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New Transparency Requirements for Group Health Plans

Updated for August 2021 FAQs

The Departments of Health and Human Services, Labor, and Treasury (the Departments) released final transparency in coverage regulations (the final transparency regulations) for group medical plans and health insurance issuers on October 29, 2020. The intent of the final transparency regulations is to provide a consumer with access to information on the cost of health care services before that consumer receives health care services, rather than after care is received. There are two main components – a requirement to provide personalized cost-sharing information and a requirement to make certain cost information publicly available. On August 20, 2021, the Departments issued FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Part 49 FAQs) clarifying the final regulations. In addition, the Part 49 FAQs also contain guidance delaying the applicability dates for several requirements.

Background for the Transparency Final Regulations

On June 24, 2019, President Trump issued Executive Order 13877, ‘‘Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.’’ In response to that Executive Order, the Departments issued proposed regulations on November 27, 2019, proposing requirements for group medical plans and health insurance issuers in the individual and group markets to provide personalized cost-sharing information upon request and to make cost information publicly available.

The final transparency regulations adopt the proposed requirements, with some modifications, for group medical plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of the individual’s cost-sharing liability for covered items or services furnished by a particular provider. Under the final rules, plans and issuers must make this information available on an internet website and, if requested, in paper form, and via telephone thereby allowing a participant, beneficiary, or enrollee (or his or her authorized representative) to obtain an estimate and understanding of the individual’s out-of-pocket expenses and effectively shop for items and services (personalized cost-sharing information). The final rules also adopt the proposed rules, with some modifications, requiring plans and issuers to disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and prescription drug pricing information through three machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending (publically available cost information).

In addition to the final transparency regulations, the Consolidated Appropriations Act, 2021 (the CAA), which President Trump signed into law on December 27, 2020, contains additional transparency requirements. The CAA transparency requirements include a new ban on certain “gag” clauses, new identification card requirements, advanced explanation of benefit requirements, special rules for continuing care patients, improved network provider directory information, and price comparison disclosures.

Below, we share highlights of each requirement.

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Personalized Cost-Sharing Information under the Final Transparency Regulations

PERSONALIZED COST-SHARING INFORMATION IN GENERAL

The transparency regulations require medical plans and health issuers to provide personalized estimates of cost-sharing liability so that consumers can have information on the cost of care and their potential financial responsibility prior to obtaining medical care. The information must be provided to employees, beneficiaries, and their authorized representatives. It does not need to be provided to individuals who are not already enrolled in a plan, nor does a plan need to make this information available to health care providers. However, individuals may obtain cost-sharing information and share that information with their providers.

APPLICABILITY AND EFFECTIVE DATE

The final transparency regulations require medical plans and health issuers to provide personalized cost-sharing information for 500 specific health care services for plan years beginning on and after January 1, 2023 and for all services for plan years beginning on and after January 1, 2024. Under a transparency provision contained in the Consolidated Appropriations Act of 2021 (CAA), some disclosures would be required for plan years beginning on and after January 1, 2022. In addition to an earlier effective date, the CAA transparency rules require plans to make information available via telephone in addition to online and in paper format. The Departments have stated that they will defer enforcement of the 2022 compliance date in the CAA until plan years that begin on or after January 1, 2023. Unfortunately, the relevant FAQ does not indicate if the 2024 date for disclosure of all services will remain 2024 or be accelerated to 2023 in accordance with the CAA. Pursuant to Part 49 FAQ #3, the Departments intend to include guidance on the telephone request requirement in future rulemaking.

Cost-sharing information includes information such as copayment and coinsurance details. The requirements apply to non-grandfathered medical plans and health issuers. Grandfathered plans, excepted benefits (such as stand-alone dental and vision plans), account-based plans (such as Health Reimbursement Arrangements and health flexible spending accounts), and Short-term Limited Duration Insurance plans are not subject to these rules.

COST-SHARING DISCLOSURE CONTENT REQUIREMENTS

The regulations outline seven cost-sharing disclosure content elements. These seven content elements generally mirror the information found in a typical Explanation of Benefits (EOB) form. However, unlike an EOB, which is produced after care has been provided, these cost sharing estimates are provided prior to obtaining services. The seven content items are:

1. **Estimated Cost-Sharing Liability** – this is an estimate of the amount the individual would be responsible for paying under the terms of the plan and includes deductibles, coinsurance, and copayments. It does not include premiums, balance billing amounts, or the cost of non-covered services. The information provided must be the estimated cost for a specific individual and service or services based on actual rates and allowed amounts, as well as the individual's specific cost-sharing limits (rather than a cost-estimate methodology or tool), and, in almost all cases, must be a

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dollar amount. The dollar value provided will be an estimate; the final cost may be different, for example, if the individual receives additional services.

2. **Accumulated Amounts** – this is the amount an individual has paid toward the plan's deductible and out-of-pocket maximums as of the date the request for information is received. The amounts disclosed must include both the amount of the cost-sharing (including deductibles and out-of-pocket maximums) and the amount the individual has already incurred (e.g., the individual has already incurred $600 of expenses that have been applied to the deductible). This does not include amounts that do not count toward the deductible and/or out-of-pocket maximums, such as premiums or the cost of non-covered services. The estimate of the accumulated amounts and amount remaining may not include amounts where the costs of services that have been provided, but where the claim has not been adjudicated.

   If the individual has coverage other than self-only coverage (e.g., family), accumulated deductible and out-of-pocket amounts must be provided for each individual covered as well as for the entire group.

   If the service to be provided is subject to a cumulative treatment limitation, such as a maximum number of days, visits, or treatments, the information provided must include that limit and the number of days/visits/treatments remaining. For example, if the plan limits physical therapy treatments to 60 per calendar year and the plan has already paid for 20 treatments, the plan must disclose the 60-treatment limit and indicate that there are 40 treatments available before the plan's limit is reached.

3. **In-Network Rates –** the plan or insurer must disclose the negotiated rate, expressed as a dollar amount, even if it is not the rate the plan or insurer uses to calculate cost-sharing liability. For example, if the plan applies a flat dollar copayment for a service, the negotiated rate for that service does not affect the calculation of how much the individual pays. However, where the plan or insurer uses percentage coinsurance, the plan must disclose the amount the individual must pay, relative to the negotiated rate, as a dollar amount.

   The plan or insurer must also disclose underlying fee schedule rates with cost-sharing liability where the underlying fee schedule is different from the in-network negotiated rate, even if the plan or insurer does not use the underlying fee schedule to determine the individual's cost-sharing amount.

   Plans and health insurance issuers must disclose the out-of-pocket cost liability and the negotiated rate for prescription drugs, but not discounts, rebates, or price concessions for a drug. If the cost-share for the prescription is $0, the plan must still disclose the negotiated rate for the drug. Note: Prescription drugs are not included in the list of 500 services that must be included beginning in 2023. Drugs must be included beginning in 2024 when information must be provided for all covered services. *(Note: It is not clear from the FAQs if the date for all services will remain 2024 or will be accelerated to 2023.)*

4. **Out-of-Network Allowed Amount** – the plan or insurer must disclose the allowed amount for an item or service. "Allowed amount" is defined as the maximum amount that the plan will pay for a

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specific item or service from an out-of-network provider. This amount may be expressed as a percentage only if the plan pays a percentage of billed charges. Plans that do not provide out-of-network coverage, such as an HMO, should list the allowed amount as zero.

5. **Items and Services Content List** – if the item or service for which cost information is being requested is subject to a bundled payment arrangement, the plan must disclose the items and services included in the bundled payment arrangement and the cost-sharing liability for the bundled items. The plan must only display the cost-sharing estimate for each item in the bundle if cost sharing applies separately to items in the bundle. For example, for an outpatient surgical procedure, the plan may reimburse the surgeon a flat dollar amount for the surgery that also includes one post-operative office visit as part of the surgery fee. If the individual is subject to a copayment (or coinsurance) for the surgical procedure and must also pay an office visit copay for the one post-operative office visit, then the plan must disclose both cost-sharing amounts.

6. **Notice of prerequisites to coverage** – the plan or insurer must specifically state if the service for which cost information is being requested requires concurrent review, prior authorization, step-therapy, or a fail-first protocol. The final regulations limit the disclosure of prerequisites to these four medical management techniques.

7. **Disclosure notice** – plans and health insurance issuers must provide a disclosure notice, written in plain language, that contains several specific statements:

    a. balance billing may apply (this statement may be excluded if state law prohibits balance billing);

    b. actual charges may be different depending on what services are ultimately provided;

    c. the estimate is not a guarantee of coverage;

    d. whether copayment assistance (or other third party assistance) counts toward the deductible and/or out-of-pocket maximum;

    e. if the plan cannot determine whether a particular service is a preventive service, the plan must display the cost-sharing assuming the service is not preventive, and must include a statement that if the service is billed as preventive, the cost-sharing amount may be $0; and

    f. any additional information, including disclaimers, the plan or insurer deems appropriate (provided such information does not conflict with the other information required to be provided).

A model notice (included with the proposed regulations) is available on the DOL's website.

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REQUIRED METHODS FOR PROVIDING DISCLOSURES

The final transparency regulations require plans to provide cost-sharing information using two methods – through a self-service internet-based tool, in paper form, and via telephone. Additional methods, such as email, fax, or mobile applications, are permitted, but not required. However, these other methods must be in addition to, not in place of, the two required methods.

Self-service Internet-based Tool

The personalized cost-sharing information provided must be available without any subscription or fee using an internet-based self-service tool. The information displayed must be up-to-date and searchable so the individual can search for cost-sharing information for a specific item or service from an in-network provider, or search for an out-of-network allowed amount that provides a reasonable estimate of what the plan will pay for a specific item or service obtained from an out-of-network provider. The individual should be able to obtain cost-sharing information by inputting: (1) a billing code (e.g., a CPT Code) or a descriptive term (e.g., rapid flu test); (2) the name of the provider; and (3) other factors used by the plan to determine cost-sharing such as a provider's zip code or the place of service (e.g., inpatient, office). The internet-based platform must include a search function that will enable users to search based on the cost-sharing for a covered service obtained from an in-network provider and the out-of-network allowed amount for an item or service from an out-of-network provider by inputting one of these three data elements (e.g., CPT Code). In addition, the user must be able to use the tool to refine and re-sort search results based on the geographic location of providers and the amount of estimated cost-sharing responsibility. The requirement to refine and re-sort search results only applies to in-network providers.

If the cost-sharing for a prescription drug is based on quantity and/or dosage, the user must be able to input that information and obtain a cost-sharing estimate based on the user's specific quantity and dosage. Prescription drugs are not included in the list of 500 services that must be included beginning in 2023. Drugs must be included beginning in 2024 when information must be provided for all covered services. *Note: It is not clear from the FAQs if the 2024 date remains in effect for all services, or if the date will be accelerated to 2023 based on the requirements of the CAA.*

The information displayed must be accurate at the time of the request. However, the final regulations note that the information provided will be an estimate and that it may not reflect claims that have not yet been processed.

Paper Format

Plans must provide cost-sharing information in paper format when requested. The information provided must be the same information that is available through the internet-based self-service platform. It must be personalized, and no subscription or fee may be required. The plan may limit the results to 20 providers per request. The information must be mailed within two business days following receipt of the request and must be sent via the U.S. Postal Service or another delivery service.

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Telephonic

The CAA adds a requirement that was not included in the final regulations. Under the CAA, plans an issuers must provide cost-sharing information via telephone when requested. The information must be the same information that is available via the internet-based self-service platform and via paper. The Departments intend to provide future guidance on this requirement (Part 49 FAQ #3).

Good Faith Compliance

There are two limited safe harbors available. First is a safe harbor that is available if the plan's website is unavailable for only a brief period of time. Under that safe harbor, a group medical plan will not fail to comply with the personalized cost estimate requirements solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan makes the information available as soon as practicable. Second, there is a safe harbor for minor errors as long as those errors are timely corrected.

ADDITIONAL RULES

The final regulations include a special rule to prevent duplication for medical plans that are insured. If there is a written agreement between an insured plan and the insurer under which the insurer agrees to provide the required disclosures, then the insurer will be responsible for compliance.

If the plan is self-insured, it is the plan that is responsible for compliance. The plan may obtain a written agreement with the Third Party Administrator (TPA) to provide the required disclosures, but it is the plan, not the TPA that is ultimately responsible for compliance.[1] The overwhelming majority of self-insured plans will not have the data needed to comply with all of the disclosure requirements and will need to rely on their TPAs to provide the required disclosures.

An additional issue that may arise is the existence of a "gag" clause under some network contracts. Plans and issuers may need to amend those agreements in order to comply. (Some contracts may have a provision that "automatically" adjusts as needed to comply with federal laws.) [2] Finally, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification rules continue to apply.

Although the effective date for personalized cost-sharing disclosures is more than a year away, a substantial amount of work will need to be done in order to comply. An employer with a fully insured plan will want to obtain a written agreement that its insurer will comply with the disclosure requirements. Employers with self-insured plans will want to obtain written agreements stating that their TPAs will provide the required information on behalf of their plans. In addition, an employer with a self-insured medical plan

[1] The regulators noted in the Preamble that while they have the authority to require compliance by plans and health insurance issuers, they do not have the statutory authority to apply these requirements to TPAs.
[2] The CAA includes a prohibition against "gag" clauses that would prevent a group medical plan from providing certain cost or quality of care information. See below, "Transparency Requirements under the CAA"

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may want to include an indemnification provision in its TPA contract to protect the plan if the TPA does not satisfy the requirements.

SEVERABILITY

Finally, this portion of the regulations includes a severability provision. Under this provision, any part of this section of the regulation that is held to be invalid or unenforceable shall be severable from the remainder of the regulation. For example, if a federal court should rule that the requirement to provide personalized cost-sharing information is invalid, the requirement to provide publically available cost information would not be affected by that ruling.

Publicly Available Cost Information under the Final Transparency Regulations

MACHINE-READABLE FILES

In addition to the personalized cost-sharing information requirements created by the final transparency regulations, non-grandfathered group health plans and health insurance issuers must also comply with requirements to make cost information publicly available. These rules build upon requirements under the Patient Protection and Affordable Care Act (ACA). The ACA mandates that transparency in coverage information "shall be provided in plain language…that the intended audience…can readily understand." The Departments determined that requiring pricing information to be publicly available could allow application developers and other innovators to develop means to present the information to consumers in a meaningful, understandable way.

Accordingly, to satisfy the requirements for public disclosure, the final transparency regulations include an obligation for group medical plans and health insurance issuers to provide three machine-readable files on internet websites that include detailed pricing data. The first file must show negotiated rates for all covered items and services between the plan or insurer and in-network providers (the "In-Network Rate File"). The second file must show both the historical payments to, and billed charges from, out-of-network providers (the "Allowed Amounts File"). The third file must show the in-network negotiated rates and historical net prices for all covered prescription drugs by plan or insurer at the pharmacy location level (the "Prescription Drug File"). Plans and health insurance issuers must provide these data files in a standardized format with monthly updates.

APPLICABILITY AND EFFECTIVE DATE

All non-grandfathered group medical plans and health insurance issuers must comply with the requirement to produce and maintain three machine-readable files for public disclosure. This requirement does not apply to grandfathered medical plans, Health Reimbursement Arrangements or other account-based group health plans such as Health Flexible Spending Accounts, excepted benefits, short-term limited-duration insurance, or expatriate health plans. The final regulations require machine-readable files for plan years beginning on or after January 1, 2022. The Departments are delaying that effective date until July 1, 2022 for all items and services other than prescription drugs (Part 49 FAQ #2).

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The final transparency regulations require production of machine-readable files with prescription drug cost information to be made available by January 1, 2022. The CAA, which was enacted after the final regulations were issued, requires plans and issuers to report certain prescription drug cost information to the Departments by December 21, 2021. (Gallagher's articles, *Stimulus Bill Provisions Impact Employer-Sponsored Benefits* and *CAA: Departments Issue Request for Information on Prescription Drug Benefits and Cost*, contain more information on drug reporting.) As a result, the Departments are delaying enforcement of the requirement to make prescription drug pricing information publicly available in machine-readable format while they consider whether the prescription drug machine-readable file remains appropriate (Part 49 FAQs #1 and #12).

FORM AND MANNER OF DISCLOSURE; TIMING

The machine-readable files must be publicly available and accessible free of charge and without conditions (such as a username/password or other credentials, or requiring personally identifiable information to access the file). The Departments will issue future guidance prescribing the form and manner for displaying the files. Group medical plans and health insurance issuers must update the files monthly, and must clearly indicate the date of the most recent update.

MACHINE-READABLE FILE CONTENT REQUIREMENTS

The final rule prescribes content requirements for each of the three machine-readable files.

In-Network Rate File

The In-Network Rate File must include data for all covered items and services except prescription drugs that are subject to a fee-for-service reimbursement arrangement. Plans and health insurance issuers will include pricing on such drugs in the Prescription Drug File.

The In-Network Rate File must include:

Identifiers: For each coverage option the group medical plan or insurer offers, the name and identifier for each coverage option offered by a group medical plan or health insurer. The identifier is either the Health Insurance Oversight System (HIOS) identifier (i.e., the 14-digit product level or 5-digit insurer level), or if the plan or insurer does not have a HIOS identifier, the Employer identification Number (EIN);

Billing Codes: A billing code, which can include a Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis Related Groups (DRG), or a National Drug Code (NDC). The NDC is required for prescription drugs. This content element also requires a plain language description for each billing code of each covered item or service under each coverage option;

Applicable Rates: All applicable rates, which may include negotiated rates, underlying fee schedule rates, or derived amounts. A plan or insurer that does not use negotiated rates must disclose derived amounts

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to the extent these amounts are already calculated in the normal course of business.[3] The "derived amount" is defined as the price a plan or insurer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data. Plans or health insurance issuers that use underlying fee schedule rates for calculating cost sharing must disclose the underlying fee schedule rates in addition to the negotiated rate or derived amount. These amounts must also be:

- Expressed as dollar amounts. If the negotiated rate is subject to change based on participant- or beneficiary-specific characteristics, these dollar amounts must be reflected as the base negotiated rate applicable to the item or service prior to adjustments for such characteristics (e.g., health status);
- Associated with the National Provider Identifier (NPI) Tax Identification Number (TIN), and Place of Service Code for each network provider;
- Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and
- Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

Allowed Amount File

The Allowed Amounts File must include:

Identifiers: For each coverage option the group medical plan or insurer offers, the name and identifier for each coverage option offered by a group medical plan or health insurer. The identifier is either the insurer HIOS number, or if the plan or insurer does not have a HIOS number, the EIN;

Billing Codes: A billing code, which can include a CPT code, HCPCS code, DRG, or an NDC. The NDC is required for prescription drugs. This content element also requires a plain language description for each billing code of each covered item or service under each coverage option;

Allowed Amounts and Billed Charges: Unique out-of-network allowed amounts and billed charges with respect to covered items or services, furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the file. The plan or insurer must omit data for a particular item or service and provider when the plan or insurer would be reporting on payment of out-of-network allowed amounts for fewer than 20 different claims for payment under a single plan or coverage. These amounts must also be:

- Expressed as dollar amounts; and
- Associated with the NPI, TIN, and Place of Service Code for each network provider.

[3] The Preamble contains a discussion of reporting cost information for plans with capitated, bundled, or other alternative payment arrangements (e.g., direct primary care or primary care providers in an HMO).

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Prescription Drug File

The Departments are delaying enforcement of this requirement until they have had an opportunity to consider through the notice and comment rule-making process whether the prescription drug machine-readable file requirement remains appropriate (Part 49 FAQ #1). (Although not part of transparency provisions, the CAA also requires plans and issuers to report certain prescription drug information to the Departments by December 27, 2021. The Gallagher articles noted earlier provide more information on that requirement.)

The Prescription Drug File must include data on negotiated rates and historical net prices:

Identifiers: For each coverage option the group medical plan or insurer offers, the file must include the name and identifier for each coverage option offered by a group medical plan or health insurer. The identifier is either the HIOS insurer number or if the plan or insurer does not have a HIOS identifier, the EIN;

NDC Name: The NDC and proprietary and non-proprietary name assigned to the NDC by the Food and Drug Administration (FDA) must be included for each covered item or service that is a prescription drug under each coverage option a plan or insurer offers.

Negotiated Rates: The negotiated rates must be stated and must be:

- Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
- Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and
- Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC.

Historical Net Prices: The historical net prices must be stated and must be:

- Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
- Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and
- Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC. The group medical plan or health insurer must omit data for a particular NDC and provider when the plan or insurer would be reporting payment of historical net prices calculated using fewer than 20 different claims for payment.

The Preamble to the final transparency regulations notes that “the negotiated rate is not generally tied to the amount a plan or issuer will ultimately pay for the prescription drug or prescription drug service due to

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the use of post-point-of-sale rebates, discounts, and other price concessions that reduce the price that plans and issuers pay for prescription drugs." (These price concessions are not always passed to consumers at the point-of-sale.) The historical net price, on the other hand, is "the retrospective average amount a plan or health insurer paid an in-network provider for a prescription drug inclusive of any reasonably allocated rebates, discounts, chargebacks, fees and/or other price concessions." Accordingly, recognizing the unique pricing attributes of prescription drugs, the regulations require disclosure of both the negotiated rate and the historical net price to more accurately reflect the amount the plan or insurer ultimately pays.

NONDUPLICATION PROVISIONS

The regulations contain a special rule for insured group medical plans. Where a plan is fully insured, and the plan and insurer have a written agreement requiring the health insurer to provide the machine-readable files, the plan will satisfy its obligations for public disclosure. In such cases, if the insurer fails to provide the files, then the insurer, but not the plan, will be in violation of this requirement.

The regulations do not contain a similar provision for self-insured plans that contract with a third party to provide the files.[4] Similar to the rules for disclosure of personalized cost-sharing, a self-insured group medical plan may contract with a TPA to provide the machine-readable files, but the group medical plan ultimately has the responsibility for compliance. In the Preamble, the Departments comment that group medical plans will want to have written agreements and may want to include indemnification provisions. The Departments also note that some existing contracts may require amendments to remove provisions such as "gag" clauses that would impede compliance with these transparency requirements.

In addition, for the Allowed Amount file, the regulations permit plans and health insurance issuers to publish allowed amount data that aggregates information from one or more plans or policies to help eliminate unnecessary duplication. To mitigate privacy concerns, the plan or insurer must meet the 20-claim threshold independently for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. In other words, a plan or insurer may only provide data for a service for which it has at least 20 claims, even if data for that service is aggregated with data from another plan or policy. Further, a plan administrator or insurer may contract with a third party to post the file the Allowed Amount File, which may be hosted on a third-party website. However, if a plan or insurer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is publicly available.

GOOD FAITH COMPLIANCE

The final transparency regulations include several good faith compliance provisions. A plan or insurer will not fail to comply with the public disclosure requirement solely because the internet website is temporarily inaccessible, provided the plan or insurer makes the information available as soon as practicable. Moreover, a plan or insurer will not fail to comply with the public disclosure requirement solely because it

[4] The regulators noted in the Preamble that while they have the authority to require compliance by plans and health insurance issuers, they do not have the statutory authority to apply these requirements to TPAs.

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relied in good faith on information from a third party from which it was required to obtain information, unless the plan or insurer knows or reasonably should have known the information is incomplete or inaccurate.

SEVERABILITY

Finally, this portion of the regulations includes a severability provision. Under this provision, any part of this section of the regulation that is held to be invalid or unenforceable shall be severable from the remainder of the regulation. For example, if a federal court should rule that the requirement to provide three machine-readable files is invalid, the requirement to provide personalized cost-sharing information would not be affected by that ruling.

Transparency Requirements under the CAA

The CAA adds six key new requirements, which are discussed below.

PROHIBITION AGAINST "GAG" CLAUSES ON PRICE AND QUALITY INFORMATION

In addition to the final transparency regulations, the CAA adds other transparency in healthcare requirements. First, the CAA prohibits what are referred to as "gag" clauses on price and quality information. More specifically, a group health plan may not enter into an agreement with a health care provider, network or association of providers, TPA, or other service provider offering access to a network of providers that would directly or indirectly restrict a group health plan from taking the following actions:

(a) 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, enrollees, or individuals eligible to become enrollees of the plan or coverage;

(b) Electronically accessing de-identified claims and encounter information or data for each enrollee in the plan or coverage, upon request and consistent with the HIPAA Privacy regulations, Genetic Information Nondiscrimination Act (GINA), and the Americans with Disabilities Act (ADA); or

(c) Sharing information or data described in subparagraph (a) or (b), or directing that such data be shared, with a business associate (as defined under HIPAA) consistent with the HIPAA Privacy regulations, GINA, and the ADA.

Group health plans will be required to submit annual attestations to HHS stating they are in compliance with these requirements. Because the section of the CAA related to the prohibitions against "gag" clauses did not contain a separate effective date, the effective date is presumed to be the same as the overall statute – December 27, 2020. Thus, plan sponsors should review their vendor agreements, including business associate agreements, to ensure that they do not violate the CAA "gag" clause provisions.

These new requirements should be included in any new agreements entered into with impacted plan service providers, and plan sponsors may wish to ask for amendments to existing agreements including language indicating that the agreement will comply with the CAA "gag" clause prohibitions and that any provisions to the contrary are no longer in effect.

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In Part 49 FAQ #7, the Departments state that they do not expect to issue regulations on gag clauses at this time. They do, however, expect to provide guidance explaining how plans and issuers should submit their attestations of compliance. No date for the guidance is given, but they do anticipate beginning collection of attestations in 2022.

NEW IDENTIFICATION CARD REQUIREMENTS

Second, for plan years beginning on or after January 1, 2022, plan identification cards issued to participants and beneficiaries must include the following:

(1) Any deductible applicable to such plan or coverage;

(2) Any out-of-pocket maximum limitation applicable to such plan or coverage; and

(3) A telephone number and Internet website address through which an individual may seek consumer assistance information.

The requirement to provide ID cards with this information beginning in 2022 remains unchanged. The Departments expect to provide additional guidance for plans with more complex coverage designs. In the interim, good faith compliance is required. Plans and issuers are expected to include the major medical deductibles and out-of-pocket maximums, a telephone number, and an internet website address on medical plan ID cards. Additional deductibles and out-of-pocket limits could also be provided on a website that is accessed through a Quick Response code (i.e., QR code) on an individual's ID card (or hyperlink in the case of a digital ID card.) See Part 49 FAQ #4.

REQUIREMENT FOR ADVANCED EXPLANATIONS OF BENEFITS

Third, health plans must provide notices with advanced EOBs for plan years beginning on or after January 1, 2022. A notice must meet certain timing requirements (between one and ten business days, depending upon the timing of the service) and contain the following information:

(1) Whether or not the provider or facility is a participating provider, and, if the provider is a participating provider, the contracted rate under the plan or coverage for such item or service (based on the billing and diagnostic codes provided by such provider or facility), or, if the provider is not a participating provider, a description of how the individual may obtain information on providers and facilities that, with respect to such plan or coverage, are participating providers and facilities, if any; and

(2) Good faith estimates of the following: (a) the cost as stated by the provider; (b) the amount the plan or coverage is responsible for paying; (c) the amount of any cost-sharing for which the participant, beneficiary, or enrollee would be responsible for such item or service; (d) the amount that the participant, beneficiary, or enrollee has incurred toward meeting the limit of the financial responsibility (including with respect to deductibles and out-of-pocket maximums) under the plan or coverage; (e) if the item or service is subject to a medical management technique (including concurrent review, prior authorization, and step-therapy or fail-first protocols), a disclaimer that coverage for the item or service is subject to such medical management technique; (f) a

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disclaimer that the information provided in the notification is only an estimate based on the items and services reasonably expected, at the time of scheduling (or requesting) the item or service, to be furnished and is subject to change; and (g) any other information or disclaimer the plan or coverage determines appropriate that is consistent with information and disclaimers required under the CAA.

The CAA requires healthcare providers to provide a good faith estimate of the cost of scheduled items or services to plans and issuers, and to the individual upon request. In response to public feedback about the challenges of developing the technical infrastructure needed for providers to transmit good faith estimates to plans and issuers, the Departments believe that compliance beginning in 2022 may not be possible. As a result the requirement to provide these estimates is delayed pending regulations (Part 49 FAQ #5). Regulations, when issued, are expected to include a prospective applicability date that will give providers a reasonable amount of time to comply. The Departments recognize that plans and issuers face similar technical challenges and accordingly are delaying enforcement of the requirement to provide an advance EOB until guidance is issued (Part 49 FAQ #6).

CONTRACT TERMINATION NOTIFICATION REQUIREMENT FOR CONTINUING CARE PATIENTS

Fourth, effective for plan years beginning on or after January 1, 2022, plans (and health insurance issuers) will be required to notify plan participants and beneficiaries who are considered to be continuing care patients when a termination of a contractual relationship causes a change in a provider's network status. The term 'continuing care patient' means an individual who, with respect to a provider or facility: (a) is undergoing a course of treatment for a serious and complex condition from the provider or facility; (b) is undergoing a course of institutional or inpatient care from the provider or facility; (c) is scheduled to undergo non-elective surgery from the provider, including receipt of postoperative care from such provider or facility with respect to such a surgery; (d) is pregnant and undergoing a course of treatment for the pregnancy from the provider or facility; or (d) is or was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) and is receiving treatment for such illness from such provider or facility.

The requirement may be triggered by an expiration or nonrenewal of an agreement (except when nonrenewal is based upon failure to meet quality standards or fraud), a termination of the benefits provided because of a change in the terms of the participation of such provider or facility, or termination of a contract between a group medical plan and an insurer. The notice must provide the continuing care patient with an opportunity to elect transitional care or to choose to have care continued as if the termination had not occurred (but only until the end of 90 days or when the individual is no longer a continuing care patient, whichever is earlier).

The Departments intend to provide regulations using a notice-and-comment rulemaking process, but not before the January 1, 2022 applicability date. They state that any rulemaking to implement these provisions will include a prospective applicability date in order to give plans, issuers, providers, and facilities a reasonable amount of time to comply. In the interim, good faith compliance using a reasonable interpretation of the statute is required, but the applicability date remains unchanged. Part 49 FAQ #10.

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REQUIREMENTS FOR IMPROVED NETWORK PROVIDER DIRECTORY INFORMATION

The CAA also includes requirements aimed at improving network provider directories. No later than January 1, 2022, each health care provider and each health care facility must have in place business processes to ensure the timely provision of provider directory information to a group medical plan or a health insurance issuer offering group or individual health insurance coverage. Providers shall submit provider directory information to a plan or issuers, at a minimum—

> (1) when the provider or facility begins a network agreement with a plan or with an issuer with respect to certain coverage;
>
> (2) when the provider or facility terminates a network agreement with a plan or with an issuer with respect to certain coverage;
>
> (3) when there are material changes to the content of provider directory information of the provider or facility (as defined under applicable law); and
>
> (4) at any other time (including upon the request of such issuer or plan) determined appropriate by the provider, facility, or the Secretary of DOL or HHS, as applicable.

For plan years beginning on or after January 1, 2022, each group medical plan and health insurance issuer shall—

> (1) establish the process to verify and update its health care provider directory at least every 90 days and remove those it cannot verify;
>
> (2) establish a protocol to respond to network health care provider inquiries within one business day and retain records of those communications for at least two years;
>
> (3) establish a database with:
>
>> (a) a list of each health care provider and health care facility with which the plan or issuer has a direct or indirect contractual relationship for furnishing items and services under the plan or coverage; and
>>
>> (b) a provider directory information with respect to each provider and facility; and
>
> (4) include a notification that the information contained in a printed directory was accurate as of the date of publication of the directory and that an individual enrolled under the plan or coverage should consult the database described above with respect to that plan or coverage or contact the plan or the issuer to obtain the most current provider directory information.

The Departments intend to issue guidance using notice-and-comment rulemaking process to implement this requirement, but will not do so prior to the January 1, 2022 effective date. In the interim plans and issuers are expected to comply using a reasonable interpretation of the statute, but the applicability date remains unchanged (Part 49 FAQ #8).

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PRICE COMPARISON

Similar to the ACA's price transparency requirements, the CAA contains a price comparison disclosure requirement. Under these requirements, a group health plan must offer price comparison guidance by telephone and also make available a price comparison tool available on its internet website that (to the extent practicable) allows an individual enrolled under the plan to compare the amount of cost-sharing that the individual would be responsible for paying under the plan for a specific item or service by a provider. The price comparison information must be provided for a particular plan year and geographic region and with respect to the plan's participating providers. Although originally effective for plan years beginning on or after January 1, 2022, enforcement is delayed until plan years beginning on or after January 1, 2023.

What's Next?

Although the "gag" clause requirements from the CAA are already effective as of the date of publication of this Technical Bulletin, other transparency requirements will become effective over the next several years. The Departments are likely to issue additional guidance over the upcoming months, and a lot of detailed programming work is likely to be in order. Even though employers may not take on the underlying mechanics to reach compliance, they should be nonetheless gearing up to discuss transparency requirements with their carriers and TPAs. The following chart summarizes the effective dates.

Provision	Effective Date
Transparency in Coverage Machine-Readable Files for In-Network Rates and Out-of-Network Allowed Amounts and Billed Charges	July 1, 2022 for plans with plan years beginning on or after January 1, 2022 and before July 1, 2022 Beginning of plan year for plans with plan years beginning on or after July 1, 2022
Transparency in Coverage Machine-Readable Files for Prescription Drug Costs	Delayed pending further guidance
Price Comparison Tools and Information by Telephone	Plan years beginning on or after January 1, 2023 (but clarification would be appreciated)
Transparency in Plan or Insurance Identification Cards	Plan years beginning on or after January 1, 2022
Good Faith Estimates by Providers and Facilities	Delayed pending further guidance for insured individuals Plan years beginning on or after January 1, 2022 for uninsured individuals
Advanced Explanation of Benefits	Delayed pending further guidance

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Provision	Effective Date
Prohibition on Gag Clauses on Price and Quality Data	December 27, 2020
Balance Billing	Plan years beginning on or after January 1, 2022
Continuity of Care	Plan years beginning on or after January 1, 2022
Reporting on Pharmacy Benefits and Drug Costs	Delayed pending further guidance

The intent of this analysis is to provide general information regarding the provisions of current federal laws and regulation. It does not necessarily fully address all your organization's specific issues. It should not be construed as, nor is it intended to provide, legal advice. Your organization's general counsel or an attorney who specializes in this practice area should address questions regarding specific issues.

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