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COMPLIANCE NEWSLETTER

IN THIS EDITION:

Do the HIPAA Privacy and Security Rules Apply to My Organization?

Part Two: Business Associates

This article is the second in a two-part series addressing whether and how the Privacy and Security Rules (the "Rules") under the Health Insurance Portability and Accountability Act (HIPAA) apply to various legal entities. Part One addressed Covered Entities and appeared in our October 2018 newsletter. This article addresses Business Associates of Covered Entities that are self-insured group health plans.[1]

Quick Recap

Covered Entities are the key stakeholders in the delivery and payment of health care, but they frequently partner with other organizations for assistance. Many of these organizations will need to come into contact with Protected Health Information (PHI) to assist the Covered Entity. Remember, PHI is:

- Information about a past, present, or future health condition, treatment for a health condition, or payment for the treatment of a health condition;
- Identifiable to a specific individual;
- Created and/or received by a Covered Entity or Business Associate acting on behalf of a Covered Entity; and
- Maintained or transmitted in any form.

What's a Business Associate?

In the group health plan context, HIPAA defines a Business Associate as a third party that requires PHI to perform some function or service on behalf of a group health plan. In other words, a third party that helps make your health plan go but needs PHI to do it. The third party might create, receive, store, or transmit[2] the PHI in this role, but it must be "PHI sticky" in at least one of those ways to be considered a Business Associate. Many of HIPAA's Privacy and Security requirements apply directly to Business Associates.

1. In Part One, we addressed that insurance carriers are the Covered Entities for fully-insured group health plans and that employers/plan sponsors generally have few obligations under the Rules for those plans.

2. A third party that only transmits PHI without accessing or storing it may qualify for an exception as a mere conduit of the information.

Typical Business Associates for a Self-Insured Group Health Plan

Yes	No	Maybe So
• Third party administrator (TPA) including pharmacy benefit manager. • COBRA administrator (more about this below). • Broker/consulting firm. • Actuaries. • Record keepers (e.g. Iron Mountain or other third parties storing physical electronic records with PHI). • Other cloud service providers such as Google if Gmail is used as the email system.	• Plan sponsor/employer. • Stop-loss carrier (more about this below).	• External legal counsel. • Accountants if will see PHI in connection with an audit or review.

COBRA Administrators

If a COBRA administrator merely receives enrollment and disenrollment information from the employer (as plan sponsor), the information it receives is not PHI and the COBRA administrator is not technically a Business Associate of the group health plan. The nature and source of the information provided is easily blurred between the employer and group health plan, and it's common for COBRA administrators to agree to be treated as Business Associates.

The Curious Case of Stop-Loss

The Rules indicate that stop-loss carriers are not Business Associates of a group health plan when the stop-loss policy insures the plan itself. The Rules are less clear about the more likely scenario where the stop-loss policy insures the employer/plan sponsor directly. In practice, stop-loss carriers are often reluctant to be treated as Business Associates and are frequently excluded. We recommend employers enter into robust non-disclosure agreements with stop-loss carriers not treated as Business Associates.

Business Associate Contracts

Your organization's group health plan is required to enter into a contractual agreement with all of your Business Associates outlining how the Business Associate may use and disclose PHI, how it will secure PHI, and other rights and obligations the parties have under the Rules[3]. The Department of Health and Human Services (DHHS) has provided sample business associate contract language. Among other items, the contract must include language addressing the parties' responsibilities when unsecured PHI is improperly used or disclosed (a "breach"). Your organization has a limited amount of time to investigate and respond to a breach.

3. A failure to enter into the contract does not mean the third party is not your Business Associate and just subjects you to potential penalties for non-compliance.

As a practical matter, it is the employer (as plan sponsor) who must secure the contract for all of the plan's Business Associates, but Business Associates will often supply their version of this contract to the employer without being prompted. It is in each party's best business interest to use a standardized contract for administrative ease rather than having to honor the commitments of contracts from different sources, so there is a natural tension between the parties who each favor their own contracts. The requirements for a Business Associate contract are pretty standard, but it is not unusual for the contract to be more favorable toward the drafting party or to include additional contractual terms beyond what the Rules require, so it is important to have this reviewed by your legal counsel.

Subcontractors

Sometimes Business Associates contract with other organizations to perform one or more functions the Business Associate was hired to perform for the group health plan ("subcontractors" who are also PHI sticky), and there is no direct relationship between the health plan and the subcontractor. Your Business Associate must represent in the Business Associate contract that they have with your organization that it has a contract in place with its subcontractor that provides for all of the same protections under the Rules with respect to any PHI related to your health plan.

Example – A self-insured medical plan engages a TPA for claims administration and other services. One of these services is claims monitoring to reduce fraud, waste, and abuse. The claims monitoring services are actually provided by a subsidiary of the TPA, and the medical plan does not have a direct contract with the claims monitoring subsidiary. The TPA is a Business Associate of the medical plan. The claims monitoring entity is a Business Associate of the TPA and should be addressed as a subcontractor within the Business Associate contract between the medical plan and the TPA.

Next Steps

You should always know who your Business Associates are and should make sure you have a list of all the current vendors who provide services related to your health plans. Of these vendors, which ones use PHI to perform a function on behalf of a group health plan?

These are your Business Associates, and you should maintain current Business Associate contracts with all of them. Don't forget to make this an implementation step when adding a new vendor who will be a Business Associate to your health plan(s).

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2018 Form 1094/1095 Reporting

Understanding Your Reporting Obligations

The IRS recently released the final Forms 1094/1095 and instructions for the 2018 reporting year. Conveniently, the forms and reporting obligations are basically unchanged from 2017. The IRS has yet to announce penalty relief for good faith mistakes made while completing the forms. This good faith relief is typically announced in middle to late December, although employers shouldn't automatically assume the IRS will grant the relief for 2018.

This article is intended to provide a brief overview of 2018 Form 1094/1095 reporting for employers.

The Deadlines

There are two deadlines for employers to be aware of:

1. **Reporting to employees/enrollees** – Employers need to provide the applicable Form 1095 to employees/enrollees by January 31, 2019. The IRS has repeatedly extended this due date, and it may do so again. A hardship extension may also be available under certain circumstances.
2. **Reporting to the IRS**
   a. *Less than 250 returns* – Employers filing less than 250 returns may file paper returns with the IRS by February 28, 2019.
   b. *Electronic returns* – Employers filing electronically must file with the IRS by April 1, 2019 (March 31, 2019 is a Sunday). An employer who files 250 or more returns must file electronically.

Employers may request an automatic 30-day extension. An additional 30-day hardship extension may be available under certain circumstances.

Which Forms Apply to Me?

This depends upon whether you are considered an applicable large employer (ALE) under the Affordable Care Act (ACA), generally defined as an employer with 50 or more full-time employees (including full-time employee equivalents).

The C Forms

The C Forms are used by ALEs to report their compliance or non-compliance with the ACA's employer shared responsibility requirements (the "employer mandate"). Employer mandate reporting is intended to address

4. This is based on the ACA's definition of full-time employee as an individual who is expected to work at least 30 hours per week or who averages this through measurement.

whether an employer offered coverage to 95% of its full-time employees,[4] whether any were eligible for subsidized coverage in the public insurance exchange, and if the employer is liable for any penalties as a result.

If the ALE offers self-insured coverage, Form 1095-C will also reflect the months any employee and/or dependents were enrolled to address the ACA's "individual mandate" to maintain health insurance coverage. The individual mandate officially ends after 2018, but this reporting also ties into whether an individual (not just the employee) is eligible for a subsidy in the public insurance exchange.

- Form C Instructions
- Form 1094-C
- Form 1095-C

The B Forms

If an ALE offers fully-insured coverage, the insurance carrier will handle the individual mandate reporting by reporting the months an employee and/or any dependents were enrolled on the B Forms. Small employers who offer self-insured coverage (including level-funded coverage) must also use the B Forms to report the months an employee and/or any dependents were enrolled.

- Form B Instructions
- Form 1094-B
- Form 1095-B

Small employers who do not offer coverage or offer only fully-insured coverage have no Form 1094/1095 reporting requirement.

Plan Type	Form 1095-C Parts I and II	Form 1095-C Part III	Form 1095-B Employer	Form 1095-B Insurance Carrier
ALE Fully-Insured	Yes	No	No	Yes
Small Employer Fully-Insured	No	No	No	Yes
ALE Self-Insured	Yes	Yes	No	No
Small Employer Self-Insured	No	No	Yes	No

Form 1095-C, Some Reporting Tips…

Part II, Line #14, Offer of Coverage

An ALE may only report an offer of coverage was made for the month if coverage was offered for *every day* of the month. If coverage began or ended mid-month, the ALE should report Code 1H for that month. Code 1H means no offer of coverage was made, but the ALE will reflect the partial coverage and avoid potential penalties in Line #16.

4. This is based on the ACA's definition of full-time employee as an individual who is expected to work at least 30 hours per week or who averages this through measurement.

Part II, Line #15, Employee Required Contribution

Line #15 is only required if certain codes are used on Line 14. The triggering codes are 1B, 1C, 1D, 1E, 1J and 1K. If required, the employer must enter the employee's monthly cost for the lowest-cost, self-only coverage meeting the ACA's minimum value requirement that was offered to the employee. The dollar amount entered is just for self-only coverage. It does not matter if the employee enrolled in a more expensive plan option, enrolled one or more dependents, or waived coverage. If the employee cost is zero, don't leave the line blank. Instead, enter "0.00."

Part II, Line #16, Section 4980H Safe Harbor and Other Relief

An ALE may only report an employee was enrolled in coverage for the month using Code 2C if the employee was enrolled for *every day* of the month. If coverage began mid-month, Code 2D should be used instead. Similarly, if coverage ended mid-month, Code 2B should be used. In both instances, Codes 2D and 2B take the employer out of potential penalty for that month.

An employer may use both the Code 2G (federal poverty limit) and Code 2H (rate of pay) affordability safe harbors for the same employee during the reporting year. This may be relevant for employers with non-calendar year plans. By contrast, if the Code 2F (Form W-2) affordability safe harbor is used for any month, it is the only affordability safe harbor that may be used for that employee during the reporting year.

Continuing Problems with Code 1A in Line #14

The use of Code 1A in Line #14 automatically demonstrates that an affordable offer of coverage was made to the employee. Employers using Code 1A must leave Line #15 blank. Since 2016, the instructions have also indicated that employers may [but is not required to] leave Line #16 blank and doesn't have to enter a code to avoid potential penalty. That said, the IRS has had difficulty processing "unaccompanied Code 1As" and tends to mark these as sources of potential penalty for employers. We recommend employers reflect a corresponding enrollment or affordability code (such as Code 2G) to avoid this.

Part III, Column (e)

In stark contrast with how Part II works, an individual should be reflected as having coverage for a month if the individual was covered for *any day* of the month. Coverage for the entire month is not required. For small employers required to file Form 1095-B, this is found on Part IV of that form.

Ready, Set, File!

Completing the 1095 forms takes longer than most employers realize. We realize most employers utilize vendors to assist with this process. If you have not begun your 2018 reporting process, we recommend you do so as soon as possible.

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An End to Pharmacy Gag Clauses

Prescription Drug Price Transparency Becomes Federal Law

It has been estimated that nearly 1 in 4 Americans pay more for their prescription drug coverage than necessary[5]. A significant contributing factor is the lack of price transparency in prescription drug plans caused by pharmacy benefit managers (PBMs) contractually prohibiting pharmacists from sharing information with participants about other options for purchasing prescription drugs that may be cheaper than purchasing them through the participant's health plan. These contractual prohibitions are known as "gag clauses." A potentially cheaper alternative may include the participant paying for a prescription out-of-pocket using an available rebate from the drug's manufacturer.

President Trump pledged to lower drug prices earlier this year which proved popular with voters and received bipartisan support from Congress. Congress passed both the Patient Right to Know Drug Prices Act and Know the Lowest Price Act which were signed into law by the President on October 10, 2018. The Patient Right to Know Drug Prices Act is effective immediately and prohibits insurers and PBMs from restricting a pharmacy's ability to provide drug price information to a plan enrollee when there is a difference between the cost of the drug under the plan and the cost of the drug when purchased without insurance. The Know the Lowest Price Act becomes effective January 1, 2020 and provides the same protection for individuals who are covered by Medicare Advantage and Medicare Part D plans.

While the liability for complying primarily falls on insurance carriers and PBMs, health plan sponsors may wish to consider confirming its insurance carriers and/or PBMs are no longer using gag clauses. Time will tell if the new legislation will significantly lower prescription drug coverage cost for health plans and their participants.

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5. *Kaiser Health News, Sydney Lupkin, March 13, 2018.*