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January 22, 2024

Members of the Employee Health Benefits Community:

The Committee on Education and the Workforce (the Committee) has jurisdiction over employer-sponsored health coverage. Employer-sponsored insurance (ESI) covers over half of the non-elderly population, an estimated 153 million employees and their dependents.[1] Employer-sponsored health benefits are governed by several laws, including the *Employee Retirement Income Security Act* (ERISA).

As the 50th anniversary of ERISA approaches, the Committee is seeking feedback on ways to build upon and strengthen ERISA, the foundation of employer-sponsored health care. Enacted in 1974, ERISA established federal guidelines governing the conduct of employee benefit plans, including employer-sponsored group health plans. Private employers that establish group health plans may implement uniform benefit plans because ERISA preempts state regulation of such plans. Approximately 99 million employees and family members have coverage from employers that self-insure their own health plans, making them subject to regulation only under ERISA and the Internal Revenue Code (the "Code").[2] The remainder of private employers offering health benefits purchase fully insured coverage from traditional insurance companies, which is generally governed by ERISA, the Code, the *Public Health Service Act* (PHSA), and state insurance laws.

ERISA generally allows multi-state employers to offer uniform health benefits to their employees, irrespective of location, by freeing the employer-sponsored plan from regulation by the states. For example, state laws mandating that specific health benefits must be included in a health plan are generally preempted by ERISA, and plans covered by ERISA can thus tailor their plans to meet the needs of their employees. ERISA's federal preemption of state insurance laws permits employers to design benefit plans tailored to the needs of employees and their families, and it is viewed by many employers as essential to their sponsorship of health and retirement benefits. Without preemption and uniformity, administrative complexity and increased costs would cause them to stop offering health benefits or to charge significantly more for employees' health coverage.

[1] https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf.
[2] *Id.*

ESI is the core of America's health care system. Employers have historically been at the forefront of creating innovative, market-driven approaches to providing health benefits, which drive down health care costs. The vast majority of Americans covered by ESI are satisfied with their employer-sponsored coverage.[3] Fifty-three percent of small firms (firms with 3-199 workers) and 98 percent of large firms (firms with over 200 workers) offered health benefits to their workers in 2023. When employees have the opportunity to participate in employer-sponsored health insurance, 75 percent enroll. [4]

However, health costs continue to rise at unsustainable rates. In 2023, annual premiums for family coverage rose by 7 percent. The increase in health costs have led large employers subject to the *Affordable Care Act* employer mandate to reduce benefits and small employers increasingly to drop coverage. For more than 30 years, National Federation of Independent Business (NFIB) members have identified the cost of health insurance as the top small business problem, with 48 percent ranking it as a critical problem.[5] In 2022, health care spending was 17.3 percent of U.S. Gross Domestic Product (GDP) or $13,493 per person.[6]

Examining ways to increase affordability of coverage and increase quality and access to care, the Committee seeks feedback on the topics outlined below. Please submit any responses to it EdandWorkforceRFI@mail.house.gov by March 15, 2024. If you have any questions about this request for information, please contact Taylor Hittle (taylor.hittle@mail.house.gov) or CJ Mahler (CJ.Mahler@mail.house.gov) with Committee staff.

Sincerely,

Virginia Foxx
Chairwoman

[3] https://www.ahip.org/news/press-releases/new-survey-consumers-say-employer-provided-coverage-vital-to-maintaining-health-and-financial-well-being-during-pandemic.
[4] https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf.
[5] https://strgnfibcom.blob.core.windows.net/nfibcom/Health-Insurance-Survey-2023.pdf.
[6] https://www.cms.gov/files/document/highlights.pdf.

Request for Information:
ERISA's 50th Anniversary: Reforms to Increase Affordability and Quality in Employer-Sponsored Health Coverage

Preemption

The purpose of ERISA is to provide a uniform regulatory framework over employee benefit plans. However, the scope of ERISA preemption has been challenged numerous times in federal court. In 2020, the Supreme Court ruled in *Rutledge v. Pharmaceutical Care Management Association* that Arkansas' State Law 900 was not preempted by ERISA because state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted, and because State Law 900 did not explicitly refer to ERISA.[7] This ruling has opened the door to several states passing laws that regulate the network and design of pharmacy benefit managers (PBM) beyond the scope of the state law at issue in *Rutledge*.

1. The Committee broadly seeks feedback on ways to strengthen and clarify ERISA preemption.
2. To what extent do state laws prevent or purport to prevent multistate employers from offering a uniform set of benefits across state lines? Please list the specific state laws which pose or may pose barriers to offering uniform benefits.
3. Should the Committee consider legislation or taking other actions to help create more clarity regarding and strengthening ERISA preemption to ensure plan sponsors are able to design, offer, and administer uniform benefits and programs pursuant to ERISA's purposes? If so, what legislation or other actions, and why?

Fiduciary Requirements

1. The Committee broadly seeks feedback on the definition of fiduciary, its use, and fiduciary obligations under ERISA as they pertain to health benefits.
2. How can Congress build upon ERISA regarding the fiduciary obligations of plan sponsors, administrators, and trustees in the management of health benefit plans?
3. How can Congress clarify the extent to which fiduciary responsibilities are applied to insurance companies, insurance agents, broker-dealers, third party administrators (TPAs), PBMs, or other service providers? Please specify the following:
    a. A description of the changes proposed and rationale for their adoption. Any practical or legal risks or challenges to making such changes to the administration of plans and delivery of benefits.
    b. Whether the fiduciary duties would apply to the plan sponsor or the plan beneficiary, and if so, why?
    c. Whether the fiduciary duties should be determined by the function performed by the entity.

[7] 592 U.S. 80 (2020).

   d. How the Department of Labor (DOL) should implement enforcement over any additional statutory fiduciaries.
   e. The complexity of clarifying fiduciary responsibilities and how Congress should approach examining such clarifications.
4. Are there specific areas where fiduciary responsibility should be more clearly defined to ensure the best interests of plan participants and beneficiaries?
5. Do the liabilities placed on plan fiduciaries create burdens on small businesses providing health coverage? If so, how?
6. The Committee seeks feedback on the fiduciary's duty to monitor and how it impacts small businesses.
7. What federal case law would be informative to the Committee to help circumscribe the fiduciary responsibilities in the statute?
8. What are the appropriate boundaries of fiduciary obligations to ensure appropriate and optimal resource allocation, to recognize control and agency of all stakeholders, and to maintain participant and beneficiary privacy and freedoms?
9. The Committee broadly seeks feedback on what Congress and DOL can do to help plans better understand their fiduciary duties.

Reporting Requirements

1. The Committee broadly seeks feedback on ways to streamline reporting and disclosure requirements.
2. The Committee seeks comments on ways Congress can better support electronic disclosure and when electronic disclosures are beneficial to the plan participant.

Prohibited Transactions

1. The Committee broadly seeks feedback on how vertical integration and consolidation in the health care sector impact ERISA's prohibited transactions.
2. The Committee seeks feedback on whether 340B discounts and pharmacy steering may constitute self-dealing and violate ERISA's prohibited transactions in certain circumstances.
3. The Committee broadly seeks feedback on how changes in transparency affect how plan sponsors determine whether spending and costs are reasonable and necessary.
4. Should DOL update its prohibited transaction exceptions, and if so, how?
5. How do different payment and contracting models, such as direct contracting, concierge services, wellness centers, on-site clinics, and capitated payments, affect dynamic fiduciary duties, prohibited transactions, and other ERISA requirements?

Data Sharing

1. The Committee broadly seeks feedback on ways to improve data sharing between employer-sponsored plans and contracted entities.

2. The *Consolidated Appropriations Act, 2021* (CAA)[8] prohibited provisions in health plans that prevent plan fiduciaries from accessing quality and costs information, known as "gag clauses." However, plan fiduciaries still struggle to receive this information from TPAs. How can Congress strengthen the prohibition on gag clauses to ensure that plan fiduciaries have access to this data?
3. The CAA requires plans to attest that their contracts do not contain these gag clauses. Is this requirement effective?
4. What are the implications of treating data as a plan asset under ERISA?
5. TPAs commonly restrict the extent to which a plan sponsor can direct the service provider to share data with other service providers and how that data can be used.
    a. How do these restrictions affect value-based payments, measuring quality, and the freedom of employers to design innovative payment models?
    b. How do these restrictions discourage service providers from creating innovative solutions to measure quality?
    c. The Committee seeks feedback on how to improve data sharing between plan sponsors and service providers.
6. The Committee seeks feedback on how to ensure uniform formatting of data to increase interoperability.
7. The Committee seeks feedback on the types of health care quality measures and how Congress may help plans uniformly measure, assess, and compare quality data.

Cybersecurity

The *Health Insurance Portability and Accountability Act of 1996* (HIPAA) was intended to allow portable insurance coverage and to remove pre-existing medical conditions as a barrier to changing jobs. Title II of HIPAA authorizes the Department of Health and Human Services (HHS) to standardize the electronic transmission of certain transactions and to ensure the privacy and confidentiality of personal health information (PHI). In 2000, HHS released the "HIPAA Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule), which implements Sections 261-264 of HIPAA and creates comprehensive federal protection for the privacy of PHI.[9] The Privacy Rule applies to health care providers, health plans, and health care clearinghouses.

The Privacy Rule regulates group health plans but not employers. Recognizing HHS' lack of jurisdiction over plan sponsors, the rule states:

> In the final rule, we recognize plan sponsors' legitimate need for health information in certain situations while, at the same time, protecting health information from being used for employment-related functions or for other functions related to other employee benefit plans or other benefits provided by the plan sponsor. We do not attempt to directly regulate employers or other plan sponsors, but pursuant to our authority to regulate health plans, we place

[8] Pub. L. No. 116-260 (2020).
[9] 45 C.F.R. pts. 160 & 164.

restrictions on the flow of information from covered entities to non-covered entities.[10]

The Committee seeks comment on whether gaps exist due to HIPAA's structure and its lack of jurisdiction over entities in the commercial market. The Committee seeks comment on whether DOL should have a more robust role in overseeing the protection of PHI, including overseeing HIPAA protections pertaining to self-funded ERISA plans and plan sponsors.

Recently, the ERISA Advisory Committee released recommendations on how DOL may address issues and vulnerabilities regarding cybersecurity issues affecting health plans.[11] The Committee seeks feedback on the ERISA Advisory Committee's findings and recommendations and whether Congress should implement any recommendations in statute. When addressing the questions outlined below, the Committee requests that stakeholders identify whether their recommendations apply to employer-sponsored self-funded plans, employer-sponsored fully insured plans, both, or some other structure.

1. The Committee is requesting comment on policies to strengthen and build upon privacy protections for employer-sponsored plans and their business associates. The Committee seeks feedback on ways DOL can better provide plan sponsors, plan fiduciaries, group health plans, TPAs, and other business associates with best practices for maintaining cybersecurity.
2. The Committee seeks comments on the types of emerging cybersecurity threats that health plans face and any policy suggestions to help combat these threats.
3. The Committee seeks feedback on privacy regulations regarding business associates under HIPAA and whether privacy protections within these agreements can be strengthened through ERISA.
4. Are privacy gaps created by not defining a plan sponsor as a "covered entity" under HIPAA? If so, how might those gaps be addressed?
5. In what ways can DOL coordinate with HHS, the Internal Revenue Service, and others to harmonize cybersecurity rules that may conflict or overlap?
6. What should the legal responsibilities of plan sponsors and plan fiduciaries be with respect to protecting against cybersecurity threats and safeguarding PHI?
7. The Committee seeks comments on DOL's guidance issued in 2021 regarding cybersecurity.[12] Should any of this guidance explicitly apply to health plans or be codified?
8. State privacy laws are not uniform and create a patchwork of standards for ERISA plans. How do state privacy laws impact ERISA self-insured plans? What are ways Congress can align state and federal privacy regulations?
9. Are there portions of HIPAA or the Health Information Technology for Economic Clinical Health (HITECH) Act which should be written into ERISA and implemented by DOL?

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[10] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82, 462, 82,508 (Feb. 26, 2001).
[11] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2022-cybersecurity-issues-affecting-health-benefit-plans.pdf.
[12] https://www.dol.gov/newsroom/releases/ebsa/ebsa20210414.

10. Many employer-sponsored health plans contract with a TPA through an administrative-services-only (ASO) agreement. The Committee seeks feedback on ways plan sponsors and plan fiduciaries can ensure proper cybersecurity protections through ASO provisions.
11. Should DOL make explicit that acting prudently with regard to cybersecurity risks is a responsibility of fiduciaries of employer health benefit plans?
12. The Committee seeks comment on what type of education and materials DOL may provide to help plan sponsors and fiduciaries better protect beneficiaries from cybersecurity threats.

Direct and Indirect Compensation

The CAA, which included the *No Surprises Act,* requires brokers and consultants to disclose direct or indirect compensation received for referrals to group health plan sponsors and individual market consumers. The CAA was intended to limit growth in health care spending through increased transparency. The law amended ERISA to provide that any "covered service provider" that enters into a contract or arrangement with a group health plan must disclose to a responsible plan fiduciary a description of the direct and indirect compensation they expect to receive in connection with the services they provide to the plan.[13] This disclosure requirement applies to the provision of brokerage services, which may have conflicts of interest that drive up costs for plans,[14] and broadly to "consultants" providing services. The Committee seeks feedback on the implementation of the CAA and requirements that brokers and consultants disclose compensation to plan fiduciaries.

ERISA Advisory Council

The Committee broadly seeks feedback on whether Congress should consider expanding the role of the ERISA Advisory Council to provide recommendations to Congress on issues affecting employer-sponsored health benefits, similar to the Medicare Payment Advisory Committee.

Medical Loss Ratio

1. The Committee broadly seeks feedback on the use of medical loss ratio (MLR) requirements and whether limiting MLR requirements may increase insurers' incentives to reduce health care spending for plans.
2. The Committee seeks feedback on whether MLR requirements have driven vertical integration in the health care sector, and if so why.

COBRA and Portability

The Committee is concerned about how the rising cost of health care may impact continuation health coverage for former employees under the *Consolidated Omnibus Budget Reconciliation Act* (COBRA). COBRA permits former employees to continue coverage from their employer-

[13] ERISA § 408(b)(2), 29 U.S.C. § 1108.
[14] https://www.propublica.org/article/lavish-bonus-luxury-trip-health-benefits-brokers-will-have-to-disclose-what-they-receive-from-the-insurance-industry.

sponsored plan post-employment for up to 18 months, but with the responsibility to cover the costs of premiums fully without subsidization from the employer. Amid already high and rising health care costs, COBRA participants are disproportionately more expensive for self-insured health plans, and enrollees pay higher premiums than active employees.[15] The Committee is interested in exploring improved portability of health benefits for employees transitioning between jobs or plans.

1. The Committee broadly seeks feedback on improving the affordability and usability for plans and enrollees of continuing health coverage under COBRA.
2. The Committee broadly seeks feedback on ways to improve portability of health benefits under ERISA.

Specialty Drug Coverage

New, innovative specialty drugs have the potential to improve the long-term health and lives of patients. The availability of new cures, including for challenging diseases like cancer, hemophilia, or sickle cell, is growing. Eighty percent of the drugs that the FDA approved last year are specialty drugs.[16] However, amid rising health care costs, employers face challenges in paying for these high-cost treatments, the prices of which can reach into the millions.[17] While plan sponsors spend on average $492 per patient per year to cover non-specialty medications, plan sponsors see an average annual cost of $38,000 to cover specialty drugs.[18] Specialty prescription-drug costs make up over half of employers' total drug spending, despite only serving 2 percent of patients. Employers are expressing concerns with the challenges associated with high-cost specialty drugs, with nearly 90 percent citing high-cost pharmacy claims, specialty drug spending, and "million dollar" drug approvals by the Food and Drug Administration among their top concerns in 2023.[19]

Coverage of high-cost specialty drugs may yield long-term savings to employers and plans through improved health for employees, reduced utilization of traditional treatments, lower hospitalization rates, and improved productivity. However, the upfront cost of the drugs may make them prohibitive for employers. Furthermore, employers struggle to share in the savings gleaned from investments in high-cost specialty drugs, as employees may change jobs, retire, or transition onto federal health care programs.

The Committee seeks feedback on innovative ways to reduce barriers for employers to cover high-cost specialty drugs for their employees and to share in the savings associated with such coverage. The Committee seeks feedback on the following items:

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[15] https://www.benefitspro.com/2023/11/07/the-dark-side-of-cobra-unraveling-its-flaws-relevance-and-alternatives/?slreturn=20240004165321.
[16] https://www.benefitspro.com/2023/06/29/specialty-drugs-employers-are-weary-and-for-good-reason/.
[17] https://newsroom.cigna.com/promise-specialty-medicine-outweigh-financial-strain-health-care-system#:~:text=Cigna%20Healthcare%20has%20found%20that,half%20of%20overall%20drug%20spending.
[18] https://www.evernorth.com/articles/specialty-drug-trends-and-utilization.
[19] https://higherlogicdownload.s3.amazonaws.com/MBGH/ef998dc2-0de9-4904-b6d7-a36b4c0cef4b/UploadedImages/Benchmarking/2022/MBGH_Annual_Survey_Infographic-Final.pdf.

1. What challenges do employers face in offering coverage of high-cost specialty drugs, and how can those challenges be addressed?
2. What role can reinsurance models play in helping employers pay for high-cost specialty drugs?
3. What barriers exist in ERISA or elsewhere that hinder employers' ability to leverage reinsurance for the purposes of mitigating the risks of covering high-cost specialty drugs?
4. What tools can employers use to expand risk pools to lower the collective costs of coverage of high-cost specialty drugs?
5. Can employers enter into multiple employer welfare arrangements or similar risk-sharing models to help decrease the cost of high-cost specialty drugs?
6. What role should the federal government play in assisting employers, drug manufacturers, and other entities to manage risks and to share the costs and savings of employer-sponsored coverage of high-cost specialty drugs?
7. What barriers exist in ERISA or elsewhere that prevent employers from entering into value-based arrangements with drug manufacturers for coverage of high-cost specialty drugs?
8. What innovative coverage models are currently in use that address the high cost of specialty drugs?