On-site Clinics: Compliance Concerns

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Question: We are considering starting an on-site medical clinic where our employees can receive medical care. Can you explain the compliance concerns for such a clinic? We are specifically interested in the following:

- **The Employee Retirement Income Security Act of 1974 (ERISA)**
- **The Consolidated Omnibus Budget Reconciliation Act (COBRA)**
- **The Health Insurance Portability and Accountability Act (HIPAA)**
- **The Patient Protection and Affordable Care Act (ACA)**
- **Section 105(h) of the Internal Revenue Code (Code)**
- **A plan design that includes a high-deductible health plan (HDHP) and health savings account (HSA)**

Summary: You have identified some of the compliance concerns we see with on-site medical clinics. Except for the most modest of clinics, they will likely be ERISA covered plans which include a requirement for a plan document, summary plan description (SPD) and likely a Form 5500 for an employer large enough to be considering such a clinic. Similarly, most clinics are covered by COBRA where consideration must be given not only to establishing a COBRA premium but also the prospect of a disgruntled former employee gaining access to the employer's premises to use the clinic through exercise of his/her COBRA rights.

On-site clinics will likely be an "excepted benefit" under HIPAA and the ACA. This may relieve the clinic of HIPAA privacy and security concerns ***as a health plan*** but the clinic still may be subject to these rules as a health care provider.

The status as an excepted benefit likely exempts the clinic from the ACA insurance group market reforms and certain other ACA requirements but some benefit professionals have expressed concern over whether the interaction of the on-site clinic with other employer group health plans may mean loss of the status as an excepted benefit.

The clinic will generally be considered a self-insured group health plan for purposes of the nondiscrimination rules in Section 105(h) of the Code. And, to the extent that the on-site clinic is part of a larger group health plan where employees contribute toward the cost of that plan on a pre-tax basis, the nondiscrimination rules under Section 125 of the Code are also implicated.

Finally, if benefits are provided to employees at no cost or a reduced cost before the deductible is met in an HDHP then, with certain exceptions, the ability to access the on-site clinic would make the employee ineligible for a HSA.

There are a host of compliance concerns that are not discussed in this Q&A. These concerns can vary based on whether the employer runs the clinic itself or outsources to another party. These issues can include contracts with medical professionals, medical liability/tort issues, leases for clinic space, state licensing, credentialing and oversight laws, possible Medicare/Medicaid issues etc. There can be state laws governing even things as mundane as signage as well as laws governing disposal

of medical waste, dispensing medicine, etc. Finally there are certain confidentiality aspects of the Americans with Disabilities Act (ADA) and Genetic Information Nondisclosure Act (GINA) that are beyond the scope of this Q&A.

Detail:

Employer on-site clinics can vary widely as to what they offer. The simplest clinic may be just a first aid station that is limited to providing first aid for on the job injuries. Such a program is likely exempt from all of the concerns raised in this Q&A. Other "full blown" clinics can be staffed with physicians, provide an on-site pharmacy, etc. The compliance concerns will vary not only on the services offered but also on the structure of the clinic and the financial arrangement between the employee/participants and the clinics. As a general rule, the greater the services provided at the clinic the greater the compliance concerns.

ERISA: Most on-site clinics will constitute ERISA welfare plans. Clinics fit under ERISA's welfare plan definition of a "plan, fund, or program... maintained by an employer... for the purpose of providing medical, surgical, or hospital care or benefits, or benefits in the event of sickness..."[1] Department of Labor (DOL) regulations, however, provide for an exemption from this definition of welfare plan for certain facilities which are: 1) maintained on the premises of the employer, 2) provide benefits to employees (not including spouses or dependents) and 3) provide treatment only for "minor injuries or illness or rendering first aid in case of accidents occurring during working hours.[2] The DOL has not provided a definition or clarification of the term "minor injuries or illness."

Most on-site clinics now provide much more than first aid for work accidents or illness and constitute ERISA welfare plans and group health plans. For example, offering preventive services or flu shots at an on-site clinic would make that clinic an ERISA welfare plan since these are medical benefits. As an ERISA welfare plan, there would be a requirement for:

- A written plan document;[3]
- A summary plan description ("SPD") to summarize plan terms in easy to understand language;[4]
- A Form 5500 unless an exception applies, such as the plan benefits fewer than 100 plan participants as of the first day of the plan year; and
- Claims and appeals procedures.[5]

Many employers handle this concern by "bundling" their traditional group health plan with the on-site clinic from a documentation perspective. This bundling, however, can be difficult where employees who do not participate in the employer's traditional group health plan are allowed to receive services at the on-site clinic. The employer must meet all of ERISA's disclosure requirements for these employees who have access to the on-site clinic but will not be on the distribution/mailing lists for those enrolled in the traditional group health plan. Finally, ERISA's fiduciary rules will also apply to the on-site clinic.[6]

Of course plans sponsored by governmental entities and church plans are not covered by ERISA.

[1] ERISA §3(1).
[2] 29 CFR §2510.3-1(c).
[3] ERISA §402(a)(1).
[4] ERISA §§102(a) and 104(b)(1).
[5] ERISA §503; 29 CFR §2560.503-1.
[6] ERISA §404.

Employers really have four different approaches they can take with regard to ERISA.

- Limit the care to employee-only first aid and minor injuries and illnesses and rely on the exemption from ERISA.
- Provide more expansive services but limit clinic access to those enrolled in the traditional group health plan and incorporate the clinic as part of that group health plan for purposes of the plan document, SPD, Form 5500, etc.
- A combination of the first two bullet points where full services are available to those enrolled in the traditional group health plan but only limited services are available to those who are not.
- Offer the more expansive services to all employees, even those not enrolled in the traditional group health plan, with the additional issues of meeting ERISA requirements for those not enrolled in the traditional group health plan.

COBRA: COBRA generally applies to group health plans which are defined as plans maintained by an employer to provide health care to individuals who have an employment-related connection to the employer.[7] With an exception noted below, the COBRA regulations state that COBRA applies to group health plans "whether provided directly or through insurance, reimbursement, or otherwise, and *whether or not provided through an on-site facility."*[8]

There is an exception for employer facilities similar to the exception under ERISA. Once again, to meet the exception the clinic must be located on the premises of the employer. The heath care must consist primarily of first aid (note the word primarily is absent in the ERISA exception). The care must be provided during the employer's working hours for treatment of a health condition, illness, or injury that occurs during those working hours. Care must be limited to current employees (no dependents and spouses) and employees may not be charged for the care.[9]

Few on-site medical clinics will meet this exception, and therefore, most on-site clinics are subject to COBRA (and ERISA).

In our experience, many employers do not fully appreciate the COBRA challenges that on-site clinics present. First, employers need to insure adequate delivery of COBRA notices. If the on-site clinic can be accessed by employees who are not otherwise participants in the traditional group health plan, they might be "forgotten" when it comes time for general or qualifying event COBRA notices. Second, unless the employer only offers the on-site clinic to those who are enrolled in the traditional group health plan and does not charge an additional COBRA premium for the on-site clinic (or otherwise offers the COBRA coverage for the on-site clinic for free), the employer will need to arrive at a COBRA premium for the clinic. This can be a difficult calculation and some employers will choose not to charge a COBRA premium for the clinic. One advantage of not charging an additional COBRA premium for the on-site clinic is that this relieves the employer from including the cost of the on-site clinic on the employee's W-2 Form under the ACA reporting requirements for the cost of health care.[10]

Also, in some instances if a COBRA beneficiary elects the on-site clinic, he or

[7] Internal Revenue Code §5000(b)(1).
[8] 26 CFR §54.4980B-2, Q/A-1(a).
[9] 26 CFR §54.4980B-2, Q/A-1(d).
[10] IRS Notice 2012-9, Q&A 32.

she will be entitled to enroll in any other COBRA covered benefits (e.g. group medical or dental) offered by the employer at the next open enrollment.[11] So if the on-site clinic was offered to employees who were not in the group health plan, the employee could select coverage for the on-site clinic initially and at a subsequent open enrollment elect other benefits. This could exacerbate the kind of adverse selection that is inherently part of COBRA elections.

Without regard to the approach taken, if the on-site clinic is covered by COBRA, the most concerning aspect of the COBRA obligation is providing access to the clinic for a disgruntled former employee that has elected COBRA coverage. Anecdotal accounts indicate that some employers design their on-site clinics to have a separate door to the outside so the former employee cannot enter any other portion of the building.

An employer, however, has wide discretion to define how many group health plans it maintains for COBRA purposes. The default rule is that all group health benefits will be considered a single plan unless it is clear from the instruments governing the plan that benefits are being provided in separate plans and they are actually operated as separate plans.[12] So the default rule would be that the traditional group health plan and the on-site clinic would be a single plan for COBRA purposes. Still, if that is the employer's intent it would be wise to make that "single plan" designation specifically in its documentation. The result is that if the employer limits the on-site clinic to employees who have elected traditional group health-plan coverage then the employer could require the employee to elect COBRA for the group health plan if he/she wants to access the clinic. This would likely reduce the number of employees who elect COBRA in order to gain access to the on-site clinic.

From a compliance standpoint, the easiest course of action would likely be to:

- Only offer the on-site clinic to those enrolled in the traditional group health plan.
- Bundle the on-site clinic with the traditional group health plan as single plan for COBRA purposes so that the only election that can be made is the traditional group health plan with the on-site clinic.
    - Revise COBRA notices to reflect that the on-site clinic is part of the overall group health plan.
- Do not charge any additional COBRA premium for access to the on-site clinic.

HIPAA: On-site clinics are considered "excepted benefits" under HIPAA and are generally exempt from HIPAA's portability, special enrollment and nondiscrimination rules based on health status (not to be confused with the Code's nondiscrimination rules).[13]

On-site clinics are also not included in the definition of "health plans" for HIPAA administrative (i.e. privacy and security) provisions.[14] But note that this only applies

[11] 26 CFR §54.4980B-5, Q/A-4(b).
[12] 26 CFR §54.4980B-2, Q/A-6(a).

[13] Internal Revenue Code §§9831(b) and 9832(c)(1)(G); ERISA §§732(b) and 733(c)(1)(G); Public Health Services Act (PHSA) §§2722(b) and 2791(c)(1)(G); 26 CFR §54.9831-1(c)(2)(viii); 29 CFR §2590.732(c)(2)(viii);.45 CFR §146.145(b)(2)(viii).
[14] 45 CFR §160.103 listing exclusions from definition of "health plan" for excepted benefits

to the on-site clinic's status as a health plan. An on-site clinic could still be covered by HIPAA's privacy and security rules as a health care provider.

The clinic would be covered by HIPAA's privacy and security rules as a health care provider if it conducts "standard transactions" electronically (e.g., billing, payments, coordination of benefits, enrollment and eligibility) or hires a service provider to perform this function.[15] This will turn on the specific facts of each on-site clinic. If the clinic bills the employer's traditional group health plan for any services then there will undoubtedly be these types of "standard transactions" and the clinic would need to abide by HIPAA privacy and security as a health care provider.

Also when dealing with protected health information (PHI) the employer should recognize that its traditional group health plan is a covered entity under HIPAA. And, while the on-site clinic might not be a covered entity either as a health plan or a health care provider, the traditional group health plan should consider closely whether it might violate any HIPAA privacy or security provisions for any information the group health plan provides to the clinic. Those disclosures might be fine for "treatment" at the clinic but wherever PHI is being disclosed, covered entities, such as group health plans, should make sure that they fall under an applicable exemption for disclosure.

The on-site clinic should be careful concerning any PHI it discloses to the employer if the on-site clinic is considered a health care provider. As long as certain procedures and documentation are in place, a group health plan as a covered entity can disclose PHI to an employer for purposes of plan administration.[16] There is no similar exclusion for a health care provider disclosing PHI to an employer.

Further some have expressed concerns that an on-site clinic could lose its status as an excepted benefit and/or exempt from HIPAA's privacy and security provisions if it is "bundled" with the employer's traditional group health plan which is clearly subject to those provisions. As discussed above, that "bundling" may be a preferred course of action because of ERISA and COBRA compliance concerns. Based on language in the regulatory exclusion that a program is excluded from the definition of a health plan (and therefore HIPAA privacy and security provisions as a group health plan) to the "extent that" it provides for excepted benefits, it may be possible to treat the on-site clinic as separately excluded even if it is bundled with the traditional group health plan. But, as with every aspect of this Q&A, an employer's own legal counsel should be consulted on this point.

Of course if an on-site clinic is subject to HIPAA privacy and security there are a myriad of compliance concerns that are beyond the scope of this Q&A such as HIPAA policies and procedures, record retention, security and privacy officers, contracts with business associates, reporting security breaches, etc.

Finally even if an argument can be made that an on-site clinic is exempt from HIPAA privacy and security, there are state laws that could be applicable and every effort should be made to keep an on-site clinic's

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that are found in PHSA 2791(C)(1) (42 USC 300(gg)-91(c)(1)).

[15] 45 CFR §160.103 (defining a healthcare provider as a "covered entity").

[16] 45 CFR §164.504(f).

records confidential and to have stringent security policies and procedures in place.

ACA/Other Laws: The on-site clinic's status as an excepted benefit under HIPAA will also exempt the clinic from certain aspects of the ACA. Specifically the on-site clinic will be exempt from the ACA individual and group market reforms (that some refer to as the PHSA Mandates).[17] These reforms include: coverage of all preventive services at no cost; no annual or lifetime caps; coverage of children to age 26, etc.[18]

Employer reporting under Code Section 6055 and 6056 on Form 1095-C for applicable large employers (ALEs) should not be triggered by the on-site clinic alone since it is an excepted benefit.[19] Of course most applicable large employers with on-site clinics also have a traditional group health plans that will require reporting.

As an excepted benefit the on-site clinic is not considered minimum essential coverage and offering the on-site clinic alone will not be sufficient to meet the employer mandate or insulate employees from the individual mandate that was in effect prior to 2019.

Form W-2 reporting was addressed above and will apply if the employer charges a COBRA premium for the on-site clinic.

At this point, it appears that on-site clinics will be taken into account in determining excess benefits under the Cadillac Tax, currently set to take effect in 2022 unless repealed. The IRS, however, has indicated that it anticipates exempting on-site clinics that provide only "de minimis" medical care to employees. An IRS notice gives the following examples of what might possibly be considered de minimis medical care: immunizations, injections of antigens that are provided by employees, aspirin and other over the counter pain relievers; and treatment of injuries caused by accidents at work.[20] There is current bi-partisan support for repeal of the Cadillac Tax.

Nondiscrimination under Code Section 105(h): An on-site clinic will generally be considered a self-insured plan subject to nondiscrimination testing under Code Section 105(h).[21] Similarly Code Section125 nondiscrimination rules can come into play where employees pay for access to an on-site clinic on a pre-tax basis as part of their group health coverage through a Section 125 (cafeteria) plan.[22] These rules are designed to insure that the

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[17] Internal Revenue Code §§9831(b) and 9832(c)(1)(G); ERISA §§732(b) and 733(c)(1)(G); PHSA §§2722(b) and 2791(c)(1)(G); 26 CFR §54.9831-1(c)(2)(viii); 29 CFR §2590.732(c)(2)(viii);.45 CFR §146.145(b)(2)(viii).

[18] The status as an excepted benefit should also exempt the on-site clinic from the former ACA Transitional Reinsurance Fee (TRF). The fact that the on-site clinic, standing alone, does not provide for minimum value is another grounds for exemption from the TRF. Also, the ACA Patient-Centered Outcomes Research Institute fee (PCORI) is not applied to excepted benefits.

[19] The rationale is that excepted benefits are not minimum essential coverage under the ACA and therefor need not be reported. The preamble to the final regulations states flatly that: reporting is not required for coverage at on-site medical clinics."

[20] IRS Notice 2015-16.

[21] Internal Revenue Code §105(h), 26 CFR 1.105-11(c).

[22] Internal Revenue Code §125; Prop. Treas. Reg. §1.125-7.

plan does not discriminate in favor of highly compensated employees/individuals.

Generally, there are not likely to be nondiscrimination problems under the Code where all employees have access to the on-site clinic or where all employees with traditional group health plan coverage have access to the on-site clinic (and assuming the traditional group health plan satisfies the nondiscrimination rules under Code Section 105(h)). But conceivably there could be nondiscrimination issues where an employer has a HDHP plan and a non-HDHP plan and, because of the HSA issues discussed below, decides to charge employees in the HDHP plan fair market value for services before the deductible is met while allowing employees in the non-HDHP plan to have services free of charge at all levels.

Also for an employer with several locations but an on-site clinic is only available at one location there are potential issues under the Code Section 105(h) eligibility test. [23]

Compatibility of an On-site Clinic with an HDHP/HSA Plan Design: HDHPs combined with HSAs is a plan design implemented by many employers. To be an eligible individual for an HSA, an employee must not only be enrolled in an HDHP but also must not have access to any other disqualifying coverage before the HDHP minimum statutory deductible is met.[24]

An on-site clinic can constitute disqualifying coverage in many instances but there are exceptions.

First, if the on-site clinic were limited to providing only preventive services then the employee would still be an eligible individual for HSA purposes.[25]

Also, in Notice 2008-59, Q&A 10, the IRS indicated that an on-site clinic would not destroy an employee's status as an HSA eligible individual if the clinic does not provide "significant benefits in the nature of medical care." The Notice provides an example of an on-site clinic at a manufacturing plant that limited its free services to: (1) physicals and immunizations; (2) injecting antigens provided by employees (e.g., performing allergy injections); (3) a variety of aspirin and other nonprescription pain relievers; and (4) treatment for injuries caused by accidents at the plant. In that instance the IRS stated that the on-site clinic would not be providing significant benefits in the form of medical care. The Notice provides another example of a hospital that provides a full array of services to its employees at the hospital "for all of their medical needs" at no charge. Here, the IRS found that the on-site clinic would be providing significant benefits in the form of medical care and the employee would be an ineligible individual for purposes of an HSA. Of course almost all on-site clinics will fall in between these two extreme examples in the Notice. Whether an on-site clinic offers "significant benefits in the nature of medical care" is a facts and circumstances determination where the employer's legal counsel should be consulted.

Remember too that in looking to see whether an on-site clinic provides significant services in the nature of medical care preventive services can be disregarded in the determination.

While Notice 2008-59 does not directly state that an employee will remain HSA eligible if the employee pays fair market value for services at the on-site clinic before

[23] 26 CFR §1.105-11(c)(2).
[24] Internal Revenue Code §223(c)(1)(A)(ii); Rul. 2004-45.
[25] IRS Notice 2004-23.

the deductible is met, many suggest that is an implicit part of this guidance.[26] That conclusion however, begs the question of what constitutes fair market value and how that is determined? Possibilities go in a range from a full actuarial study (probably the safest) to what another local clinic/urgent care center is charging. The Medicare rate multiplied by a factor could also be considered. The non-discounted reasonable and customary charges by CPT code is another possibility. Outside the full actuarial study, none of these methods is likely "bullet proof." If an employer decides to try and charge fair market value as a method of maintaining HSA eligibility, the employer's counsel should, once again, be consulted.

Although likely not a practical solution, an employer could bar access to the on-site clinic until the employee has satisfied the HDHP deductible.

In addition, as mentioned above, charging those with a HDHP fair market value while allowing those with non-HDHP coverage to have free access could raise Code Section 105(h) nondiscrimination issues.

Finally there is some tension between this guidance from the IRS and the notion that the on-site clinic is an ERISA covered plan. Fair market value would arguably have within it an element of profit. The employer sponsoring the clinic will likely be, in one aspect or another, an ERISA fiduciary of the on-site clinic it is sponsoring. Making a profit off of the plan's participants and beneficiaries might be viewed by some as inconsistent with ERISA.

Conclusion: On-site clinics can be a very valuable tool for improving employee access to health and wellness services as well as improving productivity. With a healthier population, the employer's cost of providing group medical benefits should decrease over time. An employer, however, should have a detailed strategy for addressing the issues raised in this Q&A in addition to those topics mentioned in the summary above that are not covered by this Q&A.

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[26] Q&A 10 of that Notice asks the question: "Is an otherwise eligible individual who has access to free health care or health care at *charges below fair market value* from a clinic on an employer's premises an eligible individual under § 223(c)(1)?" (emphasis added).