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Regulatory and Compliance Issues with Employer On-Site Clinics



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Agenda

- **Introduction**
- **On-site Clinic Considerations and Decision Points**
- **Compliance Issues Related to On-site Clinics**
 - ERISA
 - COBRA
 - HIPAA
 - HSAs
 - Other Laws





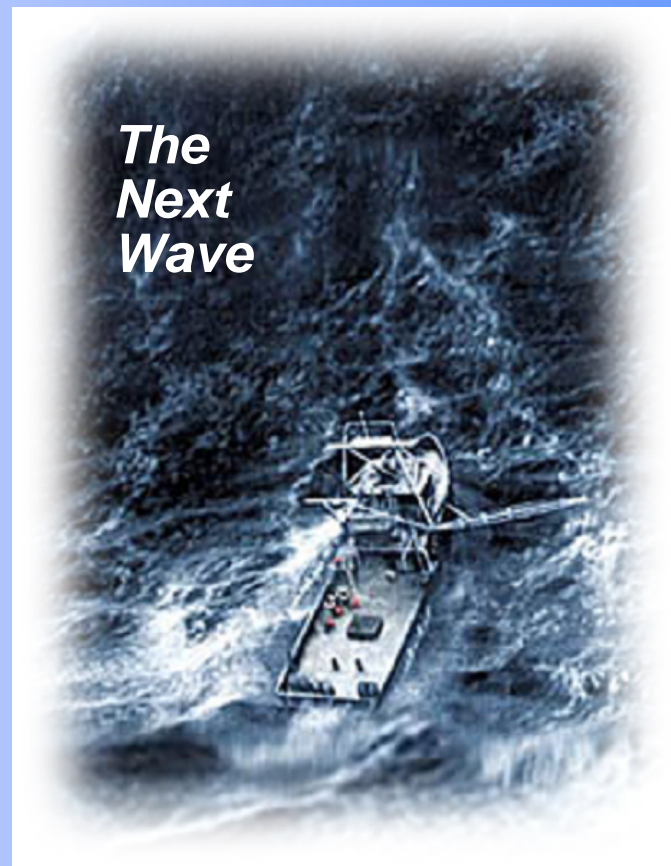
Introduction



The Perfect Storm

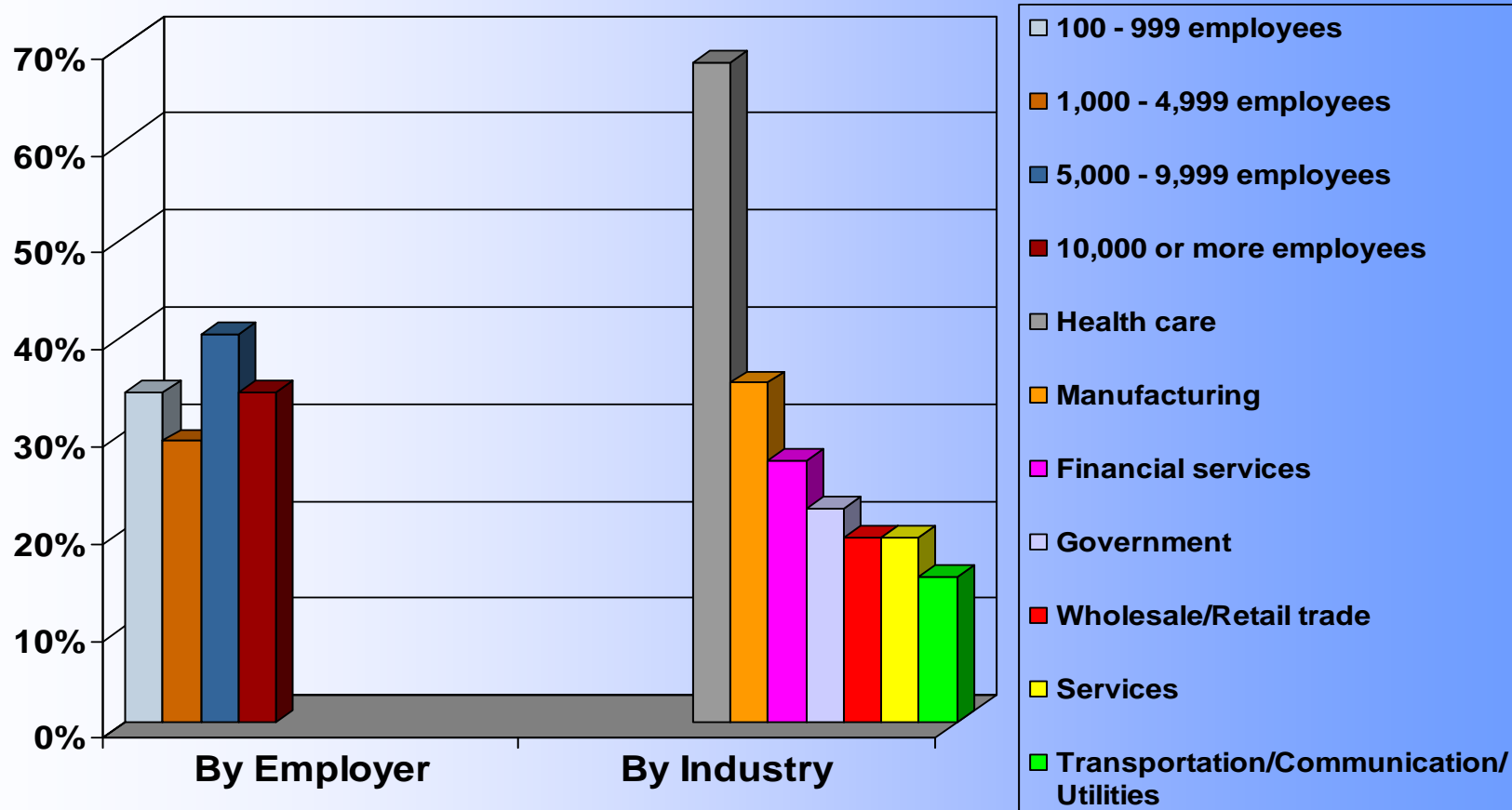
Factors driving the resurgence of on-site clinics

- Contributors to the popularity of on-site clinics
 - Increasing employee out-of-pocket costs
 - Employees face heavy stressful workloads
 - Less willing to leave worksite
 - Providers are hurried, distracted
 - The 5-10 minute office visit
 - Limited access to care, shortages of PCPs
 - Non-compliance approaches 50%
 - The Sick-care Delivery System
 - Incentives poorly aligned
- Demographics
 - Aging workforce
 - Higher chronic disease prevalence
 - Hypertension ▪ High cholesterol
 - Heart disease ▪ Depression
 - Diabetes ▪ Arthritis
- Lifestyle Risks
 - Obesity, Inactivity, Stress





How Common are On-site Clinics?



Source: Mercer/Marsh Survey on Health, Productivity and Absence Management Programs 2007



On-site Clinic Considerations and Decision Points



On-site Clinic Considerations

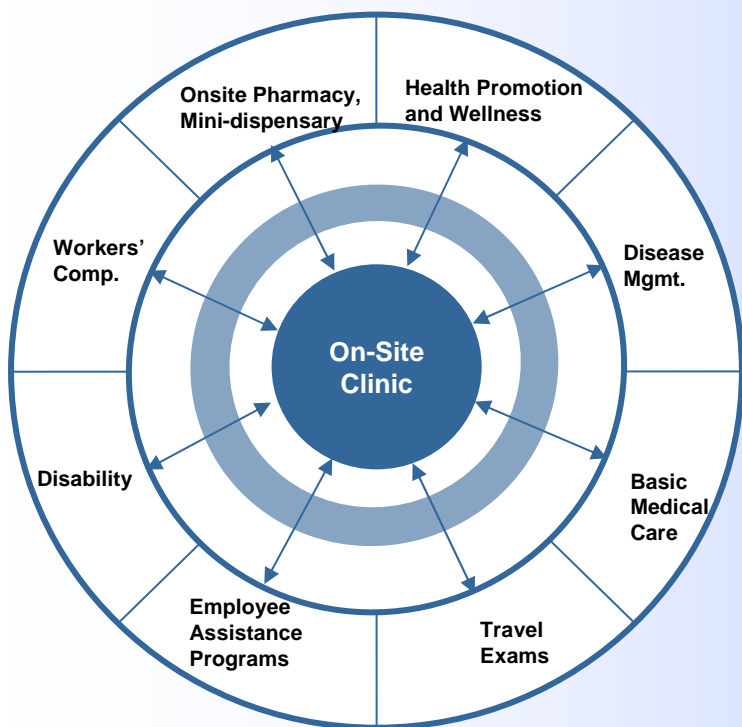
- Key decision points in assessing the feasibility of an on-site health clinic
 - Who should be eligible to use the clinic?
 - What costs underlie an on-site clinic?
 - Should there be a charge for services?
 - What services should the on-site clinic offer?
 - How should the clinic be staffed and managed?
 - What are the benefits of an on-site clinic and how should they be measured?
 - Should the clinic be a dedicated on-site facility or contracted offsite with an existing or proposed retail clinic?





On-site Clinic Services

What to offer and how to position



- **Treat primary and urgent care needs** to reduce costs and absenteeism, and improve productivity
- **Referrals to high quality community physicians and specialists** when outside care is required
- **Drive preventive health and wellness programs** to manage health risks and maximize member benefits
- **Provide health coaching and care management** serve as on-site information/education center, incl RA review
- **Dispense commonly prescribed prescription drugs** to improve generic use and formulary compliance
- **Provide initial on-site mental health triage, counseling and integration with EAP services**
- **Treat and manage travel medicine program** to minimize direct medical costs and lost work time
- **Build employee loyalty, morale and well-being**



Staffing and Managing an On-site Clinic

Predominant management models

- In-House
 - The clinic is managed directly by the employer and clinic staff are hired and paid by the employer as its employees.
- Hybrid
 - The employer contracts medical services from a local clinic or health care institution but manages business operations itself.
- Outsourced
 - The entire enterprise is outsourced to a third-party vendor or management company that controls all clinic operations and employs all clinic personnel.

When choosing a model, consider what makes sense for you and the risk your organization is willing to absorb.





On-site Health Services

Potential benefits from employer onsite clinics

- Reduced lost work time and absenteeism
- Avoidance of higher cost and time consuming settings (e.g., ERs)
- Reduced referrals to and use of costly services from specialists
- Reduced general and work-related health costs, particularly in claims for workers' compensation as well as non-occ disability
- When combined with an onsite pharmacy, improved generic and therapeutic substitution and greater formulary compliance
- Lower medical trend amongst members who use the onsite clinic
- Improved employee morale, retention and productivity





Compliance Issues Related to On-site Clinics



Compliance issues related to on-site clinics

ERISA

- Is an on-site clinic an ERISA plan?
 - General rule is broad
 - ERISA plans include any plan or program established by employer to provide health, disability or certain other benefits
 - First-aid exception

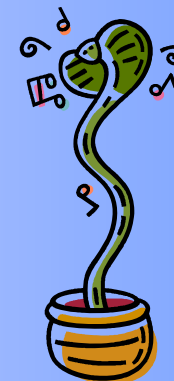


- If the clinic is an ERISA plan, what must an employer do?
 - Plan document
 - Summary plan description
 - Form 5500
- A cautionary note for certain employers



Compliance issues related to on-site clinics

COBRA



- Is an on-site clinic subject to COBRA?
 - General rule is also broad
 - Most employers sponsoring group health plans must offer COBRA continuation coverage
 - Another first-aid exception
- Implications if the clinic is subject to COBRA
 - Back-door access to the group health plan
 - Front-door access to the clinic
 - Side-door alternative for individuals not permitted on premises?

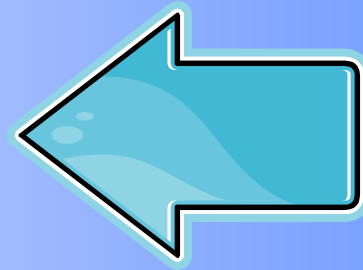
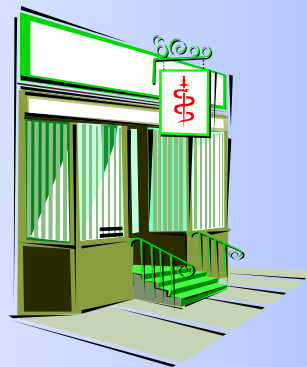
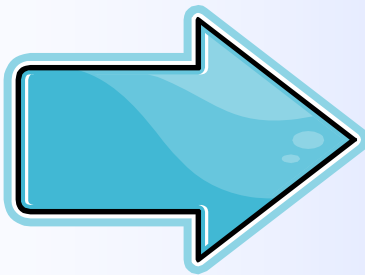




Compliance issues related to on-site clinics

HIPAA portability

- Is an on-site clinic subject to the HIPAA portability rules?
 - General rule
 - Portability rules apply to most group health plans
 - Limit application of pre-existing condition exclusions
 - Require certificates of creditable coverage
 - Establish special enrollment periods
 - Prohibit plans from discrimination based on health status
 - On-site clinic exemption
 - Ask yourself: Where are the benefits coming from?





Compliance issues related to on-site clinics

HIPAA administrative simplification

- How do the HIPAA administrative simplification rules apply to on-site clinics?
 - Privacy, security and standardization of health data
 - Only apply to covered entities
 - health plans
 - health care providers
 - health care clearinghouses
- Is an on-site clinic a HIPAA health plan?
 - *Probably not.*
- Is an on-site clinic a HIPAA provider?
 - *Depends.*
 - As yourself: Does the clinic (or any of its providers) transmit health information electronically?

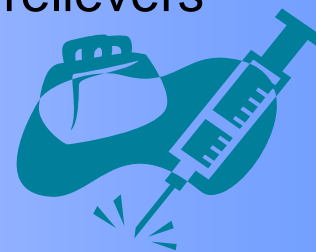




Compliance issues related to on-site clinics

A short course on health savings accounts (HSAs)

- General HSA rule
 - Employees can't contribute to an HSA if have medical coverage other than through a qualified high-deductible health plan (HDHP)
- Is eligibility to use an on-site clinic considered non-HDHP medical coverage?
- Recent IRS guidance confirms that on-site clinics won't disqualify employees from making or receiving HSA contributions, as long as the services provided aren't significant medical benefits:
 - Free physicals
 - Immunizations, allergy and other shots
 - Dispense aspirin and other nonprescription pain relievers
 - Treat work-site injuries





Compliance issues related to on-site clinics

Other laws

- Americans' with Disabilities Act (ADA)
- State licensing laws
- State or federal laws governing confidentiality of medical records may apply even to HIPAA-exempt clinics
- Occupational Safety and Health Administration standards
- Local and/or state health department rules
- Laws regulating laboratories and specimen handling
- Laws applicable to medications and handling biologicals
- Tax rules

***Don't be overwhelmed!
Discuss these issues with your
legal counsel.***





Questions?



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