




## **Track 1 – Session 6**

# **Retail Health Clinics: Innovations in Drive Through Health Care**

## About the Presenter...

**Barbara J. Zabawa, JD, MPH**, owns the Center for Health Law Equity LLC, a law firm dedicated to helping advance wellness. She also founded the nonprofit, Health Care That Matters, Inc. which recognizes and supports wellness efforts. Before starting her firm, she was Associate General Counsel and HIPAA Privacy Officer for a health insurer and led the Health Team for a large law firm. She is licensed to practice law in both Wisconsin and New York.



**Retail Health Clinics:  
Innovation in Drive-Through  
Health Care**

**2015 Health, Labor and  
Employment Law Institute**

Barbara J. Zabawa, JD, MPH  
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**Agenda**

- Retail and Onsite Clinic Background
- Scope of Practice
- Corporate Practice of Medicine/Fee Splitting
- ADA, GINA and EEOC Proposed Rules on ADA and Workplace Wellness Privacy/Security
- HIPAA Privacy in Retail & Onsite Clinics

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**What are Retail Health Clinics?**

- Ambulatory care sites
- Located in/associated with brand-name retailers
  - Pharmacies
  - Groceries
  - Big-box stores

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### What are Retail Health Clinics?

- Treat routine illnesses
  - Pharyngitis (strep throat)
  - Otitis Media (ear infections)
  - Acute Sinusitis (sinus infections)
  - Conjunctivitis (pink eye)
  - Urinary Tract Infections
- Also provide wellness services (vaccines, health screenings)

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### What are Retail Health Clinics?

- Emphasize convenience
  - Short/no wait times
  - Walk-in availability
- Extended weekday and weekend hours
- Fixed, transparent pricing
  - Posted on-site and online

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### What are Retail Health Clinics?

- Typically staffed by
  - Nurse Practitioners
  - Physician Assistants
- Some physician oversight
- Serve wide range of patients
  - Insured
  - Uninsured

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## What are Retail Health Clinics?

- Usually cost \$50,000 to \$250,000 to build out
- Between 150 to 250 sq. ft.
- Can generate revenues of \$500,000/yr
- Typically see 10-30 patients/day
- Out-of-pocket cost: \$45-\$75/visit

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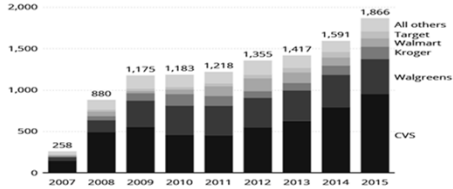
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## Retail Health Clinic Statistics

### The Drugstore Will See You Now

Major pharmacy chains and big box retailers like Walmart are looking to draw customers by offering health care services. Since 2007, the number of clinics at these stores increased more than sevenfold.

Retail clinics at the start of the year



Notes: Walmart locations include primary care clinics and basic care clinics operated as joint ventures. Walgreens also operates clinics inside the company's Duane Reade stores. The Little Clinic offers medical care at Kroger brands, including Fry's Food Stores, King Soopers and JayC Food Stores. Source: Merchant Medicine

THE HUFFINGTON POST

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## Retail Health Clinic Statistics

- Increasing number of visits
  - From 2006 to 2014, increased from 1.5M to 10.5M
- Cost of care lower
  - Retail clinic visit: \$110
  - Physician office: \$166
  - Urgent care: \$156
  - Emergency Dept.: \$570

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## Retail Health Clinic Statistics

- Recent study found, compared to Ambulatory Care Facility and ED:
  - *Superior overall quality of care*
- Survey found 90% satisfaction with quality and cost of care

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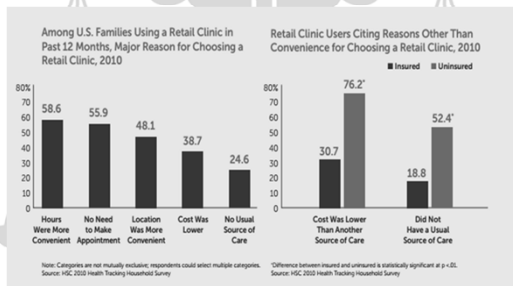
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## Retail Health Clinic Statistics



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## Onsite Clinics

- Offered by employers
- Care limited to employees, eligible retirees, and dependents
- May offer full range of primary care and occasionally specialist care
- Services may be free or have cost-sharing
  - E.g., \$25 fee or co-pay amount.

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## Onsite Clinic Statistics

- Old worksite clinics being repurposed:
  - Moving from occupational health to primary care and health promotion.
    - Wellness activities include:
      - HRAs
      - Disease management programs
      - Flu shots
      - Behavioral counseling
      - Health coaching
      - Fitness programs
      - Smoking and nutrition clinics

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## Onsite Clinic Statistics

- 24% of employers with 3000+ employees offer onsite clinics
- 14% with 100 to 2,999 employees offer
- 9% offer with <100 employees
- Smaller employers partner with nearby companies to operate “near-site” clinics.

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## Onsite Clinic Statistics

- According to Alliance survey of Wisconsin self-insured employers, onsite clinics provide:
  - Better management of chronic conditions
  - Earlier treatment of illness/injury
  - Fewer ER visits
  - Improved productivity
  - Reduced absenteeism
  - Reinforcement of wellness culture
  - Improved recruitment/retention

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## Blending of Retail and Onsite Clinics

- The focus on prevention and wellness is creating overlap between retail clinic and onsite clinic offerings.
  - Walgreens/Premise Health operate worksite health centers
    - Promote programs to improve health and costs
  - QuadMed clinics in Walmart
    - Serves both community and Walmart employees
  - 57% employer health plans cover retail health clinics
    - Treat minor illnesses/provide preventive services

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## Scope of Practice

- Retail and Onsite clinics staffed by Nurse Practitioners and Physician Assistants
- Nurse Practitioners (Advanced Practice Nurse Prescriber (APNPs))
  - Wis. Stat. s. 441.16; Wis. Admin. Code N ch. 8
- Physician Assistants (PAs)
  - Wis. Stat. s. 448.21; Wis. Admin. Code Med ch. 8

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## Scope of Practice

- APNPs
  - Registered Nurse with additional training and prescription authority.
    - May not issue schedule I controlled substances
    - May not issue certain schedule II controlled substances except in limited circumstances identified in Wis. Admin. Code s. N. 8.06(3)
    - May not prescribe steroids for athletic performance enhancing activities.

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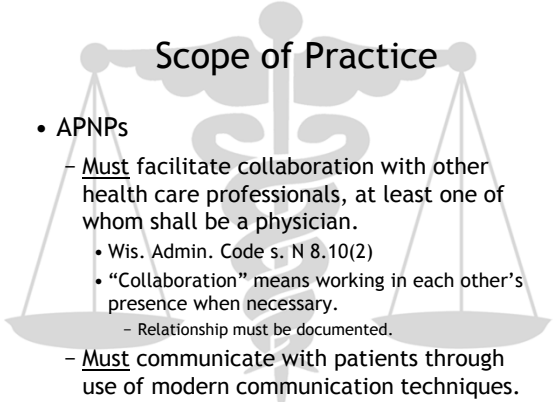
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### Scope of Practice

- APNPs
  - **Must** facilitate collaboration with other health care professionals, at least one of whom shall be a physician.
    - Wis. Admin. Code s. N 8.10(2)
    - “Collaboration” means working in each other’s presence when necessary.
      - Relationship must be documented.
  - **Must** communicate with patients through use of modern communication techniques.

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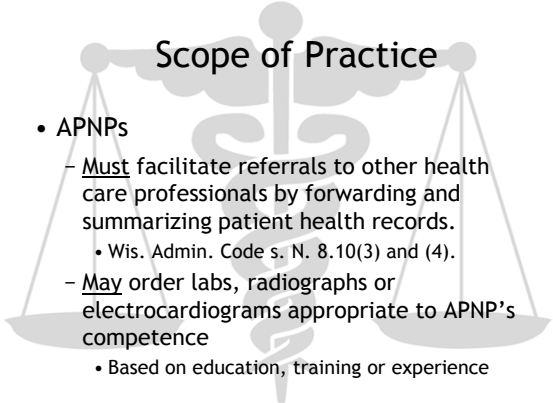
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### Scope of Practice

- APNPs
  - **Must** facilitate referrals to other health care professionals by forwarding and summarizing patient health records.
    - Wis. Admin. Code s. N. 8.10(3) and (4).
  - **May** order labs, radiographs or electrocardiograms appropriate to APNP’s competence
    - Based on education, training or experience

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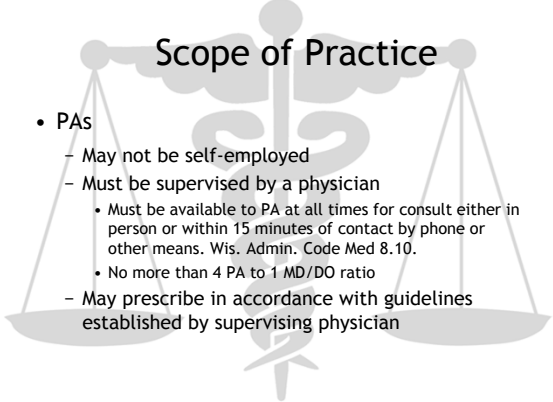
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### Scope of Practice

- PAs
  - May not be self-employed
  - Must be supervised by a physician
    - Must be available to PA at all times for consult either in person or within 15 minutes of contact by phone or other means. Wis. Admin. Code Med 8.10.
    - No more than 4 PA to 1 MD/DO ratio
  - May prescribe in accordance with guidelines established by supervising physician

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## Corporate Practice of Medicine

- “No person may practice medicine and surgery, or attempt to do so or make a representation as authorized to do so, without a license to practice medicine and surgery granted by the board.”
  - Wis. Stat. s. 448.03(1).

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## Corporate Practice of Medicine

- Exceptions:
  - Professional Service Corporation
    - Wis. Stat. s. 180.1901
  - General Partnership
    - Wis. Stat. ss. 448.08(4), 448.56(3) and 448.67(4)
  - LLCs/LLPs
    - Medical Examining Board position statement change; Injured Patient & Families Compensation Form change in 2005 Act 36
  - Hospitals Wis. Stat. s. 448.08(5)
  - Cooperatives Wis. Stat. s. 185.981
  - Defined Network Plans Wis. Stat. s. 609.01(1b)

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## Fee Splitting

- Also poses challenges for companies to employ physicians.
- Wis. Stat. s. 448.08(1m):
  - “Except as otherwise provided in this section, no person licensed or certified under this subchapter may give or receive, directly or indirectly, to or from any person, firm or corporation any fee, commission, rebate or other form of compensation or anything of value for sending, referring or otherwise inducing a person to communicate with a licensee in a professional capacity, or for any professional services not actually rendered personally or at his or her direction.”

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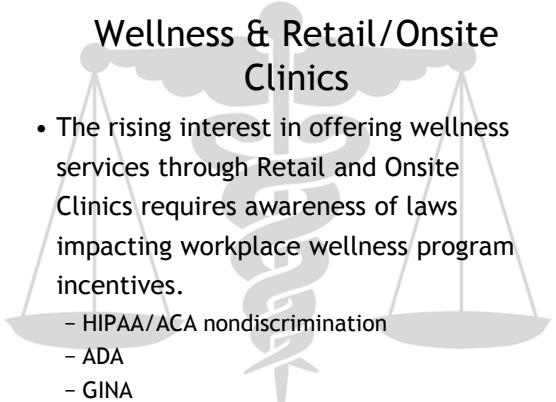
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## Wellness & Retail/Onsite Clinics

- The rising interest in offering wellness services through Retail and Onsite Clinics requires awareness of laws impacting workplace wellness program incentives.
  - HIPAA/ACA nondiscrimination
  - ADA
  - GINA

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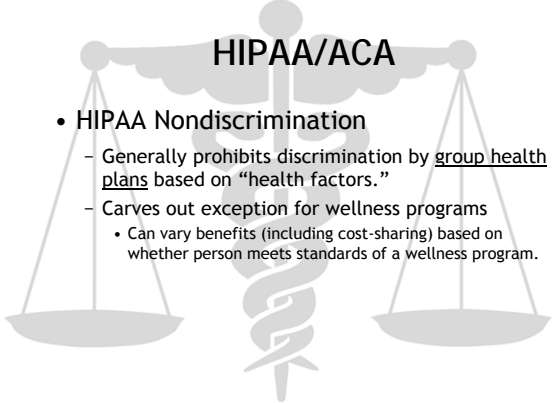
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## HIPAA/ACA

- HIPAA Nondiscrimination
  - Generally prohibits discrimination by group health plans based on “health factors.”
  - Carves out exception for wellness programs
    - Can vary benefits (including cost-sharing) based on whether person meets standards of a wellness program.

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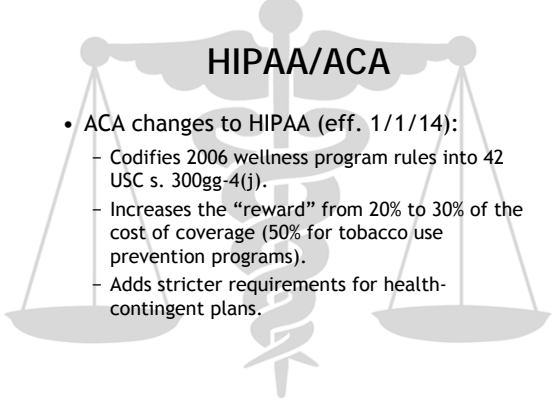
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## HIPAA/ACA

- ACA changes to HIPAA (eff. 1/1/14):
  - Codifies 2006 wellness program rules into 42 USC s. 300gg-4(j).
  - Increases the “reward” from 20% to 30% of the cost of coverage (50% for tobacco use prevention programs).
  - Adds stricter requirements for health-contingent plans.

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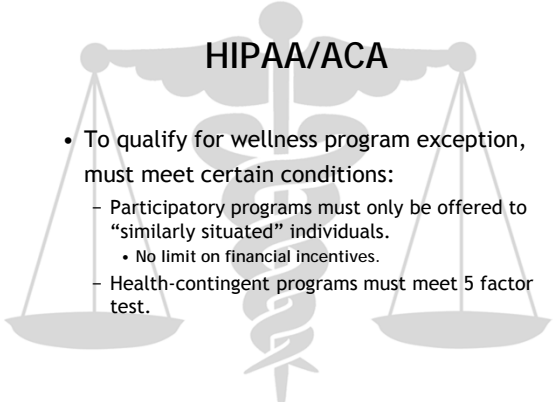
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**HIPAA/ACA**

- To qualify for wellness program exception, must meet certain conditions:
  - Participatory programs must only be offered to “similarly situated” individuals.
    - No limit on financial incentives.
  - Health-contingent programs must meet 5 factor test.



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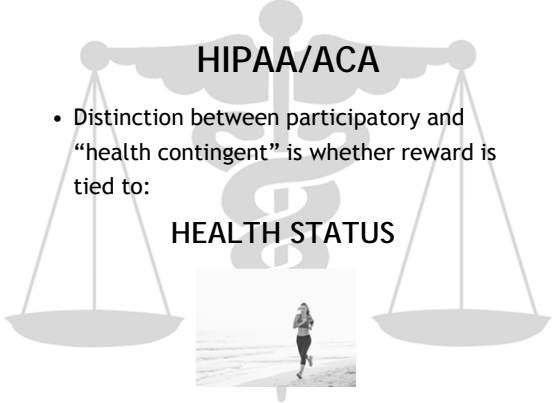
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**HIPAA/ACA**

- Distinction between participatory and “health contingent” is whether reward is tied to:  
**HEALTH STATUS**



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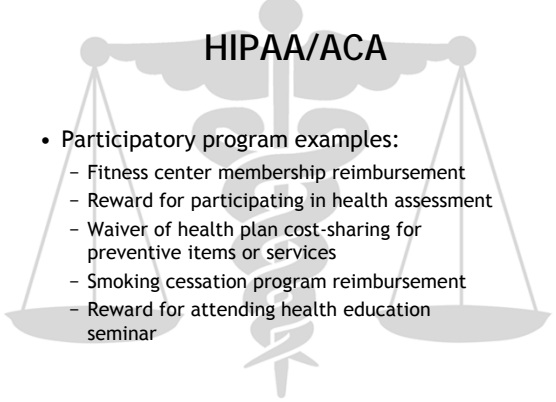
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**HIPAA/ACA**

- Participatory program examples:
  - Fitness center membership reimbursement
  - Reward for participating in health assessment
  - Waiver of health plan cost-sharing for preventive items or services
  - Smoking cessation program reimbursement
  - Reward for attending health education seminar



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## HIPAA/ACA

- Two types of health-contingent programs:
  - Activity
    - May seek verification from physician that health factor makes it unreasonably difficult or medically inadvisable to satisfy activity.
  - Outcomes-based
    - May not seek verification
- *Both must meet 5 factor test.*

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## HIPAA/ACA

- Examples of Activity-Only:
 



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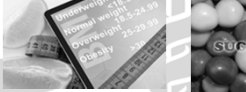

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## HIPAA/ACA

- Examples of Outcomes-based:
 

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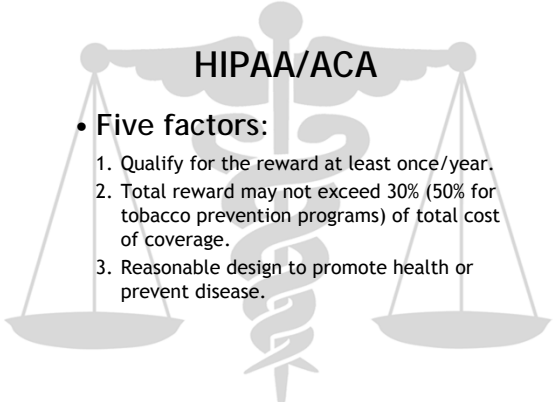
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**HIPAA/ACA**

- **Five factors:**
  1. Qualify for the reward at least once/year.
  2. Total reward may not exceed 30% (50% for tobacco prevention programs) of total cost of coverage.
  3. Reasonable design to promote health or prevent disease.

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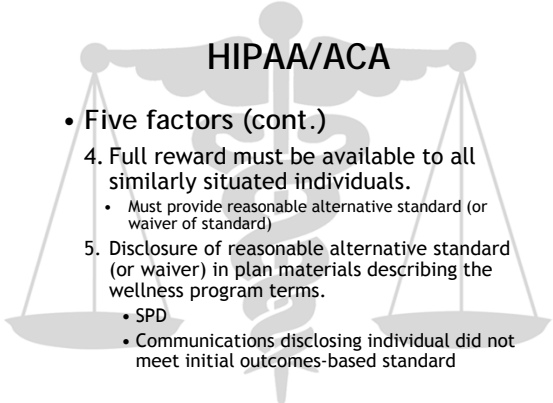
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**HIPAA/ACA**

- **Five factors (cont.)**
  4. Full reward must be available to all similarly situated individuals.
    - Must provide reasonable alternative standard (or waiver of standard)
  5. Disclosure of reasonable alternative standard (or waiver) in plan materials describing the wellness program terms.
    - SPD
    - Communications disclosing individual did not meet initial outcomes-based standard

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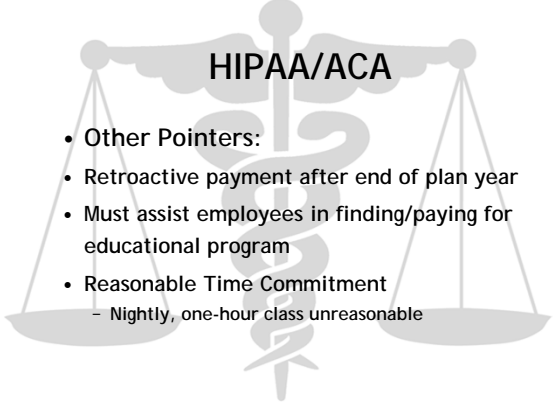
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**HIPAA/ACA**

- **Other Pointers:**
  - Retroactive payment after end of plan year
  - Must assist employees in finding/paying for educational program
  - Reasonable Time Commitment
    - Nightly, one-hour class unreasonable

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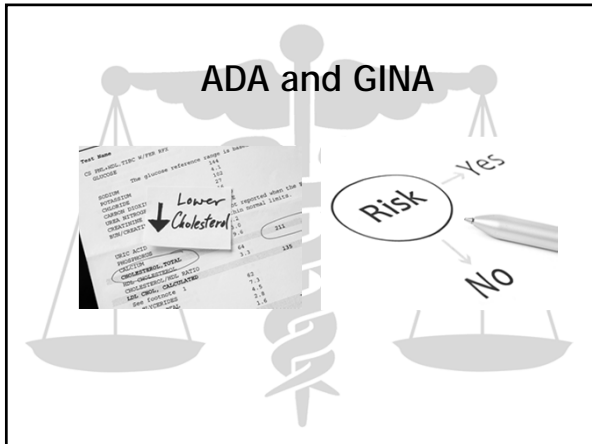
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### ADA

- Prohibits discrimination by employers on basis of disability in regard to terms, conditions and privileges of employment.
  - Discrimination includes:
    - Requiring medical examinations; and
    - Making inquiries as to whether employee has disability unless such exam or inquiry is:
      - Job-related and consistent with business necessity
- Must provide equal opportunity for disabled employees to participate in programs and offer reasonable accommodations.

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### ADA

- Medical exams include:
  - Procedures
  - Tests
- That seek information on an employee's health
- Prohibition applies regardless of whether employee is disabled.

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**ADA**

- Carves out exception for “voluntary” medical exams part of employee wellness program.
  - Pre-EEOC proposed rules, EEOC Enforcement Guidance said wellness program is voluntary as long as employer neither:
    - Requires participation; nor
    - Penalizes employees who do not participate.

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**ADA**

- Safe harbor for administering terms of bona fide benefit plan
  - Based on underwriting risks, classifying risks or administering such risks.
  - Applies whether exam/inquiry is voluntary or not.
  - *Seff v. Broward County*, 691 F.3d 1221 (11<sup>th</sup> Cir. 2012).

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**ADA**

- Requires confidentiality of medical exam/disability inquiry records.
- Must use separate forms and keep in separate medical files.
  - Accessing employee health information directly through personnel file no different than asking about health status.

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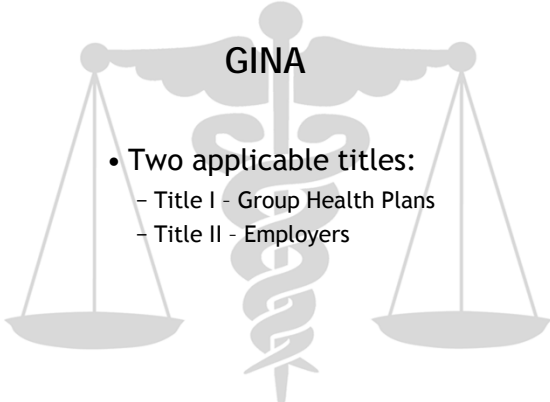
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**GINA**

- Two applicable titles:
  - Title I - Group Health Plans
  - Title II - Employers

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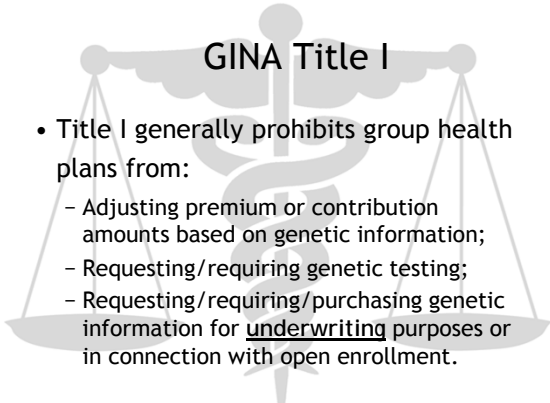
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**GINA Title I**

- Title I generally prohibits group health plans from:
  - Adjusting premium or contribution amounts based on genetic information;
  - Requesting/requiring genetic testing;
  - Requesting/requiring/purchasing genetic information for underwriting purposes or in connection with open enrollment.

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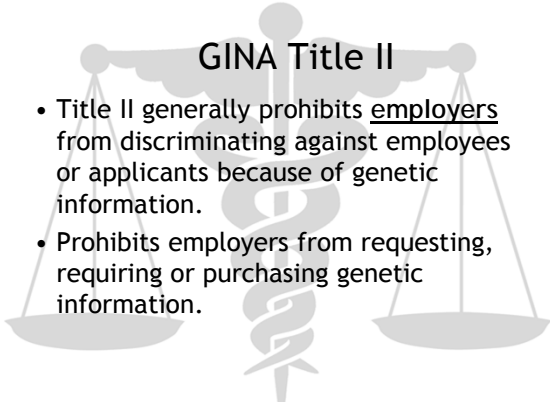
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**GINA Title II**

- Title II generally prohibits employers from discriminating against employees or applicants because of genetic information.
- Prohibits employers from requesting, requiring or purchasing genetic information.

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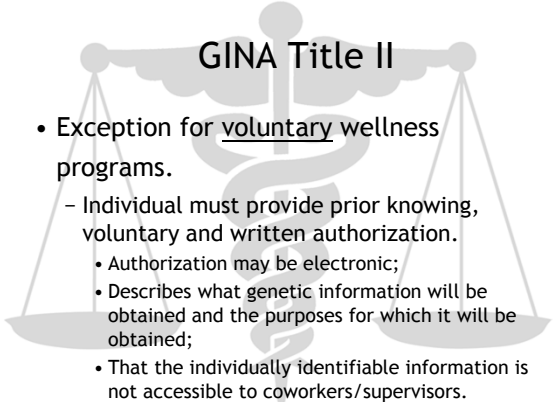
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**GINA Title II**

- Exception for voluntary wellness programs.
  - Individual must provide prior knowing, voluntary and written authorization.
    - Authorization may be electronic;
    - Describes what genetic information will be obtained and the purposes for which it will be obtained;
    - That the individually identifiable information is not accessible to coworkers/supervisors.

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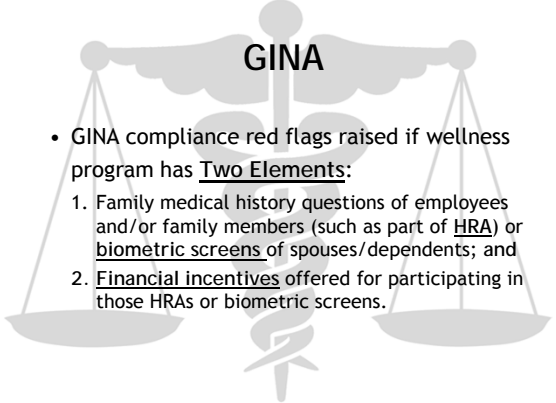
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**GINA**

- GINA compliance red flags raised if wellness program has Two Elements:
  1. Family medical history questions of employees and/or family members (such as part of HRA) or biometric screens of spouses/dependents; and
  2. Financial incentives offered for participating in those HRAs or biometric screens.

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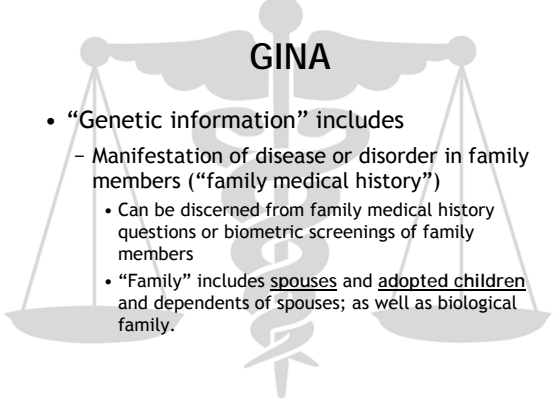
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**GINA**

- “Genetic information” includes
  - Manifestation of disease or disorder in family members (“family medical history”)
    - Can be discerned from family medical history questions or biometric screenings of family members
    - “Family” includes spouses and adopted children and dependents of spouses; as well as biological family.

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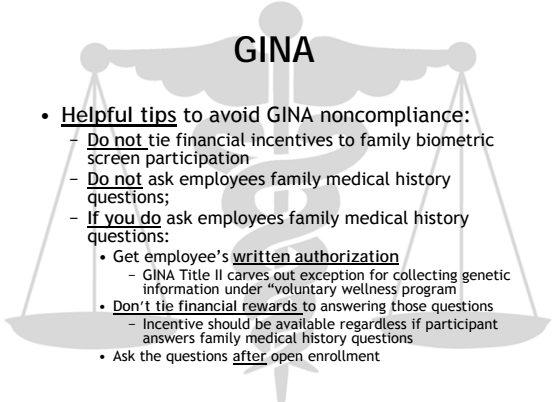
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## GINA

- **Helpful tips** to avoid GINA noncompliance:
  - **Do not** tie financial incentives to family biometric screen participation
  - **Do not** ask employees family medical history questions;
  - **If you do** ask employees family medical history questions:
    - Get employee's **written authorization**
      - GINA Title II carves out exception for collecting genetic information under "voluntary wellness program"
    - **Don't tie financial rewards** to answering those questions
      - Incentive should be available regardless if participant answers family medical history questions
    - Ask the questions **after** open enrollment

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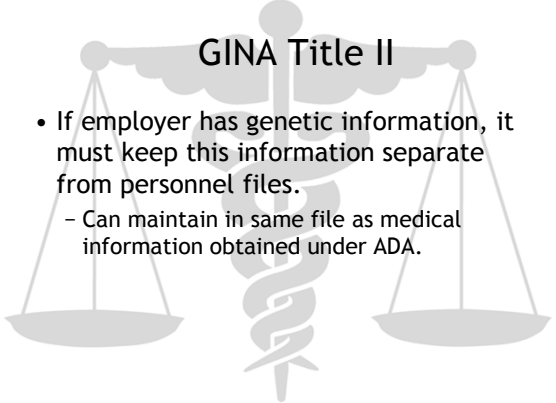
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## GINA Title II

- If employer has genetic information, it must keep this information separate from personnel files.
  - Can maintain in same file as medical information obtained under ADA.

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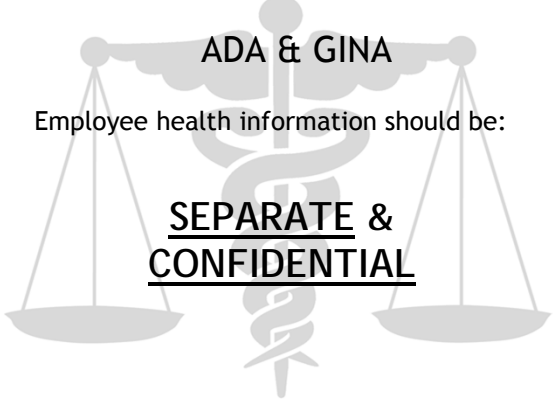
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## ADA & GINA

Employee health information should be:

**SEPARATE & CONFIDENTIAL**

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## EEOC Proposed ADA Rules

- Three primary changes:
  1. Aligns ADA with ACA by imposing 30% incentive
  2. Imposes incentive limit on participatory programs
  3. Requires employee notice and privacy/security protections with regard to wellness information

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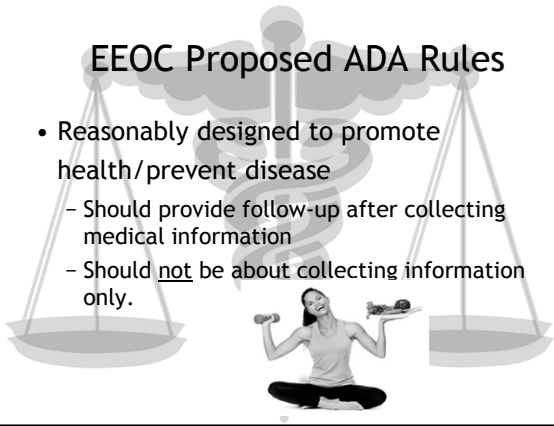
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## EEOC Proposed ADA Rules

- Reasonably designed to promote health/prevent disease
  - Should provide follow-up after collecting medical information
  - Should not be about collecting information only.



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## EEOC Proposed ADA Rules

- Must provide reasonable accommodations (Equal Opportunity)



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## EEOC Proposed ADA Rules

Equal Opportunity applies to both participatory and health contingent programs



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## EEOC Proposed ADA Rules

- Compliance with ADA rules does not mean compliance with other laws:
  - Title VII
  - Equal Pay Act
  - ADEA
  - GINA
  - Other ADA sections
- Proposed rules to align GINA with ACA incentive rules forthcoming (presumably)

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## EEOC Proposed ADA Rules

- Programs that collect medical information must provide employees with notice.



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## EEOC Proposed ADA Rules

- Employers and vendors must protect health information confidentiality



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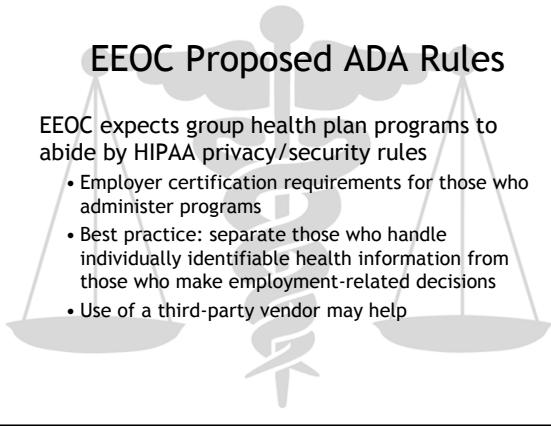
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## EEOC Proposed ADA Rules

EEOC expects group health plan programs to abide by HIPAA privacy/security rules

- Employer certification requirements for those who administer programs
- Best practice: separate those who handle individually identifiable health information from those who make employment-related decisions
- Use of a third-party vendor may help



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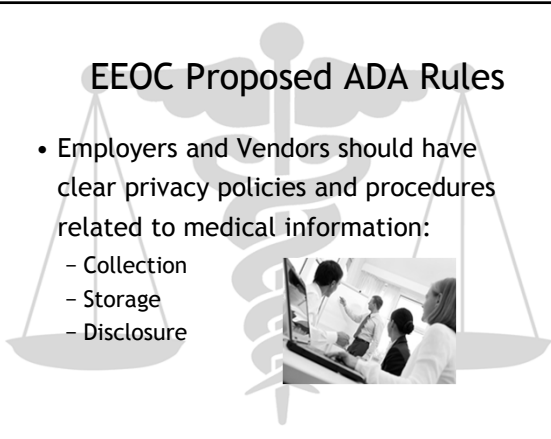
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## EEOC Proposed ADA Rules

- Employers and Vendors should have clear privacy policies and procedures related to medical information:

- Collection
- Storage
- Disclosure



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### EEOC Proposed ADA Rules

- Discusses proper training of individuals who handle medical information:
  - HIPAA
  - ADA
  - Other privacy laws
- Discipline employees who improperly disclose health information.
- Terminate vendors responsible for breaches of confidentiality.

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### EEOC Proposed ADA Rules

- Online systems/technology should guard against unauthorized access:
  - Encryption
- Employers that administer own wellness program need firewalls to prevent unintended disclosures.
- Report and investigate breaches.

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### EEOC Proposed ADA Rules

**IF COVERED BY HIPAA  
PRIVACY/SECURITY RULE,  
FOLLOW IT!**



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## HIPAA Privacy

The HIPAA Privacy Regulations protect “Protected Health Information” or “PHI.”

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## HIPAA Privacy

PHI is “Individually Identifiable Health Information” that is transmitted or maintained in any form or medium.

- PHI excludes:
  - education records
  - student medical records
  - employment records

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## HIPAA Privacy Applies to Covered Entities

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**HIPAA Privacy**

**Covered Entities:**

- Health Plans
- Providers who conduct one or more of the HIPAA-defined transactions electronically
  - KEY: HIPAA does not apply to entities that don't engage in covered electronic transactions
- Clearinghouses

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**HIPAA Privacy**

- Health Plans
  - Individual
  - Group
    - Must provide “medical care” directly or through insurance.
    - Group health plans must have 50+ participants or be administered by TPA.
    - Excepted benefits are not health plans.

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**HIPAA Privacy**

- What is “medical care?”
  - Amounts paid for:
    - a. diagnosis, cure, mitigation, treatment, or prevention of disease;
    - b. the purpose of affecting any structure or function of the body;
    - c. transportation primarily for and essential to purposes (a) or (b); or
    - d. insurance covering (a) or (b).

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### HIPAA Privacy

- Examples of “health plans” in wellness context:
  - Wellness program offered by health insurer;
  - Wellness program offered by Medicare or Medicaid;
  - Wellness program offered by employer as part of its employee health coverage plan;
  - Wellness program that provides “medical care” to more than 50 participants.

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### HIPAA Privacy

- Who are “Providers?”
  - Any person or organization who furnishes, bills, or is paid for health care in the normal course of business, AND
  - Who transmits any health information in electronic form in a “covered transaction” directly or through a business associate.

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### HIPAA Privacy

- What is “health care?”
  - Care, services, or supplies related to the health of an individual, including:
    - Preventive
    - Diagnostic
    - Therapeutic
    - Maintenance
    - Counseling
    - Assessment
  - With respect to the physical or mental condition, functional status of an individual or that affects the structure or function of the body.

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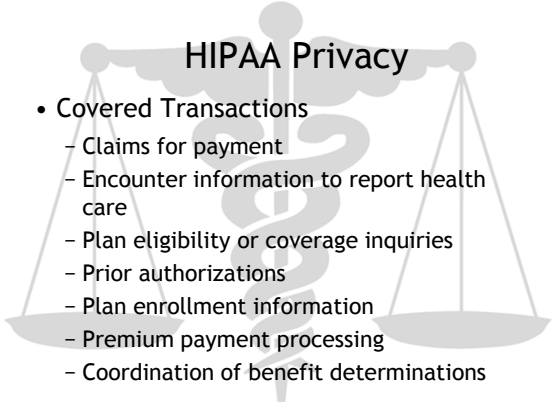
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### HIPAA Privacy

- Covered Transactions
  - Claims for payment
  - Encounter information to report health care
  - Plan eligibility or coverage inquiries
  - Prior authorizations
  - Plan enrollment information
  - Premium payment processing
  - Coordination of benefit determinations

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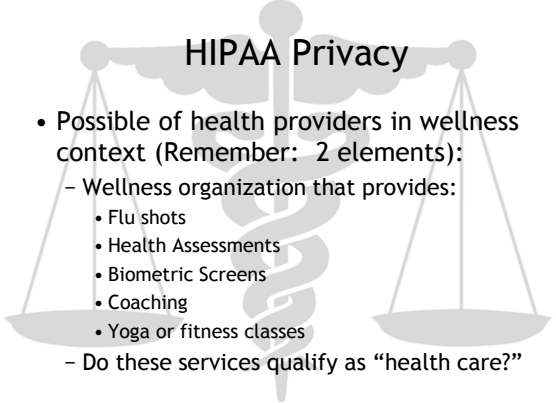
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### HIPAA Privacy

- Possible of health providers in wellness context (Remember: 2 elements):
  - Wellness organization that provides:
    - Flu shots
    - Health Assessments
    - Biometric Screens
    - Coaching
    - Yoga or fitness classes
  - Do these services qualify as “health care?”

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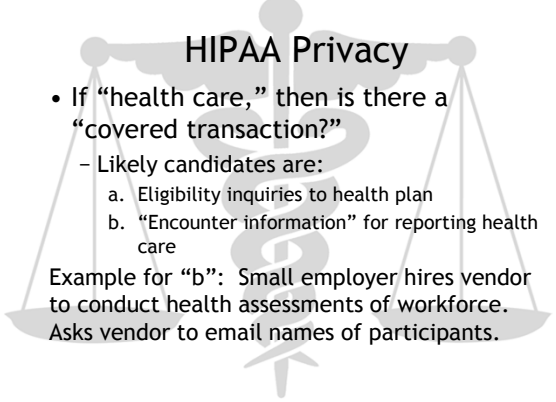
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### HIPAA Privacy

- If “health care,” then is there a “covered transaction?”
  - Likely candidates are:
    - a. Eligibility inquiries to health plan
    - b. “Encounter information” for reporting health care

Example for “b”: Small employer hires vendor to conduct health assessments of workforce. Asks vendor to email names of participants.

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**HIPAA Privacy**

Covered Entity - Provider status will likely hinge on whether you conduct a “covered transaction.”




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**HIPAA Privacy**

Many parts also apply to:

**Business Associates**




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**HIPAA Privacy**

What is a “Business Associate?”

- Not a member of the CE's workforce who, with respect to a CE:
  1. Performs a function or activity using individually identifiable health information involving:
    - Claims processing or administration
    - Data analysis, processing or administration
    - Utilization review
    - QA
    - Billing
    - **Benefit management**
    - Practice management
    - Repricing

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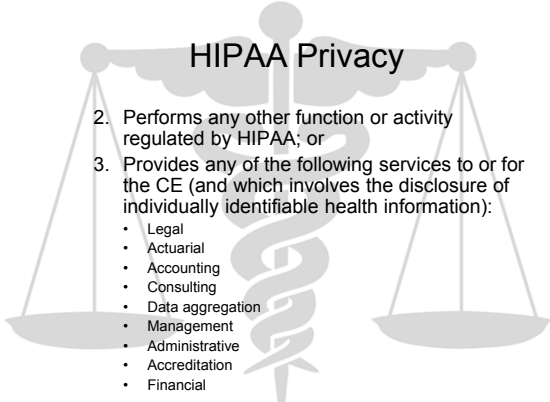
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**HIPAA Privacy**



2. Performs any other function or activity regulated by HIPAA; or
3. Provides any of the following services to or for the CE (and which involves the disclosure of individually identifiable health information):
  - Legal
  - Actuarial
  - Accounting
  - Consulting
  - Data aggregation
  - Management
  - Administrative
  - Accreditation
  - Financial

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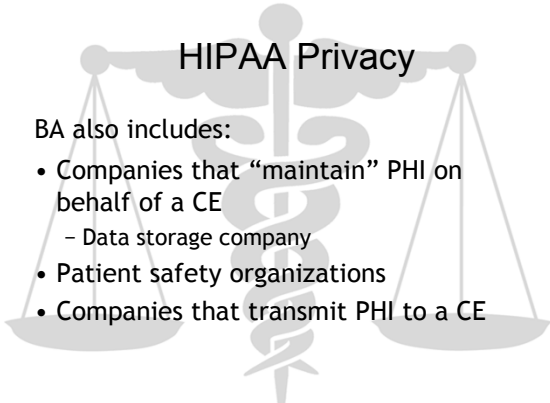
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**HIPAA Privacy**



BA also includes:

- Companies that “maintain” PHI on behalf of a CE
  - Data storage company
- Patient safety organizations
- Companies that transmit PHI to a CE

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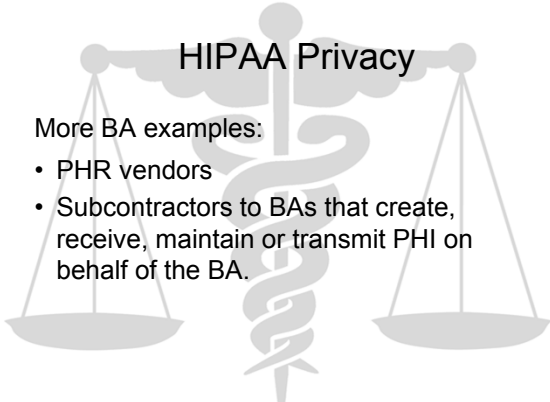
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**HIPAA Privacy**



More BA examples:

- PHR vendors
- Subcontractors to BAs that create, receive, maintain or transmit PHI on behalf of the BA.

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### HIPAA Privacy

- Wellness vendors most likely subject to HIPAA either as a:
  - Provider (Covered Entity)
    - Covered transaction key
  - Business Associate
- Workplace wellness programs most likely “health plans.”

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### Confused?



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### Case Example 1

- WECare Plan contracts with WellWays, a wellness vendor, to provide health assessment and biometric screens of plan participants. No follow-up with participant will occur. WellWays will only provide results. Is WellWays subject to HIPAA, and if so, how?

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### Case Example 2

- WellWays contracts with ACME, Inc. to provide diet and fitness services at ACME's onsite clinic. Employees interested in attending just show up; no preregistration is required. Is WellWays subject to HIPAA and if so, how?

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### Case Example 3

- ACME, an employer with 25 employees, contracts with WellWays to administer flu shots to its employees. ACME pays WellWays based on the number of shots administered. Employees volunteer to receive the shots (no incentives). WellWays administers the program, and collects and keeps the records of who received the shots. Is WellWays subject to HIPAA, and if so, how?

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### Case Example 5

- St. Mary's Hospital hires WellWays to offer health coaching and fitness classes to its health plan participants who are over a certain BMI. Participants who attend coaching sessions and/or fitness classes will have a lower premium payment. Is WellWays subject to HIPAA, and if so, how?

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## Subject to HIPAA - So What?

### Covered Entities:

- HIPAA Privacy and Security Policies & Procedures
- HIPAA Privacy and Security Official
- Notice of Privacy Practices
- Patient Authorizations
- Business Associate Agreements
- Minimum Necessary Standards
- Breach Standards
- Plan Sponsor Disclosure Standards
- Marketing Standards

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## Subject to HIPAA - So What?

### Business Associates must:

- Comply with the Business Associate Agreement (BAA)
- Comply with HIPAA Security Rule
  - Implement HIPAA Security Policies and Procedures
- Enter into a BAA with their subcontractors.
- Cooperate with government investigations into HIPAA compliance
- Designate a Security Official
- Notify CE's of breaches

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## Subject to HIPAA - So What?

### What do Privacy and Security Policies Cover?

Privacy	Security
Passwords	Internet Use
Email Use	Email Use
Access to PHI	Workforce Access
Employee Training	Facility Security
BAAs	Risk Analysis
Employee Discipline	Data Backup
Breaches	BAAs
Authorizatons	Breaches

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## Subject to HIPAA - So What?

- Plan Sponsor Disclosure Standards
  - CEs may disclose PHI, without patient authorization, to plan sponsor that administers aspects of plan if:
    - Employer certifies to plan it will safeguard PHI and not improperly use or share it.
  - CEs may disclose de-identified, aggregate information from wellness program to employer.

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## Subject to HIPAA - So What?

- Willful Neglect:
  - “The conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.”
  - 45 CFR s. 160.401

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## Questions?

- For more information, contact:  
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