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On-site medical clinics

Compliance considerations

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Law & Policy

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Agenda

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Overview

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On-site medical clinics provide employees with convenient access to healthcare services, can assist with reducing absenteeism, and improve employee satisfaction.

On-site clinics can also help control medical costs by:

- Providing employees with easy access to care and information on healthy living, potentially reducing expenses associated with traditional benefit plans by limiting the number of doctor and emergency room visits, and
- Potentially reducing long-term health plan costs by improving the overall health of employees and fostering better chronic disease management.

On-site medical clinics are subject to myriad compliance requirements and other considerations. Consult with legal counsel, as needed.

Compliance requirements

- Employee Retirement and Income Security Act (ERISA)
- Consolidated Omnibus Budget Reconciliation Act (COBRA)
- Health Insurance Portability and Accountability Act (HIPAA)
- Tax requirements governing Health Savings Accounts (HSAs) and employer-provided medical care (i.e., IRC §213(d))
- Application of various provisions of the Patient Protection and Affordable Care Act (ACA)
- Protections under the Americans with Disabilities Act (ADA)

Other considerations

- Applicable local and state laws (corporate practice of medicine, licensing, etc.)
- Costs of configuring the workplace to accommodate a clinic, of staffing and operating
- Workforce turnover rate
- Ease and convenience of obtaining medical services elsewhere
- Traditional group health plan medical experience for the services the clinic would provide

ERISA and COBRA

An ERISA employee welfare benefit plan includes any plan or program established or maintained by an employer to provide medical, surgical, or hospital care or benefits to employees and beneficiaries.

ERISA requirements for on-site medical clinics not meeting the first-aid exception

- Plan document
- Summary plan description (SPD)
- Form 5500 filing
- Summary annual report (SAR)
- Summary of material modifications (SMM)
- ERISA claims procedures and appeals process

First-aid exception under ERISA

For on-site clinics that treat minor injuries or illnesses or provide first aid for accidents that occur during work

Clinics that provide broader and more sophisticated services are unlikely to meet the first-aid exception. For example:

- Basic services and diagnostic testing similar to grocery, retail and drug store clinics
- Health care for employees' family members (e.g., spouses and dependent children)

ERISA fiduciary duties

Duty of loyalty
Act primarily to benefit participants and beneficiaries.

Exclusive benefit rule
Act for the exclusive purpose of providing benefits and defraying reasonable plan administration expenses.

Duty of care
Conduct plan activities prudently.

Operate in accordance with written plan documents
Comply with the terms of plan documents to the extent consistent with ERISA.

Duty to diversify plan assets
Diversify plan assets to minimize the risk of large losses; generally, not applicable to health and welfare plans in the absence of a VEBA or trust.

ERISA prohibited transaction rules

Overview: Prohibited transaction rules may be a concern for organizations that employ physicians or own hospitals/health clinics and use their own providers/facilities to provide health care services to employees through the ERISA-covered health plan.

Application to on-site clinics: Prohibited transaction rules may be a concern where an on-site clinic is staffed by employees of the employer sponsoring the clinic.

Precautionary measures include:

- Funding the clinic's services and staff with the company's general assets (not plan assets)
- Outsourcing clinic providers
- Always acting in the best interest of the plan participants, including when setting fee schedules and establishing credentialing criteria

Prohibited transaction rules

The **ban on self-dealing** prohibits use of plan assets for ERISA fiduciary's own interests

The **ban on deals adverse to plan participants** prohibits ERISA fiduciaries from conducting plan transactions with a party who has interests adverse to the plan or participants.

Note: State law may restrict an employer's ability to directly employ physicians to provide medical care.

An on-site clinic that provides more than mere first aid or treatment for minor injuries may be a group health plan subject to ERISA *and* COBRA.

COBRA requirements for on-site medical clinics not meeting the first-aid exception

- All individuals who could have used the clinic the day before the qualifying event may elect to continue receiving the clinic services for the duration of their COBRA coverage period.
- Qualified beneficiaries electing COBRA for clinic coverage can elect any other group health plan benefits offered to similarly situated individuals during open enrollment.
- Former employees need physical access to the clinic ***or*** accessible alternative off-site coverage.
- COBRA premium must be calculated and communicated in the election notice.

First-aid exception under COBRA

Facility must meet three conditions

1. The clinic is primarily for first-aid, providing treatment of a health condition, illness, or injury that occurred during working hours;
2. The health care is available only to current employees; and
3. Employees pay no charges to use the facility.

HIPAA

HIPAA portability provision

Prohibits pre-existing condition exclusions and discrimination based on a health status; requires special enrollment periods

Applies to group health plans and group health insurance issuers

Excluded or excepted group health plans include:

- **On-site medical clinics**
- Limited-scope dental and vision plans
- Excepted benefit health FSAs and HRAs
- Excepted benefit specified disease/illness policies
- Excepted benefit hospital indemnity or other fixed indemnity insurance
- Certain supplemental benefits
- AD&D plans
- Disability plans
- Long-term care insurance

Note: HIPAA portability applies if the clinic is available only to group health plan participants, but compliance can be satisfied as part of the major medical plan.

HIPAA administrative simplification provision

Includes the privacy, security, and breach notification rules

Applies to a group plan that provides (or pays for) medical care, including:

- Group health plans and group health insurance issuers
- Other ERISA welfare benefit plans that provide medical care
- Most group health plans that are excluded or excepted from the portability rules

Exceptions include:

- **On-site medical clinics**
- Travel insurance (provided the health benefits are not offered on a stand-alone basis and are incidental to other coverage)
- Disability or accident-only insurance

Plan or provider?

Is the on-site clinic a health care provider or a health plan?

Plans are exempt from the HIPAA administrative simplification provision, but providers are not.

Health care providers that conduct certain transactions electronically are subject to the HIPAA administrative simplification rules.

Employers that operate on-site clinics may be deemed to be health care providers subject to the HIPAA administrative simplification rules if health information is transmitted electronically in a HIPAA-covered transaction.

An on-site clinic is a health care provider if it transmits health care transactions subject to EDI standards to other covered entities.

- Review on-site clinic health care transactions transmittals to the group health plan's carrier/TPA to determine if the specific transmittals cause the clinic to be a provider.
- Address data sharing between the clinic and the group health plan.

Some employers sponsor an on-site medical clinic that offers a range of health care, from first aid to comprehensive primary care, including:

- Annual physicals
- Medical screenings
- Test interpretations
- Disease management
- Diagnosis and treatment of common injuries and illnesses such as sprains, colds, allergies, sore throat, and flu

Health care provider is defined (for this purpose) as a provider of medical or other services, or one that furnishes medical or health care services or supplies, or any other entity that furnishes, bills, or is paid for health care in the normal course of business. For example, physicians, pharmacies (traditional and online), nursing homes, therapists, technicians, aides, free clinics, and researchers that provide health care to their subjects.

HIPAA-covered transactions include:

- health claims or encounter information
- health claims attachments
- health plan eligibility
- plan enrollment and disenrollment
- payment and remittance advice
- premium payments
- first reports of injury
- health claim status
- referral certification and authorization

Does the clinic electronically transmit data for any of the above transactions?

If yes, clinic is likely to be considered a HIPAA-covered entity.

If no, clinic is unlikely to be considered a HIPAA-covered entity.

On-site clinics that operate exclusively with paper records or maintain electronic records but don't electronically transmit data are not subject to the rules.

HIPAA hybrid covered entity

One legal entity whose business activities include some HIPAA-covered functions and other functions that are not subject to HIPAA.

Hybrid entity can designate the health care components that perform HIPAA functions as subject to HIPAA's administrative simplification provisions, while other components of the operations are not.

If no action is taken, the entire entity (covered and non-covered functions) is subject to HIPAA.

Employer with an on-site health clinic subject to the HIPAA administrative simplification rules is a hybrid covered entity.

- **Employer and on-site clinic are not legally distinct entities.**
- **Some employer activities are considered HIPAA-covered functions and other employer activities are not.**
- **Employer is responsible for clinic's HIPAA compliance.**

HIPAA hybrid covered entity requirements

Privacy

Requirements for hybrid entity include:

- At first encounter, obtain general consent to share PHI for health care treatment, payment and clinic operations.
- Create physical and procedural barriers and safeguards between covered-entity functions and non-covered-entity functions.
  - Particularly where internal departments assist with the administration of the clinic.

Additional privacy rules for clinic include:

- PHI use and disclosure
- Notice of privacy practices and individual rights
- Policies and procedures and other administrative requirements

Security

Security rules for clinic include:

- Maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI including written policies and procedures.
- Ensure confidentiality, integrity, and availability of all e-PHI created, received, maintained or transmitted.
- Identify and protect against reasonably anticipated threats to the security or integrity of the information.
- Protect against reasonably anticipated, impermissible uses or disclosures.
- Comply with documentation requirements and breach notification rules.
- Ensure workforce compliance.
- Conduct ongoing risk analysis.

Electronic transaction standards

Electronic data interchange (EDI) standards for covered transactions include:

- The electronic transfer of information in a standard format between covered entities.
- Standard diagnostic and procedural code sets and identifiers to be used in the standard transactions.
- Compliance with the operating rules.

Note: Compliance with the HIPAA administrative simplification rules for a health care provider is an ongoing process that requires guidance from legal and technical experts.

Tax considerations

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Health savings accounts (HSAs)

Employers offering on-site medical care should discuss with legal counsel the potential HSA eligibility implications when assessing whether and how to offer HSAs and whether to make employer HSA contributions.

Employers with HSA plan participants should charge a fair market fee (for services other than preventive care).

- There is no formal guidance on how to establish fair market value.
- Methodologies should be reviewed with legal counsel.

Consider charging only HSA participants rather than all clinic users.
Mitigate potential employee relations issues for employees participating in HSAs by adding the clinic to the network of providers available in the HDHP so that employees can submit on-site expenses and apply them to the HDHP deductible.

An on-site medical clinic could charge for:

- All services
- Only for non-preventive care, non-permitted coverage
- Coverage provided before an employee satisfies the HDHP deductible

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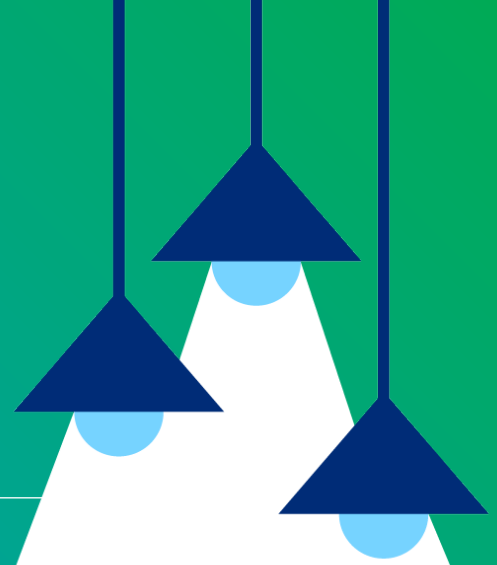

Employers that contribute to employees' HSAs are expected to confirm that the employee has HDHP coverage and no other employer-provided coverage.

IRC § 105(h) nondiscrimination testing

On-site clinics are typically considered self-insured group health plans under Section 105(h); if the clinic provides tax-free health benefits to employees, it must comply with nondiscrimination rules.

Eligibility Test. Plan can't discriminate in favor of highly compensated individuals (HCIs) as to eligibility to participate.

Benefits Test. Benefits provided must not discriminate (on the face or in operation) in favor of HCIs.

On-site clinic might need to satisfy 105(h) nondiscrimination testing if the plan design favors highly compensated employees.

Look to eligibility provisions to determine how the plan determines eligible participants and if employees pay for access to the on-site clinic.

If a health plan fails to pass either test, the favorable tax treatment for HCIs who participate in the plan will be lost (HCIs will lose their tax exclusions and will be taxed on their "excess reimbursements" from the plan).

Additional compliance considerations

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On-site clinics are excepted benefits, exempt from ACA market reforms and reporting

PHSA mandates do not apply to excepted benefits, and on-site clinics are excepted benefits.

PHSA mandates include:

- No lifetime or annual dollar limits on Essential Health Benefits
- Coverage of in-network preventive care at no cost
- Application of out-of-pocket maximums
- Ban on pre-existing condition exclusions
- Ban on excessing waiting periods
- Ban on rescinding coverage
- Provision of summary of benefits of coverage (SBC)
- Nondiscrimination requirements
- Internal claims and appeals, external review requirements

COVID and flu considerations

Employers can decide what services — whether COVID related or not — to provide through an on-site clinic, without jeopardizing its excepted-benefit status.

On-site clinic may provide flu and COVID vaccines (and administration), and COVID testing and diagnosis.

For example, clinic can conduct telehealth evaluation of employee's symptoms and arrange for COVID testing elsewhere.

- Federal law doesn't prevent on-site clinics from providing telehealth services, including to evaluate an employee for COVID testing or to care for an employee working from home.
- But telehealth could create problems for HDHP participants — for example, if predeductible telehealth coverage is provided.

Americans with Disabilities Act (ADA)

Discrimination. Services provided by the on-site clinic must not treat employees with disabilities less favorably than those without.

Accommodation. Reasonable accommodations must be provided to qualified employees with a disability.

For example, health/medical education program materials should be accessible to blind and deaf employees, and the clinic should be accessible to wheel-chair bound employees.

Wellness Programs

On-site clinics are often used to support wellness initiatives. The ADA imposes limits on employer medical exams and disability inquiries.

Wellness programs involving a disability-related exam/inquiry (e.g., biometric screening, health risk assessment, nicotine testing) should consider:

- Is employee participation voluntary?
- Is medical information kept confidential by the employer?
- Is notice provided explaining how information is collected, used and disclosed?
- Is a reasonable accommodation provided for employees with disabilities?

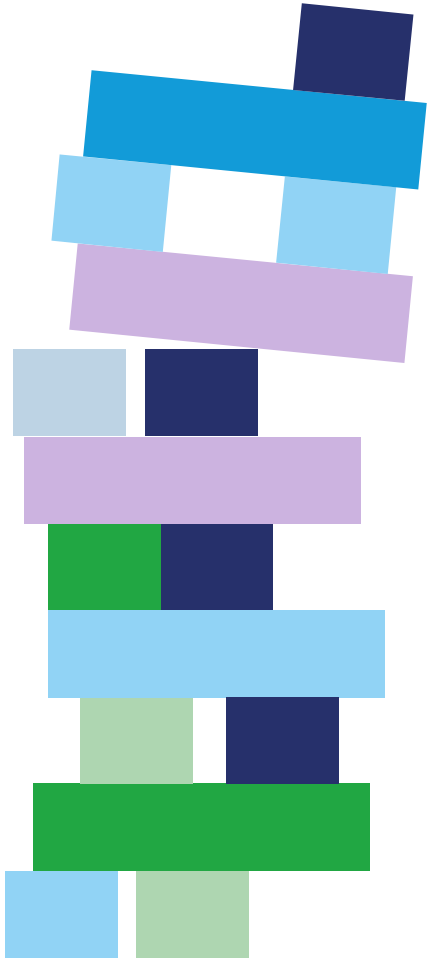
Other laws to keep in mind

Consultation with legal counsel is strongly recommended

Additional state and federal laws may apply, but the application depends on a variety of factors like the services that are provided and the on-site clinic's location.

Examples of other laws that could potentially apply include:

- Prohibition against corporate practice of medicine.
- Certain states may require licensing of on-site clinics.
- State or federal laws governing confidentiality of medical records may apply even to clinics that are HIPAA-exempt.
- A variety of Occupational Safety and Health Administration standards may govern services provided by on-site clinics (see the OSHA website for more information).
- Local and/or state health departments may require clinics to follow certain standards on sanitation and disposal of biohazardous waste.
- Clinics that perform lab work (such as drawing blood or urine samples or drug testing) may need to follow certain laws regulating laboratories and specimen handling.
- Specific laws may apply to clinics that dispense drugs, such as special rules for handling biologicals (like insulin or allergy serums) that require continuous refrigeration or storing certain medications (like narcotics) that may create significant security concerns.



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