ACA, HIPAA AND FEDERAL HEALTH BENEFIT MANDATES: PRACTICAL Q&A

The Affordable Care Act (ACA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other federal health benefit mandates (e.g., the Mental Health Parity Act, the Newborns and Mothers Health Protection Act, and the Women's Health and Cancer Rights Act) dramatically impact the administration of self-insured health plans. This monthly column provides practical answers to administration questions and current guidance on ACA, HIPAA and other federal benefit mandates.

Attorneys John R. Hickman, Ashley Gillihan, Carolyn Smith, and Dan Taylor provide the answers in this column. Mr. Hickman is partner in charge of the Health Benefits Practice with Alston & Bird, LLP, an Atlanta, New York, Los Angeles, Charlotte, Dallas and Washington, D.C. law firm. Ashley Gillihan, Steven Mindy, Carolyn Smith and Dan Taylor are members of the Health Benefits Practice. Answers are provided as general guidance on the subjects covered in the question and are not provided as legal advice to the questioner's situation. Any legal issues should be reviewed by your legal counsel to apply the law to the particular facts of your situation. Readers are encouraged to send questions by E-MAIL to Mr. Hickman at john.hickman@alston.com.

BENEFIT COMPLIANCE ISSUES THAT ARISE IN CONNECTION WITH EMPLOYER SPONSORED CLINIC ARRANGEMENTS: PART ONE

BACKGROUND

Many employers, particularly large employers, are evaluating on-site health clinic options as an additional benefit offering. Common reasons for instituting on-site clinics include enhancing worker productivity (i.e., "increasing "presenteeism"), reducing medical costs, integrating various health services, and improving access to care for employees. However, on-site clinics also pose a myriad of compliance obligations, particularly in the employee benefits arena.

This two-part article addresses the application of various employee benefit laws to coverage offered through employer-sponsored on-site medical clinics. The impact of the various laws discussed herein will depend on the structure and design of the clinic arrangement, so not all of the issues would apply in every situation. However, the discussion below should give an idea of the employee benefit compliance obligations associated with various arrangements.[1]

Part One of this article focuses on the compliance concerns that are most frequently discussed with respect to on-site medical clinics include the application of ERISA, HIPAA (and other health information privacy laws, at the federal and state level), and the Affordable Care Act. In part two of this article (in the upcoming December issue), we look at other concerns which may also arise including COBRA and other group health plan requirements; the effect on plan participants' eligibility for Health Savings Accounts (HSAs); and various tax implications for plan participants.

8.1 Billion Dollars

in Captive Insurance Premium Growth from 2016 to 2017.

- ***$8.1 billion means the amount of total annual premium growth Delaware experienced in 2017.***
- ***$8.1 billion means a 182% total premium increase from $4.4 billion in 2016 to $12.5 billion in 2017.***
- ***$8.1 billion means Delaware is the second largest U.S. captive domicile in terms of premium.***
- ***$8.1 billion means the confidence the captive insurance industry has in Delaware's captive program.***

STEVE KINION, DIRECTOR
Bureau of Captive & Financial Products
Department of Insurance

"This explosive premium growth is mostly attributed to reinsurance premium. It is a combination of the redomestication of large reinsurers to Delaware as well as existing reinsurers vastly expanding their writings. It is a clear sign of the confidence the insurance industry has in Delaware's status as a world class captive insurance domicile."

Trinidad Navarro, Insurance Commissioner

In Delaware, the captive regulators are dedicated exclusively to our captive insurance clients' needs, and work under the direction of our Captive Bureau leadership, directed by Steve Kinion.

BUREAU OF CAPTIVE & FINANCIAL INSURANCE PRODUCTS
1007 North Orange Street, Suite 1010
Wilmington, DE 19801
302-577-5280
Trinidad Navarro, Insurance Commissioner

I. ERISA

Is the On-Site Clinic a Group Health Plan Under ERISA?

As a general matter, health benefit plans sponsored by private (but not governmental or church) employers will be subject to federal regulation under ERISA.

The definition of an ERISA-covered employee welfare benefit plan is set forth in § 3(1) of Title I of ERISA, which can be broken down into the following essential elements: (1) a plan, fund, or program; (2) established or maintained by an employer or by an employee organization, or by both; (3) for the purpose of providing medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability (or other enumerated benefits); (4) to participants or their beneficiaries.

Arrangements that fit this definition will generally be required to comply with ERISA regardless of whether an employer treats a program as an ERISA plan.

The ERISA regulations include a specific exception from the definition of welfare benefit plan for "the maintenance on the premises of an employer of facilities for the treatment of minor injuries or illness or rendering first aid in case of accidents occurring during working hours." 29 CFR § 2510.3-1(c).

There is no elaboration as to when an injury or illness is minor. However, some commonly considered services (second surgical opinions, EKG and lab-work) likely go well beyond the limited "first-aid" or on-site convenience type treatments that were likely contemplated by the regulations.

Generally, the following activities/practices put on-site medical facilities at risk for falling outside the ERISA exception for on-site medical programs, thereby subjecting the program to compliance with ERISA:

- Providing coverage to dependents (and possibly retirees);
- Treating conditions that constitute more than "minor injuries or illness";
- Providing first-aid treatment for accidents that occur outside of working hours;
- Providing care that involves "substantial" expenditures."

The Department of Labor has interpreted the ERISA exception rather narrowly. In ERISA Opinion Letter 83-35A 06/27/1983, an employer, as part of its EAP-type program, hired a counselor to be on-site one day per week in order "to provide confidential and professional assistance to the employees and eligible family members" for personal problems.

After identifying the problem, the counselor would suggest a plan of action and make a referral to an appropriate professional person, agency, or service clinic if the employee agreed with the plan of action. The counselor would then serve as a coordinator with the outside service. The employer sought an opinion from the DOL as to whether the Assistance Program was included in the "on-site medical facility" exception set forth in DOL regulations.

The DOL considered whether the program fit into the exception set forth in the DOL regulation. Without providing much elaboration, the DOL stated that because benefits "extend to members of an employee's family and to problems that are more serious than 'minor injuries,'" the program did not fit into the exception described in the DOL regulation.

Apparently, extension of benefits to individuals other than employees was significant. Also, providing even an initial diagnostic screening through the counselor in order to determine which plan of action or specialist would be most appropriate to provide further treatment was considered to go beyond treating "minor injuries."

ERISA Compliance Requirements

An arrangement that (i) met the definition of employee welfare benefit plan (a broad definition that would catch many such arrangements) and (ii) did not satisfy the relatively narrow ERISA on-site clinic exception would be an ERISA group health plan.

Status as an ERISA plan would implicate several compliance issues which, if not followed, can result in fines, penalties, and exposure to costly litigation.

- **Plan Document and SPD.** The employer's ERISA plan document and Summary Plan Description (SPD) must describe scope of coverage made available;
- **Claims and Appeals Process.** The employer's ERISA plan must have a claim and appeal process addressing benefit claim denials, and follow them in the event a benefit/eligibility determination is challenged;
- **Form 5500.** The employer must file a Form 5500 (or include with another plan in a "wrap" arrangement), and any fees must be reported by the employer on a Form 5500 Schedule A (if treated as insurance) or Schedule C (for administrative expenses);
- **Reasonable Fees.** The employer agreement must be reasonable with regard to fees. In addition, penalty provisions for early termination (outside of reasonable startup costs actually incurred) cannot be included;
- **Prohibited Transactions.** The employer will need to ensure that "prohibited transactions" with related entities do not take place.

Advantages to ERISA Status

While the compliance requirements can be significant, several potential advantages may also flow from ERISA coverage. This section provides a high-level overview of the potential advantages of the application of ERISA.

- **Establishes with Specificity the Available Plan Benefits.** ERISA's written plan document and SPD requirements ensure that benefits are accurately presented and described to employees, thereby limiting an employee's claim for benefits in a properly administered plan to those provided under the written plan document and SPD. The existence of and adherence to the plan document serves as a reference and organization tool, enabling employers to be much more deliberate and consistent in their choice of benefits offered and administration of the plan.
- **Possible Preemption of Some State law Claims Related to Denial of Treatment.** For ERISA plans, preemption means that claimants cannot sue a plan or plan administrator under


HOW ARE WE CREATING THE FUTURE OF HEALTH CARE? TOGETHER.
AmeriHealth
ADMINISTRATORS
www.ahatpa.com

a state law claim if a claim under ERISA would also apply. This protection has been especially beneficial to utilization review organizations and HMOs in negligence, malpractice, breach of contract, and similar state law claims, though case law continues to evolve. One of the difficulties in this type of litigation has been distinguishing between plan eligibility decisions and treatment decisions, which can sometimes be impossible to separate. Generally, challenges to a coverage or eligibility decision will be preempted by ERISA, but a challenge to the quality of care may not. Where the two are intertwined (referred to as "mixed eligibility/treatment decisions"), preemption is generally not available, and the claimant is allowed to proceed with the state law claim.

- **Exhaustion of Remedies.** In situations where an employee is attempting to recover benefits, many courts have honored an ERISA plan's requirement that the employee exhaust all remedies under the plan before the employee can file suit. Of course, such protection requires that the plan document include ERISA-compliant claims procedures, and that the plan administrator closely follow the claims procedures. While this "exhaustion of remedies" requirement is not specifically provided by ERISA, courts almost universally honor the ERISA plan document's exhaustion requirement.

- **Deferential Standard of Review.** The standard of review applied by the court can make the difference between winning and losing. In the event that an employee or beneficiary exhausts all remedies and files a benefits claim in court, the court will usually provide the "abuse of discretion" standard of review (provided certain requirements are met), which means that a court generally will defer to the plan administrator's benefit determination, unless such decision is found to be arbitrary and capricious. On the other hand, without the protection of the abuse of discretion standard afforded under ERISA, a court is free to make its own determination as to whether benefits were properly denied under the plan, and is not required to give any deference at all to the plan administrator's discretion to interpret the plan's terms and make factual determinations. Also, many courts will expand the scope of judicial review and accept additional evidence beyond the administrative record, increasing the chances that a court will arrive at a determination different from the plan administrator's decision. In order to benefit from the deferential "abuse of discretion" standard, the plan (and the summary plan description) must state that the plan administrator has the discretionary authority to interpret the plan and resolve any conflicts or ambiguities that exist, as well as make all factual determinations.

- **Limitations on Damages.** Even if a plan beneficiary is successful in his or her claim, courts will rarely award anything more than restoration of denied benefits, and possibly interest and attorney's fees. ERISA § 502 limits the relief available to recovery of benefits due under the plan, enforcement of a right under the plan, or the clarification of rights to future benefits under the plan. Plan participants can also enjoin violations of the plan's terms or Title I of ERISA. ERISA does not provide for punitive, consequential, or similar types of damages, even if a claimant, through a state law claim, attempts to obtain an alternative remedy.

- **No Jury Trial (Generally).** Although not specifically provided in ERISA, most courts have held that a claimant in an ERISA suit has no right to a jury trial. By way of example, several courts have held that no right to a jury trial exists where the cause of action is for benefits due, COBRA violations, breach of fiduciary duty or interference with protected rights. While some exceptions to

these cases do exist, generally the right to a jury trial will not attach because most often remedies under ERISA § 502 are equitable in nature (but a right to a jury trial is always present if the cause of action is legal in nature).

- **Federal Court Jurisdiction.** With the exception of claims for benefits, ERISA provides federal courts with exclusive jurisdiction over ERISA claims. While state and federal courts have concurrent jurisdiction over claims for benefits, regardless of the amount in controversy, ERISA suits commenced in state court can be removed to federal court.

- **Funding with Medical Plan Assets.** If an on-site clinic is maintained as part of an ERISA program included as part of the larger group health plan, the employer may be able to use assets of the group health plan, rather than corporate assets, to pay for clinic services.

II. HIPAA

On-site clinic arrangements can also be subject to the privacy and other administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA), depending on the circumstances. The administrative simplification provisions of HIPAA apply to "covered entities," which includes (i) health plans and (ii) health care providers, if they transmit any health information in electronic form in connection with a transaction covered by the HIPAA electronic data interchange regulations.[2]

Health Plans

The first way an on-site clinic can be subject to HIPAA is if the arrangement is a health plan. As a general rule, an on-site medical clinic is excluded from the definition of a health plan. The definition of a health plan under HIPAA's administrative simplification rules is an "individual or group plan that provides or pays the cost of medical care." 45 CFR § 160.103. This is a broad definition that captures virtually all arrangements that provide medical care.

However, as a general rule, an on-site medical clinic is excluded from the definition of a health plan. See 45 CFR § 160.103, which excludes the "excepted benefits" listed in PHSA § 2791(c)(1); on-site medical clinics are included in the list of "excepted benefits." PHSA § 2791(c)(1)(G). Unlike the definition for "on-premises medical facility" for ERISA purposes, the controlling definition for HIPAA purposes does not include the same limiting language for first aid, injuries or illnesses taking place during work hours. Thus, because the exception for on-site medical facilities under HIPAA appears to be broad, a clinic could be structured to fit within the exception – thus avoiding categorization as a HIPAA-covered entity.

Nevertheless, an employer could lose this exemption under HIPAA if (i) the arrangement is an ERISA-covered plan; (ii) the clinic's operations are integrated with the operations of a health plan covered by HIPAA (e.g., the

company's group health plan) and/or (iii) information is exchanged between the covered health plan and the clinic. If the employer loses the exemption, the clinic arrangement would be a health plan under 45 CFR § 160.103.

Health Care Providers

The second way a clinic can be subject to HIPAA is if any of the health care providers are covered entities.[3] For purposes of the administrative simplification rules, a "health care provider" is broadly defined 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. 45 CFR § 160.103.

This broad definition could cause employers that operate on-site medical clinics to be considered to be health care providers. Even so, only health care providers that conduct any standard transactions electronically, or that engage third parties (such as billing services) to process such transactions electronically, are subject to the administrative simplification rules. Id. Standard transactions include communications regarding billing, payment, coordination of benefits, enrollment and disenrollment, and eligibility. SSA § 1173(a).

Effect of HIPAA Covered Entity Status

If the on-site clinic is subject to HIPAA as a health plan, the arrangement would be required to comply with various requirements with respect to the protected health information (PHI) of plan participants. For instance, it would need to:

- Implement HIPAA Policies and Procedures (for both the privacy and security portions of HIPAA);
- Sign Business Associate Agreements with vendors with access to PHI;
- Issue a Notice of Privacy Practices to participants;
- Provide participants with various rights regarding their PHI (including to review, amend, and receive accountings);
- Comply with various requirements imposed by the HIPAA Security Rule; and

- Address (and comply with) rules regarding the use and disclosure of PHI by the clinic.

If the on-site clinic coverage is a component of an employer's larger group health plan, the applicable HIPAA requirements may already be met by the clinic if its operations are integrated into the overall health plan (although changes might need to be made if the employer-sponsored plan is fully insured, and the employer did not previously have access to PHI). Alternatively, if the clinic arrangement is not part of a larger plan, the employer could implement separate HIPAA documentation, or revise the current documentation to include the arrangement.

If the clinic is considered to be a health care provider, a similar set of rules would apply. While the full scope of the HIPAA rules applicable to healthcare providers is outside the scope of this white paper, it would generally include rules similar (but not identical to) the rules for health plans, noted above.

III. OTHER HEALTH INFORMATION PRIVACY LAWS

In addition to HIPAA, employers sponsoring on-site clinics need to ensure that health and personal data gathered by the clinic does not violate other federal and state privacy laws. For instance, employers must comply with privacy and data use requirements under the Americans with Disabilities Act (ADA), Genetic Information Nondiscrimination Act (GINA), and workers' compensation laws (including any state equivalents thereof), to ensure that information obtained in the clinic is adequately protected and/or not improperly used in the employment context.

Various types of state laws – including those related to health privacy and data retention, HIV/AIDS, drug and alcohol testing, and mental health – could apply as well. These laws would apply to clinics that are not subject to HIPAA; in addition, to the extent a state law is stricter than HIPAA, it would apply in addition to HIPAA. Thus, even plans subject to HIPAA would need to review potentially applicable state requirements. The specific risk would depend on the state, and a state-by-state analysis would be necessary to determine the full impact of such rules.

IV. AFFORDABLE CARE ACT

Another important consideration is whether the on-site clinic is subject to the Affordable Care Act (ACA). The ACA includes a number of health insurance reforms for employer sponsored health plans. These requirements should be satisfied if on-site clinic services are part of an overall comprehensive package but could be problematic if any employer offers such benefits to any group of employees on a stand-alone basis (for instance, part-time employees who are not eligible for the comprehensive health plan).[4]

While the health insurance reforms would likely be the most problematic ACA issue for employers, and the ACA has specific exclusions for on-site clinics in some rules (for instance, information

reporting under IRC § 6055), other ACA requirements may also apply. For instance:

- Employers are subject to W-2 reporting on the cost of on-site clinic coverage, if the coverage meets the Internal Revenue Code definition of group health plan (under IRC § 5000(b)(1)) and the employer charges a premium for COBRA purposes. See IRS Notice 2012-9.
- Other aspects of the ACA, such as the "Cadillac tax," (IRC § 4980I) may apply, but further guidance is needed to make a definitive determination.

CONCLUSION

With the increasing popularity of on-site health clinics, it is becoming more important to understand the benefits compliance issues raised by this type of arrangement. This white paper addresses, at a relatively high level, the various compliance issues raised by employer-sponsored on-site clinics. Employers should consult with their own legal counsel to further analyze the issues outlined above as applied to any specific situation. ■

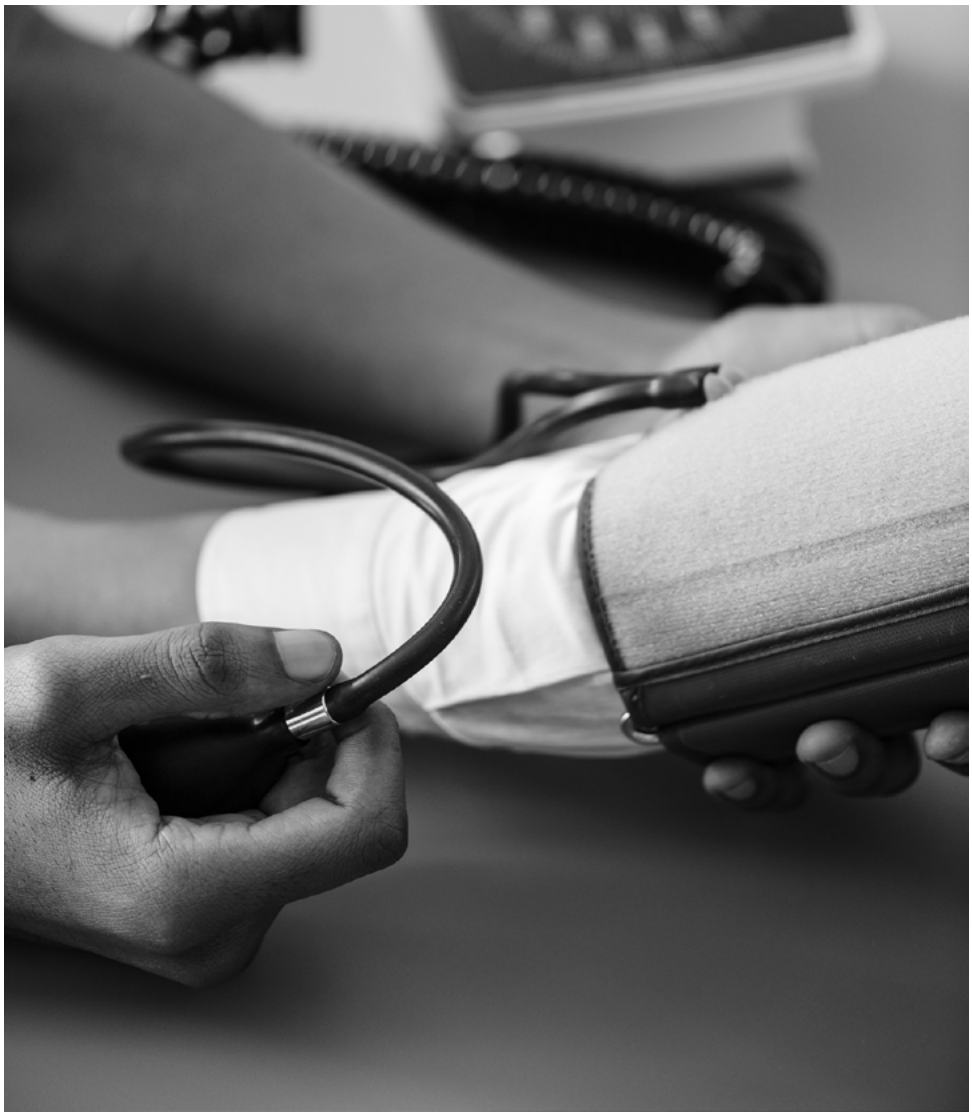
References

1 Please note that this white paper does not address all regulatory issues that will be applicable to the clinic, particularly aspects relevant to health care providers and medical facilities – e.g., OSHA standards; fraud and abuse rules (including the Stark Law, Anti-kickback laws, and the False Claims Act); or rules regarding corporate practice of medicine, disposal of medical waste, dispensing of pharmaceuticals, or clinical laboratories.

2 HIPAA's administrative simplification rules encompass privacy, security, breach notification, and electronic data interchange rules.

3 Note that while the on-site clinic may be part of the covered entity by virtue of inclusion in the medical plan, this would not automatically subject the clinic to HIPAA's requirements for health care providers; this would be a separate analysis.

4 Requirements that would be difficult or onerous to incorporate into the on-site clinic context include, for example, the prohibition on annual and lifetime limits on certain benefits (PHSA § 2711); dependent coverage for children until age 26 (PHSA § 2714); and patient protections, such as the ability for participants to designate a primary care provider (PHSA § 2719A).



Dominate In Your Self-Funding Career from the Comfort of Your Own Home

The Health Care Administrators Association (HCAA) has reenergized its Certified Self Funding Specialist® (CSFS®) online training and certification program. Now you can earn Continuing Education credits and obtain the designation to propel you to the next stage of your self-funding career.

Comprehensive and insightful, the seven courses cover every aspect that plan sponsors, brokers, employee benefit professionals and other health care professionals need to consider when establishing or maintaining a self-funded plan.

Course	Course Name
01	Introduction to Self Funding, Risk Management and the TPA
02	Stop Loss and Marketing in Self Funding
03	Cost Containment and Vendor Selection
04	Accounting, Funding and Tax Consequences
05	Actuarial, Legal, Reporting and Disclosure
06	State Regulations and Federally Mandated Benefits
07	MEWAs and VEBAs

Take your career to the next level!

- 24x7 mobile-ready access
- Study at your own pace
- Insights on the latest regulations and best practices

HCAA

Visit us online for full course descriptions and to register.

www.hcaa.webce.com
www.hcaa.org
888-637-1605