Transparency in Coverage Final Rule Updated Per FAQs - Part 49

Effective date: The rule is effective on January 11, 2021.

The rule includes:

(1) a requirement that group health plans and health insurance issuers in the individual and group markets disclose to participants, beneficiaries, or enrollees (or their authorized representative) upon request, through a self-service tool made available by the plan or issuer on an internet website, cost-sharing information for a covered item or service from a particular provider or providers, and

(2) a requirement that plans and issuers make such information available in paper form, upon request.

The final rule adopts a three-year, phased-in approach with respect to the scope of the requirement to disclose cost-sharing information.

(3) a requirement that such plans and issuers disclose pricing information in machine-readable files to the public as explained below.

Timing:

Self-service Tool:

Plans and issuers must make cost-sharing information available:

- for 500 items and services (identified at the end of this summary in Table 1 and regulators will post the list on a publicly available website) for plan years (in the individual market, for policy years) *beginning on or after January 1, 2023;* and
- for all items and services for plan years (in the individual market, for policy years) *beginning on or after January 1, 2024*.

Machine-readable Files:

The rule requires that plans and issuers disclose pricing information to the public through three machine-readable files.

- The first file requires disclosure of payment rates negotiated between plans or issuers and providers for all covered items and services.
- The second file will disclose the unique amounts a plan or issuer allowed, as well as associated billed charges, for covered items or services furnished by out-of-network providers during a specified time period.
- To reduce the complexity and burden of including prescription drug information in the negotiated rate machine-readable file, the rule requires a third file that will include pricing information for prescription drugs.

The machine-readable files are required for plan years (in the individual market, policy years) *beginning on or after January 1, 2022*. Per FAQs - Part 49, federal regulators will defer enforcement of the rule's requirement to publish machine-readable files containing 1) prescription drug pricing pending future regulations, and 2) in-network rates, and out of network allowed amounts and billed charges until July 1, 2022.

A detailed summary follows.

TRANSPARENCY IN COVERAGE FINAL RULE

SELF-SERVICE TOOL:

Required disclosures to participants, beneficiaries, or enrollees. The following summarizes transparency requirements for group health plans (ERISA and non-ERISA non-federal) and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

Bolded text are defined terms located at the end of this summary. These requirements do not apply to grandfathered health plans, health reimbursement arrangements or other account-based group health plans, excepted benefits, retiree-only health plans, expatriate health plans, health care sharing ministries or short term limited duration insurance.

At the request of a participant, beneficiary or enrollee (or their authorized representative) who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary or enrollee with the following:

A. ESTIMATED AMOUNTS

An estimate, which is accurate at the time the request is made, of the participant's, beneficiary's or enrollee's **cost-sharing liability** for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the person would receive, that is calculated based on the following information:

(i) **Accumulated amounts**;

(ii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) **Negotiated rate**, reflected as a dollar amount, for an **in-network provider** or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate **cost-sharing liability**; and

(B) **Underlying fee schedule rate**, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the **negotiated rate**;

(iii) **Out-of-network allowed amount** or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for **cost-sharing information** is for a covered item or service furnished by an **out-of-network provider**; provided, however, that in circumstances in which a plan or issuer reimburses an **out-of-network provider** a percentage of the **billed charge** for a covered item or service, the **out-of-network allowed amount** will be that percentage.

If the request for **cost-sharing information** relates to items and services that are provided within a **bundled payment arrangement**, and the **bundled payment arrangement** includes **items or**

services that have a separate **cost-sharing liability**, the group health plan or health insurance issuer must provide estimates of the **cost-sharing liability** for the requested covered item or service, as well as an estimate of the **cost-sharing liability** for each of the items and services in the **bundled payment arrangement** that have separate **cost-sharing liabilities**. While group health plans and health insurance issuers are not required to provide estimates of **cost-sharing liability** for a **bundled payment arrangement** where the cost-sharing is imposed separately for each item and service included in the **bundled payment arrangement**, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant **items or services** individually. If a participant, beneficiary, or enrollee requests information for an item or service subject to a **bundled payment arrangement**, the group health plan or health insurance issuer must provide a list of the items and services included in the **bundled payment arrangement** for which **cost-sharing information** is disclosed.

For requested items and services that are recommended preventive services by Federal law (§2713 of PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the **cost-sharing liability** that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant or beneficiary to request **cost-sharing information** for the specific preventive or non-preventive item or service by including terms such as “preventive”, “non-preventive” or “diagnostic” as a means to request the most accurate **cost-sharing information**.

B. NOTICE REQUIREMENTS

(i) If applicable, notification that coverage of a specific item or service is subject to a **prerequisite (**such as, concurrent review, prior authorization and step-therapy, but not medical necessity or other medical management techniques); and

(ii) A notice that includes the following information in **plain language**:

(A) A statement that **out-of-network providers** may bill participants or beneficiaries for the difference between a provider’s **billed charges** and the sum of the amount collected from the group health plan or health insurance issuer and from the participant or beneficiary in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the **cost-sharing information** provided pursuant to this paragraph does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant’s or beneficiary’s covered item or service may be different from an estimate of **cost-sharing liability** provided pursuant to these requirements, depending on the actual **items or services** the participant or beneficiary receives at the point of care;

(C) A statement that the estimate of **cost-sharing liability** for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts **copayment assistance** and other third-party payments in the calculation of the person's deductible and out-of- pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided.

C. **REQUIRED METHODS AND FORMATS FOR DISCLOSING INFORMATION TO PARTICIPANTS, BENEFICIARIES, OR ENROLLEES.**

The methods and formats for the disclosure are as follows:

(i) Internet-based self-service tool. Information provided must be made available in **plain language**, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on **cost-sharing information** that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for **cost-sharing information** for a covered item or service provided by a specific **in-network provider** or by all **in-network providers** by inputting:

(1) A **billing code** (such as CPT code 87804) or a descriptive term (such as "rapid flu test"), at the option of the user;

(2) The name of the **in-network provider**, if the user seeks **cost-sharing information** with respect to a specific **in-network provider**; and

(3) Other factors utilized by the plan or issuer that are relevant for determining the applicable **cost-sharing information** (such as location of service, facility name, or dosage).

(B) Search for an **out-of-network allowed amount**, percentage of **billed charges**, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by **out-of-network providers** by inputting:

(1) A **billing code** or descriptive term, at the option of the user; and

(2) Other factors utilized by the plan or issuer that are relevant for determining the applicable **out-of-network allowed amount** or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of **in-network providers**, and the amount of the participant's, beneficiary's, or enrollee's estimated

cost-sharing liability for the covered item or service, to the extent the search for **cost-sharing information** for **covered items or services** returns multiple results.

(ii) Paper method. Information required must be made available in **plain language**, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which **cost-sharing information** for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the **cost-sharing information** in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (A) through (C) of this section; and

(C) Mail the **cost-sharing information** in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or e-mail), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(iii) Special rule to prevent unnecessary duplication. (i) Special rule for insured group health plans. To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements if the plan requires the health insurance issuer offering the coverage to provide the information required to participants and beneficiaries pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements.

(iv) Other contractual arrangements. A group health plan or health insurance issuer may satisfy the requirements under this section by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this section, the plan or issuer violates the transparency disclosure requirements of this section.

(v) Applicability/Timing.

(1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services (identified at the end of this summary in Table 1 and regulators will post the list on a publicly available website), and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) This section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account- based group health plans (such as FSAs or HRAs) or short term limited duration insurance.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(vi) Good Faith Safe Harbors

(1) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under this section, provided that the plan or issuer corrects the information as soon as practicable.

(2) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(3) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

TRANSPARENCY IN COVERAGE- REQUIREMENTS FOR PUBLIC DISCLOSURE

The following summarizes the requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.

A group health plan or health insurance issuer in the individual and group markets must make available on an internet website the information required under paragraph (1) of this section in three **machine-readable files**, in accordance with the method and format requirements described in paragraph (2) of this section, and update such information as required under paragraph (3) of this section.

(1) **Required information. Machine-readable files** that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate **machine-readable file** that includes the required information under this paragraph (1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug **machine-readable file** as describe in in paragraph (1)(iii) of this section. The in-network rate **machine-readable file** must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14- digit

HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) **A billing code**, which in the case of prescription drugs must be an NDC, and a **plain language** description for each **billing code** for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: **negotiated rates**, **underlying fee schedule rates**, or **derived amounts**. If a group health plan or health insurance issuer does not use **negotiated rates** for provider reimbursement, then the plan or issuer should disclose **derived amounts** to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses **underlying fee schedule rates** for calculating cost sharing, then the plan or issuer should include the **underlying fee schedule rates** in addition to the **negotiated rate** or **derived amount**. Applicable rates, including for both individual items and services and items and services in a **bundled payment arrangement**, must be:

(1) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an **in-network provider**. If the **negotiated rate** is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base **negotiated rate** applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics;

(2) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(3) 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

(4) 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.

(ii) An **out-of-network allowed amount machine-readable file**[1], including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

[1] Nothing in the final rules prevents a plan or issuer from providing supplementary materials, including footnotes, disclaimers, data dictionaries, and other explanatory language, as accompaniments with the machine readable files. For example, a plan or issuer may choose to provide clarifying information related to how the negotiated rate, if reported as a base negotiated rate, may change depending on quality or value-dependent weighting factors, or participant, beneficiary, or enrollee-specific factors such as the severity of illness, age, or gender. Because base rates unadjusted for participant, beneficiary, or enrollee specific factors are required to be reported for reference-based pricing arrangements, the Departments note that it is a best practice to include a disclaimer noting that the rate could change subject to participant, beneficiary, or enrollee-specific characteristics.

(B) A **billing code**, which in the case of prescription drugs must be an NDC, and a **plain language** description for each **billing code** for each covered item or service under each coverage option offered by a plan or issuer;

(C) 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 **machine-readable file** (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (ii)(C) would require the plan or issuer to report payment of **out-of-network allowed amounts** in connection with fewer than 20 different claims for payments under a single plan or coverage). Nothing in this paragraph (1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique **out-of-network allowed amount** must be:

(1) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an **out-of-network provider**; and

(2) Associated with the NPI, TIN, and Place of Service Code for each **out-of-network provider**.

(iii) A prescription drug **machine-readable file**, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The **negotiated rates** which must be:

(1) 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;

(2) 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

(3) Associated with the last date of the contract term for each provider-specific **negotiated rate** that applies to each NDC; and

(D) **Historical net prices** that are:

(1) 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;

(2) 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

(3) 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 (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of **historical net prices** calculated using fewer than 20 different claims for payment). Nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) **Required method and format for disclosing information to the public.** The **machine-readable files** described must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The Departments are developing technical implementation guidance, including sample file schemas for the **machine-readable files**, for plans and issuers, which will be available on GitHub (a development platform), to assist them in developing the **machine-readable files**. The **machine-readable files** must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) **Timing.** A group health plan or health insurance issuer must update the **machine-readable files** and information required monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) **Special rules to prevent unnecessary duplication**--(i) Special rule for insured group health plans. To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this section if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this section.

(ii) **Other contractual arrangements**. A group health plan or health insurance issuer may satisfy the requirements by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this section, the plan or issuer violates the transparency disclosure requirements.

(iii) **Aggregation permitted for out-of-network allowed amounts**. Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (1)(ii) of this section by disclosing **out-of-network allowed amounts** made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated allowed amount file. Under such circumstances , health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate **out-of-network allowed amounts** for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the allowed amount file from being hosted on

a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer 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 made publicly available.

APPLICABILITY/TIMING

The provisions requiring **machine-readable files** apply for plan/policy years beginning on or after January 1, 2022 and do not apply to grandfathered health plans, or health reimbursement arrangements or other account- based group health plans or short term limited duration insurance. Per FAQs - Part 49, federal regulators will defer enforcement of the rule's requirement to publish machine-readable files containing 1) prescription drug pricing pending future regulations, and 2) in-network rates, and out of network allowed amounts and billed charges until July 1, 2022.

Nothing, in these provisions, alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

GOOD FAITH SAFE HARBORS

A group health plan or health insurance issuer will not fail to comply with these **machine-readable files** provisions solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required, provided that the plan or issuer corrects the information as soon as practicable.

A group health plan or health insurance issuer will not fail to comply with these **machine-readable files** provisions solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

To the extent compliance requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

DEFINITIONS

(i) **Accumulated amounts** means:

(A) The amount of financial responsibility a participant or beneficiary has incurred at the time a request for **cost-sharing information** is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these **accumulated amounts** shall include the financial responsibility a participant or beneficiary has incurred toward meeting his or her individual deductible or **out-of-pocket limit**, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or **out-of-pocket limit**, as

applicable. **Accumulated amounts** include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or **out-of-pocket limit** (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for **items or services** not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant or beneficiary, has used within that time period).

(ii) **Billed charge** means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) **Billing code** means the code used by a group health plan or health insurance issuer or provider to identify health care **items or services** for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, **National Drug Code** (NDC), or other common payer identifier.

(iv) **Bundled payment arrangement** means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant or beneficiary for a specific treatment or procedure.

(v) **Copayment assistance** means the financial assistance a participant or beneficiary receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) **Cost-sharing liability** means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. **Cost-sharing liability** generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by **out-of-network providers**, or the cost of **items or services** that are not covered under a group health plan or health insurance coverage.

(vii) **Cost-sharing information** means information related to any expenditure required by or on behalf of a participant or beneficiary with respect to health care benefits that are relevant to a determination of the participant's or beneficiary's **cost-sharing liability** for a particular covered item or service.

(viii) **Covered items or services** means those **items or services**, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) **Derived amount** means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers, or submitting data in accordance with the requirements of 45 CFR 153.710(c) (applies to capitated plans/risk

adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program (N/A to plans that we currently administer)).

(x) **Historical net price** means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non- product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the **historical net price** in a **machine-readable file** in accordance with this rule[2]. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under this rule[3].

(xi) **In-network provider** means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary or enrollee.

(xii) **Items or services** means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiii) **Machine-readable file** means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xiv) **National Drug Code** means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xv) **Negotiated rate** means the amount a group health plan or health insurance issuer has contractually agreed to pay an **in-network provider**, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvi) **Out-of-network allowed amount** means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an **out-of-network provider**.

(xvii) **Out-of-network provider** means a provider of any item or service that does not have a contract under a participant's or beneficiary's group health plan or health insurance coverage to provide **items or services**.

---

[2] § 2590.715-2715A3

[3] § 2590.715-2715A3

(xviii) **Out-of-pocket limit** means the maximum amount that a participant or beneficiary is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xix) **Plain language** means written and presented in a manner calculated to be understood by the average participant, beneficiary or enrollee.

(xx) **Prerequisite** means concurrent review, prior authorization, and step-therapy or fail- first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite **does not include** medical necessity determinations generally or other forms of medical management techniques.

(xxi) **Underlying fee schedule rate** means the rate for a covered item or service from a particular **in-network provider**, or providers that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's **cost-sharing liability** for the item or service, when that rate is different from the **negotiated rate** or **derived amount**.

Table 1: First 13 entries on 500 Items and Services List

Code	Description	Plain Language Description
J0702	BETAMETHASONE ACET&SOD PHOSP	Injection to treat reaction to a drug
J1745	INFLIXIMAB NOT BIOSIMIL 10MG	A biologic medication
G0102	Prostate cancer screening; digital rectal examination	
G0103	Prostate cancer screening; prostate specific antigen test (psa)	
G2061	Qualified non physician healthcare professional online assessment; 5-10 minutes	Qualified non physician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes
G2062	Qualified non physician healthcare professional online assessment service; 11-20 minutes	Qualified non physician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes
G2063	Qualified non physician qualified healthcare professional assessment service; 21+ minutes	Qualified non physician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes
G0206	Diagnostic mammography, including computer-aided detection (cad) when performed; unilateral	
G0204	Diagnostic mammography, including computer-aided detection (cad) when performed; bilateral	
G0121	Colon ca scrn; not hi risk ind	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
G0105	Colorectal ca scrn; hi risk ind	Colorectal cancer screening; colonoscopy on individual at high risk
S0285	Cnslt before screen colonosc	Colonoscopy consultation performed prior to a screening colonoscopy procedure
G0289	Arthro, loose body + chondro	Arthroscopy, knee, surgical, for removal of loose body, foreign