Scott A. Sinder

202 429 6289

ssinder@steptoe.com

1330 Connecticut Avenue, NW
Washington, DC 20036-1795
202 429 3000 main
www.steptoe.com

Steptoe

November 22, 2019

TO: The Council

FROM: Scott Sinder
Chelsea Gold
Ashley Stewart

RE: Proposed Rule on Transparency Requirements for Group Health Plans and Insurers

---

On November 15, the Departments of Health and Human Services ("HHS"), Labor, and Treasury (collectively "the Departments") released a proposed rule imposing new transparency requirements on insurers and group health plans.[1] The proposed rule comes in response to the Trump Administration's June 2019 Executive Order which directed the Departments to solicit comments on how consumers could receive cost-sharing information from insurers and plans *before* receiving care.[2]

To this end, the proposed rule requires insurers and plans to grant consumers ready access to certain information needed to estimate the potential out-of-pocket costs associated with a given health care item or service from a particular provider (e.g., estimated cost-sharing liability, accumulated cost-sharing amounts incurred to date, negotiated rates for in-network providers, etc.).

The proposed rule would also amend the medical loss ratio ("MLR") methodology to account for insurers who offer innovative benefit designs that result in "shared savings" to consumers who choose "lower-cost, higher-value" providers.

---

[1] Proposed Rule, *Transparency in Coverage* (Nov. 15, 2019), https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-25011.pdf (hereinafter "Proposed Rule").

[2] Executive Order, *Improving Price and Quality Transparency in American Healthcare to Put Patients First* (Jun. 24, 2019), https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/. Note, that while the Executive Order directed the Departments to issue an advance notice of proposed rulemaking, the Departments opted instead for a proposed rule so as to quickly address this issue.

Finally, the proposed rule contains two formal requests for information on:

- Whether the Departments should undertake a future rulemaking that requires plans and insurers to make price and cost-sharing information available via an "open" application programming interface ("API") to facilitate uniform use and data sharing in a "secure and standardized way;"[3] and
- How existing quality data on health care items and services can be leveraged to complement the proposed rule.[4]

Comments on the proposed rule and its associated requests for information are due on January 14, 2020. We would appreciate receiving feedback from interested Council members by **Monday, January 6, 2020**.

In addition to the proposed rule, on November 15, HHS released a final rule that addresses hospital price transparency in standard charges.[5] Effective January 2021, the final rule requires hospitals to make all standard charges (e.g., gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges) for all items and services publicly available, subject to monitoring and enforcement by HHS.

KEY PROVISIONS OF THE PROPOSED TRANSPARENCY IN COVERAGE RULE

I. Disclosure of Cost-Sharing Information

A. *Content of Disclosure*

The proposed rule requires group health plans and insurers in the individual and group markets to disclose, upon request, cost-sharing estimates for covered health care items and services[6] from a particular provider in advance of receiving those items or services. Modeled on explanation of benefits notices, these cost-sharing estimates would include the following "content elements," to the extent they are relevant to the individual's cost-sharing liability for the item or service:

- Estimated cost-sharing liability. The amount a participant, beneficiary, or enrollee would be expected to pay for a given covered item or service. This would include deductibles,

[3] The Departments specifically request comments on what pricing information should be disclosed through an API, whether requiring additional disclosure through an API would impose a burden on plans and insurers, and if such an arrangement would raise security and privacy concerns. Proposed Rule, *supra* note 1, at 77-92.

[4] Proposed Rule, *supra* note 1, at 93-97.

[5] Final Rule, *Calendar Year 2020 Outpatient Prospective Payment System & Ambulatory Surgical Center Price Transparency Requirements for Hospitals to Make Standard Charges Public* (Nov. 15, 2019), https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24931.pdf (to be codified at 45 C.F.R. § 180).

[6] The proposed rule defines "items or services" to mean all encounters, procedures, medical tests, supplies, drugs, durable medical equipment, and fees for which a provider charges a patient in connection with the provision of health care. This proposed definition is intended to be flexible enough to allow plans and insurers to disclose cost-sharing information for either a discrete item or service or for items or services for a treatment or procedure for which the plan bundles payment (i.e., a "bundled payment arrangement"). Proposed Rule, *supra* note 1, at 29, 31.

coinsurance requirements, and copayments, but exclude premiums, balancing billing amounts for out-of-network providers, and the cost of non-covered items or services.[7]

- Accumulated cost-sharing amounts incurred to date. The amount of financial responsibility an individual has already paid toward the plan's deductible or out-of-pocket maximum limit. This excludes any expense that does not count toward a deductible or out-of-pocket limit (e.g., any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered by the plan or insurer).

  In the case of a cumulative treatment limitation on a particular covered item or service, this would include the amount that has accrued toward the limit (e.g., the number of items, days, units, visits, or hours the individual has used).[8]

- Negotiated rates for in-network providers. The amount a plan or insurer has contractually agreed to pay an in-network provider for a covered item or service expressed as a dollar amount (i.e., not expressed as a formula). Disclosure of a negotiated rate would not be required if it is irrelevant for calculating an individual's cost-sharing liability for a particular item or service (e.g., the copayment is a standard dollar amount).[9]

  With respect to negotiated rates for prescription drugs, the Departments seek comments on whether:

  - A rate other than the negotiated rate, such as the undiscounted price, should be required to be disclosed for prescription drugs;
  - To account for rebates, discounts, and dispensing fees to ensure individuals have access to meaningful cost-sharing liability estimates for prescription drugs (and, if so, how to account for them);

[7] The proposed rules would not, however, require the cost-sharing liability estimate to either affirmatively reflect the amount that is ultimately charged to the participant, beneficiary, or enrollee, or include costs for unanticipated items or services the individual could incur due to the severity of his or her illness or injury, provider treatment decisions, or other unforeseen events. Proposed Rule, *supra* note 1, at 29.

[8] The Departments note that certain cumulative treatment limitations may vary by individual based on a determination of medical necessity and that it may not be reasonable for a plan or insurer to account for this variance as part of the accumulated amounts. As such, plans and insurers would only be required to provide cost-sharing information with respect to an accumulated amount for a cumulative treatment limitation that reflects the status of the individual's progress (i.e., not any individual determination that may affect coverage for the item or service). For example, if the terms of an individual's plan limit coverage of physical therapy visits to 10 per plan year, subject to a medical necessity determination, the plan would make cost-sharing disclosures based on the number of physical therapy visits already used, regardless of whether or not a determination of medical necessity had been made at that time. Proposed Rule, *supra* note 1, at 34.

[9] The Departments seek comment on whether there are any reasons disclosure of negotiated rates should nonetheless be required under these circumstances. Proposed Rule, *supra* note 1, at 35.

  - There are scenarios in which drug pricing information should not be included in an individual's estimated cost-sharing liability (or, conversely, whether drug costs should be required in a cost-sharing liability estimate in all scenarios); and
  - The relationship between plans/insurers and pharmacy benefit managers allows for the disclosure of rate information for drugs or if contracts would need to be amended to permit such disclosure.[10]

- Allowed amounts for out-of-network charges. The maximum amount a plan or insurer would pay for a covered item or service furnished by an out-of-network provider.

- A list of covered items and services. A list of covered items and services subject to a bundled payment arrangement that includes multiple items or services for which cost-sharing information is disclosed.[11] This would not be necessary when a participant, beneficiary, or enrollee requests cost-sharing information on a discrete item or service.

- A notice of prerequisites to coverage. A notice issued by plans and insurers to inform participants, beneficiaries, or enrollees that a particular covered item or service may be subject to a prerequisite (i.e., certain medical management techniques, like concurrent review, prior authorization, step-therapy, or fail-first protocols) before the item or service would be covered. This generally excludes medical necessity determinations and other forms of medical management techniques, though the Departments solicit comment as to whether there are any additional medical management techniques that should be explicitly included as prerequisites in the final rule.

- A notice of disclosure.[12] A notice that communicates the following information in plain language (i.e., written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee):[13]

  - A statement advising participants, beneficiaries, and enrollees of their potential exposure to balance bills;
  - A statement that the actual charges for the covered items and services may be different from those described in a cost-sharing liability estimate, depending on the actual items and services received at the point of care;

---

[10] Proposed Rule, *supra* note 1, at 36-37.

[11] In cases where an individual requests a cost-sharing liability estimate for a covered item or service that is subject to a bundled payment arrangement, plans and insurers would be required to disclose a list of each covered item and service included in the bundled payment arrangement and the individual's cost-sharing liability estimate separately associated with each covered item or service included in the bundle. Plans and insurers would not, however, be required to provide cost-sharing liability estimates separately associated with each covered item or service included in the bundle. Proposed Rule, *supra* note 1, at 39.

[12] This notice would be in addition to other disclosure requirements for qualified health plan insurers.

[13] Determining whether the "plain language" standard is met would require an exercise of considered judgment and discretion, considering a series of factors (e.g., the level of comprehension and education of typical participants, beneficiaries, or enrollees and the complexity of the terms of the plan).

- A statement that the estimated cost-sharing liability for a covered item or service does not guarantee that coverage will be provided for such item or service; and
- Any additional information, including other disclaimers, that the plan or insurer determines appropriate, as long as it does not conflict with the information required to be provided by the proposed rule.[14]

The Departments developed model language that plans and insurers could—but would not be required to—use to satisfy the proposed rule's notice of disclosure obligations. The Departments seek comment on whether any other information should be included in or omitted from the proposed model notice and/or whether any additional disclaimers would be necessary or beneficial to consumers (e.g., statements regarding non-covered items or services).

B. *Methods of Disclosure*

i. ***Upon Request***

The proposed rule would require the cost-sharing information to be available in real-time via two mediums: through a free, "user-friendly internet-based self-service tool" which provides information to the user in real time and in paper form which will be sent to the user within two business days of the request.

Plans and insurers would be charged with creating the self-service tool, which would allow users to search for cost-sharing information for a covered item or service by:

- Provider-type (e.g., specific in-network providers, all in-network providers, or out-of-network allowed amounts for a covered item or service provided by an out-of-network provider);
- Billing code (e.g., CPT code) or descriptive terms (e.g., "rapid flu test"); or
- Some combination thereof (e.g., a specific in-network provider in conjunction with a billing code or a descriptive term).[15]

The proposed search tool would also be required to account for different cost-sharing information based on multi-tier networks, drug quantities and dosages, and facility types (e.g., outpatient versus hospital setting) and allow a user to filter/reorder results based on factors like geography and the amount of cost-sharing liability estimated.

[14] The proposed rule suggests that plans and insurers may choose to provide a disclaimer that informs consumers who are seeking estimates of cost-sharing liability for out-of-network amounts that they may have to obtain a price estimate from the out-of-network provider to fully understand their out-of-pocket cost liability. Proposed Rule, *supra* note 1, at 41.

[15] The Departments are also considering requiring all plans to allow individuals to search for cost-sharing information by inputting a description of a treatment procedure (e.g., "knee replacement") that often involves the provision of multiple items and services.

The Departments seek comments on the proposed disclosure methods, including whether additional methods of providing information should be required rather than permitted (e.g., whether plans and insurers should be required to provide the cost-sharing information via telephone, email, facsimile, etc.).

ii. ***Machine-Readable Files***

In addition to requiring disclosure of data to consumers upon request, the proposed rule also requires plans and insurers to make publicly available (i.e., posted on a public internet site with unrestricted access) two machine-readable files: one on negotiated rates with in-network providers (the "Negotiated Rate File") and one on historical data showing allowed amounts for covered items and services provided by out-of-network providers (the "Allowed Amount File").

Each of these machine-readable files would contain the following content elements:

- Name or identifier for each plan option or coverage;
- Billing codes or other common identifiers to identify items or services; and
- Negotiated rates or out-of-network allowed amounts which would:
  - Be expressed in dollars (i.e., if a plan or insurer reimburses providers for an item or service based on a formula or reference-based pricing, it must provide the calculated dollar amount);
  - Be associated with the provider's National Provider Identifier; and
  - For the Allowed Amount File, cover items and services furnished by a particular out-of-network provider during the 90-day time period that begins 180 days before the publication date of the file, unless disclosing such information would violate health information privacy laws or there are fewer than 10 different claims for a provider.[16]

The proposed rule would require these files be updated at least monthly.

[16] The proposed rule provides the following example: Assume Group Health Plan A intends to publish a machine-readable file on July 1 reporting the out-of-network historical allowed amount data the Departments propose to require. Under these proposed requirements, Group Health Plan A's Allowed Amount File must detail each discrete out-of-network allowed amount the plan calculated in connection with a covered item or service furnished by an out-of-network provider between January 1 and April 1. During this 90-day time period, Group Health Plan A paid 23 claims from Provider Z seeking compensation for rapid flu tests (CPT Code 87804), a service covered under the group health plan. Group Health Plan A calculated out-of-network allowed amounts of $100 for three claims, $150 for 10 claims, and $200 for the remaining 10 claims. Under these proposed rules, Group Health Plan A would report in the file published on June 30, that it calculated three different out-of-network allowed amounts of $100, $150, and $200 for rapid flu tests (CPT Code 87804) in connection with covered services furnished by Provider Z from January 1 to April 1. On July 30, Group Health Plan A would update the file to show the unique out-of-network allowed amounts for CPT Code 87804 for Provider Z's services rendered from February through April. On August 30, Group Health Plan A would update the file to show such payments for services rendered from March through May, and so on. Proposed Rule, *supra* note 1, at 64-65.

C. *Protections for Disclosures Made in Good Faith*

The proposed rule includes several provisions to address circumstances in which a plan or insurer—acting in good faith—would not be found to have run afoul of their disclosure obligations, including if plans and insurers:

- Make an error or omission in a required disclosure, provided the plan or insurer corrects the information as soon as practicable;
- Make an error or omission due to good faith reliance on information from another entity, unless the plan or insurer knows/should reasonably have known that the information was incomplete or inaccurate; and
- Their website is temporarily inaccessible, provided the plan or insurer makes the information available as soon as practicable.

The Departments solicit comments on whether additional measures should be taken to protect plans and insurers that have taken reasonable steps to ensure the accuracy of the required cost information.

II. Amended Formula for Calculating Medical Loss Ratio

Beyond the transparency measures, the Departments also propose to change the MLR methodology to accommodate plans with "innovative benefit designs" that empower and incentivize consumers through the introduction of "new or different plans that include provisions encouraging consumers to shop for lower-cost, higher-value providers."[17] Under the proposed rule, if insurers' benefit designs result in savings, they could take credit for the "shared savings" payments in the numerator of their MLR calculations.

This provision would go into effect with the 2020 MLR reporting year.

* * * *

[17] Proposed Rule, *supra* note 1, at 97.