MY BENEFIT ADVISOR

2024: First Quarter

Compliance Digest

Compliance Bulletins Released January to March

2024 Compliance Bulletins: First Quarter

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Oregon

State Health Coverage Reporting Requirements for Calendar Year 2023

Issued date: 01/10/24

Five states (California, Massachusetts, New Jersey, Rhode Island, and Vermont) and the District of Columbia have already enacted individual health insurance mandates with their own requirements for:

- Furnishing information regarding health insurance coverage to residents of the state, and
- Filing that information with certain state agencies.

These requirements and deadlines may (or may not) align with the federal requirements. As described below, satisfying the federal requirements may not satisfy the applicable state obligations. It is important to ensure both federal and state requirements (as applicable) are met.

The following chart summarizes important deadlines related to 2023 state individual mandate reporting.

State	Deadline to Furnish Statements to Employee Residents	Deadline to File Statements with State Agency
California	January 31, 2024. However, no penalty is imposed for failing to furnish by this deadline.	March 31, 2024. No penalties will be assessed if filed by May 31, 2024.
District of Columbia	March 1, 2024	April 30, 2024 (30 days after federal deadline)
Massachusetts	January 31, 2024	January 31, 2024
New Jersey	March 1, 2024	April 2, 2024
Rhode Island	March 1, 2024	April 1, 2024
Vermont	N/A	N/A

It should be noted that the state reporting deadlines are subject to change if the states update their reporting information. This information is current as of the date of publication.

Important issues to consider regarding furnishing and filing state-level health coverage information are as follows:

- **State residents —** Employers with employees and other covered individuals residing in states with health coverage mandates should ensure the state-level health insurance distribution and state-level filing requirements are satisfied. Penalties may arise for late or incorrect filings with the state.

- **Forms**

  - California, the District of Columbia, New Jersey, and Rhode Island use the federal Forms 1094/1095 (B, C) for the state's individual mandate reporting requirements.

  - Massachusetts requires MA Form 1099-HC to be furnished to Massachusetts residents and filed with the state by January 31. In addition, Massachusetts requires employers with at least 6 employees residing in Massachusetts to file the Health Insurance Responsibility Disclosure ("HIRD") form.

- **Employers with fully insured plans**

  - Carriers issuing policies in California, Massachusetts, New Jersey, and Rhode Island are generally obligated to issue health coverage statements to plan members residing in the respective state and to file the required health coverage information to that state agency.

  - The District of Columbia requires employers that sponsor a fully insured group health plan with at least 50 full-time employees, including at least one employee who is a resident of the District, to file information returns with the Office of Tax and Revenue ("OTR").

  - It should be noted that a carrier may not automatically furnish a member statement and file with a state agency for plan members residing outside of the policy issue/situs state.

- **Employers with fully insured plans issued out-of-state —** Employers should confirm that the carrier will adhere to the required state distribution and filing obligations for plan members that reside in a state with individual mandate reporting obligations.

- **Employers with self-funded plans —** Employers should confirm with their third-party administrator ("TPA") or ACA form preparation vendor that the required state distribution and filing obligations for plan members that reside in a state with an individual mandate will be satisfied and whether any additional fees will be assessed.

For employers with fully insured plans that are written outside of a state with an individual mandate or a self-funded health plan, if the carrier or TPA will not furnish or file the forms with state residents or the applicable state agency, the employer may be required furnish and/or file. This may require involvement with your payroll provider or other ACA reporting vendor to coordinate.

Employer Action

Employers with employees and/or plan members residing in a state (and/or the District of Columbia) with individual mandate reporting requirements should confirm state reporting requirements with their carrier, TPA or ACA vendor to ensure federal as well as state-level reporting obligations will be met.

FDA Clears Way for Florida's State Programs to Import Drugs

Issued date: 01/12/24

On January 5, 2024, the U.S. Food and Drug Administration ("FDA") approved Florida's drug importation program under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") Sec. 804 which provides a pathway for states and tribes to develop and apply for approval to import drugs from Canada under a Sec. 804 Importation Program ("SIP").

Below you will find a high-level summary:

- Applicability. The program is limited to state programs including Medicaid, the prison system, and facilities run by the Department of Children & Families ("DCF"). Private sector employer group health plans are not eligible to create a SIP. Public employers such as cities and counties are likewise not eligible to create a SIP.
- Term. Florida's SIP is authorized for two years from the date the FDA is notified of the first shipment of drugs to be imported.
- Start date/process. Importation will not begin immediately. Before drugs can be imported, Florida's Agency for Health Care Administration must do all of the following:
    - Submit additional drug-specific information for the FDA's review and approval.
    - Ensure that the drugs Florida seeks to import have been tested for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards.
    - Relabel the drugs to be consistent with the FDA-approved labeling.
    - Set up a distribution center.
    - Submit a quarterly report to the FDA that includes information about the imported drugs, cost savings and any potential safety and quality issues.

Note that the onerous administrative requirements may offset expected savings.

- Challenges. Pharmaceutical Research and Manufacturers of America ("PhRMA"), the pharmaceutical industry's largest lobbying group, is expected to sue Florida regarding the program. In addition, there appear to be accessibility concerns as (1) some drug manufacturers have agreements that prohibit exporting prescription drugs out of the country and (2) Canada has taken steps to limit/prohibit exporting when their supply is low, as reiterated in a statement from Health Canada issued on January 8, 2024. Note that Canada's population is 40 million, Florida's population is 22 million, and the U.S. market is nearly 10 times bigger than Canada's.

According to the proposal, Florida will begin by providing prescription drugs in a small number of drug classes which will include maintenance medications to help individuals who have chronic health conditions such as HIV/AIDS, mental illness, prostate cancer, and urea cycle disorder. These drugs will be for individuals who are under the care of the Agency for Persons with Disabilities ("APD"), DCF, Department of Corrections ("FDC"), and Department of Health ("DOH"). The program will then expand to include providing imported prescription drugs for Medicaid members across the state. The submitted cost savings estimate for importing prescription drugs from Canada is up to $183 million per year once the program is fully implemented.

Other states, including Colorado, Vermont, and New Mexico are seeking approval for similar programs.

It is important to note that the SIP program is only allowed to import drugs from Canada. Importation of drugs from other countries (e.g., Turks and Caicos, Australia, and Turkey) is not allowed. Employers should understand that, currently, the approval of this program does not change the importation rules as they exist with respect to private sector employer plans or local state employers. Drug importation is still generally illegal and employers should be wary of vendors indicating otherwise and carefully evaluate the compliance risks associated with these programs.

We will keep you apprised of developments.

DOL Increases Penalties For 2024

Issued date: 01/16/24

The Department of Labor ("DOL") has published the annual adjustments for 2024 that increase certain penalties applicable to employee benefit plans.

Annual Penalty Adjustments for 2024

The following updated penalties are applicable to health and welfare plans subject to ERISA.

Description	2023 Penalty (Old)	2024 Penalty (NEW)
Failure to file Form 5500	Up to $2,586 per day	Up to $2,670 per day
Failure of a MEWA to file reports (i.e., M-1)	Up to $1,881 per day	Up to $1,942 per day
Failure to provide CHIP Notice	Up to $137 per day per employee	Up to $141 per day per employee
Failure to disclose CHIP/Medicaid coordination to the State	$137 per day per violation (per participant/beneficiary)	$141 per day per violation (per participant/beneficiary)
Failure to provide SBCs	Up to $1,362 per failure	Up to $1,406 per failure
Failure to furnish plan documents (including SPDs/SMMs) to DOL on request	$184 per day $1,846 cap per request	$190 per day $1,906 cap per request
Genetic information failures	$137 per day (per participant/beneficiary)	$141 per day (per participant/beneficiary)
De minimis failures to meet genetic information requirements	$3,439 minimum	$3,550 minimum
Failure to meet genetic information requirements – not de minimis failures	$20,641 minimum	$21,310 minimum
Cap on unintentional failures to meet genetic information requirements	$688,012 maximum	$710,310 maximum

Employer Action

Private employers, including non-profits, should ensure employees receive required notices timely (SBC, CHIP, SPD, etc.) to prevent civil penalty assessments. In addition, employers should ensure Form 5500s are properly and timely filed, if applicable. Finally, employers facing document requests from EBSA should ensure documents are provided timely, as requested.

Medicare Part D CMS Notification Reminder

Issued date: 01/17/24

Employers sponsoring a group health plan (whether insured or self-insured) need to report information on the creditable (or non-creditable) status of the plan's prescription drug coverage to the Centers for Medicare and Medicaid Services (CMS). In order to provide this information, employers must access CMS's online reporting system at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/CreditableCoverage/CCDisclosureForm.html.

As a reminder, notice must be provided by the following deadlines:

- Within 60 days after the **beginning** date of each plan year;
- Within 30 days after the **termination** of the prescription drug plan; and
- Within 30 days after any **change** in the creditable coverage status of the prescription drug plan.

For example, an employer with a **calendar year plan** (January 1 – December 31, 2024) must complete this reporting **no later than Wednesday, February 29, 2024**.

Additional resources on completing the form are available at:

- https://www.cms.gov/Medicare/Prescription-Drug-Coverage/CreditableCoverage/CCDisclosure.html
- Disclosure to CMS Form User Guide with screenshots: https://www.cms.gov/medicare/prescription-drug-coverage/creditablecoverage/downloads/ccuserguide.pdf

Guidance Issued On Contraception Coverage Mandate

Issued date: 01/26/24

On January 22, 2024, the Departments of Labor, Health and Human Services, and the Treasury (collectively, "the Departments") answered a new round of FAQs, providing additional guidance on the Affordable Care Act ("ACA")'s requirement for non-grandfathered medical plans to cover certain preventive services including contraceptives, without cost-sharing. These FAQs answer questions from stakeholders to help people understand the contraceptive coverage mandate and promote compliance by providing an alternate method of compliance. It should be noted that religious employers, certain non-profit religious organizations, and closely held for-profit entities can exclude contraception.

Background

Plans and issuers must cover at least one form of contraception in each of the following categories:

1. Sterilization surgery for women
2. Implantable rods
3. Copper intrauterine devices
4. Intrauterine devices with progestin (all durations and doses)
5. Injectable contraceptives
6. Oral contraceptives (combined pill)
7. Oral contraceptives (progestin only)
8. Oral contraceptives (extended or continuous use)
9. Contraceptive patch
10. Vaginal contraceptive rings
11. Diaphragms
12. Contraceptive sponges
13. Cervical caps
14. Condoms
15. Spermicides
16. Emergency contraception (levonorgestrel)
17. Emergency contraception (ulipristal acetage)

Plans must also cover any additional contraceptives approved, cleared, or granted by the FDA (including newer contraceptive products) so long as the individual's attending provider determines such care as medically appropriate and necessary. Plans may apply reasonable medical management techniques for newer products and procedures only if there exists at least one other substantially similar product or service available and medically appropriate, and that similar product or service is covered without cost sharing.

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service.

The Departments are aware of reports that plans and issuers continue to apply unreasonable medical management techniques and exclusions that present barriers to access contraceptive care without cost sharing. Examples of potentially unreasonable medical management techniques and other problematic practices include actions by plans that:

- require individuals to satisfy step therapy protocols (a medical management technique also known as "fail first") using numerous other services or FDA-approved, -cleared, or - granted contraceptive products within the same category of contraception before the plan or issuer will approve coverage for the contraceptive service or FDA-approved, -cleared, or -granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider;

- apply age-related restrictions for a contraceptive service or product that is medically necessary for the individual, as determined by the individual's attending health care provider;

- impose unduly burdensome administrative requirements as part of an exceptions process, such as onerous documentation requirements or multiple levels of processes (such as one to cover an excluded drug that is medically necessary and another to remove cost-sharing requirements), that result in denials of coverage or imposition of a cost-sharing requirement for contraceptive services or products that are medically necessary for the individual, as determined by the individual's attending health care provider; and

- require cost sharing for services provided that are integral to the preventive service provided (regardless of whether the items and services are billed separately), such as anesthesia, pregnancy tests needed before the provision of certain forms of contraceptives, or other pre and post-operative items and services integral to the furnishing of sterilization surgeries including tubal ligation.

In response to such reports, the Departments are clarifying how plans and issuers can remain compliant while applying medical management techniques, as summarized below.

Therapeutic Equivalence

As an alternative to complying with prior guidance, a plan may provide coverage consistent with the therapeutic equivalence approach outlined in these FAQs. Specifically, with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing.

The Departments will determine whether a drug or procedure is therapeutically equivalent using the FDA's "Orange Book." Forms of contraception that are not FDA-approved drugs or drug-led devices are not listed in the Orange Book. Therefore, the therapeutic equivalence approach described above does not apply to such other forms of contraception.

Exceptions Process

Regardless of approach, and even if a plan covers a substantially similar product or service in a given category, the plan must also have in place an exceptions process that would allow the individual to access the medically necessary product or service without cost sharing; the individual's provider determines medical necessity.

Example: Within the category of "oral contraceptives (combined pill)," a plan covers all FDA-approved oral contraceptives (combined pill) products without cost sharing, other than those for which there is a therapeutic equivalent that is covered without cost sharing. Specifically, the plan covers Pill A, Pill B, and generic Pill D without cost sharing. Neither Pill A nor Pill B has a therapeutic equivalent product according to the Orange Book. Pill W, Pill X, and Pill Y, as well as Pill Z (which is a more expensive brand name product) are all classified in the Orange Book as therapeutic equivalents to Pill D and are not covered by the plan without cost sharing. However, the plan provides an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on an individual or their provider (or other individual acting as the individual's authorized representative). The plan's exceptions process allows an individual to receive coverage without cost sharing for a therapeutic equivalent to Pill D (i.e., Pill W, Pill X, Pill Y, or Pill Z) if the therapeutic equivalent product is determined to be medically necessary with respect to the individual, as determined by the individual's attending provider.

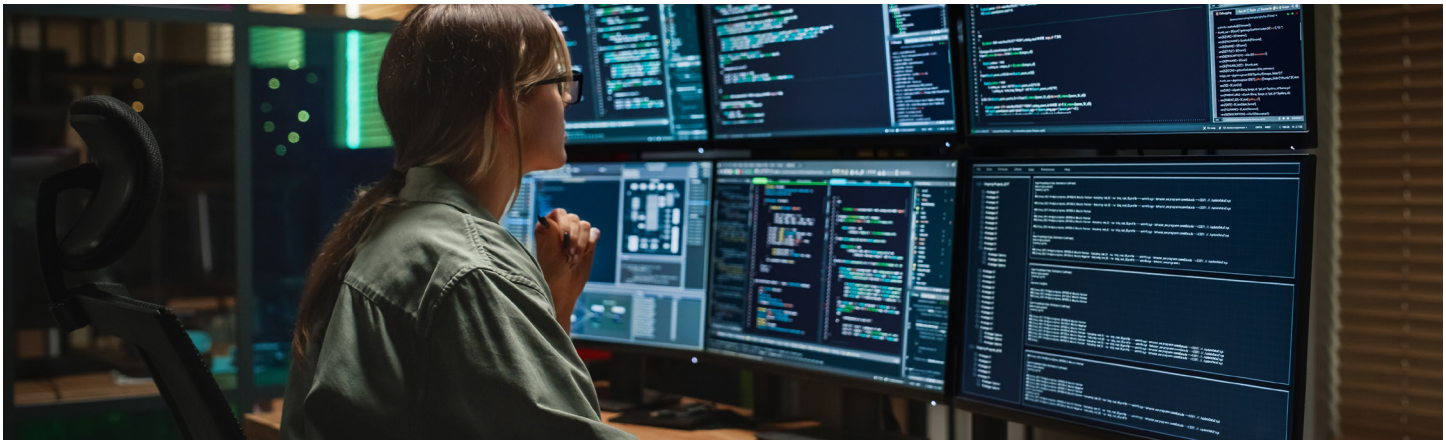
Conclusion: The plan's medical management techniques with respect to the category of "oral contraceptives (combined pill)" are generally reasonable. However, the plan's medical management techniques could be considered unreasonable if the plan imposes additional medical management techniques that are problematic, such as those highlighted earlier in this article.

Reporting Noncompliance

The FAQ provides contact information at relevant state and federal agencies that individuals with concerns about their plan's compliance with the contraceptive coverage requirements should contact.

Employer Action

It is important for plan sponsors to understand that the Departments do not view this set of FAQs as adding any additional requirements to health plans and plan designs that were compliant before the publication of this guidance remain compliant. Groups that have a fully insured plan can defer to the insurance carrier to deploy reasonable medical management techniques and designs. For groups that are self-insured, it is recommended to review the plan design and any medical management techniques with their third-party administrators in order to ensure compliance with the ACA's contraceptive care requirements.



New Cybersecurity Breach Notice Requirement

Issued date: 01/30/24

A recent amendment to 23 NYCRR Part 500, commonly referred to as the "Cybersecurity Regulation," now requires entities and individuals licensed under the New York Insurance Law to notify the New York Department of Financial Services ("DFS") within 72 hours after learning of a cybersecurity incident that has occurred at a third-party service provider. Although the original regulation required notice within 72 hours, the updated regulations require notice where a third-party service provider has a cybersecurity incident. These changes to the notice and reporting provisions went into effect on December 1, 2023.

Background

DFS enacted the Cybersecurity Regulation in 2017 establishing cybersecurity requirements that apply to, among others, any entity or individual who is required to be licensed under the New York Insurance Law. The Cybersecurity Regulation was amended in 2020, and again more recently in November 2023 (the "Amendment"). Insurance agents, producers and brokers who are licensed (or should be licensed) to sell life and health insurance in New York are Covered Entities under the Cybersecurity Regulation and are required, among other things, to provide timely notice of a cybersecurity incident to DFS.

Changes Under the Amendment

While the Cybersecurity Regulation has been around since 2017, the Amendment made some notable changes to the definition of a cybersecurity incident and to the notice provisions that apply to Covered Entities. It should be noted that this Bulletin does not discuss the Cybersecurity Regulation in its entirety, as it has existed for some time; rather its focus is to provide you with important changes that were made under the Amendment. In short, agents, producers and brokers must (as of December 1, 2023) notify DFS of a cybersecurity incident even if that incident took place at one of their vendors.

Definition of Cybersecurity Incident

The Amendment changes the definition of a cybersecurity incident. Under Section 500.17, a cybersecurity incident is now defined as an event that has occurred at the Covered Entity, its affiliates, or a third-party service provider that:

1. Impacts the Covered Entity and requires the Covered Entity to notify any government body, self-regulatory agency or any other supervisory body;

2. Has a reasonable likelihood of materially harming any material part of the normal operation(s) of the Covered Entity; or

3. Results in the deployment of ransomware within a material part of the Covered Entity's information systems.

Notification of Cybersecurity Incident

While Covered Entities were already required to notify the Superintendent of Financial Services electronically through the DFS Portal of a cybersecurity incident as promptly as possible, but in no event later than 72 hours after determining that a cybersecurity incident has occurred, the Amendment now requires Covered Entities to provide this notice if the cybersecurity incident occurred at the Covered Entity, its affiliates, or a third-party service provider. Thus, if a breach occurs at an insurance carrier or other third-party administrator or vendor, and such breach would be considered a cybersecurity incident, agents, producers and brokers must now notify DFS. This is true even if the third-party service provider is also providing notice to DFS. Covered Entities must also promptly provide DFS with any information requested regarding the incident and update DFS with material changes or new information previously unavailable.

Notification of Extortion Payment

DFS continues to discourage making extortion payments. Under the Amendment, Covered Entities must:

a. Notify DFS within 24 hours of any extortion payment made; and

b. Within 30 days of a payment, provide DFS with a written description of the reasons payment was necessary, alternatives to payment considered, diligence performed to find alternatives to payment and to ensure compliance with applicable regulations, including those of the Office of Foreign Assets Control.

Certification of Compliance

In addition to notifying DFS of the above, beginning April 15, 2024, every year Covered Entities must electronically submit a certification of material compliance with Part 500 or acknowledgment of noncompliance to DFS. If the Covered Entity did not comply, its written acknowledgment must:

a. Acknowledge that, for the prior calendar year, the Covered Entity did not materially comply with all the requirements of Part 500;

b. Identify all sections of the Cybersecurity Regulation that the Covered Entity has not materially complied with and describe the nature and extent of such noncompliance; and

c. Provide a remediation timeline or confirmation that remediation has been completed.

The Covered Entity's certification of compliance or acknowledgment of noncompliance must be submitted electronically in the form set forth on the department's website and must be signed by the Covered Entity's highest ranking executive and its Chief Information Security Officer ("CISO"). If the Covered Entity does not have a CISO, the certification or acknowledgment must be signed by the highest-ranking executive and by the senior officer responsible for the cybersecurity program of the Covered Entity.

Action

All Covered Entities, which include agents, producers and brokers, should review the Amendment and evaluate their obligations under all applicable laws. In the event a Covered Entity determines a cybersecurity incident has occurred at the Covered Entity, its affiliate, or at a third-party service provider, such as an insurance carrier, third-party administrator or other vendor, or is notified of same, the Covered Entity must report same to DFS within 72 hours. Each Covered Entity must provide a certification of material compliance or acknowledgment of noncompliance to DFS before April 15, 2024.

Resources

NYS DFS Cybersecurity Resource Center:
https://www.dfs.ny.gov/industry_guidance/cybersecurity

For a copy of the Amendment:
https://www.dfs.ny.gov/system/files/documents/2023/10/rf_fs_2amend23NYCRR500_text_20231101.pdf

DFS Portal:
https://myportal.dfs.ny.gov/

Instructions for Reporting A Cybersecurity Incident:
https://www.dfs.ny.gov/system/files/documents/2023/11/reporting-cybersecurity-incidents.pdf

Instructions for Reporting an Extortion Payment:
https://www.dfs.ny.gov/system/files/documents/2023/11/instruct_reporting_extortion_payments.pdf

2023 RxDC Reporting Instructions Released

Issued date: 02/12/24

The Centers for Medicare and Medicaid Services ("CMS") recently released updated Prescription Drugs Data Collection ("RxDC") reporting instructions related to reporting 2023 data. There are some notable changes.

Background

As previously reported, plan sponsors of group health plans (typically, employers) must submit information annually about prescription drugs and health care spending ("RxDC reporting") to CMS. The first deadline was December 27, 2022 (extended to January 31, 2023) for reporting on calendar years 2020 and 2021. For reporting on calendar year 2023, the next deadline is June 1, 2024, which is a firm date even though it falls on a Saturday. It should be noted that carriers, pharmacy benefit managers ("PBMs"), and third-party administrators ("TPAs") assisting with the reporting may have earlier deadlines for employers to respond to them with certain data points (e.g., plan name, average monthly premiums).

RxDC reporting consists of uploading to CMS a total of nine spreadsheets, consisting of a plan list (P2 is used for group health plans) and eight data files (D1 through D8), plus a "narrative response." In some situations, a TPA or PBM will not handle the full filing. This often requires the employer to file at least the D1 file, and occasionally the D2 file. A P2 list file must accompany all "D" filings.

New Instructions

The following are the most notable changes for reporting for the 2023 reference year compared to the prior year:

- Changes providing clarification about what should be reported in D1:
    - Now simplified, determine the "average monthly premium" calculation by taking total annual premiums, or premium equivalents for self-insured plans, and dividing by 12, rather than dividing by "member-months" as in prior years. The calculation is done for the "average monthly premium paid by members" and the "average monthly premium paid by employers," respectively.
    - Include under premiums or premium equivalents paid by members:

        - Member payments for COBRA coverage, including the 2% administrative fee
        - Spousal and tobacco surcharges
        - Amounts paid for coverage of an owner of an S-Corporation or Partnership if the owner works for the business and pays their premium out of personal funds
    - Now optional for premium equivalents, report on a cash basis (i.e., when claims are paid) or on a retrospective basis (i.e., when claims are incurred)
- Change providing clarification about what should be reported in D2:
    - Include information for pharmaceutical supplies, medical devices, nutritional supplements, and OTCs in the appropriate spending category in D2 if the products are covered under a plan's medical benefit
- Change related to the P2 list:
    - Provide specific language in Column C as to the specific type of carve-out benefit being reported, which is mandatory for the 2023 reference year:
        - Pharmacy only
        - Medical only
        - Behavioral health only
        - Fertility only
        - Specialty drugs only
        - Hospital only
        - Other
- Other changes generally clarifying or otherwise impacting mainly issuers, TPAs or PBMs:
    - Exclude medical devices, nutritional supplements, and over the counter (OTC) drugs from prescription drug lists (D3, D4, D5, D7, D8) unless the NDC for the product is on the CMS Drug and Therapeutic Class Crosswalk
    - Follow instructions on how to submit data when plan list or data files exceed the maximum allowable size limit in HIOS – should be quite rare at the employer level
    - Follow aggregation restrictions, which will be enforced starting with the 2023 reference year
        - Data can generally be submitted on an aggregated basis – generally by state and by market segment, then at the reporting entity level, which will generally be the:

    - Employer level,
    - Issuer level, or
    - TPA level
- This is generally dictated by what is submitted on a D2 file, and employer level reporting is considered the most “granular”
- The level of aggregation applied on the D2 must be applied at the same, or more granular, level to the data in D1 and D3 to D8 – examples:
    - Data submitted in D2 is aggregated according to the employer EIN, the data in D1 and D3 to D8 must also be aggregated according to the employer EIN
    - Data submitted in D2 is aggregated according to the TPA EIN, then the reporting entities for D1 and D3 to D8 may choose to aggregate at the TPA level or to aggregate according to the plan sponsor EIN. The reporting entities for D1, D3, D4, D5, D6, D7, and D8 do not have to make the same decision. For example, if D2 is at the TPA level, the reporting entity for D1 could aggregate at the plan sponsor level and the reporting entity for D4 could aggregate at the TPA level
- Ideally for self-insured plans, D2 data will be submitted by the TPA, which will dictate the aggregation levels for D3 to D8 data. An employer will still be able to submit D1 data at the employer level

HIOS Guidance

The HIOS RxDC User Manual and RxDC HIOS Access Guide have not changed since their last updates of July 2023 and March 2023, respectively. If an employer needs to submit one (or more) of the “D” files (e.g., D1) on behalf of the group health plan because a TPA or PBM is not handling the full filing, the employer must sign up for a HIOS account.

Employer Action

With respect to these new instructions, employers should:

- Identify which of the above changes will impact their filing this year.
- Work with carrier partners, TPAs, PBMs and other vendors, as appropriate, to submit the requisite 2023 data.

The instructions themselves are very helpful and answer questions about the filing requirement and provide relevant examples when appropriate.

Additional guidance and/or relief could be issued before the June 1, 2024, filing deadline. We will continue to monitor and inform you of any applicable changes.

Pharmacy Costs Under Scrutiny In Recent Litigation

Issued date: 02/16/24

A class action lawsuit was filed in federal court by participants, alleging that their employer, Johnson & Johnson ("J&J"), and group health plan fiduciaries breached their fiduciary duties under ERISA.

Briefly, the plaintiffs allege that J&J mismanaged its group prescription drug benefits program, costing its employees millions of dollars in the form of higher payments for prescription drugs, higher premiums, higher deductibles, higher coinsurance, higher copays, and lower wages or limited wage growth. The plaintiffs challenge the plan and its fiduciaries' processes for evaluating, selecting, and monitoring the pharmacy benefit manager ("PBM"). This is supposedly most evident in the prices it agreed to with its PBM for generic-specialty drugs.

The complaint includes multiple examples of alleged overpayment for prescription drugs in the J&J plan. One such example shows that someone with a 90-pill prescription could fill that prescription, without even using their insurance, at multiple pharmacies for prices that ranged from $28.00 – $77.00. Defendants, however, agreed to make their ERISA plans and their beneficiaries pay over $10,000 for each 90-pill prescription of the same drug.

This case has garnered a significant amount of attention in the benefits community. The following summarizes the complaint and provides some high-level considerations for group health plan fiduciaries.

Background

An ERISA fiduciary is held to a very high standard of behavior, which requires more careful decision-making and more disclosure to plan participants and beneficiaries than would be required in a normal business relationship. The relevant principal duties of ERISA fiduciaries are:

- to act solely in the best interest of plan participants and beneficiaries (the duty of undivided loyalty);
- to use plan assets for the exclusive purpose of paying plan benefits or reasonable expenses of plan administration (the exclusive benefit rule);

- to act with the care, skill, prudence and diligence that a prudent person in similar circumstances would use; and
- to act in accordance with the documents and instruments governing the plan so long as those documents are consistent with ERISA.

Selection of service providers is an important fiduciary responsibility because service providers work on behalf of plan participants and beneficiaries and often are paid with plan funds. Fiduciaries should periodically monitor their selected providers' performance.

Specific Allegations in the Lawsuit

The detailed complaint alleges various breaches by the group health plan fiduciaries regarding the pharmacy benefits in the group health plan. Below are highlights of some of the core issues of the plaintiff's arguments.

Plan Design

- The classification of a generic drug as a "specialty" drug can have a major impact on the price the plan will be required to pay. Because there is no definitive set of objective factors to determine whether any given drug is a specialty drug, the classification of a drug as "specialty" should have been the subject of negotiations between plan fiduciaries and PBMs.
- Prudent fiduciaries will replace brand-name drugs on the formulary when lower-cost, FDA-approved generics become available. Alternatively, prudent fiduciaries will add the generics to the formulary at lower prices and then incentivize plan beneficiaries to obtain these lower-cost generics instead of the more expensive brand-name drugs.
- Prudent fiduciaries are aware of the conflicts of interest that PBMs have in making formulary decisions.
- J&J should not have steered beneficiaries toward the PBM's mail-order pharmacy as the prices are routinely higher than amounts retail pharmacies charge for the same drugs.
- An arrangement in which a plan's members are incentivized or required to obtain "specialty" drugs only from the PBM's own "specialty" pharmacy provides powerful incentives for PBMs to designate generic drugs as "specialty" drugs and/or to inflate the prices of specialty drugs.

Choosing and Monitoring Service Providers

- J&J should have used its bargaining power to obtain better rates from their own PBM or another traditional PBM; could have moved all or parts of their prescription-drug plan to a "pass-through" PBM that bases its prices on actual pharmacy acquisition costs rather than inflated and manipulable benchmarks, etc.
- Prudent fiduciaries conduct open RFP processes to obtain competitive bids for PBM services at regular intervals and ensure that the rates and terms to which they agree continue to reflect the best rates and terms available in light of the plan's size, bargaining power, and other characteristics. The plaintiffs allege J&J did not have an open RFP process and did not consider the full range of available options for PBM services.
- Prudent fiduciaries should evaluate service providers, like consultants, for potential conflicts of interest including whether the service provider may have a financial interest in steering a plan toward certain PBMs or including certain provisions in PBM contracts that do not correlate to the financial or other interests of plan participants and beneficiaries.

Failure to Provide Plan Documents

- The plaintiff alleges the fiduciaries of the group health plan failed to comply with a request for plan documents. Under ERISA, fiduciaries must furnish participants and beneficiaries with plan documents upon request. Penalties of up to $110/day may apply to these failures.

Requested Relief

The plaintiff's request:

- Recovery of any losses of plan assets and any profits (or disgorgement of profits) as a result of the breaches.
- Injunctive and equitable relief including removal of the current fiduciary and appointment of an independent fiduciary.
- $110/day in penalties beginning on January 19, 2024, for failure to provide plan documents upon request.

J&J Response

J&J has not responded to the complaint filed against the group health plan. J&J is expected to file a response that will likely counter the multiple claims filed by the plaintiff and offer potential defenses.

Employer Action

This appears to be the first case by plan participants alleging a fiduciary breach tied to pharmacy costs under the plan. Employers offering group health plans should monitor developments in this case.

In addition, employers may take this opportunity to review fiduciary best practices as it relates to group health plans, including:

- Who are the ERISA group health plan fiduciaries?
- Are plan documents in place and provided upon request to participants and beneficiaries?
- How are service providers monitored and are conflicts of interest identified?
- How are fees and plan expenses evaluated for reasonableness?
- Has the ERISA group health plan obtained the required compensation disclosure under ERISA 408(b)(2) from service providers who are providing brokerage and consulting services? This is a recent requirement that was part of the Consolidated Appropriations Act of 2021 ("CAA-21").
- Is the group health and welfare plan (and its fiduciaries) covered by a fiduciary liability insurance policy?

We will continue to follow this litigation and will monitor developments.

New Attention On IVF Benefits

Issued date: 03/11/24

On February 16, 2024, the Alabama Supreme Court (“the Court”), the highest court in the state, ruled that the destruction of human embryos created through in vitro fertilization (“IVF”) violates the state’s Wrongful Death of a Minor Act (“the Act”). The Court determined that there is no exception to the Act based on an embryo’s location within or outside of a biological uterus. This has sparked a national discussion around IVF, which may impact employers offering fertility benefits.

While many fertility clinics in Alabama initially stopped IVF services, a recent legislative change may allow some IVF service providers to resume services. However, as discussed below, the legislative fix may not be enough to resume full services for all providers in the state.

Background

The plaintiffs in this case had embryos created through IVF being stored at a fertility clinic operated by the Center for Reproductive Medicine, P.C. (“the Center”). The embryos were artificially gestated and placed into a “cryogenic nursery.” A cryogenic nursery is a facility designed to keep extrauterine embryos alive at a fixed state of development, which is done by keeping them at an extremely low temperature.

In December 2020, a patient in the local hospital where the Center is located entered the cryogenic nursery and removed several embryos resulting in their destruction.

Lawsuit

The plaintiffs allege that the Center was obligated to keep the cryogenic nursery secured and monitored at all times and brought two lawsuits against the Center and the Hospital. Two sets of parents filed the first suit jointly, and the third set of parents filed the second suit. The suits claimed (1) wrongful death under the Act, and (2) common-law negligence claims if the court ruled an embryo was not a child.

The trial court granted the defendants' motions to dismiss on the basis that the IVF embryos involved in the case did not meet the definition of a person or a child, and therefore could not give rise to a wrongful death claim. The Alabama Supreme Court overturned the dismissal finding that embryos created through IVF should be considered children, the Act can apply when embryos are destroyed, and the plaintiffs may continue with their lawsuit. Based on this finding, the Court ruled that the negligence claims were moot.

Why is this Important?

The most immediate impact of the Court's decision is that many fertility clinics in Alabama have halted their IVF services as they attempt to address the impact of this decision on their IVF practices. In particular, these clinics are concerned with the civil and potential criminal liability that their entities, physicians, and patients may face as a result of the Court's determination that the Act applies to IVF embryos.

On March 6, 2024, the governor signed into law a bill to restore access to IVF treatment in the state. The bill has a retroactive effect and provides for civil and criminal immunity for "death or damage" to an embryo as part of IVF services. However, some practitioners have expressed concern that the legislation may be ambiguous and does not go far enough to protect access to IVF. Some providers may not resume services until issues are further resolved.

Additionally, defendants in the lawsuit filed an application with the Court to rehear the case. Rehearing is not common and the Court may decide to deny the application.

Implications for Benefits

Many employers offer fertility benefits, including IVF, as part of a comprehensive benefits package. Some state insurance laws require coverage for certain fertility benefits. While there appear to be some immediate concerns for IVF providers and facilities in Alabama, at this time it is unclear how the Court's decision will impact employee benefits programs.

This case has ignited a national discussion around IVF with state and federal governments, considering legislation to protect IVF providers from liability. We are in a "wait and see" period as outcomes could range from additional protection for IVF providers in some states, with other states considering further regulation that may limit accessibility to IVF.

Employer Action

Employers offering fertility benefits within Alabama may want to discuss with their carriers or fertility services vendor to confirm the current state of fertility benefit availability. Some IVF providers may begin to resume services as a result of the state's legislative action. Employers may consider adding or enhancing travel benefits to allow employees continued access to fertility benefits if unavailable in the employee's state of residence.

As for employees residing outside Alabama, it's possible that other state governments (or courts) could take similar action with respect to IVF. As such, employers outside of Alabama should monitor developments at their state level. This issue is rapidly changing across the country as federal and state governments evaluate next steps. We will continue to monitor this topic to keep you informed as this issue develops.

IRS Addresses Nutrition Wellness And General Health Expenses

Issued date: 03/18/24

The Internal Revenue Service ("IRS") is reminding taxpayers that expenses related to nutrition, wellness, and general health are not likely to qualify as reimbursable medical expenses under Internal Revenue Code ("Code") section 213. In a news release and frequently asked questions ("FAQs"), the IRS:

- Clarifies the requirement that reimbursable medical expenses must be related to a targeted diagnosis-specific activity or treatment; and
- Cautions employers about companies who are misrepresenting the circumstances in which food and wellness expenses can be paid or reimbursed by a tax favored plan.

Background

Qualified medical expenses under Code section 213(d) can be reimbursed on a tax-favored basis by a health savings account ("HSA"), health flexible spending account ("FSA"), or a health reimbursement arrangement ("HRA"). Generally, amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure of function of the body are included under this definition. These expenses can include costs for legal medical services rendered by physicians, surgeons, dentists, and other medical practitioners. They include costs for equipment, supplies, and diagnostic devices needed for medical care. They also include costs for medicines and drugs prescribed by a physician or purchased over the counter. Medical expenses do not include personal expenses that are merely beneficial to general health.

IRS News Release

The IRS has expressed concern that taxpayers may be misinformed about the circumstances in which food or wellness expenses can be medical expenses. On March 6, 2024, the IRS issued a press release to remind taxpayers that personal expenses are not reimbursable on a tax-favored basis through FSAs, HSAs, or HRAs.

The IRS also warned taxpayers about companies that are misleading taxpayers into believing nutrition, wellness, or general health expenses can be reimbursable simply by obtaining a note from a doctor that can be submitted with a claim for reimbursement. These companies offer to provide doctor's notes to taxpayers for a fee. In this news release, the IRS cautions documentation or a note from a doctor based on self-reported health information cannot convert personal expenses into medical expenses.

The IRS directs taxpayers to FAQs that provide examples of medical expenses that can qualify for reimbursement.

Examples of expenses that are not reimbursable as medical expenses include:

- Cost of exercise such as swimming or dancing lessons or memberships,
- Cost of weight loss programs that do not treat a specific disease diagnosed by a physician,
- Cost of food or beverages for weight loss that satisfies normal nutritional needs,
- Cost of food or beverages that does not alleviate or treat an illness,
- Cost of food or beverages that is not prescribed by a physician,
- Cost of drugs that aren't prescribed by a physician,
- Cost of nutritional supplements that are not recommended as treatment for a specific medical condition diagnosed by a physician.

The proper treatment of medical expenses is required for an employer benefit plan that provides benefits through an FSA or HRA. FSA and HRA plans that reimburse expenses that are not eligible can risk the tax qualified status of the entire plan.

The IRS has also recently emphasized the high standards for FSA claim substantiation. The failure to meet substantiation requirements can result in the employee losing their tax benefits under the plan or the employer's entire plan losing its tax-favored status.

Employer Action

Employers that sponsor benefit plans that reimburse medical expenses should confirm with their service providers that the plans only reimburse qualified medical expenses and that all claims processed are properly substantiated prior to reimbursement. This could require plan sponsors to review how claims are substantiated for reimbursement when paid by a debit-card or other point of sale reimbursement.

Employers should closely evaluate vendors who promote programs that use pre-tax dollars for nutritional or other wellness expenses and, for a fee, provide doctor's notes in an attempt to substantiate these claims.

Paid Leave Oregon Updates

As previously reported, leave and wage replacement benefits under Paid Leave Oregon ("PLO") became available on September 3, 2023. Recently, the definition of safe leave was expanded to include bias crimes. Additionally, the Oregon Employment Department ("ED") announced a delay in the first annual reporting requirement for equivalent plans.

Background

PLO took effect January 1, 2023 and began providing benefits to covered individuals on September 3, 2023. PLO is funded by employer and employee contributions deducted from employee paychecks. ED administers PLO and sets the benefit amounts and contribution limits. Alternatively, employers may self-administer a PLO equivalent plan provided by insurance or self-funded to comply with PLO requirements.

Safe Leave Expansion

During the 2023 legislative session, the Oregon legislature passed, and the Governor signed House Bill 3443 (HB 3443) that amended the definition of safe leave to include leave for victims of bias crimes. According to PLO:

- Bias is a prejudice in favor of or against one thing, person, or group compared with another, usually in a way considered to be unfair.
- A bias crime is motivated in part or whole by bias against another person's race, color, disability, religion, national origin, sexual orientation, or gender identity.

The changes in HB 3443 became effective on January 1, 2024. This means that, as of that date, PLO and any equivalent plan should be approving safe leave requests for employees that are victims of bias crimes in addition to leave for reasons related to domestic violence.

Equivalent Plan Reporting Delay

Equivalent plans are required to submit annual aggregate benefits usage reports and aggregate financial information to PLO due no later than the January 31 for the prior year. The reporting period is the calendar year. The aggregate benefit usage report must include for the reporting period:

- the number of benefit applications received and the qualifying leave purpose.
- the number of benefit applications approved, the qualifying leave purpose, and the total amount of leave.

- the number of benefit applications denied, the qualifying leave purpose, the number of denials appealed, and the outcome of the appeals.
- If the equivalent plan is funded by employee contributions, a separate annual report for the same reporting period is required to report the following:
- the total amount of employee contributions withheld.
- total plan expenses paid including benefit amounts and total administrative costs.
- The balance of employee contributions held in trust at the end of the reporting period.

Both the annual aggregate benefit report and financial information reports may require additional information and the employer should respond within ten calendar days of a notice from ED requesting information about the equivalent plan.

The reporting period for equivalent plans that were effective in 2023 is the period between the effective date of the plan and December 31, 2024. The reporting period for equivalent plans that were effective in 2024 is the period between the effective date of the plan and December 31, 2024. This means that the first annual reporting for all equivalent plans that became effective in 2023 or 2024 will be due by January 31, 2025.

Equivalent Plan Reapproval

Equivalent plans are required to apply for reapproval annually for the first three years that they offer PLO benefits to employees. The application is due 30 days before the anniversary of the effective date of the plan. Equivalent plans that were effective Sept. 3, 2023, must submit their reapproval applications no later than August 3, 2024.

Employer Action

Employers sponsoring equivalent plans should confirm their carriers or administrators have incorporated the expanded definition of safe leave into their approval process.

Equivalent plan sponsors should also confirm their carriers or administrators are preparing the information required for the annual reporting and they will timely provide the information before the reporting deadline.

Employers should also confirm their carriers or administrators will provide the required equivalent plan information needed to timely submit the application for reapproval.

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