WELLNESS PROGRAMS AND ONSITE HEALTH FACILITIES: KNOW THE RULES

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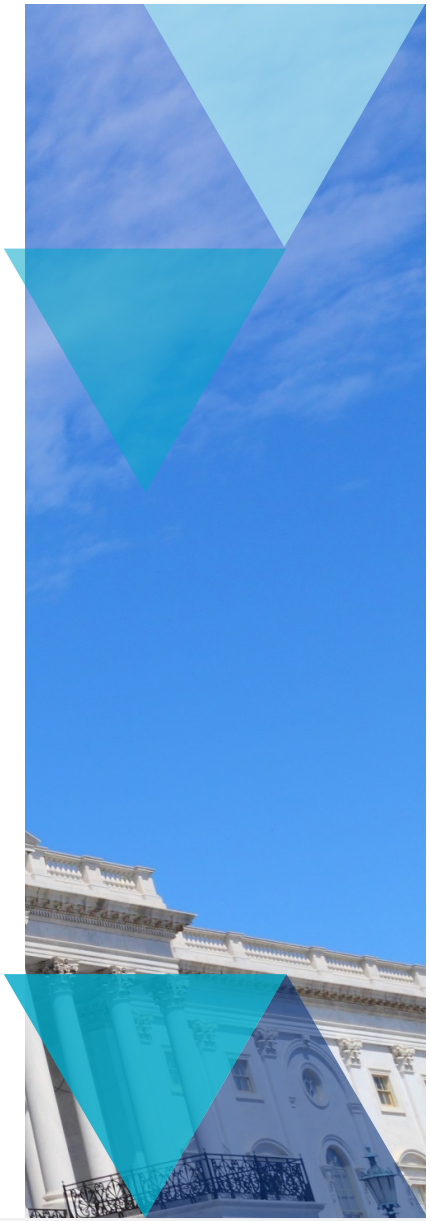


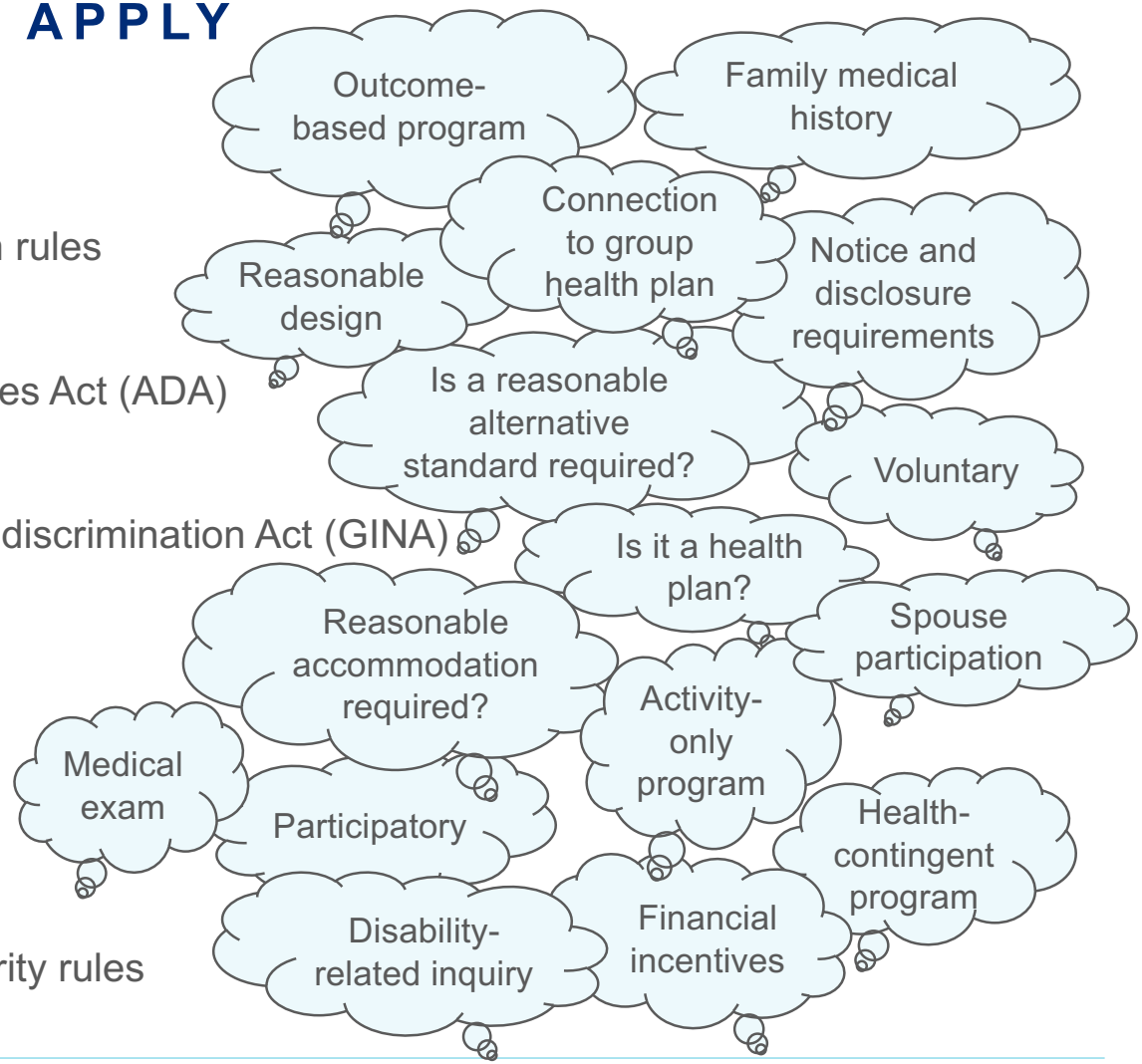
AGENDA

1. WELLNESS PROGRAM LEGAL REQUIREMENTS OVERVIEW
2. THORNY WELLNESS PLAN COMPLIANCE ISSUES
3. ON-SITE HEALTHCARE LEGAL ISSUES
4. QUESTIONS

WELLNESS PROGRAM LEGAL REQUIREMENTS OVERVIEW

APPLICABLE FEDERAL LAWS
ONE OR MORE MAY APPLY

- HIPAA nondiscrimination rules
- Americans with Disabilities Act (ADA)
- Genetic Information Nondiscrimination Act (GINA)
- ERISA
- Internal Revenue Code
- HIPAA privacy and security rules



HIPAA WELLNESS RULES

- In general, a group health plan may not establish any rule for eligibility that discriminates against any individual or dependent of the individual because of a "health factor".

Wellness Program Exception

- However…a group health plan may vary benefits, including cost sharing mechanisms, or premiums that are required, based on whether the individual has met the standard of a "wellness program".

HIPAA WELLNESS RULES

HIPAA rules apply when the wellness program is tied to group health plan eligibility, benefit, or premium

Participatory programs

Smoking cessation	Diagnostic testing	Health education seminars	Health risk assessment

- No incentive limit
- Availability of incentive must not be conditioned on satisfying a standard or undertaking an activity related to a health factor
- Incentive must be available to all similarly situated individuals

Health-contingent programs

Activity-only		Outcome-based		
Walking goals	Exercise program	Target BMI	Target blood pressure	Abstain from tobacco use

- Annual qualification opportunity
- Limited incentive
- Reasonable design

- Reasonable alternative standard
- Notice of reasonable alternative

ADA WELLNESS RULES

Americans with Disabilities Act (ADA)

Prohibits employment discrimination against disabled individuals and limits the circumstances in which an employer may require physical examinations or answers to medical inquiries.

However, voluntary medical exams and inquires are permitted as part of an employee health program if :

- participation in the program is, in fact, voluntary
- information obtained is not used to discriminate against an employee

So what is "voluntary"?

EEOC regulations sought to answer that question as well as address Genetic Information Non-Discrimination Act (GINA) restrictions on collection or use of family medical history and other genetic information

EEOC WELLNESS RULES
ADA AND GINA

Scope of EEOC regulations

- Regulate wellness programs regardless of connection to a group health plan
- Apply to any program with a medical exam or inquiry (like biometric screenings, health risk assessments, nicotine/cotinine testing)
- Apply to participatory as well as health-contingent programs

Financial incentive limitations different than HIPAA's

Other notable features

- Reasonable-design requirement similar to HIPAA's
- Advance-notice requirement (and advance authorization for spouse)
- Participation must be voluntary
- Gatekeeping prohibited
- Reasonable accommodation required for employees with disabilities

HIPAA & EEOC INCENTIVE RULES COMPARED

<table>
<tr><th colspan="2">2016 EEOC (ADA/GINA) incentive rules</th><th colspan="3">HIPAA incentive rules</th></tr>
<tr><td colspan="2" rowspan="2">Any program to promote employee health asking disability-related questions, using medical exams, or seeking dependents' health information</td><td colspan="3">Program is a group health plan or relates to a group health plan</td></tr>
<tr><td colspan="2">Health-contingent program</td><td>Participatory program</td></tr>
<tr><th>HRA/testing/exam used</th><th>No HRA/testing/exam</th><th>Activity-Only reward</th><th>Outcome-Based reward</th><th></th></tr>
<tr><td>Combined wellness rewards as a share of total employer/employee costs for self-only coverage cannot exceed:
For employees: 30%, including any tobacco related incentives if biomedical testing done to detect nicotine/tobacco use
For spouses: an additional 30% of self-only coverage, except tobacco related incentives for spousal biomedical testing for nicotine/tobacco use do not "count" towards the additional 30%
For children: no incentives allowed.</td><td>No EEOC limit:
Tobacco-related incentives based on self-reporting still subject to HIPAA 50% cap</td><td colspan="2">Combined health contingent rewards as a share of total employer/employee costs for coverage actually elected (e.g., employee, employee +1, or family) cannot exceed:
30% for incentives unrelated to tobacco use
50% for tobacco-related rewards alone or for a combination of tobacco-related rewards and other incentives (subject to the 30% cap on non-tobacco rewards)</td><td>No reward limits</td></tr>
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Both sets of rules have additional requirements, including (but not limited to) requirements for reasonable design, reasonable alternative standards, notices, authorizations and prohibitions against gateway designs.

WELLNESS PROGRAMS
EEOC LIMBO

EEOC rules for incentives

- **Biometric screening**
- **Risk assessment**
- **Spouse info**

Lawsuit challenges rules' incentives

Court vacates incentive provisions

Effective Jan. 1, 2019

EEOC expected to issue new rules in 2019

IMPORTANT REMINDERS

- **All other parts of EEOC wellness rules (e.g., gateway prohibition, notice/authorization) remain in effect**
- **HIPAA wellness rules remain in effect**

IF EEOC INCENTIVE RULES REMAIN VACATED, ARE INCENTIVES PERMISSIBLE?

YES	• For HIPAA-regulated wellness programs that don't contain health screenings (e.g., no biometric screening, physical exam, health risk assessment, or nicotine/cotinine testing) • For the non-ADA/GINA components of the wellness program (e.g., health coaching or well-being activities like step challenges)
???	• What about programs and components that are subject to the ADA or GINA? • If some incentive is permissible, how much incentive is too much? • Will EEOC enforcement under new leadership be less aggressive than it was before the rules were issued? • Will the courts be left to decide how much incentive is too much when private lawsuits are brought?

PLANNING FOR UNCERTAINTY
STRATEGIC PATHWAYS

While we cannot quantify the risk of litigation associated with this uncertainty, here are some possible approaches for employers

POSSIBLE PATHWAYS MOVING FORWARD

- Keep existing financial incentives, but modify the wellness program to eliminate biometric screenings, HRAs, and other elements that could subject the program to the provisions under the ADA and GINA related to health screenings

- Remove financial incentives from voluntary wellness programs subject to the ADA or GINA because they include a health screening (common ones are biometric screenings and HRAs), and look for other ways to encourage participation until further guidance is issued

- Modify to a multicomponent wellness program that allows participants to receive the maximum incentive without requiring completion of an element subject to the ADA/GINA
- For example, create a program that contains six elements, where at least three aren't health screenings under the ADA or GINA, and allow a participant to earn the maximum incentive by completing any three components

- Keep current program in place without changes
- Employers contemplating this approach should review with legal counsel the risk of litigation by the EEOC or plan beneficiaries related to the voluntary nature of the existing program

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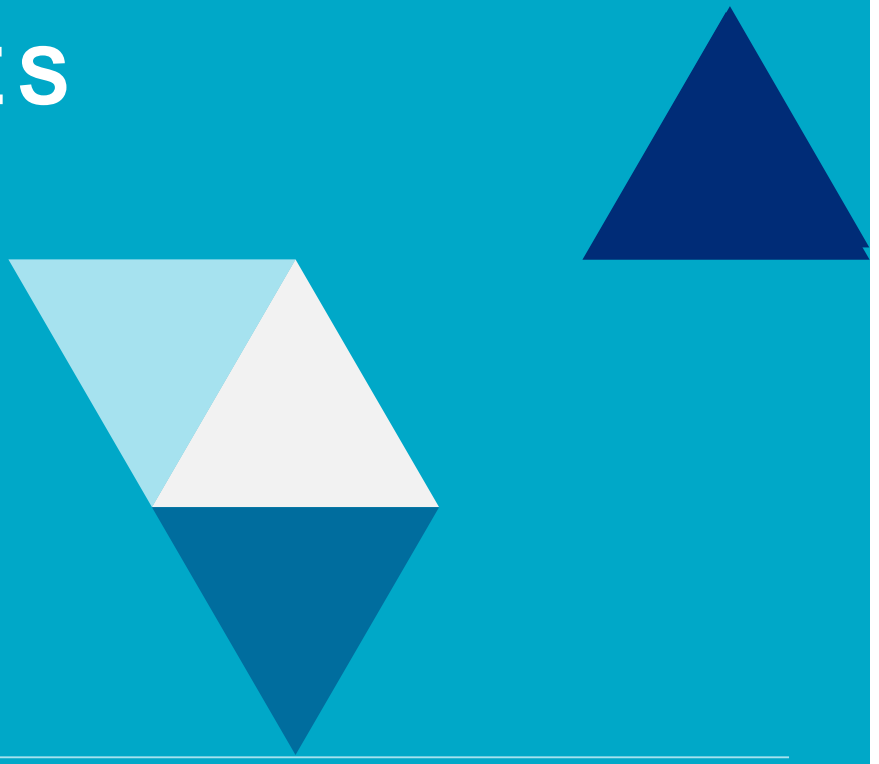
PLANNING FOR UNCERTAINTY
STRATEGIC PATHWAYS

Action	Pros	Cons
Least Conservative		
• Leave financial incentive model as is, including ADA- and GINA-protected activities	• Least disruption and less communication needed • HIPAA rules remain with 30% / 50% incentive threshold & reasonable alternative standard requirement for health-contingent incentives	• Highest risk of potential legal challenge by EEOC, individuals or groups related to the voluntary nature of the existing program
More Conservative		
• Remove HRAs, physical exams, biometric screenings, as prerequisites for earning other incentives • Encourage HRAs, physical exams and biometric screening as part of multicomponent points model • Require attestation to tobacco use rather than blood test or cheek swab	• Should address the "voluntary" issue for HRAs, physical exams and biometric screenings • If structured well, may still have participation in HRAs, physical exams and biometric screenings	• Likely to see lower participation in HRAs, physical exams and biometric screenings • Potential to lose some valuable time-over-time program impact data • Multicomponent concept is based on informal EEOC guidance so still some risk of potential legal challenge. See above.
Most Conservative		
• Eliminate HRAs, physical exams and biometric screening altogether, or • Remove any financial incentive for HRAs, physical exams or biometric screening	• Lowest risk of potential EEOC enforcement, litigation	• Would significantly reduce ability to track health risks • Potential loss of ROI estimate If health risk reduction is used for ROI calculation

THORNY WELLNESS COMPLIANCE ISSUES



STAND-ALONE PROGRAM OR PART OF GROUP HEALTH PLAN?

FEDERAL COMPLIANCE
GROUP HEALTH PLAN RULES

Some stand-alone wellness programs are likely to be group health plans. If a program is an ERISA plan, it may have to meet federal laws, including:
ERISA disclosure and reporting rules (SPD, SMM, SAR, Form 5500)
ERISA health benefit claims and appeals rules
COBRA continuation rights and QMCSOs
HIPAA privacy and security
Medicare secondary payer rules and Medicare notice of creditable drug coverage
FMLA and USERRA
ERISA “Part 7” rules (MHPAEA, newborns, HIPAA nondiscrimination, WHCRA, etc.)
Genetic Information Nondiscrimination Act (GINA)
Employer shared-responsibility/reporting
ACA benefit reforms and mandates (no annual $ limits, preventive care, SBC, etc.)

STAND-ALONE WELLNESS PROGRAMS
FEDERAL LAW CONSIDERATIONS FOR EMPLOYERS

Is the program a group health plan?

YES: Check compliance with relevant federal rules

NO: Most federal rules don't apply, but tax and state requirements may apply. Not MEC

If it is a group health plan, is it an "excepted benefit"?

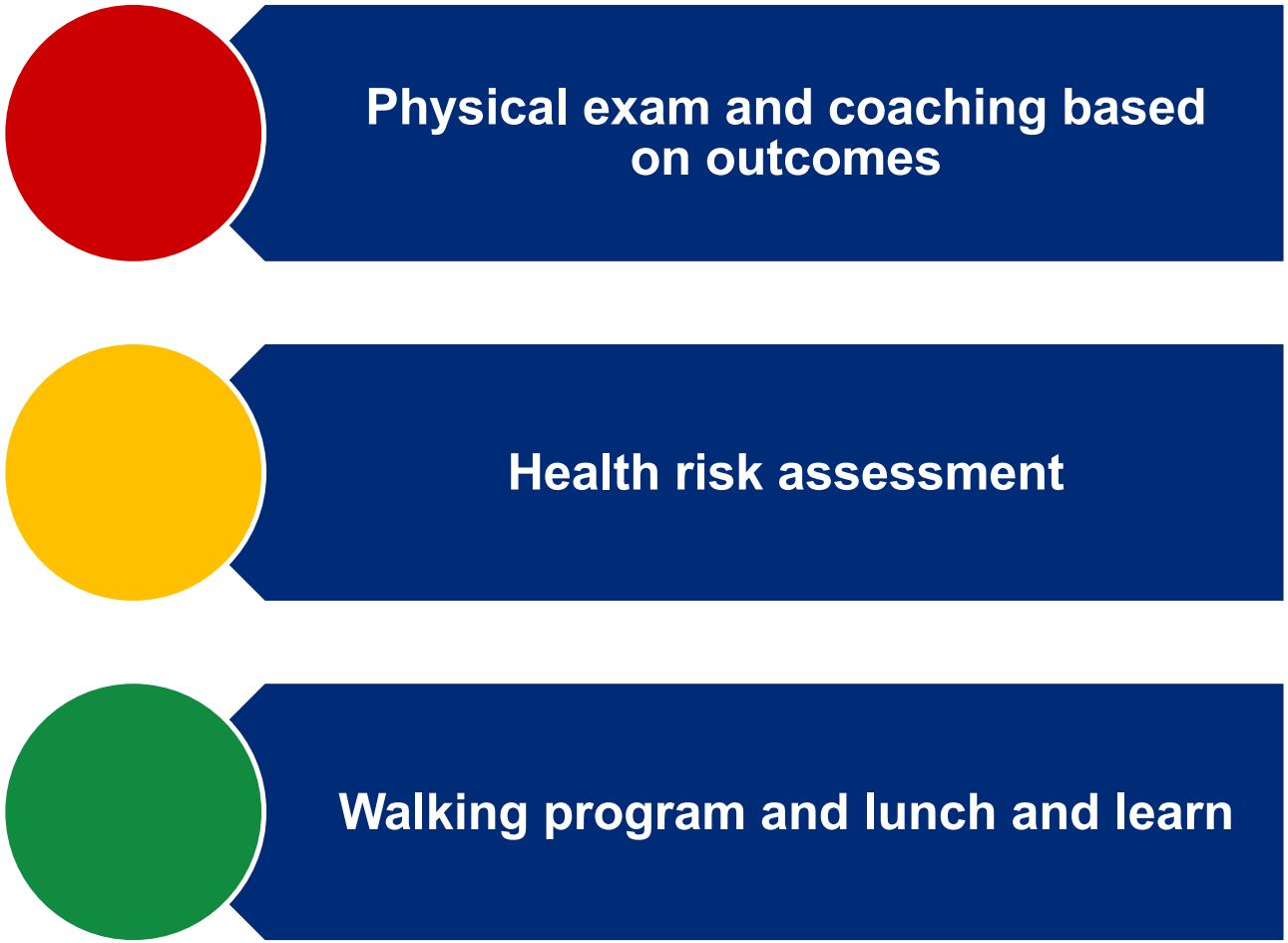
YES: EAP or on-site medical clinic

Subject to federal rules

If it's excepted, what rules apply?

Many ACA reforms don't apply (annual dollar limits ban preventive care requirement, etc.)	**Certain other mandates like mental health parity and HIPAA nondiscrimination won't apply**	**But others may apply: COBRA, ERISA standards, HIPAA privacy and security**

GROUP HEALTH PLANS
RED, YELLOW, OR GREEN LIGHT



TAXATION OF WELLNESS INCENTIVES

Incentives that are medical expenses are ***NOT*** taxable

- Premium reductions/surcharges
- Copay/coinsurance waiver
- Reduction in deductible or out-of-pocket maximum

Cash and cash equivalents are taxable

- Gift cards
- Prizes (e.g., Fitbits)
- Any other reward that is beyond a *de minimis* benefit (e.g., a participation T-shirt)
- Even if provided by third-party vendor
- No minimum threshold for cash or cash equivalents

HIPAA PRIVACY AND SECURITY

1. Most wellness information through a group health plan will be considered protected health information (PHI) subject to HIPAA rules
2. Wellness information unrelated to a group health plan is not subject to HIPAA rules (but if subject to ADA and GINA rules, confidentiality is required)
3. Employers may not use wellness information for employment purposes
4. Employers may use wellness information for limited purpose of administering incentives & surcharges
5. Wellness vendors are business associates (and must execute a Business Associate Agreement that addresses, among other things, HITECH Act breaches)
6. HIPAA policies should address privacy and security of wellness information, especially electronic PHI both at rest and in transit
7. Non-medical plan wellness participants must receive Notice of Privacy Practices (at time of participation)

ON-SITE HEALTHCARE LEGAL ISSUES

OVERVIEW
ON-SITE CLINICS

On-site clinics are powerful tools to provide employees with convenient access to healthcare services, reduce absenteeism, and improve employee satisfaction.

On-site clinics raise a number of business related questions, as well as a number of legal issues, the most common of which are as follows:

- 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 and employer-provided medical care.
- Application of various provisions of the Patient Protection and Affordable Care Act (PPACA).
- Protections under the Americans with Disabilities Act (ADA).

Other potential issues include local and state law considerations.

ERISA
IS AN ON-SITE CLINIC AN ERISA PLAN?

- ERISA governs any plan or program established by an employer to provide health, disability, or certain other benefits to its employees.
- The more robust the scope of services offered by a clinic, the more likely the clinic is to be an ERISA plan.
  - ERISA gives an exception for on-premises employer facilities that provide first aid after job accidents or treat minor injuries or illnesses, including clinics providing minor occupational health services.
  - Services such as issuing prescriptions and treatment of medical conditions, even minor illnesses, can make a plan an ERISA plan.
- What should an employer do if the clinic is an ERISA plan?
  - Satisfy ERISA's documentation requirements, including having a plan document, filing a Form 5500, and providing an SPD and other disclosures to plan participants.
    - Incorporate information about the on-site clinic into existing ERISA documentation, if possible.
  - Know that the ERISA claims procedures and appeals processes must be followed.

COBRA

DOES COBRA APPLY TO ON-SITE CLINICS?

COBRA is similar to ERISA in categorizing employer on-site clinics as a group health plan.

COBRA provides three conditions for an exception:

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

What are the COBRA implications if the clinic is a group health plan?

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

TAX ISSUES
SPECIAL CONSIDERATIONS WITH RESPECT TO HDHP/HSA PLANS

Access to on-site medical care may make employees ineligible for HSA contributions if the program provides "significant benefits in the nature of medical care or treatment."

Examples of services that are not "significant benefits" in the nature of medical care:

- Preventive care physicals and immunizations.
- Provision of allergy injections, a variety of aspirin and other nonprescription pain relievers.
- Treatment of injuries caused by accidents at the workplace.
- Education, fitness, sports, or recreation activities; stress management measures; and health screenings to promote overall health and prevent illness.

Access to on-site clinics that provide anything other than preventive services or do not charge fair market value (FMV) for non-preventive services would disqualify an individual from making or receiving HSA contributions.

HEALTH SAVINGS ACCOUNTS
CHARGING FOR SERVICES AS AN APPROACH

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.

Another option is to charge 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 high-deductible coverage so that employees could submit their on-site expenses and apply them to their HDHP deductibles.

Employers with HSA plan participants should seek to charge a fee (for services other than preventive care) that is considered fair market value. Formal guidance on establishing fair market value does not exist, and methodologies should be reviewed by the employer's legal counsel.

ACA
CONSIDERATIONS ON ACA PROVISIONS

On-site clinics are generally exempt from ACA except for two important provisions:

- W-2 Reporting of the cost of coverage.
- 2022 “Cadillac” Tax

W-2 Reporting of the cost of coverage

- If the employer charges a premium for COBRA qualified beneficiaries to continue on-site medical clinics, then the cost of coverage must be reported on Form W-2s for active employees.
- If the employer does not charge for COBRA access to the on-site clinic, the cost is NOT required to be reported on Form W-2s*.

2022 “Cadillac” Tax

- Comprehensive on-site clinics are likely included in the 40% excise tax calculation.
- Further guidance is needed to understand how to include on-site clinics in this calculation.

OTHER LAWS

ARE THERE OTHER LAWS THAT MAY APPLY TO ON-SITE CLINICS?

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

Some examples of other laws that potentially apply:

- 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.
- ADA – providing services appropriately to those with disabilities
- Clinics that perform lab work (such as drawing blood or urine samples or doing Pap smears 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.

Consultation with legal counsel is recommended on these items.

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