ALSTON & BIRD

HEALTH & WELFARE PLAN LUNCH GROUP

November 14, 2024

One Atlantic Center
1201 W. Peachtree Street
Atlanta, GA 30309-3424
(404) 881-7885
E-mail: john.hickman@alston.com
©2024 All Rights Reserved

INDEX

1. Health & Welfare Benefits Monthly Update Presentation

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

© Alston & Bird LLP 2024

0

Health & Welfare Benefits
MONTHLY UPDATE

November 2024 Agenda

- Compliance Grab Bag
- MHPAEA Final regulation action steps
- Wellness case update
- Disaster relief
- Preventive care regs/ACA FAQs 68
- HIPAA Update
- Year end Reminders

1 ALSTON & BIRD

1

ALSTON & BIRD

Compliance Grab Bags

2

Health & Welfare Benefits
MONTHLY UPDATE

Regulatory Status Update

Recently Finalized Rules

- DOL-EBSA Final Rule for **Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021**; received at OMB July 1, 2024; comment period for proposed rule ended Oct. 17, 2023; First released on Sept. 9, 2024; published in FR on Sept. 23, 2024.

Recently Proposed Rules

- HHS-CMS proposed rule for **Enhancing Coverage of Preventive Services under the Affordable Care Act**; published in FR Oct, 28, 2024.
- HHS-CMS proposed rule **Notice of Benefit and Payment Parameters 2026**; received at OMB July 17, 2024; published in FR Oct. 10, 2024.

Disaster Relief

- DOL-EBSA and Treasury/IRS published **Extension of Time Frames;** posted Nov. 7, 2024; published in FR Nov. 8, 2024.

New Proposed Rule at OMB

- HHS-OCR proposed rule for **Proposed Modifications to the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information**; proposed rule received at OMB Oct. 18, 2024.

3 ALSTON & BIRD

3

Health & Welfare Benefits
MONTHLY UPDATE

2024-2025 Cost-of-living Adjustments

	2025	2024
HSA contribution max (including employee and employer contributions)	4300/8550 in 2025 Rev Proc 2024-25	$4,150/$8,300 Rev. Proc. 2023-23
HSA additional catch-up contributions	$1,000	$1,000
HDHP annual deductible minimum	1650/3300 in 2025 Rev Proc 2024-25	$1,600 ($3,200 family)
Limit on HDHP OOP expenses	$8300 and 16,600 in 2025 Rev Proc 2024-25	$8,050 ($16,100 family)
ACA limit on OOP expenses	$9,450 ($18,900 family)	$9,200 ($18,400 family)
Limit on amounts newly available under an Excepted Benefit HRA	$2150 in 2025	$2,100
Health FSA salary reduction max	3300 in 2025	$3,200
Health FSA carryover max	660 in 2025 (carried into 2026)	$640 (carried into 2025)
Transit and parking benefits	325 in 2025	$315

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

IRS Preventive Care Guidance for HSAs

- IRS Notice 2024-71
  - Condoms qualify as 213(d) medical care for FSAs/HRAs/HSAs
- IRS Notice 2024-75 recognizes the following as preventive care for HSA HDHP purposes (i.e., reimbursable below the deductible)
  - OTC oral contraceptives and condoms
    - Does not address male sterilization or other male contraceptives
  - Breast cancer screenings other than mammograms (e.g., MRI, ultrasound)
  - Continuous glucose monitors (as is the case with other glucometers)
  - Insulin and insulin delivery products

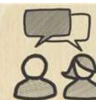
ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

More on HSAs

- Possible expiration of CARES Act HDHP virtual care exception (unless re-enacted) on December 31, 2024 (not a plan year exception)
  - Potential problem areas for any "treatment" below the deductible
  - Possible exceptions
    - Health coach
    - Disease management
    - Treatment that (in the aggregate) is not significant
      - How do you measure significance?

Health & Welfare Benefits
MONTHLY UPDATE



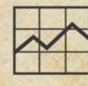
What's in store for 2025 on the regulatory front?

- Open season on existing regulations ?
  - If regulations final and in effect
    - Repeal of Chevron means less deference by Courts
    - Possible 1996 Congressional Review Act repeal by House/Senate
      - Used 15 times by Trump Administration in 2017
      - Simple majority
      - Regulations enacted within 60 "session days" (August 1st ?) of publication
    - Otherwise repeal requires new NPRM by agency
  - If regulations final and published but not yet effective
    - New Administration can direct agency to "suspend" and reconsider
  - If regulations not yet published or only proposed
    - New administration can withdraw
- New regulations ?
  - Exec Order 13771 – The "2 for 1" rule
  - Ten for one?

ALSTON & BIRD

MHPAEA FINAL RULE: WHAT SHOULD PLAN SPONSORS BE DOING NOW?

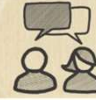
Health & Welfare Benefits
MONTHLY UPDATE



COMPARATIVE ANALYSIS

- Comply with the comparative analysis requirements for 2025.
- Do you have a comparative analysis?
  - If not prepare one.
  - If you do, then review the six detailed requirements and be prepared to update the comparative analysis for the Final Rule except for:
    - The meaningful benefits standard,
    - The prohibition on discriminatory information used in the design and application requirements, and
    - The relevant data evaluation requirements.
  - ***Technically required on January 1, 2025 for a calendar year plan.***
    - Will the Departments exercise enforcement discretion if the process of preparing an updated comparative analysis is underway? Remember time periods responding to a Department's request are very short.
    - The Departments refused to provide an example of a compliant comparative analysis but will "continue to consider what additional resources and guidance are necessary to assist the regulated community" and that they are "committed to providing additional guidance."

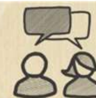
Health & Welfare Benefits
MONTHLY UPDATE



COMPARATIVE ANALYSIS

- How will multiple service providers be handled?
  - Carve out for behavioral health.
  - Carve out for prescription drugs.
  - Carve out for telehealth.
  - Carve out for centers of excellence.
- Comparative Analysis must include all. ASOs/TPAs unlikely to include carve-outs in any comparative analysis they provide unless the carve-out service provider is an affiliate of the ASO/TPA.

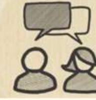
Health & Welfare Benefits
MONTHLY UPDATE



COMPARATIVE ANALYSIS

- Review the certification requirement with applicable plan fiduciaries.
  - Who will be selected to prepare the comparative analysis?
  - Document a "prudent process" to select one or more "qualified service providers" to prepare the comparative analysis.
  - How will the required monitoring of the qualified service provider be accomplished and documented?
  - In the preamble DOL states that it expects that the service provider will make an assurance that, to the best of its ability, the comparative analysis complies with the requirements of MHPAEA and applicable regulations.
    - Will the service provider make that assurance?
  - In the preamble DOL states that, alternatively, the fiduciary could provide a certification that the comparative analysis is in compliance.

Health & Welfare Benefits
MONTHLY UPDATE



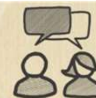
PLANNING FOR 2026

- Identify any areas where there may be a plan design issue with the "meaningful benefits/core treatment" requirement and be prepared to address those in 2026.
  - Are any plan/SPD amendments required?
- Review the information used in designing NQTLs. Is any of it biased or not objective in a manner that discriminates against MH/SUD benefits? Who will make that determination?
- ***Data collection will be the most challenging aspect of the Final Rule.***
  - Still many unknowns on what the final data collection requirements will be.
  - Watch for further guidance on data collection including an updated MHPAEA Self-Compliance Tool from the Departments.
    - DOL has informally stated that the Self-Compliance Tool will be available in the near future.
  - Discuss with TPAs/ASOs on the ability to collect the data.
  - Does the TPA/ASO have the technology to collect this data?
  - Based on the data, who will determine whether there are "material differences" in access to MH/SUD benefits as compared to Med/Surg benefits? How will that determination be made? Statistical or actuarial experts?
  - What action will be taken if there are material differences?

12 ALSTON & BIRD

12

Health & Welfare Benefits
MONTHLY UPDATE



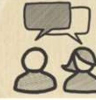
SERVICE PROVIDER AGREEMENTS

- Make sure any ASO/TPA agreement addresses responsibilities for a comparative analysis.
- Will the ASO/TPA be the "qualified service provider" to perform the comparative analysis for purposes of the fiduciary certification?
  - Issues with carve-out service providers.
  - Providing the DOL expected service-provider "assurance" of compliance.
- If the ASO/TPA will not be the qualified service provider does the agreement provide for cooperation with that provider? Timing in providing information to that provider? Consequences if information is not provided?
- Specifically address data collection and meaningful benefits/core treatments?
- Don't forget QTL testing.

13 ALSTON & BIRD

13

Health & Welfare Benefits
MONTHLY UPDATE



WATCH FOR FURTHER DEVELOPMENTS

- Will the Final Rule be challenged under *Loper Bright* or otherwise:
  - In particular, there may be challenges to the relevant data evaluation and meaningful benefits requirements.
- What about the Congressional Review Act?
  - Bipartisan support around addressing MH/SUD benefits but maybe Congress will want the Departments to "start over".
- There should be additional sub-regulatory guidance.
  - Additional guidance repeatedly promised in the preamble.
  - Updated MHPAEA Self-Compliance Tool. Soon?
  - Prior Trump administration attempted to stop reliance on any sub-regulatory guidance (guidance that had not gone through notice and comment).

14 ALSTON & BIRD

14

ALSTON & BIRD

FIFTH CIRCUIT DECISION IN TMA III

15

Health & Welfare Benefits
MONTHLY UPDATE

TMA III

- The calculation of the Qualifying Payment Amount (QPA) under the No Surprises Act (NSA) has been subject to a number of challenges by the Texas Medical Association (TMA) in in a district court in Texas.
- For NSA covered claims (out-of-network emergency; out-of-network provider in an in-network facility; and out-of network air ambulance) QPA is used in determining a participant's cost-sharing as well as a factor in what the insurer/plan will pay the provider if a NSA claim goes to independent dispute resolution (IDR).
- There were four cases known as TMA I, TMA II, TMA III and TMA IV. These cases involved the weight given to QPA when a claim goes to IDR and also how to calculate QPA.
- Biden Administration lost each of the TMA decisions in district court.
- But, in somewhat of a surprise, on October 30th the 5th Circuit Court of Appeals reversed the district court and upheld the Biden Administration regulations on several aspects of calculating QPA.

16 ALSTON & BIRD

16

Health & Welfare Benefits
MONTHLY UPDATE

TMA III

- QPA generally involves a median contracted rate for a specific service. In TMA III, the Fifth Circuit reversed the district court in three areas where the district court found the regulations to be invalid:
  - "Ghost rates"—These are described as rates for a service negotiated between a provider and a plan/insurer but for which there are no actual claims. The district court held these "ghost rates" could not be used in calculating QPA. The Fifth Circuit ruled they could.
  - Incentives—The district court held that risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments must be included in calculating QPA. The Fifth Circuit, upholding the regulatory provision, said they could be excluded.
  - Special case specific agreements with provider—The district court held that these agreements must be taken into account when calculating QPA even though the regulations stated they could be excluded . The Fifth Circuit, again upholding the regulatory provision, held that they cannot be taken into account.
- This generally means the regulations were upheld as written for these provisions.

17 ALSTON & BIRD

17

Health & Welfare Benefits
MONTHLY UPDATE

TMA III

- The Fifth Circuit also held that plans/insurers do not have to provide more information on QPA than is currently provided by the regulations.
- The Fifth Circuit did not address (because the government apparently did not appeal this issue) the district court's prohibition of a third-party administrator calculating QPA based on its entire self-funded plan "book of business" rather than on a plan-by-plan basis. This aspect of the district court's decision in TMA III appears to be still applicable and may be an issue—especially for smaller self-funded plans. How this could possibly work for a small level funded plan is unknown.
- The Fifth Circuit ***upheld*** the district court on the 30-day statutory deadline for a plan to make a decision on an NSA claim. The regulations provided that the 30-day period was only triggered bye a "clean claim." The district court held, and the 5th Circuit agreed, that this was contrary to the statutory text. The 30-day period begins to run from the receipt of the claim, whether clean or not.
- CMS website states: "The Departments and OPM are reviewing the Fifth Circuit's decision and intend to issue further enforcement guidance in the near future."
- Litigation may not be over. *En banc* or Supreme Court review is possible.

ALSTON & BIRD

Smoking Cessation Program Litigation

Health & Welfare Benefits
MONTHLY UPDATE

Smoking Cessation Program Litigation

- 20+ class action cases filed
- 3 general claims are being made:
  - No notice of alternative standard
    - Rules require notice of right to alternative standard in all materials describing the program
  - Reward not applied retroactively when alternative standard satisfied
    - Rules require that same reward be available to those who complete the alternative standard
  - Time period for completing alternative standard too short
    - Rules do NOT prescribe a specific time period

ALSTON & BIRD

ALSTON & BIRD

DISASTER RELIEF

Disaster Relief: IRS Filing Extensions

Deadlines vary depending upon the disaster and locality. Details on all recent disaster relief for presidentially-declared disasters are on the Around the nation page on IRS.gov. Currently:

- Taxpayers in all or parts of Connecticut, Florida, Illinois, Kentucky, Louisiana, Minnesota, Missouri, New York, Pennsylvania, Puerto Rico, South Dakota, Texas, Vermont, Virgin Islands and Washington state have until Feb. 3, 2025, to file their 2023 tax year returns.
- For Helene or Milton, taxpayers in **all of** Alabama, Florida, Georgia, North Carolina, South Carolina, and in affected parts of Tennessee and Virginia will have until May 1, 2025, to file their 2023 tax year returns.

- The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area. The DOL automatically recognizes these extensions for Form 5500 filing. Visit https://www.irs.gov/newsroom/tax-relief-in-disaster-situations for more information.

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief: Extensions of Timeframes

- DOL/EBSA and Treasury/IRS published **Extension of Time Frames** in FR on Nov. 8, 2024 for Hurricane and Tropical Storm Helene and Hurricane Milton. *Note: "Disaster areas" are those areas designated as eligible for Individual Assistance by FEMA due to a particular storm. It is narrower in some states than the IRS tax filing relief***.**
- *Who*: Relief applies to
  - Participant, beneficiary, qualified beneficiary, or claimant in GHPs, disability and other employee welfare benefit plans (including pension) subject to ERISA or the Code who (i) **resided, lived, or worked** in one of the disaster areas at the time of the hurricanes or tropical storm; or (ii) whose coverage was under an employee benefit plan that was directly affected.
  - Group health plans subject to ERISA and IRC and their sponsors and TPAs **affected by** the hurricanes or tropical storm.
- *What*:
  - For participants/beneficiaries/QBs/claimants: Mandatory extensions until May 1, 2025 that operate similar to the COVID Outbreak Period in that the "Relief Period" must be disregarded for certain deadline and timeframes.
  - For GHPs (and their sponsors and TPAs): Disregard "Relief Period" for purposes of COBRA election notices.
- *When*: Effective immediately.

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief—Plans Affected

- GHPs, disability and other employee welfare benefit plans (including pension) subject to ERISA or the Code that were directly affected.
- Employee benefit plan is "directly affected" if the following was located in one of the disaster areas at the time of the hurricane or tropical storm:
  - the principal place of business of the employer (for single-employer plan);
  - the principal place of business of employers that employ more than 50% of the active participants covered by the plan (for plans covering employees of more than one employer);
  - or the office of the plan or the plan administrator;
  - or the office of the primary recordkeeper serving the plan (for pension plans).

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief—Timeframes Extended

- Extensions for Participant, beneficiary, qualified beneficiary, or claimant apply to:
  - Special Enrollment requests (30 or 60 days)
  - COBRA 60-day election period
  - COBRA premium payment deadlines
  - Deadline for disability determination notices
  - Claim filing deadline
  - Deadline for filing appeals of adverse benefit determinations
  - Deadline for filing requests for external review
  - Deadline for filing information to perfect a request for external review
- Extensions for GHP, sponsor or TPA:
  - Providing COBRA election notice

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief Period

- Sept. 23, 2024-May 1,2025: Florida disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane Helene.
- Sept. 24, 2024-May 1,2025: Georgia disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane Helene
- Sept. 25, 2024-May 1,2025: North Carolina, South Carolina and Virginia disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane or Tropical Storm Helene
- Sept. 26, 2024-May 1,2025: Tennessee disaster areas designated as eligible for Individual Assistance by FEMA due to Tropical Storm Helene
- Oct. 5, 2024-May 1,2025: Florida disaster areas *not* designated as eligible for Individual Assistance by FEMA due to Hurricane Helene but designated as eligible for Hurricane Milton.

26 ALSTON & BIRD

26

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief—Example #1

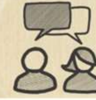
- *Example #1: Facts*. Jane resides in Chatham County, GA. Before Helene, Jane was receiving COBRA coverage under a GHP. More than 45 days had passed since Jane had elected COBRA, and her monthly premium payments are due by the first of the month. The plan does not permit QBs longer than the statutory 30-day grace period for making premium payments. Jane made a timely Sept. payment, but did not make the Oct. payment or any subsequent payments during the Relief Period. As of May 1, 2025, Jane has made no premium payments for Oct., Nov., Dec., Jan., Feb., Mar., Apr., and May. Does Jane lose COBRA coverage, and if so for which month(s)?

- *Conclusion*. The Relief Period is disregarded for purposes of determining whether monthly COBRA premium installment payments are timely. Premium payments made by 30 days after May 1, 2025, (May 31, 2025), for Oct., Nov., Dec., Jan., Feb., Mar., Apr., and May, are timely, and Jane is entitled to COBRA these months if she timely makes payment. Because the due dates for Jane's premiums would be postponed and her payment for premiums would be retroactive during the initial COBRA election period, Jane's insurer or plan may initially deny claims and then, after premiums are paid, must make retroactive payment for covered benefits and services received during this time.

27 ALSTON & BIRD

27

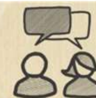
Health & Welfare Benefits
MONTHLY UPDATE



Disaster Relief—Examples 2&3

- *Example #2: Facts.* Same facts as Example #1. By May 31, 2025, Jane made a payment equal to two months' premiums. For how long does Jane have COBRA coverage?
- *Conclusion*. Jane is entitled to COBRA coverage for Oct. and Nov. of 2024, the two months for which timely premium payments were made, and she is not entitled to COBRA continuation coverage for any month after Nov. 2024.
- *Example #3: Facts.* (Internal appeal-disability plan). Gary resides in Gulf County, Florida (Relief Period: Sept. 23 2024-May 1 2025) and received a notification of an adverse benefit determination from his disability plan on August 28, 2024. The notification advised Gary that there are 180 days within which to file an appeal. What is Gary's appeal deadline?
- *Conclusion*. When determining the 180-day period within which Gary's appeal must be filed, the Relief Period is disregarded. Consequently, his last day to submit an appeal is 154 days (180 – 26 days following August 28 to September 23) after May 1, 2025, which is October 2, 2025.

Health & Welfare Benefits
MONTHLY UPDATE



Leave Donation/Sharing Programs

- Employers can assist employees to help others cope with disaster through a leave donation program.
- As a general rule, employees would be taxed on the full value of any leave they donate under longstanding tax concepts.
- If certain requirements are met, the taxation may shift to the recipient of the donated leave.
- There are three different options available:
  1. EEs transfer leave to EEs absent from work due to presidentially declared major disaster.
  2. EE gives up unused leave and ER donates the cash value to charitable organization.
  3. EE transfers leave to EE absent from work due to medical emergency.

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

Leave Donation Programs: Presidentially Declared Disasters

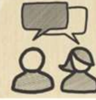
- IRS Notice 2006-59 provides guidance for major disasters as declared by the President that warrant individual assistance or individual and public assistance from the federal government.
- If IRS requirements are satisfied, leave donation is not taxable to donor (and no deduction is available), but is taxable to recipient as compensation for payroll tax (FICA and FUTA) and income tax purposes.
- Employer is entitled to a deduction for the payment of wages to the leave recipient (just at is would have been if the donating employee had taken the leave) and is responsible for payroll taxes and wage withholding on such amounts
- Requirements include (not limited to):
  - Written plan; donor cannot choose recipient; donated amount capped at maximum donor can accrue in a year; recipient must exhaust all available paid leave; request and approval of leave must be in writing; leave must be used for purposes related to the major disaster; reasonable time limit tied to event, after which unused leave is returned to donors; no cash-out, but recipient can eliminate a negative balance from advanced leave; amount of leave awarded must be reasonable and need-based.

Health & Welfare Benefits
MONTHLY UPDATE

Leave Donation Programs: Charitable donation disaster-related programs

- Cash value of EE's donated leave is donated by ER to a charitable organization related to the disaster.
- Cash value is taxable to the EE unless IRS grants a temporary exception; no exception has yet been granted for Helene or Milton.
- On previous occasions when IRS has granted an exception, qualifying leave donations made by a deadline set by the IRS was not taxable to the donor.

Health & Welfare Benefits
MONTHLY UPDATE



Leave Donation Programs: Medical Emergency

- IRS guidance on such programs dates back to the 1990s.
- Not taxable to donor but taxable to recipient on W-2.
- "Medical emergency" need not be related to a disaster. A "medical emergency" is a medical condition of the employee or their family member that will cause prolonged absence from work.
- Requirements for such a program and tax consequences are generally similar to those leave donations a programs related to a disaster (some differences).
- Informal, nonbinding remarks: IRS has stated that donor may be able to designate the recipient.

ALSTON & BIRD

Enhancing Coverage of Preventive Services under the ACA

Health & Welfare Benefits
MONTHLY UPDATE

Proposed Rule: Enhancing Coverage of Preventive Services

- On October 28, 2024, HHS-CMS published in the FR the proposed rule for Enhancing Coverage of Preventive Services under the Affordable Care Act.
  - Clarifies and codifies an exception process for reasonable medical management techniques for preventive items/services not generally covered by the plan.
  - Proposes that plans cover OTC contraceptive items without a prescription or imposing cost-sharing.
  - Proposes that plans cover certain recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent is covered without cost-sharing.
  - Proposes a disclosure for coverage and cost-sharing for OTC contraceptive items.
- Applicable to non-grandfathered GHPs and health insurance issuers offering non-grandfathered group or individual health insurance coverage

Health & Welfare Benefits
MONTHLY UPDATE

Proposed Rule: Reasonable Medical Management Techniques

- For a medical management technique to be considered "reasonable":
  - The plan/issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or attending provider (or authorized representative).
    - Preamble describes a facts & circumstances test.
  - Process must ensure the individual can receive coverage, without cost-sharing, for the item/service specified in a recommendation or guideline for mandated preventive health services.
  - Coverage must be according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual.
  - The medical necessity determination is made by the individual's attending provider.
    - Preamble suggests providers might consider factors such as severity of side effects, differences in permanence and reversibility of a recommended preventive service, and ability to adhere to the appropriate use of the recommended preventive service.

Health & Welfare Benefits
MONTHLY UPDATE

Reasonable Medical Management Techniques (cont.)

Preamble provides that an exceptions process is:

- Easily accessible if plan documentation includes relevant information about the process, including :
  - how to access exceptions process w/o initiating an appeal under internal claims/appeals procedures;
  - the types of reasonable information the plan requires as part of a request; and
  - contact information for a plan representative to questions.
- Transparent if, at a minimum, the information about the process (e.g., exceptions form with instructions) is included and prominently displayed in plan documents and materials (e.g., the SPD, plan website) that describe the terms of coverage of preventive services.
  - whether and how plan/issuer provides notice of the availability of exceptions process
  - what steps patient/provider/representative is required to initiate and complete
- Sufficiently expedient if it makes a determination according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service/post-service) and the medical exigencies involved for urgent care claims.
- Unduly burdensome if the Plan denied coverage and made the patient go through the appeals process instead of having an exceptions process in place.

Health & Welfare Benefits
MONTHLY UPDATE

Proposed Rule: Coverage of Contraceptive Items

- Departments are interested in minimizing barriers to coverage and expanding the scope of coverage without cost sharing for *all recommended preventive services,* but because changes could be significant for current plan administration, Depts propose an "incremental approach" to allow for feedback, starting with contraceptive coverage:
  - Proposal that plans cover recommended OTC contraceptive items w/o a prescription or cost-sharing, provided the applicable recommendation/guideline does not require Rx;
  - Proposal that to be "reasonable", medical management techniques must utilize a therapeutic equivalence approach for recommended contraceptive drugs and drug-led combination products.

Coverage of Contraceptive Items: OTC Items

- Additional details from preamble:
  - INN/OON rules apply—cost-sharing can be applied to OON only if the plan has a network that can provide OTC contraceptives w/o Rx and w/o cost-sharing at POS.
  - Coverage must be "comparable" to coverage for other preventive services (e.g., can't impose "mail order only", shipping cost, or require post-purchase reimbursement)
  - Plans w/o networks are encouraged to establish processes ensuring OTC contraceptive items can be obtained w/o out-of-pocket costs or significant barriers to access (e.g., pre-paid accounts, linked apps or QR code; should have sufficient guardrails to prevent spending on non-OTC contraceptive items).
  - One-month supply limit w/o a clinical basis for the limit would not be "reasonable."
  - Age- and gender-based medical management would not be reasonable unless the medical management technique relies on a clinical rationale and is consistent with FDA approvals of any particular OTC contraceptive product.

ALSTON & BIRD

Coverage of Contraceptive Items: Therapeutic Equivalent

- On January 22, 2024 DOL, HHS and IRS issued FAQs Part 64, which set forth an optional therapeutic equivalence approach ("TEA") that plans could, but are not required to, use (in combination with an exceptions process) to comply with PHSA with respect to FDA-approved contraceptive drugs and drug-led devices, as an alternative to standards that had been set forth in previous guidance. **The Depts now propose to make this TEA a requirement instead of optional**.
- Therapeutic equivalents are identified in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), designated with a code with the first letter "A".
  - Orange Book available at: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.
- If the Orange Book does not identify a therapeutic equivalent for a given drug or drug- led combination product, that drug or drug-led combination product would have no therapeutic equivalent, and a plan would not be permitted to use medical management techniques to deny coverage of (or impose cost sharing on) that drug or drug-led combination product.
- Orange Book does not identify OTC contraceptive items.

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

ACA FAQs Part 68

- On October 21, 2024, DOL, HHS and IRS issued FAQs Part 68,.
- GHPs that cover mastectomies are required to provide coverage for chest wall reconstruction with aesthetic flat closure as a type of breast reconstruction under Women's Health and Cancer Rights Act (WHCRA).
- Plans and issuers must cover, without cost sharing, specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services, consistent with the 2023 USPSTF recommendation published on August 22, 2023, for plan years beginning on or after one year from the issue date of the recommendation (in this case, plan or policy years beginning on or after August 31, 2024).
- Proper medical service coding is required to identify when item/service are furnished as preventive items or services not requiring cost-share. Modifier 33 can be appended to signal preventive care.
- Unless the plan has individualized information to establish that items/services are not recommended preventive items/services, plan should pay when code denotes a preventive item/service. Also applies any time the code identifies item/service that generally meets the preventive care definition, even without a modifier.

Health & Welfare Benefits
MONTHLY UPDATE

ACA FAQs Part 68 (cont.)

- Plans can deny claims even if preventive care code is used if plan has information **establishing** that item/service was not furnished as a recommended preventive item/service (or was not integral to the furnishing of a recommended preventive item/service.)
- If information **suggests**, but does not **establish** as much, the plan is not in violation if it has made reasonable and unsuccessful efforts to obtain the information necessary from the provider to make a proper determination prior to imposing cost sharing on (or denying coverage for) the item or service. Cost-sharing must be reversed promptly upon being made aware that item/service was preventive.
- Steps to ensure preventive care through network providers is not improperly denied: review coding guidelines, claims processing systems, and other relevant internal protocols and make any necessary modifications.

ALSTON & BIRD

HIPAA Updates: Reproductive Rights and New Security Requirements

42

Health & Welfare Benefits
MONTHLY UPDATE

Compliance Deadlines HIPAA Reproductive Rights Final Rule

Requirement	Date by which covered entities must comply
Update HIPAA Policies and Procedures (“P&Ps”)	December 23, 2024
Update the Notice of Privacy Practices (“NPPs”)	February 16, 2026
HIPAA Training for 2024 Privacy Rule	December 23, 2024
Obtain Attestations for Certain Uses and Disclosures	December 23, 2024
Revise existing business associate agreements (“BAAs”)	December 23, 2024

43 ALSTON & BIRD

43

Health & Welfare Benefits
MONTHLY UPDATE

Proposed HIPAA Security Regulations Coming for Year-End?

- An upcoming proposed rule from HHS would formalize cybersecurity requirements and allow the Office for Civil Rights (OCR) to expand enforcement.
  - The proposed rule is a response to ransomware and hacking to access electronic protected health information and will likely align with HHS' Cybersecurity Performance Goals HHS released earlier this year HPH Cybersecurity Gateway.
  - The proposed rule may also codify HHS' tracking technologies guidance.
- This is a link to the **abstract** HHS filed with the White House Office of Information and Regulatory Affairs regarding the proposed rule.
- The proposed rule is expected to be published by the end of the calendar year.

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

New Legislation on Health Care Security – Health Infrastructure Security and Accountability Act

- Senators Ron Wyden (D-OR) and Mark Warner (R-VA) have introduced the Health Infrastructure Security and Accountability Act (HISA) in an effort to counter cyber security attacks against the U.S. health care system.
- This legislation would require HIPAA covered entities and their business associates to maintain minimum security requirements and removes the statutory caps on fines for HIPAA violations.
- A one-page summary of the bill can be found here. A section-by-section summary can be found here. The legislative text can be found here.

ALSTON & BIRD

ALSTON & BIRD

Year-End Compliance Reminders

46

Health & Welfare Benefits
MONTHLY UPDATE

Year-End Compliance—Gag Clause Instructions

Group health plans (GHPs) and health insurance issuers must annually attest compliance with Gag Clause Prohibition and submit Gag Clause Prohibition Compliance Attestations (GCPCAs) by December 31st every year.

- CMS says brokers, agents, TPAs, PBMs and other entities attesting on behalf of GHPs and issuers should notify the GHP or issuer.
- GHPs or issuers, or those submitting on their behalf, should submit GCPCAs via https://hios.cms.gov/HIOS-GCPCA-UI.
- GCPA Instructions, User Manual, and Excel Template are available at https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/gag-clause-prohibition-compliance-attestation.

47 ALSTON & BIRD

47

Health & Welfare Benefits
MONTHLY UPDATE

Year-End Compliance—Gag Clause Instructions (cont.)

DOL, HHS, and IRS have jointly updated the Submission Instructions and User Manual for the Gag Clause Prohibition Compliance Attestation (GCPCA):

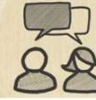
- Webform and template allow for precisely defining the date range to which the attestation applies.
- Employer plan types are expanded to include 3 categories for GHPs: (1) ERISA group health plan (GHP) or sponsor of ERISA plan,* including a plan sponsored or established by a union; (2) (Non-Federal) governmental group health plan; (3) Church plan
- "Reporting Entity" changed to "Responsible Entity" and Responsible Entity types expanded in the instructions to clarify that ERISA group health plan (GHP), or sponsor of ERISA plan, includes a plan sponsored or established by a union.
- Clarified labels in webform and template regarding types of provider agreements: (1) Medical network; (2) Pharmacy benefit manager network; (3) Behavioral health network; (4) Other
- Modified attestation language to remove forward-looking agreement actions to accommodate date range and information provided through the submission process: I attest that […] the group health plan(s) […] on whose behalf I am signing ~~will not enter into an agreement, and has not, subsequent to December 27, 2020~~has not, for the dates specified and as provided in the foregoing information, entered into an agreement with a health care provider, network or association of providers […]

Health & Welfare Benefits
MONTHLY UPDATE

Year-End Compliance—Nondiscrimination in Health Programs and Activities (1557)

- HHS-OCR Proposed Rule on **Nondiscrimination in Health Programs and Activities (1557)** (Aug. 4, 2022); comment period ended October 2022; Final Rule published in FR on May 6, 2024.
- Generally, any health program or activity that receives Federal financial assistance (FFA) from HHS or that is administered by an executive agency or by an entity established by Title I of the ACA is covered by the 2024 Rule (limited exemption for Federal religious freedom and conscience objections).
- Definition of "health program or activity":
  - Includes "health insurance issuer," which has implications for insurer TPAs and the self-insured plans they administer.
  - Does not include GHPs, though GHPs could be subject to the 2024 Rule if the GHP itself receives FFA.
- 2024 Rule does not apply to any "employer or other plan sponsor" of a GHP with regard to its "employment practices", including the "provision of employee health benefits", which "includes when the Federal financial assistance received is for their employee health benefits."
- Applies to telehealth; Medicare Part B is FFA.

Health & Welfare Benefits
MONTHLY UPDATE

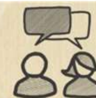


Year-End Compliance— Nondiscrimination in Health Programs and Activities (1557) (cont.)

Although the 2024 Rule is generally effective on July 5, 2024, the complexities of this rule require separate effective dates for various provisions:

Section 1557 Requirement	Date by which covered entities must comply
Designate a §1557 Coordinator	Within 120 days of July 5, 2024 ("within" 120 days seems to mean November 2, 2024).
§1557 Policies and Procedures	Within one year of July 5, 2024.
§1557 Training	Following a covered entity's implementation of the policies and procedures, and no later than 300 days of July 5, 2024.
Notice of Nondiscrimination	Within 120 days of July 5, 2024.
Notice of Availability of Language Assistance Services and Auxiliary Aids and Services	Within one year of July 5, 2024.
Nondiscrimination in health insurance coverage and other health-related coverage (benefit design changes)	For health insurance coverage or other health-related coverage that was not subject to the 2024 Rule as of May 6, 2024, by the first day of the first plan year beginning on or after January 1, 2025.

Health & Welfare Benefits
MONTHLY UPDATE



Year-End Compliance— Federal Grab Bag (not exclusive list)

- *Non-discrimination testing* – Some non-discrimination tests for health FSAs, dependent care FSAs, HRAs, and group term life require corrections, which might include refunds, before the end of the year.
- *Summary Annual Report* - If Form 5500 is extended, the SAR is due December 15, 2024.
- *CHIPRA notice* – provide to all employees annually (no date specified). DOL model notice available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/2010-2409 (as visited November 7, 2024).

Health & Welfare Benefits
MONTHLY UPDATE

Year-End Compliance— Federal Grab Bag (not exclusive list – cont.)

- *Telehealth (covered earlier)* - Unless Congress acts, after December 31, 2014 calendar year HSA compatible HDHPs cannot cover telehealth before a participant reaches their deductible. Non-calendar year HDHPs can allow pre-deductible telehealth through the end of the plan year beginning before January 1, 2025.
- *HIPAA Reproductive Rights Compliance (covered earlier)* - By December 23, 2024, HHS requires business associates and covered entities (including, but not limited to, plans like HRAs and FSAs) to:
  - Revise existing business associate agreements ("BAAs")
  - Update HIPAA Policies and Procedures
  - Provide HIPAA Training for 2024 Privacy Rule
  - Obtain attestations when making Certain Uses and Disclosures
- January 2025:
  - *2023 Form W-2-Health Plan Coverage Reporting* - The W-2 must report the total value of "applicable employer sponsored coverage" provided to the employee during 2024 no later than January 31, 2024. See https://www.irs.gov/affordable-care-act/form-w-2-reporting-of-employer-sponsored-health-coverage (as visited November 7, 2024).

ALSTON & BIRD

Health & Welfare Benefits
MONTHLY UPDATE

Year-End Compliance— State and Local Reminders (not exclusive list)

- *California Flexible Spending Account Notice* - Notify FSA participants of rules regarding withdrawal of funds before end of year. This law is unclear as to whether it applies in any situation other than a situation where an employee terminates mid-year and is subject to a short run out period. Regardless of when it applies, it must be provided in two forms, one of which can be electronic. See https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201920200AB1554 (as visited November 7, 2024).
- *Illinois Essential Health Benefits Comparison Chart* - The state DOL utilizes the employee's "base of operations" test to determine whether an employer and its employees are subject to this Act. Chart must be provided upon hire, <u>annually</u> thereafter, and upon request. See https://labor.illinois.gov/laws-rules/fls/consumer-coverage-disclosure-act.html; https://labor.illinois.gov/faqs/consumer-coverage-disclosure-faq.html; https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=4217&ChapterID=68 (as visited November 7, 2024).
- *Massachusetts HIRD Form* - Applicable to employers who employed 6 or more employees in Massachusetts in any month in the 12 months preceding the due date of the report (12/15/24). Must file no later than December 15, 2024, for 2024. See https://www.mass.gov/info-details/health-insurance-responsibility-disclosure-hird-faqs (as visited November 7, 2024).
- *2024 Form MA 1099-HC (early 2025)* - Furnish 1099-HC by January 31, 2025 to any Massachusetts residents (including COBRA enrollees) if they were covered at least one month with "creditable coverage" as defined by Massachusetts.
- *Vermont Health Care Contribution Fund* - File form WHT-436 with Department of Taxes by the 25th day after the quarter ends. No contributions owed for "uncovered" employees if you have less than 5 full-time equivalents working in Vermont. See https://tax.vermont.gov/business/hcfca (as visited November 7, 2024).
- *Washington Partner Access Line Assessment* - Insurers and employer sponsors of self-funded plans must pay a quarterly assessment for covered lives of Washington residents. The "Overview" section of the website states that quarterly filings are due April 30, July 30, October 30, and January 30, but the FAQs state that assessment payments are due within 45 days following the end of the quarter (i.e., February 15, May 15, August 15, and November 15). See https://www.wapalfund.org/ui/payers (as visited November 7, 2024).
- *San Francisco HCSO payments for those not enrolled in plan* - No later than 30 days after the end of the quarter for employers making health care expenditures to the City Option on behalf of HCSO-covered employees. See https://www.sf.gov/information/health-care-security-ordinance (as visited November 7, 2024).
- *San Francisco HCAO/ HAO "Know Your Rights" Form* - Applies only to employers of employees covered by SFO's Quality Standards Program (QSP). must be provided within the first pay period an employee becomes a QSP employee, and <u>annually</u> thereafter. Must use the latest form from the OLSE, links for which can be found at https://sf.gov/information/understanding-healthy-airport-ordinance (as visited November 7, 2024).

ALSTON & BIRD

ALSTON & BIRD

Questions

54