quality standards, and how often quality is measured. Most importantly, plan fiduciaries must do their own research and utilize independent resources that currently exist to not only evaluate quality but assist their employees and plan participants in accessing quality information as well, so that they can be informed consumers.

Forward-thinking health plan fiduciaries are already working with their service providers that have expertise in this area on developing methods of providing quality care and outcome information in a format that can be understood easily by interested participants. The more digestible and user-friendly

the information surrounding care quality and outcomes is presented to plan participants, the more likely plan participants are to utilize the information to make well-informed decisions. Even as specific regulations pertaining to the CAA remain in the future, or are unclear or untested, making the effort to proactively inform plan participants of quality and cost choices will go a long way toward demonstrating meaningful commitment to the fiduciary standard. This means doing more than just cutting and pasting links to websites that contain such material, and there are several disruptive tech companies in this area with the goal of providing easy-to-use calculators, comparison algorithms, and smartphone apps to make accessing information relating to the quality of health care at least as accessible for people as accessing information regarding the quality of restaurants in the same area. Figuring out which metrics are material to the quality analysis is a constantly evolving area, but independent expertise exists to help make this determination.

On the upside, in the absence of regulations in place specifying the provision and materiality of quality data to health plan participants, fiduciaries that make a good faith effort to provide what they believe to be the best information available to help participants understand their choices when it comes to quality, outcomes, and other important metrics will already be far ahead of their peers in this area. Additionally, the old adage that "you can lead a horse to water, but you cannot make it drink" is apt; while disclosing quality data to plan participants is a sound move for prudent fiduciaries, it is unclear what the benefits of such disclosure will be, e.g., whether that will lead plan participants to make decisions on providers and facilities based on that data. Like every other part of being an ERISA fiduciary, ***it is more important to establish and put in place a prudent process*** for evaluating and providing material information relating to quality of care to plan participants; whether it is ultimately effective does not impact the fiduciary obligation to act. Putting a sound process in place for identifying and disclosing material quality of care information in a user-friendly manner is another area where ERISA fiduciaries can minimize future risks of litigation and DOL enforcement.

RESOURCES FOR EVALUATING AND EDUCATING PLAN PARTICIPANTS ON QUALITY

As DOL noted in the preamble to the Transparency in Coverage rule, there is substantial quality data available from both government and private sources. This paper is not meant as a comprehensive guide to those resources, but a brief overview for fiduciaries taking needed action.

For background on measuring and reporting quality, a good starting point is The National Quality Forum (NQF), a private standard-setting organization that evaluates and endorses standardized performance measurements that it makes available on its website.[x] While NQF does not report the performance of providers, it is the standard-setting body for which measures are endorsed for use in public reporting. To aid those looking to measure the performance of their health plan, NQF provides a printable version of a primer on measuring health care performance titled "The ABCs of Measurement."[xi] Because the endorsement process is comprehensive of science, testing, and broad stakeholder consensus, it is advisable for employers to look for NQF-endorsed measures of performance when selecting a quality reporting strategy.

A good start for health plan fiduciaries is The Leapfrog Group (Leapfrog), an organization that was founded over 20 years ago by employers whose vision anticipated the fiduciary standards set forth in the CAA. A national nonprofit founded by the Business Roundtable for the express purpose of independently assessing the quality and safety of health care providers, Leapfrog is one of the nation's most powerful advocates of health care transparency which has led to far more resources for public reporting than existed at its founding. In addition to public policy advocacy, Leapfrog acts on behalf of purchasers to collect voluntarily provided data from hospitals and ambulatory surgery centers, which it publishes to inform value-based purchasing and improved public decision-making.[xii] Leapfrog brings together experts in clinical quality and measurement to ensure public access to high-integrity data that is most relevant and consequential for plan participants.

Leapfrog delivers provider comparisons that plan sponsors can easily access in a variety of ways, either directly as a free link or through vendors and others described below that aggregate quality data and make it accessible to consumers. Leapfrog data comes from (1) the Leapfrog Surveys, which collect data voluntarily from hospitals and ambulatory surgery centers on safety, quality, and resource use, and (2) the Leapfrog Hospital Safety Grade, a consumer-geared letter grade system evaluating nearly 3,000 hospitals on how well they keep patients safe from medical errors, infections, and injuries. Leapfrog also provides plans and purchasers with a Value-Based Purchasing Program, a pay-for-performance program aimed at aligning payment to outcomes.[xiii]

Leapfrog and other employer-driven nonprofits were leading advocates for CMS to publicly report the performance of providers. Today CMS offers a rich set of search tools and public databases on the quality of outcomes at health care facilities to calculate quality for many hospitals, long-term care facilities, rehab facilities, ambulatory surgery centers, and other settings. The largest set of data from CMS is CMS's Hospital Inpatient Quality Reporting Program, under which CMS collects quality data from certain hospitals with the goal of driving quality improvement through measurement and transparency. The metrics reviewed by CMS include mortality, safety of care, readmissions, patient experience, effectiveness and timeliness of care, as well as the efficient use of medical imaging. The data collected through the program is available to consumers and providers on the Care Compare website.[xiv] What Leapfrog and CMS have in common is a commitment to revealing all levels of performance, from excellent to poor, which is important information for plan participants to avoid problem facilities. Most other sources of public data exclusively report on the highest achievers.

Accreditation status is a key quality credential to report to plan participants. Accreditors increasingly report quality data beyond the achievement of accreditation, but only for those facilities that earned accreditation. The Joint Commission (TJC) is an organization that accredits hospitals, nursing homes, and other facilities and develops and applies standards that focus on patient safety and quality of care. Accreditation from TJC requires on-site evaluation, which assesses compliance with its standards and verifies improvement activity. Health care organizations that receive accreditation or certification from TJC are awarded the patented *Gold Seal of Approval*. TJC provides a searchable website, qualitycheck.org, containing health care organizations that have earned the *Gold Seal of Approval* by TJC.[xv]

The National Committee for Quality Assurance (NCQA) accredits health plans as well as medical providers and practices. NCQA evaluates 90 measures across six "domains of care," including the effectiveness of care, access/availability of care, and experience of care.[xvi] According to its website, the NCQA Health Plan Accreditation program builds upon more than 25 years of experience to provide a current, rigorous, and comprehensive framework for essential quality improvement and measurement, including both clinical performance through HEDIS and consumer experience through CAHPS.[xvii] Prudent fiduciaries can use the NCQA standards to evaluate and report on health plans and medical practices that achieve NCQA accreditation, examining metrics including:

- quality management and improvement
- population health management
- network management
- utilization management
- credentialing and recredentialing
- members' rights and responsibilities
- member connections
- Medicaid benefits and services

NCQA offers many additional programs geared at raising the quality of health plans, including health equity accreditation programs, an emerging focus in health care closely related to quality of care. Improving health equity across all populations requires a commitment to eliminating health disparities in underserved populations; doing so results in better health outcomes across the board while reducing overall treatment costs. Integrating information related to health equity into the process of providing material information related to quality of care is a great way to limit plan fiduciaries' future exposure to enforcement action and litigation.

Plans can report on quality, including health equity data, by directing participants to user-friendly websites that provide such information. The Leapfrog Hospital Safety Grade site is a good example of quality data that fiduciaries can utilize and provide to plan participants immediately at no charge and is presented in a format that users can easily understand and interact with.[xviii]

The CMS searchable website allows anyone to compare providers, hospitals, nursing homes, home health care, hospice care, inpatient rehabilitation facilities, dialysis facilities, and long-term care facilities. This provides quite a bit of data for almost every possible health care need, and it is used by other vendors as well as incorporating it into public-facing sites. Additionally, the Office of Personnel Management (OPM), the public agency that administers federal employee benefits, provides a searchable site where anyone can enter their zip code and compare health care quality and customer experience scores for plans in the same area. This is particularly useful for employees choosing among more than one health plan as it gives all types of quality data from the customer experience perspective in addition to the quality of care.[xix]

All of these sources of quality data are limited in scope, and there is a need for a wider range of ratings on more nuanced issues, like the quality of individual hospital units or the outcome record of individual surgeons or other clinicians. A number of additional vendors and popular rating websites are innovating to improve the breadth of data available to plan sponsors to integrate into their benefit design, usually for a fee. Most build from other data, which may include data from Leapfrog, CMS, The Joint Commission, and NCQA. These vendors include Castlight, Embold Health, WebMD, and others that offer tools for searching out quality data including by physician as well as by hospital or facility. Some vendors offer direct access for consumers as well, such as Healthgrades, Vitals, and ZocDoc. These sites offer information designed to reflect what consumers use for their own assessment of quality, ranging from the percentage of patients who suggest a health care provider to the wait time once in the office, parking accessibility, and many issues in between, including quality and patient reviews, type of insurance accepted, distance, and the doctor's gender. Some of these sites also provide data showing how long health professionals have been in practice, as well as their education and training, licensure and certification, hospital affiliations, and languages spoken.[xx]

STRATEGIES FOR MAKING QUALITY HEALTH CARE FOUNDATIONAL TO A BENEFITS PROGRAM

Ensuring that plan participants have access to independent comparative quality data to help them make decisions about where to seek care is the first step for providers of group health plan coverage. It is important that health plan fiduciaries begin discussing quality and performance data and how to provide the most helpful data in a format usable by plan participants. Many vendors, advocates, and government agencies such as those described above will offer innovative tools for effective communication.

In addition to accessing and sharing quality of care information, there are other measures health plan fiduciaries can investigate and consider as methods of facilitating participant access to the best quality of care and to determine whether the quality of their health plans could be improved. Plan design strategies in health care can be a game changer, producing better outcomes with quality as the cornerstone, and further aligning with the principles of good fiduciary stewardship. Some of these measures include:

- **Switching to a narrow, high-performance provider network, or keeping a broader network but incentivizing employees to choose higher quality providers**.

There are ways to keep a broad network while incentivizing employees to choose higher-quality providers. Some of these include implementing (a) centers for excellence programs for some medical procedures such as knee replacement surgery; (b) a tiered network system where employees are financially incentivized to go to high-quality providers and disincentivized to go to low-quality providers; (c) alternative payment models (APMs) that shift financial risk to providers and reward quality; and (d) value-based plan design models that lower cost-sharing for high-value services.

- **Use advanced value-based payment strategies.**

In addition to network selection, there are a number of new models of agreements focused on payment and contracting terms with selected providers that allow plan sponsors to properly reflect quality and cost-effectiveness in payment terms. These include bundled payments, value-based bonuses or penalties, capitation, and tiered payment levels. Such contracting innovations are not robust for many TPAs and health plans, but some plan sponsors unable to find a TPA to contract adequately for value have implemented direct contracts with providers for select services, which shows that plans can implement value-based contracts on their own, in some cases eliminating the need for a TPA. Excellent resources for plan sponsors are available from Catalyst for Payment Reform[xxi].

- **Care coordination.**

While the new transparency tools available as the result of the Hospital Price Transparency Final Rule, Transparency in Coverage Final Rule, CAA, and NSA will provide anyone who wants access to cost information, employees tend not to shop for health care even when they have access to price shopping tools. Many employees simply don't have the time or education to study quality or price before getting care, and our health care system is particularly confusing, not lending itself to easy investigation. Though it has been changing rapidly, the reality today is that many plan participants go to whichever hospital is close by or wherever their doctor sends them. A strong navigation system combined with a coordination of care system would help encourage patients to favor high-quality providers. For some medical conditions, such as diabetes or substance use disorders, a care coordinator could save plans and participants substantial sums of money and greatly improve the participants' quality of care.

- **Reevaluate the value of your high deductible health plan.**

Plan sponsors and fiduciaries should evaluate whether levels of deductibles and copays provide the best value or if they might be undermining the goal of increasing quality. Plans can give employees access to the best providers and a great quality health care plan, but if the participants cannot afford to pay the deductible required to go to the doctor, then the plan is not achieving its goals. When plan participants forego or delay routine healthcare management, it often leads to higher cost care.[xxii]

One of the stated purposes of high deductible health plans when first permitted by Congress was to facilitate consumer "shopping" for health care services as a means of creating a market for high-value care. At the same time, Congress established Health Savings Accounts, triple-tax-protected accounts that may be created to accompany a high-deductible health plan that employers have the option to subsidize. A subsidized high-deductible health plan supports the incentive to "shop" without eroding access to plan participants unable to afford the deductible. No matter how plan fiduciaries structure deductibles, copays, and subsidies, the CAA clarifies the obligations fiduciaries have to ensure transparency for participants in an effort to facilitate informed decision-making, including both cost and quality of care. That obligation for transparency is accentuated with high deductible plans, which require more informed decision-making by plan participants to achieve value.

- **Health Equity.**

In reviewing their health care plans, sponsors and fiduciaries should also consider their health plan's population. Utilizing existing data can help fiduciaries tailor a program to the particular needs and health risks of the plan's employee population and inform plan participants of treatments and providers that are most likely to provide equitable care. For example, telehealth may be an option that allows workers in rural areas to obtain better quality health care than what is available where they live and give them access to a network of specialists they might not otherwise have. Black women are three times more likely to die from childbirth than other women, so informing Black plan participants of key issues to consider in selecting a hospital for delivery demonstrates strong fiduciary leadership; conversely, failure to inform the same plan participants of these key issues could potentially increase the litigation risk to the employer, depending on the facts and circumstances.

CONCLUSION: A HISTORIC MOMENT

ERISA and the CAA amendments pivot on the adage that a journey of a thousand miles begins with a single step. The process plan sponsors use to aim for the right outcomes is the first critical step--not the outcomes themselves, which come later. Employers must engage in a documented process to show that they are acting in the best interest of their employees. ERISA does not require perfection, but it does require a meaningful analysis of quality as well as costs.

A marketplace of tools and resources exists for plan sponsors to utilize in their efforts to support employee decision-making and to promote the quality and value of care. Utilizing these tools demonstrates loyalty to the interests of their employees. Not only will employers be able to improve outcomes and reduce costs to themselves and their employees, but they will have major bona fides to recruit and retain a healthy, high-quality workforce. High-quality health care is in everyone's best interests, and with the passage of the CAA, employers have a unique opportunity – and responsibility – to make a tangible difference in the health of our country.

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FOOTNOTES

[i] https://www.kff.org/other/state-indicator/total-population/?
[ii] 29 U.S.C. § 1104(a)(1)(A) and (B)
[iii] 29 U.S.C. § 1106(a)(1)(C); 29 U.S.C. § 1108(b)(2).
[iv] 29 C.F.R. § 2250.404a-5.
[v] DOL Information Letter 02-19-1998.
[vi] *Id*.
[vii] www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/understanding-your-fiduciary-responsibilities-under-a-group-health-plan.pdf.
[viii] Transparency in Coverage, 85 Fed. Reg. 72213 (Nov. 12, 2020).

[ix] https://nam.edu/an-equity-agenda-for-the-field-of-health-care-quality-improvement/
[x] https://www.qualityforum.org/Home.aspx
[xi] www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=44311
[xii] https://www.leapfroggroup.org/
[xiii] https://www.leapfroggroup.org/ratings-reports
[xiv] *See* CMS Hospital inpatient Quality Reporting Program web page at *https://www.medicare.gov/care-compare/?providerType=Hospital&redirect=true*.
[xv] https://www.qualitycheck.org/
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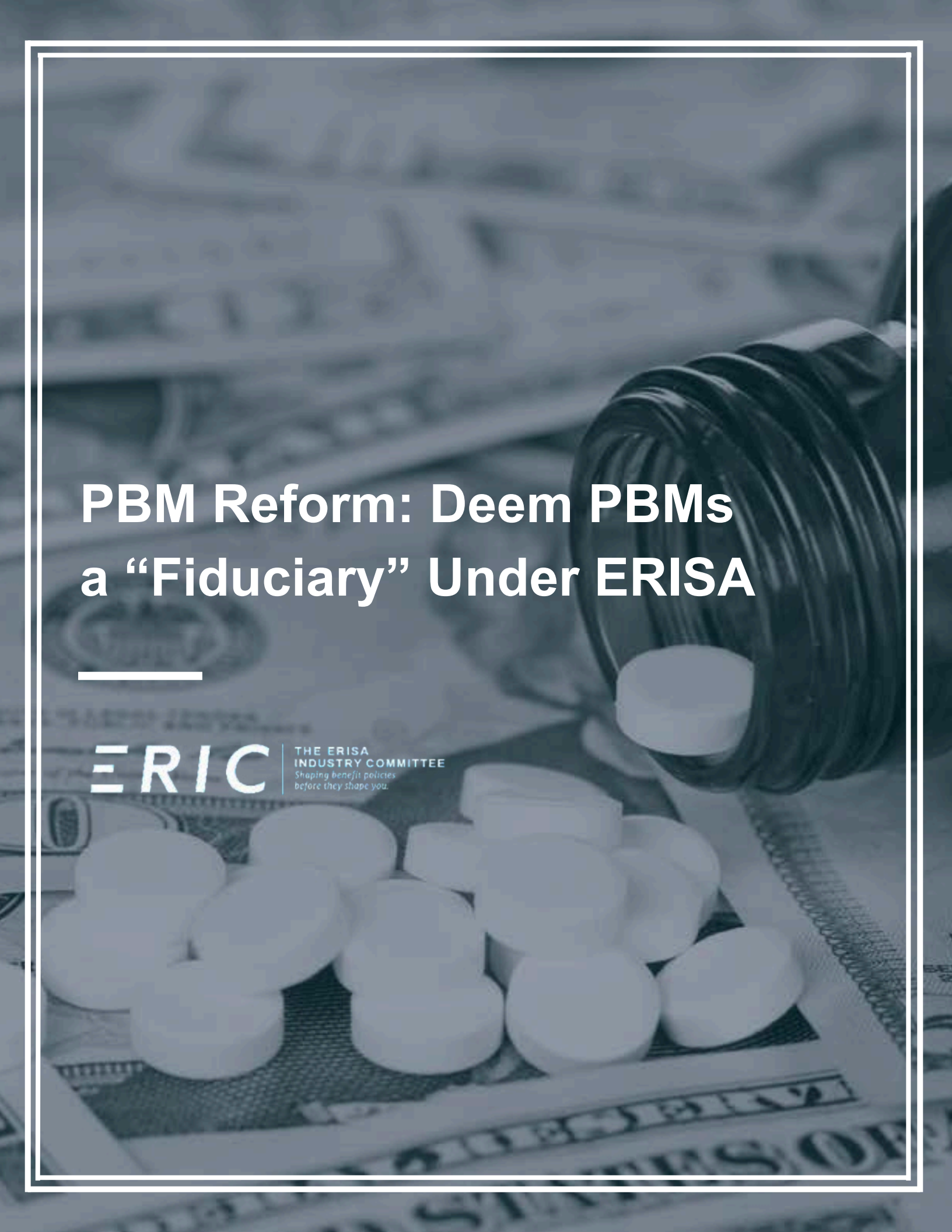
PBM Reform: Deem PBMs a “Fiduciary” Under ERISA



ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

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ERIC is a national advocacy organization that exclusively represents large employers that provide health, retirement, paid leave, and other benefits to their nationwide workforces.

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With member companies that are leaders in every sector of the economy, ERIC advocates on the federal, state, and local levels for policies that promote flexibility and uniformity in the administration of their employee benefit plans.

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ERIC works with lawmakers on Capitol Hill and in the states to ensure they and their staff understand legislative policies that impact large employers whether it be policies related to prescription drugs, health insurance premiums, or even mental health benefits. ERIC also meets with regulatory agencies and Administration officials to advance benefit regulations through the political process. ERIC continues to push forward in representing large employers in employee benefit policies at the state and federal levels.

Introduction

Pharmacy Benefit Managers ("PBMs") engage in many practices that have the potential to raise costs for employees and their family members enrolled in an employer-sponsored self-insured health plan. Unfortunately, these practices continue largely unabated because the laws governing employee benefits and health insurance currently do not hold PBMs sufficiently accountable. However, Congress can take decisive action to fix this regulatory gap by deeming PBMs "a fiduciary" under the Employee Retirement Income Security Act ("ERISA").

In doing so, PBMs would be subject to the same fiduciary duties that have applied to employer health plan sponsors for 50 years now, and the same fiduciary duties that have protected plan participants and beneficiaries from paying unreasonably high prices for covered benefits and excessive or hidden fees. If subject to the same ERISA fiduciary duties as plan sponsors, PBMs would effectively be required to act in the best interest of plan participants and help keep plan costs low. Importantly, PBMs could not engage in self-dealing or other profiteering tactics like many do today.

The Issue Brief:

Explains current law as it applies to an ERISA fiduciary, describing who is an ERISA fiduciary and who is not, and details ERISA's fiduciary duties and the consequences for breaching an ERISA fiduciary duty.

Pages 4-7

Illustrates what actions or inactions taken by an employer plan sponsor can result in claims of fiduciary breach filed against them, with additional illustrations of various PBM practices that could result in liability if the PBM was considered an ERISA fiduciary. These illustrations are intended to put into context how harmful PBM-related practices would be curbed if PBMs are subject to ERISA's fiduciary duties.

Pages 8-10

Provides information regarding how plan sponsors and PBMs could satisfy their ERISA fiduciary duties if they gave due consideration to reducing the cost of covered prescription drugs by including biosimilars in drug formularies made available to employer-sponsored health plans.

Page 11

Includes a case study comparing the cost of Humira® and Humira® biosimilars. It concludes by examining what Congress needs to do to apply ERISA's fiduciary duties to PBMs.

Pages 12-13

Overview

ERISA is a federal law governing health benefit plans sponsored by private-sector employers and other organizations like labor unions. In addition to specific notice and disclosure requirements, [1] health claims procedures, [2] and prohibitions against discrimination based on health status, [3] ERISA sets forth specific fiduciary duties that an employer-sponsor and certain third-party entities must adhere to, or face consequences for a fiduciary breach. [4]

Who Is an ERISA Fiduciary?

An ERISA fiduciary is a person or entity that has discretionary authority and control over:

The management and operation of a health plan

How the plan's assets are spent.[5]

An employer that sponsors a health benefit plan (referred to as the "plan sponsor")[6] always has discretionary authority and control over:

The management and operation of a health plan

How the plan's assets are spent.

As such, the plan sponsor is *always* an ERISA fiduciary.

ERISA also contemplates a "plan administrator,"[7] which is typically a third-party entity that is hired by the plan sponsor to assist in administering the plan. Here, the plan sponsor will delegate to the plan administrator the requisite discretionary authority over:

The plan's operations

How the plan's assets can be spent

As a result, the plan administrator is *always* an ERISA fiduciary.

It is important to distinguish a plan administrator from other third-party entities that provide services to an ERISA-covered self-insured health plan (referred to as "TPAs"). As stated, a plan administrator has been given the requisite authority over **(1)** the plan's operations and **(2)** how the plan's assets can be spent, and thus, *is* an ERISA fiduciary. However, as discussed more fully below, in most if not all cases, TPAs are typically *not* delegated any authority to make decisions on **(1)** plan operations and **(2)** spending plan assets, and thus, these TPAs are generally *not* an ERISA fiduciary.

Overview, Cont.

Who is NOT an ERISA Fiduciary? As noted above, TPAs that are not otherwise hired as the plan administrator – but are hired to provide specified services to the plan – are not considered an ERISA fiduciary.

Why? As also noted above, these TPAs typically do not have discretionary authority over (1) the plan's operations and (2) how the plan's assets can be spent. It is true that these TPAs will perform certain functions or take on certain tasks that cost the health plan money. However, that is not the same thing as having "discretionary authority" to, for example, make decisions on how the plan's assets are spent. Those TPAs that are typically not considered an ERISA fiduciary include:

- A TPA hired to perform enrollment and other benefit administration functions for the plan, typically referred to as the "enrollment TPA" or "ben admin TPA."
- A TPA hired to adjudicate and process health claims incurred by plan participants, typically referred to as a "claims adjudication TPA."
- A TPA that establishes and maintains a network of medical providers that participants of the plan may access. This type of TPA (in most cases, an insurance company) is referred to as the "owner of the provider network" that "rents" its provider network to, for example, a self-insured health plan.
- A PBM is yet another service provider (like a TPA) to the health plan. Here, the PBM is hired to establish and maintain a prescription drug provider network for the plan, and the PBM will also develop and maintain the plan's prescription drug formulary. The PBM will also serve as an intermediary between the plan and drug manufacturers that make and sell prescription drugs

Note, in the event a TPA or a PBM happens to perform a task or take a certain action – like making their own decisions on how the plan's assets are spent – the TPA or PBM *will* cross-over into being considered an ERISA fiduciary. Whether a TPA or PBM crosses-over into being considered an ERISA fiduciary is a facts and circumstances-based determination made by a court of law. Employer plan sponsors and/or plan participants may file a lawsuit claiming that a TPA or PBM acted with the requisite "discretionary authority" over (1) the plan's operations or (2) how the plan's assets can be spent to make them an ERISA fiduciary. Nevertheless, the plan sponsor and participants have the burden of proving that – based on a specified set of facts and circumstances – the TPA or PBM in question did indeed cross-over into ERISA fiduciary territory, which is often difficult to prove.

Overview, Cont.

ERISA's Fiduciary Duties

For those entities that are considered an ERISA fiduciary, they must adhere to the following fiduciary duties:

- **Duty to Act In the Best Interest of Plan Participants**: An ERISA fiduciary must "*act for the exclusive purpose of providing benefits to plan participants*," which is often characterized as requiring the fiduciary to "*act in the best interest of plan participants*."[8] Examples of acting in the best interest of plan participants include making decisions to keep the cost of covered benefits low and covering benefits and services that will improve the health and security of participants.
- **Duty to Help Control Costs**: An ERISA fiduciary must also "defray the reasonable expense of administering the plan."[9] Here, the fiduciary must ensure that the plan is *not* paying unreasonable or excessive fees to an entity providing services to the plan, and that the plan is not covering benefits and services that are unreasonably priced.
- **Duty to Act With Prudence**: This duty – commonly referred to as the "prudent man standard" – requires an ERISA fiduciary to "*act with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.*"[10] For example, a fiduciary must make all plan-related decisions in a way that shows that the fiduciary put effort, care, and thought into the outcome of the decision. Among other things, a prudent fiduciary must also monitor the plan's service providers to ensure that the service provider is performing its hired functions and keeping health plan costs low.
- **Prohibition Against Self-Dealing and Conflicts of Interest**: ERISA fiduciaries are also prohibited from engaging in "*self-dealing*"[11] or acting with a "*conflict of interest*."[12] Self-dealing occurs when the fiduciary undertakes an action where they use the plan's assets for their own interests or make decisions which allow the fiduciary to profit from the plan. A conflict of interest occurs when the fiduciary represents or is affiliated with an entity that will profit from the plan, and the fiduciary makes a decision where this entity financially benefits from contracting or doing business with the plan.
- **Co-Fiduciary Duties**: If a fiduciary knows (or should know) that a fellow fiduciary to the plan is breaching any one of ERISA's fiduciary duties, and if this fiduciary either assists in the breach or does not take any action to stop or remedy the breach, this fiduciary is similarly liable for its fellow fiduciary's breach.[13] In addition, if a fiduciary undertakes actions that prevent a fellow fiduciary from satisfying their fiduciary duties, thereby causing the fellow fiduciary to breach their duties, this fiduciary will also be liable for its fellow fiduciary's breach.[14]

Note, an ERISA fiduciary is not required to find the cheapest options for the plan and its participants. Rather, the fiduciary must choose the ***best*** options that a prudent person in a similar situation would agree provides the ***best*** value to the plan and its participants.

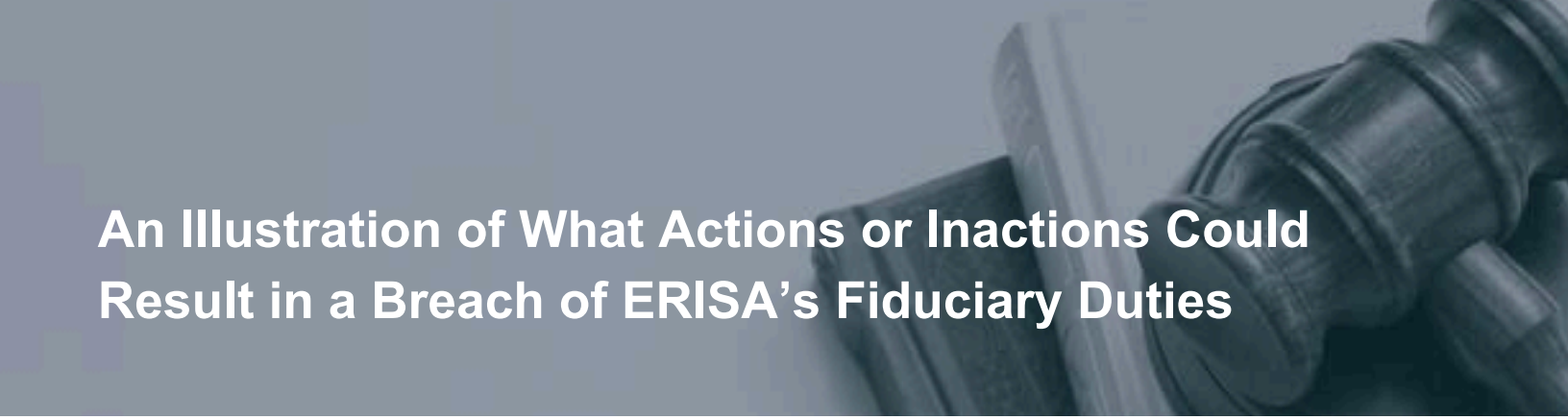
Overview, Cont.

Consequences for Breaching ERISA's Fiduciary Duties

If an ERISA fiduciary breaches any one of ERISA's fiduciary duties (described above), the fiduciary may be required to under law and enforced by the U.S. Department of Labor (DOL) and/or the courts to do any of the following, depending upon the circumstances:

- **Restore Plan Losses**: If a fiduciary breach causes the plan to suffer financial losses, the fiduciary could be required to fully restore any losses to the plan that resulted from the breach.[15] For example, if a fiduciary is found to have breached their duties by overpaying for covered benefits or paying excessive fees to an entity providing services to the plan, the fiduciary may be required to re-pay to the plan the difference between reasonably priced benefit costs or reasonable service fees and the amount paid out of the plan.
- **Disgorge Profits**: If the fiduciary profits from the plan in some way, the fiduciary would be required to re-pay to the plan any profits received.[16] For example, if a fiduciary enriches themselves by requiring the plan to pay unreasonably high prices and the fiduciary retains the proceeds, the fiduciary must re-pay to the plan those proceeds.
- **Civil Monetary Liability**: Depending on the nature of the fiduciary breach, the fiduciary may face a civil penalty of up to 20 percent of the amount recovered from the fiduciary.[17] In cases where the fiduciary is an individual, the fiduciary could be personally liable for monetary damages.
- **Criminal Liability**: If a fiduciary willfully engages in coercive interference of a participant's rights under ERISA, a criminal offense punishable by fines and/or imprisonment could apply.[18] Fiduciaries can also face fines and/or imprisonment if convicted of certain Federal crimes, such as theft, embezzlement, or bribery relating to an ERISA-covered plan.[19]

The above-described consequences apply to a fiduciary when **(1)** the DOL makes a judgment during a DOL enforcement proceeding and/or **(2)** a lawsuit is filed in Federal court against the fiduciary, resulting in the court rendering a binding decision on the fiduciary.



An Illustration of What Actions or Inactions Could Result in a Breach of ERISA's Fiduciary Duties

On February 5, 2024, an employee-participant of a health plan sponsored by Johnson & Johnson ("J&J") filed a lawsuit claiming that J&J (as plan sponsor) breached its fiduciary duties by failing to prevent the plan from overpaying for covered benefits.

In particular, the employee-participant argued that – over a period of years – J&J's health plan paid the plan's PBM for covered prescription drugs in excess of 200 percent – and in some cases 500 percent– times the cash-price for the covered drugs, and thus, J&J (as plan sponsor) breached the following fiduciary duties for the following reasons:

Duty to Act In the Best Interest of Plan Participants.

The lawsuit contends that J&J failed to act in the best interest of plan participants when J&J failed to recognize that the prices charged by the plan's PBM were much higher than prices charged by other PBMs operating in the market, and in many cases, higher than the cash-price of the drug.

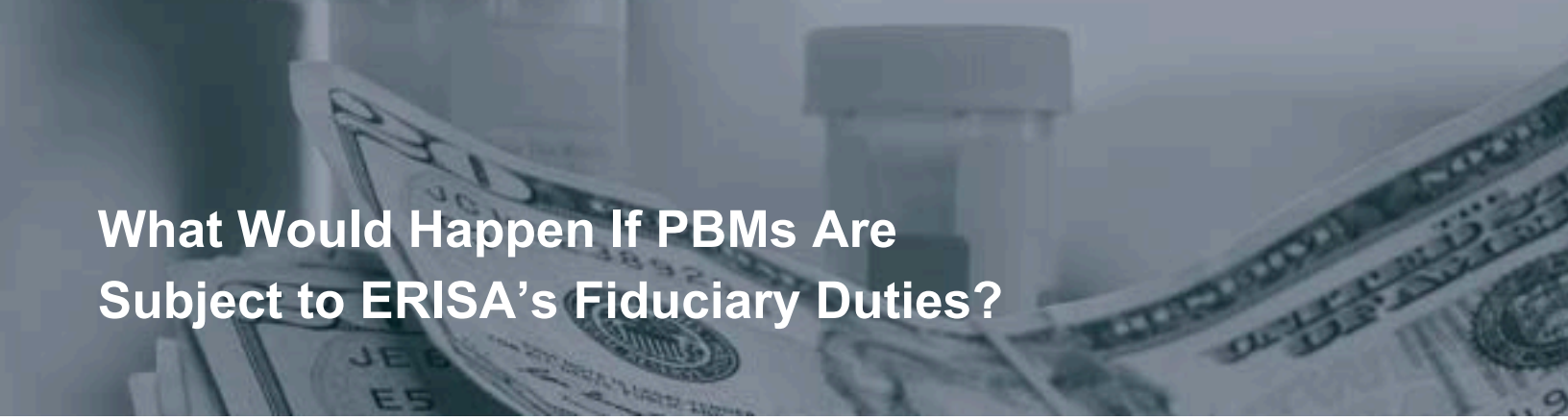
Duty to Help Control Costs.

The lawsuit also contends that J&J failed to take available steps to rein in the PBM's high prices by re-negotiating the contract with the PBM. Also, J&J failed to carefully analyze different PBM payment models to determine what PBM payment model will be most beneficial and cost-effective for the plan and its participants.

Duty to Act with Prudence.

The lawsuit further asserts that **(1)** no prudent fiduciary would have allowed the plan and its participants to pay such high prices for the covered prescription drugs, **(2)** and that prudent fiduciaries must continually monitor their PBM's actions to ensure that the PBM is minimizing costs and maximizing outcomes for plan participants, and **(3)** J&J failed to actively manage and oversee key aspects of the plan's prescription drug program by allowing the PBM to steer participants to the PBM's own mail-order pharmacy, forcing participants to pay higher prices for drugs when lower-priced drugs were otherwise accessible at non-PBM-owned pharmacies.

Recently, an employee-participant of a health plan sponsored by Wells Fargo filed an almost identical lawsuit as the J&J suit, asserting breach of the same ERISA fiduciary duties to act in the best interest of participants, the duty to help control costs, and the duty to act with prudence. Among other claims set forth in this lawsuit, the employee-participant asserts that the plan's PBM charged the plan and its participants upwards to 15 times the cash-price for a covered prescription drug and the PBM steered plan participants to a mail-order pharmacy owned by the PBM, thereby forcing the plan and its participants to pay higher prices for covered prescription drugs. The plaintiff also contends that the plan's PBM charged – and the plan paid – excessive administrative fees.



What Would Happen If PBMs Are Subject to ERISA's Fiduciary Duties?

As a Fiduciary, the PBM In the J&J and Wells Fargo Lawsuits Could Be Liable for Their Actions.

If a PBM is required to adhere to the same ERISA fiduciary duties that are applicable to a plan sponsor, many of the PBM practices highlighted in the J&J and Wells Fargo lawsuits would be mitigated if not eliminated entirely. The following illustrates this point:

Duty to Act In the Best Interest of Plan Participants.

If the PBM is an ERISA fiduciary, the PBM would be liable for failing to act in the best interest of plan participants by forcing the plan and its participants to pay higher prices for prescription drugs that the PBM knows (or should know) are currently available in the market at lower prices

Duty to Help Control Costs.

If the PBM is an ERISA fiduciary, the PBM would be subject to liability for charging unreasonably high prices for prescription drugs and demanding excessive fees, especially at a PBM-owned pharmacy.

Duty to Act with Prudence.

It would not be prudent for a fiduciary (here, the PBM) to enter into a contract with the plan that requires the plan and its participants to pay higher prices for prescription drugs that the PBM knows (or should know) are currently available in the market at lower prices. A prudent fiduciary would also pass-through any rebates or discounts the fiduciary received for covered benefits bought and paid for with the plan's assets.

Prohibition Against Self-Dealing and Conflicts of Interest.

As an ERISA fiduciary, a PBM could *not* purchase prescription drugs from a drug manufacturer for a particular price and charge the plan and its participants a *higher* price for the same drugs and then *retain* the difference between the prices paid (which is often described as PBM "spread pricing"). In addition, a PBM would be subject to liability if the PBM took steps to steer plan participants to pharmacies owned by the PBM and ultimately forced participants to pay higher prices to the PBM-owned pharmacies than pharmacies not owned by the PBM.

Co-Fiduciary Duties.

If the PBM withheld pricing and/or claims data from the plan sponsor (purposefully or inadvertently), and the plan sponsor was found liable for failing to exercise prudence in agreeing to contract terms that caused the plan to overpay for covered prescription drug benefits, the PBM would similarly be liable for the plan sponsor's breach.

What Would Happen If PBMs Are Subject to ERISA's Fiduciary Duties? Cont.

As an ERISA Fiduciary, PBMs Could Not Engage in Other Price-Inflating Behavior.

Related to the actions that we see in the J&J and Wells Fargo lawsuits, there are additional examples where the conduct of PBMs appear to be increasing costs for employers and plan participants, and such behavior would be curbed if ERISA's fiduciary duties applied to PBMs. For example, a PBM could *not*:

- Exclude certain drugs – like biosimilars [20] – from the plan's drug formulary in exchange for deep discounts and rebates that enrich the PBM and the drug manufacturer. The Federal Trade Commission (FTC) and Congress recently reported that drug manufacturers agree to deep discounts and large rebates with PBMs in exchange for the PBM excluding biosimilars from the PBM's drug formulary that a health plan utilizes. [21]
- Steer participants to expensive biologics, if cheaper biosimilars are available on the market. Studies show that biologics spending has increased significantly since 2017, even as lower-cost biosimilars have been entering the market. [22]
- Steer participants to brand name specialty drugs through the use of rebates and discounts when an equivalent biosimilar specialty drug with a lower net price is readily available in the market. [23]
- Charge exponentially higher prices for drugs purchased from PBM-owned mail-order pharmacies compared to the prices charged at retail pharmacies in the PBM's network. [24]

- Establish new offshore entities to "private label" the PBM's own biosimilar products only to sell those biosimilars – at a marked-up price – through the PBM's own established drug formularies. Reports indicate that PBMs hide behind new offshore entities designed to avoid public scrutiny and use their vertical integration to unfairly drive-up costs. [25]
- Use off-shore entities to collect manufacturer fees based on list price, keep a percentage of rebates and spread pricing, and mark-up drugs to the plan at exponential rates compared to what the PBM pays the drug manufacturer for the drug. [26]
- Inflate the costs of biosimilars through spread pricing or co-pay claw-backs. This leads to overpayments for these biosimilars when lower-cost, safe, and effective substitute biosimilars are also available. [27]

Offering Access to Biosimilars Satisfies ERISA's Fiduciary Duties

Low-Cost Biosimilars with Identical Treatment and Efficacy.

As stated above, a fiduciary is not required to find the cheapest options for the plan and its participants. Rather, the fiduciary must choose the ***best*** options that provide the ***best*** value to the plan and its participants.

In the case of biosimilars, an ERISA fiduciary satisfies both standards. Specifically, when a fiduciary (e.g., a plan sponsor or a PBM acting as an ERISA fiduciary) affirmatively chooses to include biosimilars in a health plan's drug formulary, the fiduciary is not only lowering costs for the plan (which is a prudent decision and in accord with acting in the best interest of plan participants), but the fiduciary is also providing value to plan participants, as biosimilars are effectively identical in the treatment and efficacy to their biologic counterparts (which is, similarly, prudent and in accord with acting in the best interests of plan participants).

When it comes to cost, biosimilars lower costs in two ways: **(1)** the average sales price for biosimilars is 50 percent lower than the relative price for the reference biologic; and **(2)** biosimilars promote competition, forcing reference biologic manufacturers to compete with biosimilars and leading to lower costs for prescription drugs for the entire health care market.

Both mechanisms to lower costs are responsible for $56 billion in savings from 2013 to 2022, as biosimilars began to establish their presence in the market.[28] Moreover, both mechanisms have the potential to save the U.S. health care system up to $133 billion by 2025.[29]

A win-win for both plan participants and the market as a whole.

However, if biosimilars continue to be frozen out of the market because, for example, PBMs continue to exclude biosimilars from a health plan's drug formulary, the status quo will extend the monopolistic behavior of the reference biologic to the detriment of plan participants and the market as a whole (which is imprudent and contrary to acting in the best interest of plan participants).

Case Study: Humira® Biosimilars Are Now on the Market

Humira® – the world's best-selling drug – has seen a price increase of 470% since the brand-name drug first entered the market. Humira® – having faced virtually no competition in the health care market – now has a price-tag of upwards to $84,000.

Importantly, a wave of Humira® biosimilars were finally introduced in the market in 2023. The list prices of Humira® biosimilars are up to 85 percent lower-cost than the brand-name Humira®.[30] If added to drug formularies for employer-sponsored health plans, these recent launches will create a more competitive market, helping to mitigate ever-rising drug spending by employers that contribute to increases in plan premiums and expenses. Importantly, this will also help reduce out-of-pocket costs for plan participants who share the responsibility for paying premiums in addition to paying co-pays and co-insurance.

A recent report found that Humira® biosimilars competition has occurred in less than 2 percent of the U.S. market.[32] This is due in large part to PBM practices. As noted above, far too often PBMs and drug manufacturers enter into agreements to exclude biosimilars from the PBM's drug formularies in exchange for large rebates offered to the PBM by the manufacturer for the reference biologic. Then, the PBM pockets the difference between what the plan pays for the reference biologic (which is typically the biologic's list price) and what the PBM pays the drug manufacturer (which is the biologic's list price, minus the large rebate offered to the PBM. [33]

If a PBM is an ERISA fiduciary – and thus subject to ERISA's fiduciary duties – the PBM would be liable for a fiduciary breach if they engaged in the above stated practice. That is because the PBM would be held accountable to make the prudent decision to include the Humira® biosimilars in its drug formularies. Why? Because **(1)** plan participants save money and **(2)** plan participants are effectively getting the exact same health outcomes from the same type of treatment.

For example, the cost of Humira® is roughly **$84,000...**

compared to...

the cost of a Humira® **biosimilar** is approximately **$12,600**.

That means **a patient receiving Humira® would pay $16,800** a year (20% copay)

compared to...

a patient receiving a Humira® biosimilar would pay $2,520 a year (20% copay).

The result? ***The Humira biosimilar equals significant savings.***

Overall, the adoption and utilization of Humira® biosimilars throughout the health care system *could save more than $5 billion a year*. [31]

Congress Can Put an End to PBM Practices That Harm Participants and Keep Health Care Costs High

Congress can amend ERISA and specifically apply ERISA's fiduciary duties to PBMs. It's that simple. Here, a PBM could be added to the definition of "fiduciary" under ERISA section 3(21) by adding a new subparagraph (C).

Congress has the flexibility to be prescriptive in defining the types of actions that a PBM may undertake that would result in ERISA fiduciary status.

Or Congress may simply provide that a PBM shall become an ERISA fiduciary upon entering into an agreement to provide services to an ERISA-covered health plan. Then, all affected parties can work together within the regulatory process to further define the appropriate parameters and guardrails to ensure that PBMs cannot continue to harm plan participants and keep health care costs high.

Some may argue that requiring PBMs to adhere to ERISA's fiduciary duties is a significant change. However, significant change is exactly what is needed. Congress should not endeavor to legislate to each cost-inflating behavior highlighted in this Issue Brief.

PBMs will continue to innovate new arbitrage strategies to maintain their current revenue streams.
Congress has the pen. We encourage them to use it.

Citations

[1] Sections 101-111 of the Employee Retirement Income Security Act (ERISA).
[2] ERISA section 503.
[3] ERISA section 702.
[4] See ERISA section 404(a).
[5] ERISA section 3(21)(A).
[6] See ERISA section 3(16)(B).
[7] See ERISA section 3(16)(A).
[8] ERISA section 404(a)(1)(A)(i).
[9] ERISA section 404(a)(1)(A)(ii).
[10] ERISA section 404(a)(1)(B).
[11] ERISA section 406(b)(1), (3).
[12] ERISA section 406(b)(2).
[13] ERISA section 405(a).
[14] Id.
[15] ERISA section 409.
[16] Id.
[17] ERISA section 502(l).
[18] ERISA section 511.
[19] 18 U.S. Code section 664.
[20] A Biosimilar is a biological medicine highly similar to another already approved biological medicine and can compete with the original reference biologic after the biologic's manufacturer's period of exclusivity is completed.
[21] Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, July 2024, pages 66 - 70 at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.; see also, House Committee on Oversight and Accountability, The Role of Pharmacy Benefit Managers in Prescription Drug Markets, July 2024.
[22] See IQVIA Institute for Human Data Science, Biosimilars in the United States 2023-2027, Jan. 31, 2023 at https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.
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[29] See Cardinal Health, 2022 Biosimilars Report: The US Journey and Path Ahead at https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-2022-biosimilars-report.pdf.
[30] See Managed Healthcare Executive, 8 Humira Biosimilars Are on the Market, July 4, 3023 at https://www.managedhealthcareexecutive.com/view/8-humira-bosimilars-are-on-the-market.
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