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View From McDermott: Navigating Legal Issues in Connection with Employer Sponsored On-Site Health Clinics

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I. Introduction

Employers are increasingly concerned with the high cost of health care and executives in the C-Suite are beginning to take notice. The Affordable Care Act ("ACA") required employers who sponsor group health plans to adopt a number of reforms, many of which significantly increased the cost of offering group health plan coverage to employees, former employees and their dependents. Among these reforms were the extension of coverage to adult dependent children, elimination of life-time and annual limits on essential health benefits and the elimination of pre-existing condition exclusions[1]. In addition, employers are now subject to a whole host of new tax and reporting requirements under the ACA, namely the employer shared responsibility mandate that requires large employers to offer minimum essential coverage to full-time employees or face a significant tax penalty.[2] Even if an employer does provide coverage, penalties can also be triggered if the coverage is not affordable for full-time employees or does not provide minimum value.[3] Most significantly, the tax on high cost health care[4]—the so-called Cadillac Tax—which is scheduled to take effect in January of 2018 has caused employers of all sizes to assess their current health plan offerings and make modifications in attempts to escape the tax, or at a minimum, reduce the amount of excess coverage that would be subject to taxation.

One approach employers have been increasingly adopting as a way to foster preventive care and control health plan costs over the long term is the adoption of employer sponsored health clinics at the worksite. In fact, in a follow up to its National Survey of Employer-Sponsored Health Plans, Mercer found that 29% of employers with 5,000 or more employees provided an on-site or near-site clinic offering primary care services, up from 24% in the prior year.[5] Improving access to quality care is also a reason cited by employers for adoption of on-site clinics; even though certain types of on-site clinics are included in calculation of the Cadillac Tax (see below under ACA Issues).

An employer implementing an on-site clinic must proceed with caution in order to comply with the plethora of federal and state laws applicable to employer-sponsored on-site health clinics (referred to in this article as "on-site clinics"). On-site clinics can take a variety of forms and the services offered at the on-site clinic dictate which laws that must be satisfied in structuring and operating the clinic. On-site clinic models can range from an extension of occupational health by offering services to treat minor injury and illness at the worksite to a full-service primary care clinic that provides medical services, pharmacy services, preventive care and disease management. On-site clinics can also provide a home base to manage employee wellness programs by offering bio-metric screening, health

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[1] ERISA Section 715 and implementing regulations; Code Section 9815 and implementing regulations.

[2] Code Section 4980H(a).
[3] Code Section 4980H(b).
[4] Code Section 4980I.
[5] Follow up survey conducted by Mercer of participants in "National Survey of Employer Sponsored Health Plans, 2014.

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coaching, disease management, health education classes, behavioral modification programs for smoking cessation and weight loss and even acupuncture and massage therapy.

This article provides a high level overview of the patchwork of legal requirements applicable to employer sponsored on-site clinics and challenges that arise when an employer decides to implement an on-site clinic or expand clinic offerings to be more robust. In general, employer sponsored on-site clinics that are limited in purpose to providing first aid and treating minor illness and injury at the workplace will be exempt from most of the federal laws discussed below. However, on-site clinics that provide more robust services, such as preventive care, primary care, laboratory and pharmacy benefits are subject to greater regulation.

II. Legal Issues

A. ERISA Issues. One threshold issue is whether the on-site clinic is subject to the Employee Retirement Income Security Act of 1974 (''ERISA'') under the rules that apply to employer-sponsored welfare benefit plans. Under ERISA, an employee welfare benefit plan is generally a plan, fund or program established or maintained by an employer or employee organization, or both, that provides participants and beneficiaries under the plan with benefits such as medical, dental, vision, prescription drug, sickness, accident, disability or death benefits.[6] These benefits may be provided on either a fully-insured or self-insured basis, or a combination of both.

ERISA exempts certain on-site clinics from the definition of an employee welfare benefit plan. Specifically, a Department of Labor (''DOL'') regulation provides that the term ''employee welfare benefit plan'' does not include the maintenance on the premises of employer facilities for the treatment of minor injuries or illness or rendering first aid in case of accidents occurring during working days.[7] There is no definition in ERISA as to what constitutes the treatment of minor injuries or illness for purposes of this exemption. Complicating matters is that many of today's clinics also offer telehealth services, which makes it difficult to assess the exact nature and location of services being provided.

If treatment of employees at an on-site clinic is limited to the treatment of minor injuries and first aid for accidents occurring during working hours, the clinic would meet the ERISA exception for on-site clinics and would not be subject to ERISA. However, if the on-site clinic is providing more robust services, such as preventive care services, primary care services, screenings, diagnostic services and wellness exams, it is likely subject to ERISA. An on-site clinic that is subject to ERISA must comply with the fiduciary and reporting and disclosure requirements of ERISA, such as the requirement to maintain a written plan document, issue summary plan descriptions and summary of material modifications for the plan, file annual reports (Form 5500s) with the DOL and provide notices to participants for various federal mandates contained in ERISA. An on-site clinic can either be included as a component participating plan in the employer's consolidated health and welfare benefit plan or can be documented and reported as a stand-alone ERISA plan.

B. COBRA Issues. COBRA[8] is a federal law that permits continuation of group health plan coverage upon certain qualifying events. Virtually all group health plans will be subject to COBRA unless an exception applies. COBRA does not apply to an on-site clinic if (i) the health care provided at the on-site clinic consists primarily of first aid that is provided during the employer's working hours for treatment of a health condition, illness or injury that occurs during those working hours, (ii) the health care is available only to current employees, and (iii) employees are not charged for the use of the facility.[9]

If the on-site clinic does not meet this limited exception, it would be considered group health plan coverage subject to COBRA that must be offered to a qualified beneficiary upon the occurrence of a qualifying event. There are unique compliance challenges in offering continuation coverage for on-site clinics. An employer may make the on-site clinic available to all employees at the company, not just those who are eligible for, or who elect, company health plan coverage. This broadens the scope of individuals who must be provided with COBRA notices and makes calculation of a separate COBRA premium for coverage difficult. Some of these complications can be mitigated if the on-site clinic is considered part of the employer's medical plan. In that case, COBRA continuation coverage under the on-site clinic would be bundled with other medical plan coverage offered to the employee upon a qualifying event. This is usually not the case, however, where access to an employer's on-site clinic is open to all company employees regardless of whether they are enrolled in the employer's medical plan. The obligation to provide continuation coverage under an on-site clinic to former employees may also pose security challenges if former employees who have elected COBRA need to enter company premises to obtain care at the on-site clinic. In addition, depending on how the on-site clinic benefit is structured for COBRA purposes, a COBRA qualified beneficiary may be able to elect other types of group health plan benefits at open enrollment, such as medical and dental, even if the individual was not covered under such plans at the time of the qualifying event.

Employers can charge a premium for separate COBRA access to the on-site clinic or bundle the cost of the on-site clinic COBRA coverage with medical COBRA coverage, depending on how the benefit is structured. Under the ACA, if no separate COBRA premium is charged for the on-site clinic, the employer is exempt from reporting the on-site clinic costs on an employee's Form W-2 (see below under ACA Issues).

C. Federal Income Tax Issues. Under the Internal Revenue Code (''Code''), if an on-site clinic is either part of an employer's health plan or qualifies as a stand-alone group health plan, any employer-paid expenses for medical services qualifying under Code Section 213(d) provided by the on-site clinic are generally not taxable

[6] ERISA § 3(1).
[7] 29 C.F. R. 2510.3-1(c).

[8] Consolidated Omnibus Budget Reconciliation Act, set forth at Code Section 4980B.
[9] Treas. Reg. 54.4980B-2, Q&A 1(d).

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to employees.[10] In addition, an employer is permitted to deduct the cost of an on-site clinic as a business expense under Code Section 162. However, any services that do not qualify as medical care under Code Section 213(d) are taxable to employees and subject to withholding. On-site clinics that are self-insured group health plans are also prohibited from discriminating in favor of highly compensated employees.

D. HIPAA Issues. Title I of the Health Insurance Portability and Accountability Act ("HIPAA") sets forth the requirements of a group health plan with respect to portability, special enrollment, mandated benefit requirements and non-discrimination protections. Such protections are applicable to most group health plans subject to ERISA and the Code, except for those that fall within HIPAA's definition of "excepted benefits." On-site clinics are considered excepted benefits for purposes of Title I of HIPAA.[11] Therefore, on-site clinics are not required to comply with HIPAA's portability, special enrollment, mandated benefit requirements and health non-discrimination rules. To date, federal regulators have not provided a definition of "on-site clinic" for purposes of this HIPAA exception.

On-site clinics are also excluded from the definition of "health plans," under the administrative simplification provisions in Title II of HIPAA regarding privacy and security of protected health information.[12] Nevertheless, an on-site clinic may be subject to HIPAA's privacy and security requirements if it meets the HIPAA definition of a covered entity health care provider. A health care provider subject to the HIPAA privacy and security rules is one that sends or receives health information in electronic form in connection with specifically prescribed electronic transactions.[13] Moreover, an employer's on-site clinic that provides substantial medical services (i.e., not just first aid) could get swept in under the definition of a group health plan if it is treated as an ERISA plan by the employer/plan sponsor. On-site clinics that are subject to HIPAA's privacy and security rules must comply with the technical, physical and administrative safeguarding requirements of HIPAA, including appointing a privacy and security officer, maintaining HIPAA policies and procedures, issuing HIPAA Notices of Privacy Practices to employees, properly maintaining HIPAA records and reporting security breaches.

An on-site clinic must be able to keep its medical records confidential from the employer. From a practical standpoint, ensuring employees of this strict separation is often a key factor in increasing employee utilization of an on-site clinic. In addition to restrictions under HIPAA, an employer is prohibited by the Americans with Disabilities Act from using such information in making decisions regarding hiring, promotion or termination. Additionally, the Genetic Information Nondiscrimination Act of 2008 strictly limits disclosure of a person's genetic information, including family medical history, and prohibits discrimination based on genetic information in any aspect of employment, including hiring, promotions, terminations, and salary. Employers need to be able to craft ways to de-identify information if they seek a return on investment information such as how the clinic is being used by the workforce, how patients are managed and to ensure that the clinic vendor is meeting its goals/satisfying its contractual obligations. For medical information subject to HIPAA, and which does not relate to treatment, payment or health care operations of the on-site clinic, the on-site clinic may need to seek a signed authorization from its patients prior to sharing such information with the employer.

E. Affordable Care Act Issues. If an on-site clinic is deemed to be an employer group health plan for purposes of ERISA, it will also be subject to certain requirements under the Affordable Care Act. Coverage for on-site clinics is generally exempt from many of the ACA's provisions because such coverage is deemed to be an "excepted benefit" for purposes of HIPAA;[14]however, some ACA requirements still apply to on-site clinics.

1. Form W-2 Reporting

Even as an "excepted benefit," certain requirements under the ACA will apply to on-site clinics, including reporting the cost of employer-sponsored coverage of Form W-2. Under health care reform, employers must report the aggregate cost of applicable employer-sponsored coverage on an employee's Form W-2. The W-2 reporting requirement was first required for the 2012 tax year—that is, the value of coverage was required to be reported on the Form W-2 issued in January 2013 for the 2012 tax year. Under ACA guidance, an employer is not required to report the cost of on-site clinic services on the employee's Form W-2 if the employer does not charge a premium with respect to the on-site clinic services under the COBRA continuation rules.[15]

2. Cadillac Tax

Code Section 4980I(a), which was added to the Code by the ACA, imposes a forty percent (40%) excise tax on a "coverage provider" if an employee is covered under any "applicable employer-sponsored coverage" of an employer at any time during a taxable period and there is any excess benefit with respect to that coverage (the so-called "Cadillac Tax"). For purpose of the excise tax, "applicable employer-sponsored coverage" is, with respect to an employee, defined as coverage under any group health plan made available to the employee by an employer which is excludible from the employee's gross income under Code Section 106, or would be so excludable if it were employer-provided coverage.

Certain types of coverage are excluded from the definition of "applicable coverage." Specifically, many of the HIPAA excepted benefits under Code Section 9832(c) are excluded from the Cadillac Tax, but on-site clinics are included in the statutory definition of "applicable coverage" and are subject to the tax.[16] In a recent Notice issued by the IRS requesting comments and informing the rulemaking process under Code Section 4980I, the IRS stated that it is seeking comments on ex-

[10] Code Sections 105 and 106.
[11] Code Section 9832(c)(1)(G).
[12] 45 CFR § 160.103, definition of "health plan" at (2)(i) (excludes "excepted benefits" listed in PHSA § 2791(c)(1), 42 U.S.C. § 300gg-91(c)(1); "coverage for on-site medical clinics" is one of the excepted benefits listed).
[13] 45 C.F.R. 160.103
[14] Code Section 9832(c)(1)(G).
[15] IRS Notice 2012-9.
[16] Code Section 4980I(d)(1)(B)(i) exempts coverage under Code Section 9832(c)(1)(other than coverage in subparagraph (G) thereof, or for long term care.

cluding clinics that meet the criteria described in the COBRA regulations, and proposed that certain services could be provided by an on-site clinic without subjecting it to the Cadillac Tax, such as: (a) immunizations; (b) injections of antigens (for example, for allergy injections) provided by employees; (c) provision of a variety of aspirin and other nonprescription pain relievers; and (d) treatment of injuries caused by accidents at work (beyond first aid) (See 36 PBD, 2/24/15). [17]

F. Health Savings Account Issues. An individual participating in a high deductible health plan (''HDHP'') is permitted to make tax deductible contributions to a health savings account (''HSA'') to fund his or her medical needs.[18] Generally, an individual is eligible to establish an HSA if, with respect to any month, he or she:

- is covered under a HDHP on the first day of that month;
- is not also covered by any health plan that is not an HDHP (with certain exceptions discussed below);
- is not entitled to benefits under Medicare; and
- may not be claimed as a dependent on another person's tax return.[19]

Generally, an eligible individual may not be covered under non-HDHP coverage and still maintain eligibility to make HSA contributions. There are three exceptions that permit other health plan coverage to be disregarded.[20] Disregarded coverage includes:

1. Coverage for any benefit provided by permitted insurance.[21] The term ''permitted insurance'' means, insurance if substantially all of the coverage provided under such insurance relates to—

- liabilities incurred under workers' compensation laws,
- tort liabilities,
- liabilities relating to ownership or use of property, or
- such other similar liabilities as the Secretary may specify by regulations,
- insurance for a specified disease or illness, and
- insurance paying a fixed amount per day (or other period) of hospitalization.

2. Coverage, whether through insurance or otherwise, for accidents, disability, dental care, vision care, or long-term care.[22]

3. Coverage under an HRA that reimburses premiums for accident and health coverage.[23]

On-site clinic coverage that is considered group health plan coverage would normally disqualify an individual from eligibility to make and/or receive HSA contributions. However, access to free health care or health care at charges below fair market value (FMV) from an employer's on-site clinic will not disqualify an individual from HSA eligibility as long as the clinic does not provide significant benefits in the nature of medical care (in addition to disregarded coverage or preventative care).[24] Guidance from the Internal Revenue Service (''IRS'')[25] provides the following examples in their interpretation of whether an on-site clinic would violate the HSA eligibility rules:

Example 1. A manufacturing plant operates an on-site clinic that provides the following free health care for employees: (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. A: The clinic does not provide significant benefits in the nature of medical care in addition to disregarded coverage or preventative care.

Example 2. A hospital permits its employees to receive care at its facilities for all of their medical needs. For employees without health insurance, the hospital provides medical care at no charge. For employees who have health insurance, the hospital waives all deductibles and co-pays. A: Because the hospital provides significant care in the nature of medical services, the hospital's employees are not eligible individuals under an HSA.

An employer that also sponsors a HDHP and makes contributions to its employees HSAs must evaluate all of the facts and circumstances surrounding the type of clinic services before deciding whether it can offer clinic services to employees at or below FMV or even without charge. It appears from IRS guidance, that an employer could offer limited EAP benefits or preventive care benefits at an on-site clinic without jeopardizing an employee's eligibility to make or receive HSA contributions. Preventive care for purposes of not disqualifying an HSA[26] includes, but is not limited to, the following:

- Periodic health evaluations, including tests and diagnostic procedures ordered in connection with routine examinations, such as annual physicals.
- Routine prenatal and well-child care.
- Child and adult immunizations.
- Tobacco cessation programs.
- Obesity weight-loss programs.
- Screening services.

However, preventative care does not generally include any service or benefit intended to treat an existing illness, injury, or condition.

G. State Law Issues. A full discussion of state laws that would apply to an on-site clinic is beyond the scope of this article. However, many states have laws prohibiting a corporation from employing a physician (or other health professional), controlling a physician's practice of medicine or splitting professional fees with non-licensed individuals or entities. On-site clinics must be structured in a manner to comply with applicable state laws. The corporate practice of medicine laws may

[17] IRS Notice 2015-16.
[18] Internal Revenue Code § 223
[19] Code Section 223(c)(1); Code Section 223(b)(6) and (7).
[20] Internal Revenue Code § 223(c)(1)(B)
[21] Internal Revenue Code § 223(c)(1)(B)(i)
[22] Internal Revenue Code § 223(c)(1)(B)(ii)
[23] IRS. Notice 2008-59, Q&A 1
[24] IRS Notice 2008-59
[25] IRS Notice 2008-59, Q&A 10
[26] Internal Revenue Code § 223(c)(2)(C); Notice 2004-23.

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also govern how the on-site may be offered to employees. For example, a number of states require medical clinics affiliated with lay corporations to have a separate entrance, signage, etc. State law may also impact the credentialing, oversight and supervision requirements for mid-level providers, such as nurse practitioners and physicians assistants which may impact clinic staffing. On-site clinics are also likely subject to a variety of state and local laws and regulations that govern specific aspects of the clinics operations, e.g., laboratory services, disposal of biomedical waste, and potentially the dispensing (and administering) of pharmaceuticals.

Conclusion

On-site clinics can be a valuable addition to an employer's overall health care strategy with respect to promoting prevention, improving quality outcomes and reducing the employer's overall trend in health care spending. However, given the myriad laws that apply to such clinics, an employer is well-advised to develop a comprehensive legal compliance strategy in designing and implementing the structure and operation of its on-site clinic. Employer on-site clinics with more robust health care offerings will likely trip the ERISA wire and require compliance with a patchwork of federal and state laws.