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HEALTH & WELFARE PLAN LUNCH GROUP

October 2, 2025

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October 2025 Health Benefits Update

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October 2025 Agenda

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- HIPAA Deep Dive: Recurring Issues
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Legislative and Regulatory Update

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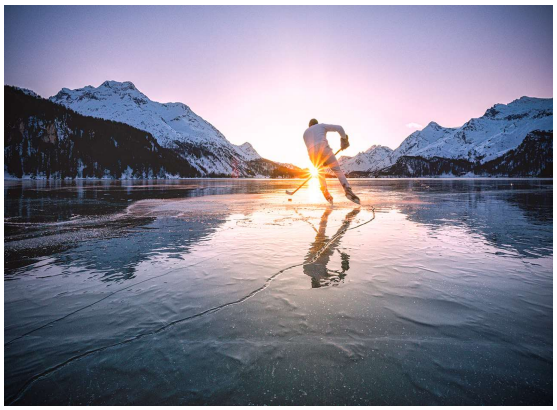
Regs on (Thin?) Ice



- **2024 Short-Term Limited Duration Insurance (STLDI) Regulations**:
  - Departments issued a statement of intent *not* "to prioritize enforcement actions" for violations related to failing to meet the definition of STDLI in the 2024 final rules, including the notice provision.
- **Mental Health Parity and Addiction Equity Act:**
  - **Nonenforcement policy:** Departments issued a Nonenforcement Policy and will not enforce the 2024 Final Rule or otherwise pursue enforcement actions, based on a failure to comply that occurs prior to a final decision in ERISA Industry Committee v. Department of Health and Human Services et al, plus an additional 18 months.
- **HIPAA Reproductive Health Care Final Rule:**
  - **Appeal Dismissed**: In **June 2025**, a Texas district court vacated most provisions of the Final Rule in *Purl v. HHS*, finding HHS exceeded its statutory authority On **September 10, 2025**, the Fifth Circuit dismissed an appeal by proposed intervenors, confirming the vacatur and ending the litigation.
  - **Surviving Portions of the Rule**: HIPAA Part 2 updates to the **Notice of Privacy Practices**. Compliance deadline: **February 16, 2026.**
  - No recent docket activity on *Texas v. HHS*.

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Semiannual Unified Agenda

- **Enhancing Coverage of Preventive Services under the Affordable Care Act**: [Proposed October 28, 2024; withdrawn January 25, 2025] (CMS, EBSA, and IRS)
- **Independent Dispute Resolution Operations** [Proposed November 3, 2023] (CMS and EBSA)
- **Making Technical Changes and Clarifying How OCR Addresses Conscience Authorities in Health Care; Delegation of Authority** (OCR)
- **Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability** (CMS)
- **Conspicuously absent**: Copay accumulator rule that would have addressed whether drug manufacturer cost assistance should count towards a patient's annual cost sharing limits.
  - Will HHS include it in its annual Notice of Benefit Payment Parameters rule?

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At the Office of Management and Budget (OMB)

These proposed rules are under review at OMB and are not yet publicly available:

- Proposed Rule: **Requirement to Provide Paper Statements in Certain Cases-Amendments to Electronic Disclosure Safe Harbors**, rec'd 9/30/2025 (DOL-EBSA)
- Proposed Rule: **Improving Transparency into Pharmacy Benefit Manager Fee Disclosure**, rec'd 9/10/2025 (DOL-EBSA)
- Proposed Rule: **Transparency in Coverage**, rec'd 8/21/2025 (HHS-CMS)
- Proposed Rule: **Global Benchmark for Efficient Drug Pricing (GLOBE) Model**, rec'd 09/25/2025 (HHS-CMS)

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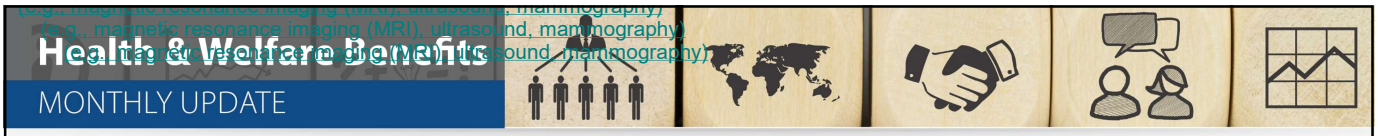
New Leadership at EBSA

- **Daniel Aronowitz confirmed as EBSA head.** During confirmation hearing, Aronowitz outlined goals, including:
  - **Improve Enforcement of Fiduciary Law**
    - End "open-ended investigations that go on for years."
    - End use of common-interest agreements with plaintiff lawyers.
  - **Provide Regulatory Clarity**
    - Move away from "regulation by litigation" by issuing clear, effective rules for employee benefit plans.
    - Pledge to "restore discretion to plan fiduciaries as Congress intended in the ERISA statute, so that fiduciaries, not the government or plaintiff lawyers, decide what is best for plan participants."
    - Modernize regulations in key areas, including mental health parity and cybersecurity protections.
  - **Champion Benefit Expansion**
    - Expand access to health benefits for independent contractors including through association health plans.



Updates: Health Resources and Services Administration (HRSA)

- **Effective for 2026:**
  - Additional imaging (e.g., MRI, ultrasound, mammography) or pathology required after initial screening.
  - Patient navigation services added: For breast and cervical cancer screening and follow-up, as relevant, to increase utilization of screening, based on patient's needs for navigation services. Patient navigation services involve person-to-person (e.g., in-person, virtual, hybrid models) contact with the patient.
- **Notice of Proposed New Guideline:**
  - HRSA Notice of Request for Comments on Draft Recommendations to Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Cervical Cancer. Comment Period ends 30 days after the date of publication in the F.R.
  - Women aged 30 to 65 years:
    - Primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not available, continue screening with cytology alone every 3 years.
    - Patient-collected hrHPV testing should be offered as an option for cervical cancer screening in women at average risk.
  - Women of all screening ages: If additional testing (e.g., cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services also are recommended.

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Newly Enacted Legislation

- **Effective Date: Plan years beginning after December 31, 2024 (effectively bridges existing arrangements)**
  - *Telehealth Exception for HSAs made permanent. (OBBBA)*
- **Effective Date: After December 31, 2025**
  - *Direct Primary Care (DPC)*: Direct primary care arrangements (up to $150 individual/$300 for two or more per month) compatible with HSA eligibility and an HSA-eligible expense. *(OBBBA)*
  - *Bronze and Catastrophic Exchange Plans*: These plans are now treated as HSA compatible irrespective of deductible level. *(OBBBA)*
  - DCAP benefits increased to $3750/$7500 (up from $2500/$5000) - no indexing. *(OBBBA)*
  - *Permanent extension for student loan repayment assistance*: CARES Act tax-free student loan repayment assistance under Code Section 127 of up to $5,250 annually. Adjusted for cost of living (after 2026). *(OBBBA)*
  - *Bicycle Commuter Benefit:* Provision for bicycle commuter benefit NOT extended beyond 12/31/2025. Inflation adjustments for other commuter benefits modified. *(OBBBA)*

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New Proposed Legislation

- H.R.5509 (text not yet available) Introduced 09/19/2025 by Allen, Rick W. [Rep.-R-GA-12] and referred to the House Committee on Education and Workforce
  - Would a amend ERISA to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.
- **Small Business Health Options Awareness Act of 2025** (H.R.5498) Introduced 9/18/25 by Rep. Van Duyne, Beth [R-TX-24]: Would require the Small Business Administration ("SBA") to provide more outreach and information about the availability of ICHRAs as a means for small businesses to deliver health care coverage for their employees. The press release for the bill states that "low awareness of this option has prevented more widespread utilization."
- **"Patients Deserve Price Tags Act" (**S. 2355) Introduced 7/17/25 by Sen. Marshall [R-KS].: Would amend ERISA and the PHSA to align with the gag clause rules.
- "**Workers' Disability Benefits Parity Act**" (H.R. 3758) Introduced 6/05/2025 by Rep. DeSaulnier [D-CA-10]: Would amend ERISA to establish parity in the treatment of behavioral health and physical health conditions under disability benefit plans.

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October Reminders

- Medicare Part D Creditable Coverage Notices: Required **before** October 15 annually
- Form 5500 Extension: File by October 15.

Health Benefits Litigation Update

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State PBM Litigation: Arkansas Rule 128

Cent. States v. McClain *(N.D. Ill., Sept. 2, 2025)*

- Plaintiffs (ERISA plan and trustee) challenged Rule 128 as preempted by ERISA.
- Court dismissed the case; Held Rule 128 is not preempted by ERISA
- Notice of appeal filed on September 30, 2025.
- Rule 128:
  - Requires all health benefit plans and healthcare payors (including self-funded and governmental plans) to submit pharmacy compensation information to the Arkansas Insurance Commissioner.
  - Commissioner reviews data to determine if reimbursements to pharmacies are "fair and reasonable." If not, Commissioner can require plan to pay additional pharmacy dispensing cost ("Dispensing Fee Requirement")

Key Findings:

- **Rule 128 applies broadly** to all health benefit plans and payors, not exclusively to ERISA plans (not exclusive to ERISA plans) → No "reference to" ERISA plans
- **Reporting Requirement:** Incidental to cost regulation, not central to ERISA plan administration (*Gobeille*)
- **Dispensing Fee Requirement:** Dispensing fee requirement is permissible because it regulates cost, and does not dictate plan design or coverage; follows *Rutledge* (state rate regulation affecting costs ≠ preemption)

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State PBM Laws: A Compliance Roadmap

- **Assess ERISA Preemption**: May be preempted if they govern central matters of plan admin. or interfere with nationally uniform administration.
- **Determine Applicability to Self-Funded Plans**: Read statute and rules, and defined terms carefully.
- **Determine whether Compliance/Enforcement Liability**: Do the enforcement provisions apply only to the PBM?
- **Assess HIPAA Issues:** Does the state PBM law require disclosure of PHI? Under which permitted use/disclosure would the request fall?
- **State-by-State Compliance:** If ERISA does not preempt, can the PBM administer the plan differently in a particular state?

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Telephone Consumer Protection Act (TCPA)

McLaughlin Chiropractic Associates Inc. et al. v. McKesson Corp. et al. (S.C., June 20, 2025)

- TCPA, among other restrictions, prohibits unsolicited fax ads to "telephone facsimile machines" unless an opt-out notice is provided.
- Class certification for all recipients was sought, whether they received faxes on traditional fax machines or online fax services.
- FCC issued order (while case was pending) interpreting the TCPA to exclude faxes received via online fax services.
- Held: District courts are not bound by an agency's interpretation and must independently interpret the statute, giving appropriate respect to the agency's view but not deferring to it as binding.

Action Items for Plan Sponsors:

- *Review third party administrator agreements for methods of outreach (text, fax, cell phone)*
- *Ensure proper consents are obtained if no exception applies*
- *Be mindful of how the healthcare exception applies to messages from covered entities--consent is still required and must be in advance and express*
- *Obtain indemnification from TPA if TPA is responsible for obtaining consent (penalties per violation: $500-$1500)*
- *Be mindful of TCPA-like state laws that may be more stringent and have additional penalties*

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Compliance Corner: HIPAA Top 10 Current Issues

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1. Documentation

- Do you have business associate agreements in place with all vendors with access to PHI?
  - Medical, Rx, Wellness
  - All third party administered health FSAs and HRAs
  - EAP Vendors
- Do YOU have . . .
  - Privacy and Security Policy and Procedures document
  - WRITTEN risk assessment

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Notice of Privacy Practices (NPP)

- Have you issued NPPs and updated them (reminder notice every three years).
  - February 2026: deadline to update NPP for HIPAA Part 2
  - In general, Part 2 protects Substance Use Disorder information obtained by any federally assisted program
- What updates need to be made to the HIPAA NPP for HIPAA Part 2?
  - HHS promised model language, which has not yet been issued.
  - On August 27, 2025, HHS's delegation of authority to the HHS Office for Civil Rights (OCR) to enforce the confidentiality of substance use disorder (SUD) patient records under 42 CFR Part 2 was published in Federal Register.

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2. Risk Analysis

- All e-PHI created, received, maintained or transmitted by an organization is subject to the Security Rule.
- Security Rule requires entities to:
  - evaluate risks and vulnerabilities in their environments
  - to implement reasonable and appropriate security measures to protect against reasonably anticipated threats or hazards to the security or integrity of e-PHI.
  - Risk analysis is the first step in that process.

Risk Analysis

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI held by the covered entity.
  - Identify e-PHI within your organization? This includes e-PHI that you create, receive, maintain or transmit.
  - What are the external sources of e-PHI? For example, do vendors or consultants create, receive, maintain or transmit e-PHI?
  - What are the human, natural, and environmental threats to information systems that contain e-PHI?

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Security Risk Assessment Tool

- The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with the HHS Office for Civil Rights (OCR), developed a downloadable Security Risk Assessment (SRA) Tool to help guide you through the process.
  - Security Risk Assessment Tool | HealthIT.gov

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3. Breach Reporting

- Privacy breaches involving less than 500 individuals occurring during the calendar year MUST be reported to HHS/OCR annually.
  - Check with BA to see if reporting
  - Recommend keeping an internal breach report
- File report within 60 days of the end of the calendar year – generally March 1
- This notice must be submitted electronically at: https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf?faces-redirect=true
- Sample Tracking Form
- https://ocrportal.hhs.gov/ocr/breach/doc/Breach_Portal_Questions_508.pdf

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4. Marketing – Reminders for Annual Enrollment

- A communication by covered entity (CE) or business associate (BA) that is about a product/service and encourages recipient to purchase or use same is NOT considered a Health Care Operation (HCO).
  - UNLESS it:
    - describes a health-related product/service (or payment for same) that is provided by or included in the plan of CE making communication;
    - is for treatment; or
    - is for case management or care coordination for the individual or to direct/recommend certain alternative treatments, therapies, health care providers, or settings of care to the individual.

Marketing (Continued)

- If a communication meets one of the exceptions in prior slide AND CE receives payment, directly or indirectly, for making such communication by a third party whose product is being described in the communication , then it is NOT an HCO
  - EXCEPT where:
    - The communication describes only a drug/biologic **currently prescribed** for recipient, AND
    - payment received by the CE is reasonably related to the cost of making the communication.

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Helpful FAQs

- Marketing | HHS.gov
- Marketing - Refill Reminders | HHS.gov

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5. Firewalls – Workforce Security

- Are you feeling a little "in" secure about your e-PHI?
- CEs and BAs are required to protect PHI and ePHI
- Implement policies and procedures to ensure that members of the workforce have appropriate access to PHI and E-PHI and to prevent those who should not have access from obtaining access.

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Suggested Compliance Tips

- Use security clearances, if appropriate, such as password protections for files containing E-PHI
- Consider role-based access to PHI database.
  - What if employee changes positions?
- Establish procedures to revoke terminated employee access to your information system, require employees to turn in key cards, keys or other methods of gaining access to your facilities and systems
- Think about whether a former employee might be able to access the system remotely.

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6. E-mails

- CEs and BAs are required by HIPAA to implement technical security measures to guard against unauthorized access to E-PHI that is being transmitted over an electronic communications network.
- Currently encryption of data is required you determine there was a high risk that E-PHI could be intercepted while being transmitted
- Recommend removing PHI from e-mails or using encryption when communicating
- Consider state data privacy laws

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7. EBSA Cybersecurity

- Reminder: DOL is now policing your cybersecurity compliance too!
- Cybersecurity guidance issued by EBSA applies to *all employee benefits plans*, including non-HIPAA welfare plans. Compliance Assistance Release No. 2024-01
- EBSA Cybersecurity Guidance has 3 parts:
  - **Tips for Hiring a Service Provider**: contains recommended RFP questions and contract terms for plan sponsors
  - **Cybersecurity Program Best Practices**:
    - Lists 12 cybersecurity best practices for service providers that EBSA would expect to see if auditing the plan or service provider.
    - States that pension and health and welfare plans are tempting targets for cyber criminals because the plans: (i) often hold millions of dollars in assets; and (ii) store and/or transfer participants' personally identifiable data.
  - **Online Security Tips**: Contains tips for participants and beneficiaries to reduce the risk of fraud.

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EBSA Cybersecurity

- EBSA is auditing cybersecurity practices of health and welfare plans and their service providers.
  - This includes *all welfare plan benefits* – not just health plans covered by HIPAA.
- EBSA thinks that ERISA plan fiduciaries have a duty under ERISA to prudently select a service provider with strong cybersecurity practices and monitor its activities.
- EBSA also thinks that responsible plan fiduciaries have an obligation to ensure proper mitigation of cybersecurity risks.
- EBSA expects plan fiduciaries to distribute the online security tips to plan participants and beneficiaries who check their plan information online.

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Cybersecurity

- EBSA also referred to HHS publications for health plans and their service providers to maintain good cybersecurity practices
  - Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients
  - Technical Volume 1: Cybersecurity Practices for Small Healthcare Organizations
  - Technical Volume 2: Cybersecurity Practices for Medium and Large Healthcare Organizations

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8. Proposed HIPAA Security Rules

HHS issued proposed HIPAA Security Rules on December 27, 2024

- Notable new administrative, physical, and technical safeguards
  - eliminates the distinction between "addressable" and "required" safeguards, so plans might find less flexibility
- New BA requirements and BAAs
- Requires written contingency plan for CE, BA and Plan Sponsors
- Plan amendment
- Compliance with most requirements will be required within 240 days after the Final Rule is published

9. Authorizations and Attestations

- ERISA 104(b) Requests
  - HIPAA authorization?
- Legal Requests from State Agencies – PBM Claims
  - HIPAA Reproductive Rights Attestations Required?

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10. HIPAA Individual Rights Requests

- HHS has issued new FAQ guidance
  - 2042-What personal health information do individuals have a right under HIPAA to access from their health care providers and health plans? | HHS.gov
- Clarifies that Individuals can only request access that the CE or BA maintains in a designated record set (DRS)
  - DRS includes medical records, billing records, payment and claims records, health plan enrollment records, case management records, as well as other records used, in whole or in part, by or for a CE to make decisions about individuals
- CE or BA is not required to create new information such as explanatory materials or analysis not already in the DRS
- CE or BA is not required to disclose information outside of DRS
  - Ex. an individual would not have the right to access internal memos related to the development of a formulary

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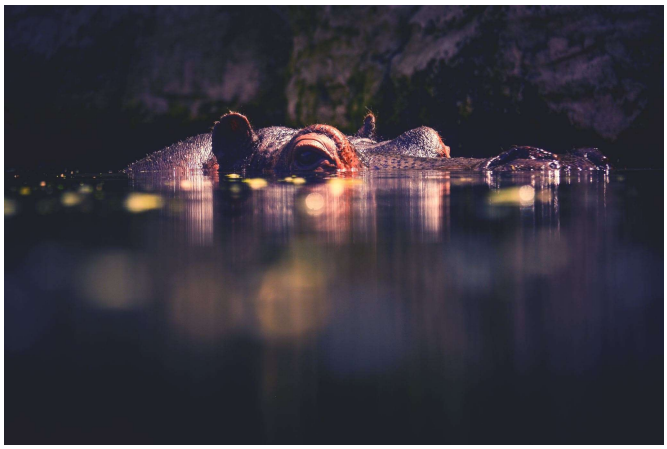
HIPAA Deep Dive: Recurring Issues



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Enrollment Data and HIPAA

- HIPAA's broad definition of PHI would include health plan enrollment data
  - Complicates Health plan administration for employer
    - Payroll deduction calculations
    - COBRA notices and communications
- Agency's practical approach
  - "Pure enrollment data" (name, coverage category, contribution amount) is not subject to HIPAA in employer/plan sponsor's hands
  - Pure enrollment data is PHI in hands of health plans, insurers, and service providers
  - What about pure enrollment data returned to employer
    - Likely not PHI
    - OCR may not understand nuance

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HIPAA and EOB Data

- EOB claims data is PHI
- Impact on claims administration and communications with employee/participant
- Agency's practical approach
  - Health plans must be able to send EOBs to policyholders. Sending EOB correspondence to a policyholder by a covered entity is a disclosure…but it is a disclosure for purposes of payment. Therefore, subject to the provisions [relating to] Confidential Communications, it is permitted even if it discloses to the policyholder protected health information about another individual.
  - Thus EOB data (Dr name, treatment date, dollar amount) can be shared with employee/participant/contract holder

HIPAA and Claims Data Mining

- PHI can be used for treatment, payment, and health care operations,
  - This (subject to required consents and other limitations such as GINA, etc.) will generally allow health data to be shared for wellness and disease management purposes
    - Check HIPAA privacy notice for scope
  - Is data being used for an impermissible plan/function
    - E.g., administration of a non-health plan (e.g., underwriting, claims, enrollment/disenrollment, etc.)

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HIPAA and Wellness Program Communications

- Communications regarding wellness programs and participation should be carefully reviewed for PHI and HIPAA compliance
  - Example: The ABC Corp health plan includes many features to encourage a healthy weight and lifestyle. More information can be obtained by . . .
  - Example: Your last several claims encounters indicate a predisposition to metabolic syndrome. Please contact [wellness program] for assistance . . .

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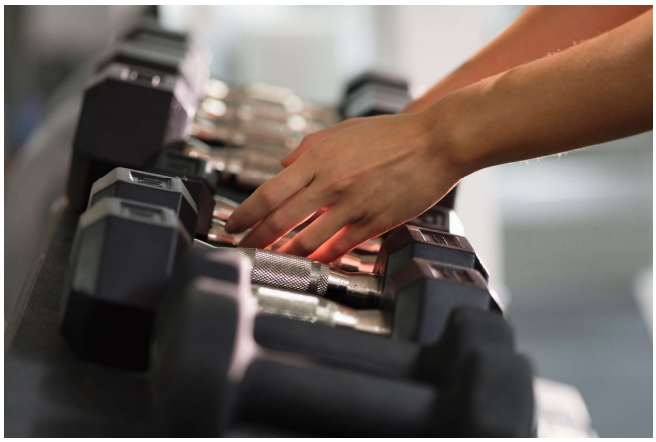
Compliance Issues: GLP-1s and Disease Management



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How to Combat High Costs?

- Medical management techniques
- Gatekeeper programs
- Annual or lifetime dollar limits
- Exclusions
  - Total exclusion
  - Condition based exclusions

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Legal Implications

- ADA---if a limitation or exclusion of GLP is tied to a specific condition, consider whether the condition is a disability
  - E.g. would a limitation imposed on GLP-1 for weight loss that is not imposed on GLP-1 use for other conditions an ADA issue?
- HIPAA non-discrimination---would any limit or exclusion tied to a condition violate HIPAA's prohibition against discrimination in benefits based on an individual's health condition
  - HIPAA permits condition-based limitations/exclusions so long as they apply equally to all similarly situated participants. In other words, you cant target.
  - Targeting is presumed if condition-based limitations/exclusions are implemented mid-year.
- ACA: if annual or lifetime dollar limits are imposed on GLP-1 drugs, consider whether the drugs are essential health benefits (EHBs).

Practical Implications

- Manufacturer/third party assistance may be available
  - But not everyone eligible for assistance
  - How do you properly facilitate?
- What long term impact does lowering the cost have on future expenditures?

Questions