

GAG CLAUSE PROHIBITION AND ATTESTATION: A GUIDE FOR EMPLOYERS

Employers, as plan sponsors, must ensure their applicable contracts do not contain gag clauses and must timely attest to compliance. The first attestation was due by December 31, 2023 (for contracts in 2021, 2022, and 2023), and subsequent attestations are due annually thereafter by each December 31.

The gag clause prohibition provisions of the Consolidated Appropriations Act, 2021 (CAA 2021) took effect on December 27, 2020. These provisions prohibit group health plans and insurers from entering agreements containing certain types of gag clauses. In the healthcare context, a “gag clause” refers to a contract term that directly or indirectly restricts information that a group health plan or insurer can make available to another party. Additionally, the CAA 2021 requires plans and insurers to attest to compliance with the gag clause prohibition annually by each December 31.

Like other CAA 2021 provisions, the DOL, HHS, and IRS (the departments) have not issued formal implementation guidance regarding the gag clause prohibition. Rather, the departments released informal guidance in the form of FAQs in [February 2023](#) and [January 2025](#) to explain the law and promote compliance. The FAQs also provided instructions for plans and insurers to submit their attestations of compliance with the gag clause prohibition.

Accordingly, employers, as plan sponsors, must ensure their applicable contracts do not contain any prohibited gag clauses and must timely attest to compliance. The first attestation of compliance was due by December 31, 2023, attesting to compliance for contracts entered into from December 27, 2020, through the date of the first attestation. Subsequent attestations are due annually thereafter by each December 31. Although the annual attestation must be submitted by December 31, attestations may be made at any time during the calendar year. Each attestation covers the period from the date of the last attestation through the date of the subsequent attestation.

Given the legal implications of any contract or attestation, employers should generally consult with legal counsel for guidance regarding their specific contracts and related gag clause compliance obligations.

This publication includes two helpful appendices, both of which are described in further detail below: **Appendix A, Sample Letter to Service Provider Requesting Removal of Prohibited Gag Clause**, and **Appendix B, Group Health Plan Attestation Language (from the CMS GPCCA User Manual, Section 17, pg. 62).**

BACKGROUND

Historically, service providers offering group health plans access to healthcare provider networks have imposed contractual limitations on the disclosure of data that they consider to be confidential or proprietary. These provisions have prevented employers from knowing negotiated provider rates and other costs of healthcare services.

However, under ERISA, employers, as plan sponsors, have a fiduciary duty to ensure plan assets are administered prudently and solely in the interest of participants. Accordingly, employers must be able to review and control plan costs. They must also monitor plan service providers to verify they are performing their obligations under the applicable service agreements. Employers must also ensure that their service providers’ compensation is reasonable.

To fulfill these fiduciary duties, employers need access to provider reimbursement rates and de-identified claims data — and the ability to share this information with business associates. This is particularly important for self-insured plans, where the employer assumes not only financial responsibility for participants' medical claims and incurred administrative costs, but also a higher level of fiduciary duty to administer the plan prudently and in the best interest of plan participants. For further information about the fiduciary duties of plan sponsors, see the PPI publication [ERISA Fiduciary Governance: A Guide for Employers](#).

Additionally, to satisfy requirements under the Transparency in Coverage (TiC) Final Rules, which amended ERISA, employers need access to plan cost and claims data. For example, under the TiC Final Rules, provider-specific cost information must be made available to participants through an internet self-service tool. Employers must also publicly disclose their plan's network rates and historical out-of-network allowed amounts and billed charges in machine-readable files (also referred to as MRFs).

Despite employers' legal obligations, some service provider contracts continue to include provisions that impermissibly limit employer access to or use of plan cost and claims information. Accordingly, employers often face challenges and barriers when seeking to obtain their own plan's data from a service provider. Such disputes could potentially lead to undesired litigation.

THE GAG CLAUSE PROHIBITION REQUIREMENT

Congress realized employers could not fulfill their plan fiduciary obligations without the necessary access to plan information, including healthcare provider rates and claims data. To improve transparency in the group health plan context, the CAA 2021 amended ERISA to require the removal of gag clauses in service provider contracts. In addition, employers annually must formally attest to satisfying this requirement.

Specifically, under the gag clause prohibition, group health plans and insurers are prohibited from entering into agreements with a healthcare provider, provider network, third-party administrator (TPA), or other service provider offering access to a provider network that include:

1. Restrictions on the disclosure of provider-specific cost or quality of care information or data to the plan sponsor, participants, beneficiaries, or enrollees (or those eligible to become participants, beneficiaries, or enrollees of the plan or coverage).
2. Restrictions on electronic access to de-identified claims and encounter information for each participant, beneficiary, or enrollee upon request and consistent with HIPAA, GINA, and ADA privacy regulations.
3. Restrictions on sharing information or data described in (1) and (2) or restrictions on directing that such information or data be shared with a business associate, consistent with applicable privacy regulations.

Accordingly, the first prong of the gag clause prohibition provision is designed to ensure plan sponsors and participants have the necessary access to both provider-specific costs and quality of care data, which measures healthcare services in terms of effectiveness and efficiency, among other items. Employers need this data to evaluate plan costs in relation to plan benefits and make informed healthcare decisions. Service providers can no longer limit the release of such data by deeming it proprietary.

The second prong makes clear that service provider contracts must also allow plan sponsors unrestricted access to de-identified claims and encounter data for all participants. Encounter data indicates the healthcare provider's diagnosis and the items or services provided to treat the participant's condition. Encounter data may be considered to determine healthcare provider reimbursement rates. Notably, the CAA 2021 requires access to information on a per-claim basis, including the healthcare provider, billed amount, allowed amount, service codes, and other data elements. Per-claim data allows for better assessment of the healthcare costs related to a particular item or service.

The third prong prohibits restrictions on sharing the provider reimbursement rates and de-identified claims information with a business associate. Plans often rely upon business associates (e.g., accountants, lawyers, brokers, and consultants) to perform a variety of services for or on behalf of the plan. Accordingly, it is important the contract terms do not limit the plan's ability to share data with a business associate that is necessary for performance of the business associate's functions. For example, if an agreement permits the plan to share network rates or de-identified claims data with a business associate only at the discretion of the TPA offering access to a network, the agreement contains an impermissible gag clause. However, service provider contracts can include reasonable restrictions on the *public* disclosure of information.

Additionally, employers should recognize that the gag clause prohibition not only precludes plans from directly entering into agreements that contain gag clauses but also prohibits any restrictions contained in "downstream" agreements. For example, contract terms between a TPA and a provider network that restrict the TPA from sharing relevant cost information with a plan, so that the plan could not provide such information to a business associate, would indirectly restrict the plan (even if the plan is not a party to the network agreement). As a result, the plan would be in violation of the gag clause prohibition.

Accordingly, to ensure compliance with the gag clause prohibition, employers should request written confirmation from TPAs and other service providers that they have not entered network contracts with prohibited gag clauses. Employers should also seek to have such confirmation memorialized in their service contracts.

APPLICABILITY TO PLAN TYPES

The gag clause prohibition applies to fully insured and self-insured (including level-funded) group health plans and insurers offering group or individual health insurance coverage. Note that for fully insured plans, both the group health plan and insurer are subject to the requirements, including the attestation. However, if the insurer agrees to attest on behalf of a fully insured plan, agency guidance provides that the fully insured employer can rely on the insurer's attestation that their provider contracts are in compliance. In such case, the carrier is essentially accepting the burden and responsibility for the attestation. Therefore, the employer does not need to take any further action with respect to that particular fully insured contract for purposes of complying with the gag clause prohibition. (Note this does not relieve such employers of compliance responsibilities with respect to any other applicable plans they sponsor.) By contrast, if a TPA agrees under a written agreement to submit the attestation for a self-insured plan, the burden and responsibility for compliance remains with the employer sponsor of the self-insured plan.

Group health plans subject to the gag clause prohibition and attestation requirements include, but are not limited to, major medical plans, prescription drug plans, and pharmacy benefit plans. Point solution programs that are group health plans are subject to the requirements unless an exception applies. See the PPI publication [Point Solution Programs: A Guide for Employers](#) for information on determining whether a point solution program is a group health plan. There are no exceptions for non-federal governmental plans (such as plans sponsored by state and local governments), church plans, or grandfathered or grandmothers plans.

However, the gag clause prohibition and attestation requirements do not apply to short-term limited duration insurance and ACA excepted benefits, such as limited-scope dental and vision plans, long-term care plans, certain hospital or other fixed indemnity insurance, specific disease or illness insurance, and accident, disability, and workers' compensation benefits. Nor do the requirements apply to retiree only plans. Additionally, the departments are not enforcing the requirements with respect to HRAs (including ICHRAs) or health FSAs.

EMPLOYER ACTION PLAN FOR GAG CLAUSE PROHIBITION COMPLIANCE

Fully Insured Plans (Without Carrier's Attestation on Behalf of Plan) and Self-Insured Plans

To comply with the gag clause prohibition, employers should establish procedures to review service provider contracts and identify and address any potentially problematic provisions. The process will involve analysis of precise contract terms and negotiation and communication with the service provider to modify contract language as needed. Accordingly, employers should engage experienced legal counsel in the contract review process. Importantly, this process must be conducted each time a service provider contract is entered or renewed. Employers should also focus on this issue during the request for proposal (RFP) process to ensure that they will have full access to necessary plan data before engaging a particular service provider.

Generally, a compliance action plan requires employers to perform the following steps:

1. Determine which benefits are group health plans subject to the gag clause prohibition.

Please see the [Applicability to Plan Types](#) section above. For some employers, the gag clause prohibition and related attestation may be limited to a group medical plan and perhaps a prescription drug plan. For others, the applicable plans may also include pharmacy benefits and other carve-out benefits that do not qualify as ACA excepted benefits (and therefore would be subject to the gag clause prohibition and attestation requirements). See the PPI publication [Point Solution Programs: A Guide for Employers](#) for further information regarding excepted benefits. Employers should carefully review each benefit offering to ensure all applicable plans are identified. As noted previously, if an insurer has agreed to attest on behalf of a fully insured plan, the sponsoring employer does not need to take further action with respect to that contract.

2. Locate the applicable contracts related to each group health plan benefit identified in Step 1.

Typically, employers enter a primary agreement with a carrier, TPA, pharmacy benefit manager (PBM), or other service provider, such as an insurance contract, network agreement, TPA agreement, or administrative services agreement. If a TPA agreement with a plan references a network agreement between the TPA and healthcare providers, employers should either request a copy of such network agreement to review for gag clauses or ask the TPA to provide the plan with a written assurance (preferably in the primary agreement) of compliance for the network agreement. In some cases, the parties

will enter additional contracts, including nondisclosure agreements and confidentiality agreements. Furthermore, these agreements may be modified or supplemented with an amendment or addendum. Accordingly, employers should gather all these relevant contracts and amendments for review purposes.

3. Review each applicable contract for problematic gag clauses.

Each contract is unique with provisions that must be reviewed in the context of the entire agreement. Accordingly, prohibited gag clause language will vary and encompass many forms.

For example, gag clauses that impermissibly restrict the disclosure of provider-specific cost and quality of care data may include:

- A provision that specifies the employer's access to provider-specific cost and quality of care information is at the TPA's discretion.
- Language stating the plan may not disclose provider rates to participants or beneficiaries because the TPA considers such rates proprietary.
- A requirement that plan data, such as pricing information, fees, and network discounts, be used by the employer solely for plan administrative purposes, without clearly defining "plan administrative purposes" in a way that complies with the gag clause prohibition.

Additionally, any unreasonable limitation on the scope, scale, or frequency of electronic access to de-identified claim and encounter information "upon request" is prohibited. For example, the following restrictions on an audit or claims review would be considered impermissible gag clauses:

- A limitation on access to a statistically significant or the "minimum necessary" number of de-identified claims.
- A restriction on the scope of access to the data to specific, narrow purposes (such as restricting access to the context of an audit).
- An unreasonable limit on the frequency of claims reviews (e.g., no more than once per year).
- A limitation on the number and types of de-identified claims that a plan may access.
- A restriction on access to de-identified claims data only on the TPA's or service provider's physical premises.

In some cases, the prohibited clauses may impermissibly limit the plan or insurer's ability to share information with a business associate by imposing restrictions beyond the requirements of HIPAA and other privacy laws, such as:

- A provision that does not allow the plan to share claims information with a business associate (in accordance with HIPAA privacy rules) unless required by law.
- A requirement that the plan obtain additional written consent from the service provider before sharing network rate information with a business associate.

The above examples are by no means intended to be exhaustive.

In certain contracts, prohibited gag clause language may be indirect and thus less evident. For example, a nondisclosure agreement may define the purpose of the agreement so narrowly that it has the effect of substantially restricting the plan's right to share information with a business associate or inappropriately limiting how the business associate may use it on the plan's behalf.

During the review process, the question may arise as to whether a standard contract provision requiring each party to comply with applicable laws may be sufficient. Unfortunately, the limited available guidance does not address this question. Congress was likely aware of such common contract language but chose to require the removal of problematic provisions. Plans considering reliance on such language should review the issue with their legal counsel.

Upon completion of the review of a contract, if no gag clauses are found, the employer can proceed to Step 6.

If prohibited gag clauses are identified, the employer should continue with Step 4.

4. Instruct the service provider to remove the gag clause to bring the contract into compliance.

It is important for employers to notify service providers of any prohibited gag clauses in the parties' agreement(s) and instruct the provider(s) to remove or amend the language to comply with the CAA 2021. Employers should document their communications.

If the service provider is not responsive or does not agree to make the requested contract modifications, the sponsor should send a formal written letter. A sample letter is provided in [Appendix A, Sample Letter to Service Provider Requesting Removal of Prohibited Gag Clause](#). Employers should consult with legal counsel for specific advice and guidance regarding the drafting of their letter.

If the service provider removes the gag clause in response to the letter, the employer can proceed to Step 6 below. Otherwise, they should continue to Step 5.

5. Consider reporting the violation of the gag clause prohibition to the appropriate regulatory authorities.

If the employer's efforts to remove the gag clause (as outlined in Step 4) are unsuccessful, there is an additional step they can take. According to the February 2023 FAQ guidance, employers that sponsor ERISA plans can contact the DOL for help at www.askebsa.dol.gov or 866.444.3272. For non-ERISA plans, employers can contact the No Surprises Help Desk at 800.985.3059, submit a complaint at <https://www.cms.gov/nosurprises/policies-and-resources/providers-submit-a-billing-complaint>, or contact the applicable state authority. As noted above, these steps should be taken in consultation with legal counsel.

If reporting the violation results in the removal of the prohibited gag clause, the employer can proceed to Step 6. If the service provider still refuses to remove the prohibited gag clause, employers should be aware that the January 2025 FAQ guidance indicates the plan must identify the noncompliant provision as part of their attestation. Please see the **GCPCA Submission Process** section below for further details.

6. Complete the Gag Clause Prohibition Compliance Attestation, as described in the Attestation Overview and Submission Process sections below.

GAG CLAUSE PROHIBITION COMPLIANCE ATTESTATION OVERVIEW

As explained earlier, group health plans and health insurers must annually submit an attestation of compliance with the gag clause prohibition. CMS released [GCPCA Annual Submission Instructions](#) that provide an overview of the annual submission process. The first Gag Clause Prohibition Compliance Attestation (GCPCA) was due no later than December 31, 2023, attesting to compliance for contracts entered into from December 27, 2020, through the date of attestation. Subsequent attestations are due annually thereafter by each December 31 for contracts entered into or renewed since the last attestation. Plans and insurers that do not submit their required attestation by the deadlines may be subject to enforcement action.

Attestation Submission for Fully Insured Plans

With respect to fully insured plans, the group health plan and insurer are each required to annually submit an attestation. However, as noted previously, if the insurer submits the attestation on behalf of itself and the plan, then both the plan and insurer will have satisfied the requirement.

Attestation Submission for Self-Insured Plans

Self-insured (including level-funded) plans may satisfy the attestation requirement by entering into a written agreement under which the plan's service provider(s) (such as a TPA) will attest on the plan's behalf. However, if self-insured (including level-funded) plans enter into such an agreement with the plan's service provider(s), the legal requirement to provide a timely attestation remains with the plan.

Employers should routinely communicate with their insurers, TPAs, PBMs, and other service providers regarding whether those parties will attest on the plan's behalf and should obtain written confirmation that all agreed-upon attestations were timely submitted.

GCPCA SUBMISSION PROCESS

If the TPA or service provider does not submit the attestation on the plan's behalf, then the employer must do so directly. As outlined on the [CMS Gag Clause Prohibition Compliance Attestation \(GCPCA\)](#) web page, the attestation must be submitted online via a CMS webform (the "GCPCA Webform"). (Unlike the requirements for the CAA 2021 pharmacy benefit reporting, the gag clause attestation does not require formal registration and establishment of a CMS Health Insurance Oversight System (HIOS) account.)

To access the GCPCA Webform, the individual designated by the plan sponsor to submit the attestation (termed the "submitter") must first obtain an authentication code by going to the GCPCA website at [Gag Clause Attestation | Welcome! \(cms.gov\)](https://www.cms.gov/gag-clause-attestation) and

selecting “Don’t have a code or forgot yours?” The submitter will be asked to provide their email address. The system will generate an authentication code and send it to the email address provided within about 10 minutes. The code is valid for approximately 14 days.

The submitter can then return to the GPCCA website, enter the email address and code where indicated, and select “Login to the system” to proceed with submitting the attestation. The submitter should follow the step-by-step directions in Section 2 of the [GPCCA Annual Submission Instructions](#) and in the [HIOS GPCCA User Manual](#) (which includes illustrative screenshots). Note that the attestation year selected should be the year of the submission. For example, an attestation submitted on October 10, 2025, for a plan that submitted its GPCCA for the prior attestation year on November 30, 2024, would have an attestation period of December 1, 2024, to October 10, 2025, and an attestation year of 2025.

The submission process requires entry of data regarding the submitter, the attester (individual with legal authority to attest for the plan, who may be the same as the submitter), the responsible entity (e.g., ERISA plan), and whether the submission is for all provider agreements of the employer or just a particular type (e.g., medical plan agreement). Many employers will not need to complete the GPCCA spreadsheet, which is required when the submitter attests on behalf of more than one entity (as may be the case with carriers and TPAs). Any special considerations that the submitter would like to share with CMS can be entered in the “Additional Information” text box.

Pursuant to January 2025 FAQ guidance, the “Additional Information” textbox can be used to report information on a situation in which a TPA or service provider refused to remove a prohibited gag clause from a contract, such as the TPA or service provider’s name and a description of their conduct, and to report information on the plan’s efforts to remove the gag clause. According to the FAQ, if a plan submits a GPCCA with such additional information, the plan will have satisfied the GPCCA requirement but may still be subject to enforcement action, although their good faith efforts to self-report the gag clause would be taken into account. Employers should always discuss their attestation submission for noncompliant provisions with legal counsel, especially since the plan’s self-reporting in accordance with this FAQ does not necessarily alleviate enforcement action against the plan.

Submission of the attestation is the final step. The attestation language is included in the user manual; a screenshot is included as [Appendix B, Group Health Plan Attestation Language \(from the CMS GPCCA User Manual, Section 17, pg. 62\)](#). The attester is not asked to provide a narrative response, nor can they edit the attestation language; rather, the attester simply inserts their full name and submits the attestation. The system will confirm if the submission was successful and provide a downloadable receipt. The GPCCA dashboard will also indicate if the submission was completed.

According to the user manual, employers needing assistance with the physical submission process can contact the CMS Marketplace Service Desk at 855.267.1515 or at CMS_FEPS@cms.hhs.gov.

SUMMARY

The gag clause prohibition is designed to promote greater price transparency in the health insurance context by removing contractual restrictions that unnecessarily limit a group health plan sponsor’s access to certain plan data. Employers should be aware of the gag clause prohibition and the related annual attestation requirement. In consultation with counsel, employers should carefully review their applicable contracts with insurers, TPAs, and other service providers and take the necessary actions to address any prohibited gag clauses. Employers should coordinate the submission of their annual GPCCA with each plan service provider to ensure it is timely submitted. Prospectively, before entering or renewing contracts, employers must verify the terms do not reflect prohibited gag clauses.

RESOURCES

[ERISA Section 724 \(as amended by the CAA 2021\)](#)

[FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 57 \(dol.gov\)](#)

[FAQs About Consolidated Appropriations Act, 2021 Implementation Part 69](#)

[Gag Clause Prohibition Compliance Attestation \(GPCCA\)](#)

[GPCCA Access Page Gag Clause Attestation | Welcome! \(cms.gov\)](#)

[GPCCA Annual Submission Instructions](#)

[HIOS GPCCA User Manual \(cms.gov\)](#)

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APPENDIX A

Sample Letter to Service Provider Requesting Removal of Prohibited Gag Clause

To Whom It May Concern:

We write to express our concern with [name of contracting party (e.g., insurer/carrier, administrative service only (ASO) provider, third-party administrator (TPA), pharmacy benefit manager (PBM), etc.)]'s failure to remove prohibited "gag clauses" from our contractual agreement, as required by federal law.

In line with our compliance obligations under the Consolidated Appropriations Act, 2021 (CAA 2021), Title II (Transparency), division BB, a group health plan must not enter into agreements with providers, TPAs, or other service providers that include gag clauses (i.e., language that directly or indirectly restricts specific data and information that a plan can disclose or make available to another party). Specifically, the CAA 2021 prohibits:

1. Restrictions on the disclosure of provider-specific cost or quality of care information or data to referring providers, the plan sponsor, participants, beneficiaries, enrollees, or individuals eligible to become participants, beneficiaries, or enrollees of the plan or coverage.
2. Restrictions on electronic access to de-identified claims and encounter information or data for each participant, beneficiary, or enrollee upon request and consistent with the privacy regulations promulgated pursuant to section 246(c) of HIPAA, GINA, and the ADA.
3. Restrictions on sharing information or data described in (1) and (2) or directing that such information or data be shared with a business associate, as defined in 45 CFR 160.103.

[CLIENT] has requested that prohibited gag clause language be removed or amended from the (specify contract, e.g., "Third-Party Administrative Services Agreement" between CLIENT and (Name of other contracting party (e.g., the TPA, PBM, etc.)). The identified noncompliant provision(s) are:

(Identify and explain problematic contract section(s), provision(s), or clause(s)).

Retention of this language precludes us from complying with our CAA 2021 obligations and our fiduciary duties under ERISA. Although the gag clause prohibition permits a service provider to impose reasonable restrictions on the public disclosure of the data, [ASO/TPA]'s restrictions go well beyond that limited scope.

Ultimately, [CLIENT] requests that the specified language be modified or stricken as soon as possible, so [CLIENT] can uphold their obligations and truthfully and timely attest to such compliance, as required by federal law.

We look forward to your prompt response and a compliant resolution of this matter.

Regards,

APPENDIX B

Group Health Plan Attestation Language (from the CMS GPCCA User Manual, Section 17, pg. 62)

HIOS GPCCA User Manual v 09.00.00

17 - Group Health Plan and Health Insurance Issuer Attestation Statements

Table 1 - Group Health Plan and Health Insurance Issuer Attestation Statements

Note: These are the statements the Attester needs to read and attest to, based on whether they are attesting for a group health plan, a health insurance issuer, or both.

Type of Entity	Statement
Group health plans, including non-federal governmental plans, and health insurance issuers offering group health insurance coverage	<p>I attest that, in accordance with section 9824(a)(1) of the Internal Revenue Code, section 724(a)(1) of the Employee Retirement Income Security Act, and section 2799A-9(a)(1) of the Public Health Service Act and the language herein, the group health plan(s) or health insurance issuer(s) offering group health insurance coverage on whose behalf I am signing has not, for the dates specified and as provided in the foregoing information, entered into an agreement with a health care provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict the group health plan(s) or health insurance issuer(s) from —</p> <ol style="list-style-type: none"> 1. Providing provider-specific cost or quality of care information or data, through a consumer engagement tool or any other means, to referring providers, the plan sponsor, participants, beneficiaries, or enrollees, or individuals eligible to become participants, beneficiaries, or enrollees of the plan or coverage. 2. Electronically accessing de-identified claims and encounter information or data for each participant, beneficiary, or enrollee in the plan or coverage, upon request and consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the amendments made by the Genetic Information Nondiscrimination Act of 2008 (GINA), and the Americans with Disabilities Act of 1990 (ADA), including, on a per claim basis — <ol style="list-style-type: none"> a. Financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract. b. Provider information, including name and clinical designation. c. Service codes; or d. Any other data element included in claim or encounter transactions; or 3. Sharing information or data described in items (1) or (2), or directing that such data be shared, with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of HIPAA, the amendments made by GINA, and the ADA.