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, Ken Johnson, Amy Heppner, and Laurie Kirkwood 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, Carolyn, Ken, Amy, and Laurie are senior members in 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.

CAN I GET A WITNESS? PREPARING FOR GAG CLAUSE ATTESTATIONS

Beginning this year, group health plans are required to submit an annual gag clause compliance attestation to the Department of Health and Human Services (HHS), which is collecting the attestations on behalf of itself and the Departments of Labor and Treasury.

The attestation is required to confirm that certain contracts do not prevent disclosures of cost, quality of care data, or certain other information required as part of the Consolidated Appropriations Act of 2021 (CAA).

The Centers for Medicare and Medicaid Services (CMS) have posted several compliance resources on its website, including Annual Submission Webform Instructions ("Submission Instructions") that provide an overview of the process; a User Manual for making attestations through the Health Insurance Oversight System (HIOS) that walks through the submission process step-by-step with screenshots from the webform; and FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 57 (FAQs Part 57), which were issued by the departments on February 23, 2023.

The annual attestation requirement applies to most group health plans, including both self-insured and fully-insured ERISA plans, church plans, non-Federal governmental plans, and grandfathered plans.

Account-based plans, such as health reimbursement arrangements and health flexible spending accounts, or excepted benefit plans (e.g., hospital indemnity, dental, vision, long-term care) are not required to submit attestations.

The rule against gag clauses was part of the surprise medical billing transparency disclosures that require plans to disclose price and quality information to plan participants, as required by the CAA.

The attestation confirms that the plan has not, since December 27, 2020, entered into any agreement with a provider, network of providers, TPA, or any other service provider offering access to a network or association of providers that contains any prohibited gag clause. Attestations must be made through HIOS by December 31, 2023, and annually by December 31 thereafter.

Plans will need to take a number of steps to prepare for the attestation. In this article we look at the practical aspects of preparing ahead for submissions from both the self-insured plan side and TPA side.

Plan sponsors should consider preparing an inventory of their contracts and agreements and determine which ones require an attestation. Advanced coordination with TPAs and service providers will be needed to determine whether the plan or the TPA will submit the attestation.

The plan sponsor will need to identify and authorize an appropriate individual within the plan to make the attestation or authorize a TPA to do so on the plan's behalf. TPAs should review the Submission Instructions and User Manual to gather all the relevant information for each entity on whose behalf they will be attesting.

Lastly, plans that have contracted with a service provider to attest on behalf of the plan will want to obtain proof that the attestation was submitted.

INVENTORY OF COVERED AGREEMENTS

Compiling an inventory of all current plan agreements/ renewals and amendments will help plan sponsors organize and document their attestation process. At a minimum, an inventory will tag the execution dates, effective dates, and subject matter (e.g., medical, pharmacy benefits, behavioral health) for each agreement (include renewals and amendments) and should include a review column indicating whether the agreement is free from prohibited gag clauses.

The dates of the agreement are relevant for ensuring that the attestation covers only those agreements within the applicable reporting period. Tagging agreements by type is necessary if a plan sponsor will not be attesting on its own behalf for all of its agreements.

As discussed below in *Who Submits?*, TPAs and other service providers can attest on behalf of a plan for a subset of plan benefits (e.g., pharmacy benefits), so plans will need to have a methodology for tracking who is attesting for each type of agreement.

Which types of agreements/ contracts are subject to the requirement? The gag clause rules apply to agreements with providers, network of providers, TPA, or any other service provider offering access to a network or association of providers. Because account-based plans are exempt from these rules, agreements with, for example, a service provider that provides services only for administration of a health reimbursement arrangement or health flexible spending account would not need to be included in the inventory.

Does every agreement currently in effect need to be reviewed for gag clause compliance? The short answer is yes, at least for long-term compliance, although it may be that only a subset of current agreements fall within the initial period for gag clause attestation purposes. FAQs Part 57 Q6 states that the first attestation covers the period beginning December 27, 2020, or the effective date of the applicable group health plan (if later), through the date of attestation.

This language does not state whether amendments are needed for agreements entered into prior to December 27, 2020 and still in force on/after that date. The attestation language in the CMS User Manual is somewhat clearer, requiring attestation that the plan "will not enter into an agreement, and has not, **subsequent to December 27, 2020**, entered into an agreement" that contains a prohibited gag clause (emphasis added).

The implication here is that an amendment to remove a gag clause from an agreement entered into prior to December 27, 2020 is not required for making the attestation. So, for purposes of the attestation due by December 31, 2023, only agreements entered into or amended "subsequent to December 27, 2020" need to be reviewed.

PRACTICE POINTER: THE INVENTORY OF AGREEMENTS CAN BE USED BY PLAN SPONSORS TO MAKE NOTE OF THE NEED TO REMOVE THE GAG CLAUSE FROM EARLIER AGREEMENTS UPON RENEWAL OR AMENDMENT.

This raises another issue: amendment to the agreement. The current FAQs Part 57 do not address how to treat agreements that were entered into prior to December 27, 2020 but later amended, and whether this places the agreement within the current reporting period.

For example, if a service agreement that included a gag clause was entered into on January 1, 2020 (i.e., prior to December 27, 2020), and then amended January 1, 2021 for fee adjustments, does the post-December 27, 2020 amendment place the entire agreement within the current reporting period?

What if the amendment were to a part of the agreement more closely associated with gag clauses, such as the confidentiality or privacy provisions? These questions are not answered in the FAQs Part 57, and additional guidance would be helpful.

What is a prohibited gag clause? Once the plan sponsor has identified which agreements require attestation, each agreement needs to be reviewed to ensure that it does not contain a gag clause. Plan sponsors attesting on their own behalf may want to engage legal counsel to assist with this process.

Generally, a prohibited gag clause is a direct or indirect restriction on sharing certain types of information with certain plan stakeholders (see the FAQs Part 57 for more detail).

The prohibition against gag clauses does not prevent the data owner from including reasonable restrictions on public disclosure of the information. Nor does it mandate that service providers freely provide this information to the plan sponsor or its business associates.

The review, for attestation purposes, is to ensure that the agreement includes no direct or indirect prohibition. When looking at an agreement entered into after December 27, 2020, the plan sponsor should, at a minimum, ask the following:

- Does this agreement contain language that restricts sharing provider specific cost or quality of care information with a plan stakeholder (i.e., other providers, eligible employees/ participants, and the plan sponsor) through a consumer engagement tool or with a business associate?
- Does this agreement restrict the plan's or a business associate's electronic access to de-identified claims and encounter information (financial information such as the allowed amount, provider name and clinical designation, service codes and any other data included in claims and encounter information)?
- If there are limits on that access, are they the result of privacy laws or are they intended to restrict public disclosure of the information?

With regard to privacy laws and restrictions on public disclosures, HIPAA (Health Insurance Portability and Accountability Act) limits disclosure of protected health information to the "minimum necessary" to satisfy the purpose or carry out a function.

And, of course, reasonable requirements to protect the data from breach and/or unauthorized access would be permissible. So even if the agreement contains some restrictions, the restrictions do not violate the prohibition against gag clauses if the restriction is in place due to HIPAA or other applicable privacy laws.

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PRACTICE POINTER: GOING FORWARD, PLAN SPONSORS MAY WANT TO NOT ONLY REVIEW NEW AGREEMENT FOR GAG CLAUSES, BUT ALSO INCLUDE AFFIRMATIVE LANGUAGE THAT CLARIFIES THEIR RIGHT TO DISCLOSE PROVIDER SPECIFIC COST/ QUALITY OF CARE THROUGH CONSUMER ENGAGEMENT TOOL OR OTHER MEANS, ACCESS CERTAIN DE-IDENTIFIED CLAIMS AND CLAIM ENCOUNTER INFORMATION, AND SHARE WITH BUSINESS ASSOCIATES AS PERMITTED BY PRIVACY LAWS.

Can a plan sponsor "cure" a prohibited gag clause by amendment? There is no guidance on whether an agreement with a prohibited gag clause entered into after December 27, 2020 can be "cured" for attestation purposes by an amendment to remove the gag clause prior to attestation.

Moreover, neither the User Manual nor the Submission Instructions allow for an attester to disclose an amendment to remove a gag clause to a post-December 27, 2020 agreement. The attestation format is set up to allow attestations in the affirmative, with no opportunity to voluntarily disclose agreements that were "cured" by amendment. More guidance from the departments would be welcomed.

SUBMITTING THE ATTESTATION

Who submits the attestation? As explained in the Submission Instructions, the attester is the person who actually signs off on the attestation, and the "submitter" is the person who enters the data into the webform.

The submitter and attester can be the same person, but if they are not, each person will need to provide their contact information in the webform. Submitters will want to read the User Manual and Submission Instructions in advance in order to gather all the required data for the submission.

A self-insured plan can submit an attestation on its own behalf, or it can contract with service providers such as its third-party administrator (TPA) or pharmacy benefit manager (PBM) to submit an attestation on behalf of the plan.

Plan sponsors that submit on their own behalf will need to identify an appropriate individual within the plan to be the attester. Attesters are required to affirm that they are properly authorized as part of the attestation process.

The Submission Instructions explain that if the plan uses more than one TPA to administer various subsets of plan benefits, each TPA can attest on behalf of the subset of the plan that it administers.

The submission form includes three categories of agreements—medical, pharmacy, and behavioral health—along with a wild card column for "other types of provider agreements." A plan could, for example, attest on its own behalf for medical and behavioral health, but contract with the PBM to attest on the plan's behalf for pharmacy.

What is the process for accessing HIOS for purposes of the attestation submission? As explained in the FAQs Part 57 Q12 and Submission Instructions, an authentication code is required to access the HIOS webform where the attestation is completed and submitted.

The process seems straightforward: a code is generated by email within 10 minutes to any user who properly requests one. Codes are active for 15 days, and after the code expires, a new code must be obtained.

What time period does the plan's attestation cover? The first attestation is due no later than December 31, 2023, covering the period beginning December 27, 2020 (or the effective date of the applicable group health plan, if later) through the date of attestation. Attestations covering the period since the last preceding attestation are due by December 31 of each year thereafter. Consequently, attestations for each plan will cover different time periods based the date of attestation.

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What is the process for TPAs submitting on behalf of a plan? A plan can authorize a TPA or other service provider to be the official "attesting entity" and submit the attestation on behalf the entire plan or subset(s) of plan benefits. As part of the attestation submission process, the attester will be required to affirm that it has proper authorization from the plan (or applicable reporting entity).

Because this affirmation is made by the attester and not the plan sponsor, attesters will want to ensure that proper authorizations are in place prior to submitting the attestation.

If a TPA is acting as attester on behalf of multiple plans, information for each plan will be entered on a single template. This information includes (among other items) the Employer Identification Number, plan number used on Form 5500s, plan mailing address, and the name of the plan's point-of-contact, as well as that person's email address and phone number.

The TPA will need to properly identify the type of plan (i.e., ERISA plan, church plan, non-federal governmental plan, or health issuer) and the type of provider agreements that apply to the attestation (e.g., medical, PBM, behavioral health). See the explanation for "Option B" in the Submission Instructions for more details on TPAs submitting attestations on behalf of multiple plans.

ENFORCEMENT ACTION

Regardless of whether the plan or the TPA is tasked with submitting, the plan is ultimately responsible if there is a failure to submit an attestation on time.

The agencies state in FAQs Part 57 Q7 that failure to submit timely attestations may subject the plan to enforcement action, without specifying what type of action. Presumably the general penalty of $100 per day under the Internal Revenue Code could be applied, but it isn't clear if this would apply per attestation, or per person affected by the violation.

The Submission Instructions explain that after the attestation is successfully submitted by the TPA, the submitter can download

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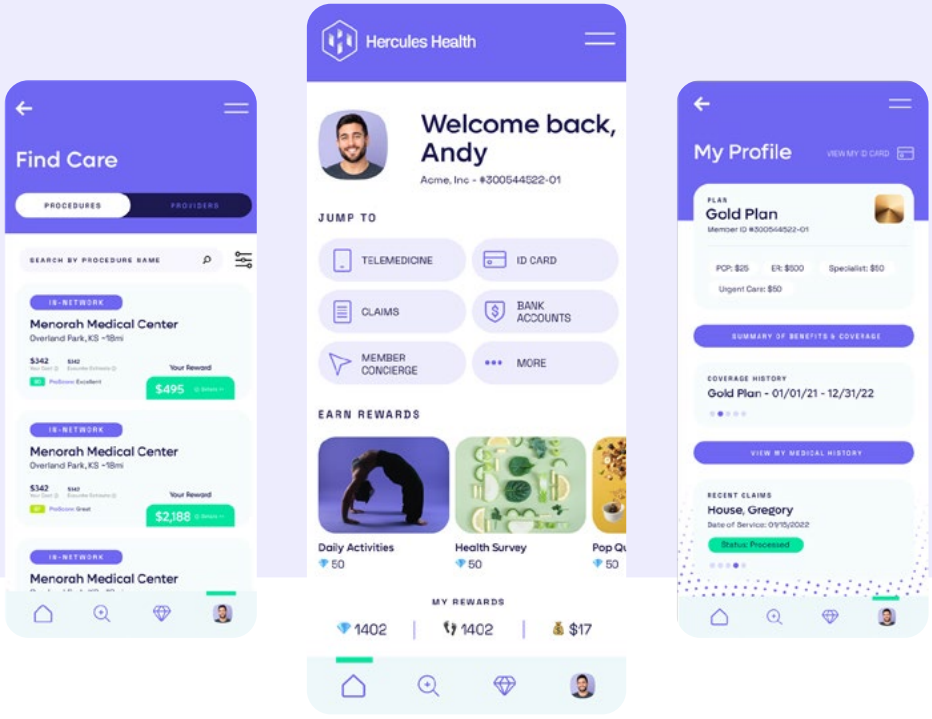

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a confirmation receipt as a PDF file. Plans should contact any TPA or service provider that attested on the plan's behalf and request a copy of this receipt.

SUMMARY CHECKLIST

In preparing for the attestation process, plan sponsors may find it helpful to:

- Compile an inventory of covered agreements
- Maintain a sub-list from the inventory of agreements entered into prior to December 27, 2020 that will subsequently need to be amended to remove prohibited gag clauses
- Identify an appropriate individual to make the attestation and ensure that proper authorizations are in place
- If contracting with a TPA to make the attestation, ensure that proper authorizations are in place
- Obtain proof of submission from TPAs attesting on behalf of the plan or any subset of plan benefits ■