OCR RELEASES PHASE 2 HIPAA AUDIT PROTOCOL

Background

The U.S. Department of Health and Human Services Office for Civil Rights (OCR) launched Phase 2 of an audit program on March 21, 2016, designed to assess whether covered entities and business associates satisfy selected standards and implementation specifications of the Privacy, Security, and Breach Notification Rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).

“Covered entities” are:

- Health care providers that send covered transactions in electronic format (e.g., doctors and hospitals);
- Health plans (e.g., company health plans and HMOs); and
- Health care clearinghouses.

Business associates are persons or entities that perform certain functions or activities for covered entities involving the use or disclosure of protected health information (PHI) (e.g., a vendor that shreds medical records).

The Phase 2 Audit Process

Last month, the OCR released its Audit Protocol, which provides a detailed chart describing the specific regulations the OCR will audit for (Section and Key Activity), the questions auditors will ask (Audit Inquiry), and what actions constitute compliance with the regulations (Established Performance Criteria). The OCR is currently soliciting public commentary on the Protocol and compiling an audit pool. Once the Protocol is finalized, the OCR will select from a diverse pool of covered entities and business associates to audit.

The OCR anticipates conducting around 2000 desk audits and 10-25 on-site audits. During the desk audits, the OCR will request an auditee’s written policies and procedures and other documents to review for compliance with specific portions of the Privacy, Security, or Breach Notification Rules, as set forth in the Protocol. Those selected for a desk audit will receive email notifications, and be asked to submit certain documents electronically within 10 business days of the request. Those selected for on-site audits will also receive email notifications, and OCR auditors will be on-site for 3-5 days to assess the auditee’s practices and procedures for compliance with HIPAA. On-site audits will be more comprehensive and cover a wider range of requirements than the desk audits.

How to Prepare For the Phase 2 Audits

The following is an outline of the activities that covered entities (and business associates) may want to do in preparation of an audit, and generally, to strengthen their privacy and security practices:

Initial Steps:

- Determine if you are a covered entity or a business associate;
- If you are a covered entity, compile a list of your business associates; and
- Look for emails from the OCR requesting contact information, questions about the size and type of operations, and contact information of your business associates.
OCR Releases HIPAA Audit Protocol  (Continued)

Documents to Review and Revise:

- Make sure there are current Business Associate Agreements in place (review and revise Agreements as necessary);
- If you are a business associate, make sure you have subcontractor contracts in place for any subcontractors that have access to PHI;
- If there is a possibility that you may come into contact with your employees’ PHI, and need to share the PHI with a third party, make sure you have current Authorization Forms in place for those employees;
- For self-funded plans, FSAs, or free-standing EAPs, a Privacy Notice must be provided to all plan participants upon enrollment and every three years;
- Develop and/or update HIPAA privacy and security policies and procedures;
- Develop and/or update procedures for detection and reporting of suspected breaches; and
- Develop and/or update policies restricting use and disclosure, designation of personnel with access to PHI, and establishment of firewalls (particularly important for self-funded plans).

Take Action!

- Appoint a Privacy Officer to oversee security and privacy concerns and complaints;
- Conduct a security risk assessment;
- Develop corrective action plans for areas of high risk, and document steps taken toward compliance; and
- Develop or hold HIPAA training sessions for employees with access to PHI, and maintain records of the training date, topics, and attendance.

Gold Star

- Review the OCR’s HIPAA Audit Protocol (link below) to gauge potential audit topics.

Given the expansive scope of the Phase 2 audits and the short window for responses, covered entities, including employers that run health plans, should not wait until the Protocol is finalized, or until they receive notification of audit letter before taking steps to ensure compliance with HIPAA.

Action Required

All employers who run health plans are covered entities and may be subject to an OCR Phase 2 Audit. Although the risk of an audit may be minimal, employers should take this opportunity to review their policies and procedures relating to privacy, security, and breach notification rules under HIPAA.

For the complete details, see:


Phase 2 Audit Protocol:  http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit

Sample OCR Verification Email:  http://www.hhs.gov/sites/default/files/ocr-address-verification-email.pdf
DOL ISSUES ANOTHER FAQ RELATED TO IMPLEMENTATION OF THE AFFORDABLE CARE ACT

The U.S. Department of Labor (DOL) issued its 31st Frequently Asked Questions (FAQs) on the implementation of the Affordable Care Act (ACA) on April 20, 2016. The topics covered in the FAQs include:

- Coverage of Preventative Services
- Rescissions of Coverage
- Out-of-Network Emergency Services
- Clinical Trial Coverage
- Cost-Sharing Limitations
- The Mental Health Parity and Addiction Equity Act of 2008; and
- The Women’s Health and Cancer Rights Act

The above topics are separately discussed below.

Coverage of Preventative Services

As a reminder, non-grandfathered group health plans and health insurance coverage offered in the individual or group market must offer preventative services without any cost-sharing from the plan participant.

FAQ #1 discusses colonoscopy services. Essentially, the DOL states that bowel preparation medications, when medically appropriate and prescribed by a health care provider, are necessary for preventative screening colonoscopies, and therefore the plan must pay entirely for those bowel preparation medications.

FAQ #2 discusses access to contraceptives. The DOL states that so long as a health plan utilizes a reasonable medical management technique within a specified method of contraception, a plan or issuer may develop and utilize a standard exception form and instructions, to ensure that the plan/carrier provides an easily accessible, transparent, and sufficiently expedient exceptions process.

Rescissions

Under the ACA, plans may not retroactively rescind coverage to a participant, except in very limited circumstances. In FAQ # 3, the DOL provides an example related to a teacher that was enrolled in coverage during the plan year and resigned on July 31st of that year. The plan retroactively terminated her coverage back to May 31st, when the school year for that teacher effectively ended. Because the termination of coverage occurred retroactively, and was not due to fraud or intentional misrepresentation of a material fact by the employee, or for lack of payment of premiums, such rescission of coverage was prohibited under the Affordable Care Act. Rather, cancellation of coverage in this example should have been implemented prospectively.

Out-of-Network Emergency Services

The DOL has stated that a non-grandfathered health plan or health insurance issuer (who is subject to ERISA) must disclose the method on how it calculated the "minimum payment standard" for out-of-network emergency services. The reason for this is because ERISA requires that such information would generally be included under the disclosure requirements under ERISA, and would need to be delivered to a plan participant within 30 days of a plan participant’s request for such documentation.

Coverage for Individuals Participating in Clinical Trials

If a non-grandfathered health plan or health insurance issuer offers coverage to a qualified individual (i.e., an individual who is eligible to participate in an appropriate clinical trial, with approval from a health care professional), the plan cannot do the following:

- Deny prevention treatment or detection treatment of an illness
- Deny coverage of routine patient costs associated with such clinical trials; and
- Discriminate against the individual based upon their participation in a clinical trial.

Therefore, the guidance provided by the DOL in FAQs #5 and #6 states that a plan or issuer that commonly covers chemotherapy treatment for cancer in a non-clinical trial must also provide that same coverage for patients participating in chemotherapy in an approved clinical trial, which may include such items as anti-nausea medication. In addition, plans and issuers cannot deny coverage of such items and services when those services are provided to diagnose or treat complications or adverse events (e.g. side effects) in connection with the participation of an individual in a clinical trial.
DOL ISSUES ANOTHER FAQ RELATED TO IMPLEMENTATION OF THE AFFORDABLE CARE ACT  (Continued)

Limitations on Cost-Sharing
The ACA now requires that non-grandfathered health plans must ensure that an individual’s out-of-pocket expenses do not exceed a certain threshold amount. Only in-network services count towards this out-of-pocket limit.

However, under FAQ #7, the DOL states that if a health plan uses reference-based pricing (i.e., the health plan only pays a fixed amount for a particular procedure), but the health plan fails to have adequate access to quality providers that would accept the reference price in full, a plan can be required to count an individual’s out-of-pocket expenses for providers who do not accept the reference-based pricing towards the individual’s maximum out-of-pocket limit.

Mental Health Parity and Addiciton Equity Act of 2008
Generally, the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) requires that the financial requirements and treatment limitations imposed on mental health and substance use disorder benefits cannot be more restrictive than the “predominant” financial requirements and treatment limitations that apply to “substantially all” medical and surgical benefits offered by a non-grandfathered health plan.

If the financial requirements and quantitative treatment limitations applied to mental health/substance use disorders in a classification do not apply to at least 2/3 or more of medical/surgical benefits in the classification, the plan does not meet the “substantially all” and “predominant” tests, required to meet MHPAEA.

FAQ #8 indicates that a health plan cannot base its “substantially all” and “predominant” tests on the overall book of business expected to be paid for the year or in a specific region or State. The data should be based upon group-specific health plans.

FAQ #9 addresses what providers of health care may request as disclosure, to ensure a plan’s compliance with MHPAEA. The following documents were listed as potential documents of disclosure:

- Summary Plan Description (SPD) for ERISA plans, or similar information from non-ERISA plans
- Specific plan language regarding the imposition of Non-Quantitative Treatment Limitations (NQTL)
- The specific underlying processes, strategies, evidentiary standards, and other standards when applying the NQTL to particular mental health benefits/substance use disorders
- Information regarding the NQTL to any medical/surgical benefits in the category of benefit classification at issue
- The specific strategies in determining the NQTL for medical/surgical benefits
- Any analysis performed by the plan as to how the NQTL complies with MHPAEA

FAQ #10 confirms that health plans and issuers must disclose a copy of the medical necessity criteria for coverage of mental health conditions to not only participants of the health plan, but also to potential enrollee or contracting provider requests.

FAQ #11 confirms that MHPAEA does apply to any benefits a plan may offer for Medication Assisted Treatment for opioid use disorders.

Women's Health and Cancer Rights Act
FAQ #12 states that health plans and issuers offering individual or group health plans that cover mastectomies must also provide nipple and areola reconstruction as a required stage of breast reconstruction under the Women's Health and Cancer Rights Act.

Action Required
Employers should ensure that any health plans they offer are in compliance with the above categories of coverage. Employers should also be knowledgeable about the above issues regarding coverage, in the instance an employee is denied coverage under one of the above categories.

For the complete details, see:
FAQs about Affordable Care Act Implementation (Part 31):
https://www.dol.gov/ebsa/faqs/faq-aca31.html
IRS RELEASES MAXIMUM ANNUAL HSA AND HDHP LIMITS FOR 2017

The Internal Revenue Service (IRS) released its 2017 Health Savings Account (HSA) and High-Deductible Health Plan (HDHP) annual limits, adjusted for inflation. These limits include: (1) HSA contribution limits; (2) HDHP minimum deductibles; and (3) HDHP maximum out-of-pocket (OOP) limits.

Although there was a slight increase in the HSA contribution limits for self-only coverage from 2016 to 2017, there were no changes for the HDHP minimum deductible or maximum OOP limits for 2017. Highlights from the IRS Revenue Procedure 2016-28 detailing these limits are as follows:

HSA and HDHP Limits for Self-Only and Family Coverage, 2016-2017

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<th>Limit Type</th>
<th>2016</th>
<th>2017</th>
<th>Change</th>
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<tbody>
<tr>
<td>HSA Statutory Contribution Amount</td>
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<tr>
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<tr>
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<tr>
<td>• Family</td>
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</tr>
</tbody>
</table>

In February of 2016, the Department of Health and Human Services (HHS) released its finalized out-of-pocket (OOP) maximums for non-HDHP coverage for 2017. These ACA OOP maximums for 2017 for non-HDHP coverage are $7,150 for self-only coverage, and $14,300 for family coverage.

No Action Required

Employers should be aware of these 2017 annual limits, specifically the increase in HSA contribution limits for self-only coverage, and ensure the health plans they offer are in compliance with these limits.

For the complete details, read IRS Rev. Proc. 2016-28:

CALIFORNIA BILL NO. 908 INCREASES WAGE REPLACEMENT BENEFITS DURING FAMILY LEAVE

Previously, California was one of four states to offer partial wage replacement of up to six weeks of work to bond with a new child or care for a sick family member. Originally, the wage replacement benefit would only replace 55% of an employee's wages.

On April 11, 2016, Governor Jerry Brown signed into law an increase (beginning in 2018) for the wage replacement benefit to increase to 60% of an employee's wages, which is capped at approximately $1,100 per week. For lower income workers (who earn around $20,000 a year or less), they would receive 70% of their regular pay during the leave.

No Action Required

Employers should be aware of the increase to employees' wage replacement benefits, as employees may have many questions related to this law as 2018 approaches.

For the complete details, see:

AB 908:

https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB908
COMPLIANCE REMINDER: FORM 1094-C AND 1095-C PAPER FILINGS DUE MAY 31ST AND ELECTRONIC FILINGS DUE JUNE 30TH

The Affordable Care Act (ACA) requires Applicable Large Employers (ALEs) to file Form 1094-C (Transmittal of Employer-Provided Health Insurance Offer and Coverage Information Returns) and Form 1095-C (Employer-Provided Health Insurance Offer and Coverage), to report information regarding their offers of health coverage to full-time employees, and the enrollment of employees and family members in their health coverage (if the ALE is a self-funded plan).

WHO Must File?

ALEs must file Form 1094-C and Form 1095-C each year. An ALE is generally defined as an employer with 50 or more full-time and full-time equivalent employees in the previous year. ALEs may use a third party to file these Forms on their behalf. ALEs choosing to file the documentation themselves can find instructions below for both electronic and paper copy filing. If an ALE chooses to transmit these Forms electronically without the assistance of a third party, the ALE must register online and obtain a Transmitter Control Code (TCC), which can take significant time to receive. We suggest ALEs register and obtain their TCC immediately, if they are choosing to file these documents electronically without the assistance of a third party.

WHEN are ALEs Required to File?

Both Forms 1094-C and 1095-C may be filed in paper or electronic format. However, ALEs who are filing 250 or more information returns (i.e., Form 1095-Cs) must file and provide returns electronically. The due dates for paper and electronic filings are as follows:

- Paper Filings Due: May 31, 2016
- Electronic Filings Due: June 30, 2016

HOW to File?

Electronic Filing – For Employers who are NOT Using a Third Party to File Returns on their Behalf

These instructions are for ALEs who are NOT using a third party to file returns electronically on their behalf.

**STEP 1:** All responsible officials and contacts in the business or organization must be registered to use IRS e-Services.
- Register Here: Registration Services

**STEP 2:** Once you register, you will receive a confirmation code via U.S. Postal Mail. You must log back into the e-Services website to enter the confirmation code you received by mail within 28 days of registration.
- **NOTE:** Due to the length of time it may take to complete the e-Service registration and confirmation process, ALEs should ensure they begin the e-filing process now, in order to meet the June 30th deadline.

**STEP 3:** ALEs need to complete an application to obtain a Transmitter Control Code (TCC). Responsible Officials will be required to sign the terms of the TCC agreement with the PIN created during the e-Service registration process.
- For more information on completing the TCC application, see: Tutorial for Affordable Care Act Application for TCC

**STEP 4:** ALEs transmitting their Forms must pass software and electronic transmissions communications testing with ACA Assurance Testing System (AATS).
- For complete details on the AATS and different requirements for software developers and issuers/transmitters, see: Publication 5164, Test Package for Electronic Filers of Affordable Care Act (ACA) Information Returns (AIR)
- For AATS testing information, see: Affordable Care Act Information Returns (AIR) Assurance Testing System (AATS)

**STEP 5:** After completing the above steps, employers are able to electronically file the Forms by logging in on the IRS website. The individual who logs in must be listed as the Contact or Responsible Official on the AIR TCC Application.
- Login: AIR UI Channel Login - Production

For an IRS overview of the AIR Program, see: Affordable Care Act Information Returns (AIR) Program

Paper Filing

1. **Submit forms to the IRS in a flat mailing by First-Class Mail.**
   - If you need to file numerous paper Forms in multiple packages, write your name on each package and number the packages consecutively, placing Form 1094-C in package number one.

2. The address where the Forms should be sent varies depending on the location of the business, office, or residence. The addresses are as follows:
   - AL, AZ, AR, CT, DE, FL, GA, KY, LA, ME, MA, MS, NH, NJ, NM, NY, NC, OH, PA, RI, TX, VT, VA, WV
     - Department of Treasury Internal Revenue Service Center, Austin, TX 73301
   - AK, CA, CO, Dist. of Columbia, HI, ID, IL, IN, IA, KS, MD, MI, MN, MO, MT, NE, NV, ND, OK, OR, SC, SD, TN, UT, WA, WI, WY
     - Department of Treasury Internal Revenue Service Center, Kansas City, MO 64999
QUESTION OF THE MONTH

Q: Our company will soon be adopting a cafeteria plan so that our employees can pay their share of the premiums for health insurance coverage with pre-tax salary reductions. The plan will also include a health FSA and a DCAP. I understand that cafeteria plans, health FSAs, and DCAPs are subject to nondiscrimination tests. How many tests are there, and are there any exceptions for small businesses like ours?

A: Cafeteria plans, health FSAs, and DCAPs are subject to nondiscrimination requirements under the Code that are generally intended to prevent these plans from providing benefits that unduly favor individuals who are highly paid or key to the business. The Code uses specific definitions of the individuals in whose favor discrimination is prohibited, and these definitions vary among the nondiscrimination tests that are described below. In this answer, we use the terms “highly paid employees” and “key employees” as shorthand references. If a plan doesn’t pass the tests for a plan year (i.e., it is discriminatory), then highly paid or key employees, as applicable, may have adverse tax consequences. Non-highly paid employees and non-key employees will not be taxed, however, and the plan’s status under the Code won’t be affected. Except for the simple cafeteria plan safe harbor discussed below, small employers are not exempt from these requirements.

There are nine nondiscrimination tests that can apply to a cafeteria plan and its separate benefits, but those tests focus on only three topics: eligibility, availability, and utilization. Imagine that you are planning a party, with the benefits under your company’s plan being the appetizers. The nondiscrimination requirements essentially ask, “Have enough non-highly paid employees been invited to the party?” (eligibility), “Are enough non-highly paid employees being offered the appetizers?” (availability), and “Are enough non-highly paid or non-key employees actually taking the appetizers?” (utilization). Here is a summary of these tests and two safe harbors:

- **Cafeteria Plan Tests.** Three nondiscrimination tests apply to cafeteria plans: (1) an Eligibility Test (cafeteria plans cannot discriminate in favor of highly paid employees as to eligibility to participate); (2) a Contributions and Benefits Test (cafeteria plans cannot discriminate in favor of highly paid employees as to contributions and benefits); and (3) a Key Employee Concentration Test (nontaxable benefits provided to key employees under a cafeteria plan cannot exceed 25% of the nontaxable benefits provided to all employees under the plan).
- **Health FSA Tests.** If a health FSA is added, two more tests apply: an Eligibility Test and a Benefits Test. (These tests also apply to self-insured medical, dental, and vision plans, as well as health reimbursement arrangements (HRAs).)
- **DCAP Tests.** If a DCAP is added, there are four additional tests: (1) an Eligibility Test; (2) a Contributions and Benefits Test; (3) a More-Than-5% Owners Concentration Test; and (4) a 55% Average Benefits Test.
- **Premium-Only Safe Harbor.** There is a safe harbor for “premium-only” cafeteria plans: A plan that offers only an election between cash and payment of the employee share of employer-provided accident and health insurance premiums is deemed to satisfy the cafeteria plan nondiscrimination requirements if it passes the Eligibility Test.
Question of the Month (Continued)

- Simple Cafeteria Plan Safe Harbor for Small Employers. A “simple cafeteria plan” is treated as meeting the nondiscrimination rules for cafeteria plans and certain component benefits (including health FSAs, and DCAPs), so long as specified contribution, eligibility, and participation requirements are met. In general, only employers with an average of 100 or fewer employees during either of the preceding two years may establish a simple cafeteria plan. (There are special rules for new and growing employers.) Simple cafeteria plans may be of interest to eligible employers that might otherwise have difficulty passing one or more of the nondiscrimination tests, if they are willing and able to make the required contributions and meet the additional requirements.

Health care reform also established nondiscrimination requirements for certain insured health plans, although compliance is not required until the government issues regulations or other guidance on the new requirements.

Contributing Source: EBIA Staff.