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Impact of 2020's Final Transparency Requirements on Employer-Sponsored Health Plans

On October 29, 2020, the Centers for Medicare and Medicaid Services (CMS) along with the Department of Labor (DOL) and Treasury issued a final rule on price transparency to enable patients to accurately predict health care costs in order to make more fully informed and value-conscious decisions.

So What?

The Transparency Rule employs two significant price and coverage disclosure requirements that require non-grandfathered group health plans and insurance issuers (with certain limited exceptions) to:

- Individually disclose cost-sharing information to plan participants.
- Publicly disclose negotiated rates for in-network providers and allowed amounts for out-of-network (OON) providers.

Plan sponsors only have until January 1, 2022 to prepare for the public disclosure requirements. They enjoy an additional year to prepare for the initial wave of cost-sharing disclosure requirements and two years to ascertain full compliance.

Principal Takeaway

When applicable, the Transparency Rule[1] will impose significant disclosure requirements on the plan and, in turn, employer plan sponsors and health plan issuers. However, the Transparency Rule contains several enforcement safe harbors that are only available if the plan is exercising good faith and reasonable diligence. The creation of a compliance plan, by plan sponsors or issuers, is critical to establish the requisite compliance with the requirements imposed by the Transparency Rule. Taking prudent actions and planning now can help ensure that these responsibilities are timely met.

Transparency: Not Re-creating the Wheel, Just Making It Spin Faster

The Transparency Rule is intended to require similar information to what is generally required to appear on explanation of benefits disclosures (EOBs), and it specifically notes that only costs for anticipated items or services that a person could incur are covered by the Transparency Rule—as opposed to every possible cost imaginable[2].

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[1] Try not to confuse the Transparency Rule with the recently promulgated hospital price transparency rule that HHS finalized in 2019. That rule is currently being challenged in court. While initially upheld by a federal district court judge, it was argued on appeal in front of the U.S. Court of Appeals for the D.C. Circuit on October 15, 2020.

[2] Anticipated items or services does not mean unexpected costs that an individual *could* incur due to the severity of her illness or injury, decisions made by providers, or other unforeseen events.

Transparency Rule's Two Main Disclosure Requirements

The Transparency Rule includes significant new requirements for non-grandfathered health plans and issuers of non-grandfathered health insurance coverage in the group and individual markets:

- **Cost-Sharing Disclosure:** For plan years beginning on or after January 1, 2023, plans and issuers must disclose to enrollees—through a self-service online tool—personalized cost-sharing information and negotiated rates for the identified 500 "shoppable" services. For plan years beginning on or after January 1, 2024, this disclosure requirement will expand to all covered health care items and services.
- **Public Disclosure:** For plan years beginning on or after January 1, 2022, plans and issuers must make publicly available, through three standardized, monthly updated, machine-readable files:
  - Negotiated rates for in-network providers.
  - Historical allowed amounts for OON providers.
  - Prices for prescription drugs (Rx drugs).

Safe Harbor Compliance and Excluded Plans

The Transparency Rule is subject to the same enforcement structure as other Affordable Care Act (ACA) requirements. Under this enforcement regime, the tri-agencies (DOL, Treasury/IRS, and Health and Human Services (HHS)) can generally assess a fine or excise tax equal to $100 per person per day per violation.[3]

The Transparency Rule includes a safe harbor for plan sponsors of fully insured group health plans that permits compliance based on a written agreement with the health insurance issuer. Under this relief, the issuer will be liable for noncompliance only if the plan enters a written agreement requiring the issuer (offering the coverage) to provide the required information. The intent of the Transparency Rule's safe harbor relief is to prevent unnecessarily duplicative disclosures. Similar relief is not available to sponsors of self-funded plans (including most pharmacy benefit managers (PBMs) and level-funded plan arrangements); however, plan sponsors should insist on compliance representations from their service providers and perhaps indemnification if the standard is not met.

In addition to the fully insured safe harbor, the Transparency Rule provides relief for good-faith compliance efforts. A group health plan will not fail to comply with the rule solely because it makes an error or omission, or a website is temporarily inaccessible, as long as it is acting in good faith and with reasonable diligence. However, the plan must correct any error as soon as possible. If a plan acting in good faith and reasonable diligence needs to obtain information from another entity to comply, it will not fail to comply unless it knows or reasonably should have known that the information is incomplete or inaccurate.

The Transparency Rule also specifically exempts certain types of coverage from compliance, including:

- Grandfathered health plans (but not so-called "grandmothered" transitional relief plans).
- Plans providing only excepted benefits.
- Account-based plans (HRAs, QSEHRAs, ICHRAs).
- Retiree-only health plans.
- Short-term limited-duration insurance (STLDI).

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[3] Further, under the Internal Revenue Code, nongovernmental group health plans may be subject to an excise tax of $100 per person per day per violation. The DOL has enforcement authority over group health plans subject to ERISA. HHS has authority over non-federal governmental plans and insurance issuers, although HHS generally leaves insurance enforcement to the states. For example, in the case of insured plans, states generally have primary enforcement authority, and HHS will enforce only if HHS finds that a state has failed to substantially enforce applicable requirements.

The Devil Is in the Details

This section discusses certain significant requirements, features, and carve-outs of the final rule. Stated differently—this is the time to buckle up, sip some coffee, and enjoy not having to digest the entire Transparency Rule, just appreciate its initial implications.

Cost-sharing disclosure

Effective for plan years beginning on or after January 1, 2023, plans and issuers will be required to provide cost-sharing information to participants, beneficiaries, or enrollees (consumers). Advocates for this disclosure point to the substantial overlap between this information and information already required in an EOB. However, the timing (before service) and context (before the claim being incurred) of the information disclosure will make it exceedingly difficult for plan sponsors (and even issuers and third-party administrators (TPAs)) to provide.

The information required to be disclosed includes the following:

- **Estimated cost-sharing liability** for the furnishing of a covered item or service by a particular provider or providers. The "estimation" pertains to the consumer's share of the cost under the plan or coverage.
- **Accumulated amounts** are the financial responsibility that a consumer has due to her accrued deductible or out-of-pocket payment amount, as well as accrued items or services for which the plan imposes a cumulative limitation.
- **Negotiated rate**, reflected as a dollar amount, for the in-network provider payment amount for an item or service, to the extent necessary to determine the consumer's cost-sharing liability. Note that the Transparency Rule revised the definition of "negotiated rate" to mean the amount a plan or issuer has contractually agreed to pay for a covered item or service, whether directly or indirectly through a TPA or PBM, to an in-network provider (including an in-network pharmacy or other prescription drug dispenser) for covered items or services.
- **Out-of-network allowed amount**, which is the maximum amount a plan would pay an OON provider for a covered item or service.
- **Items and services content list** for which cost-sharing information is disclosed. For bundled services, health plans would have to disclose a list of each covered item and service and cost-sharing liability as a bundle.
- **Notice of prerequisites to coverage**. When consumers request cost-sharing information, health plans must inform them if the item or service is subject to concurrent review, prior authorization, step-therapy, fail-first protocols, or other medical management requirements.
- **A "disclosure notice"** (not to be confused with the second main thrust of the Transparency Rule) communicating certain information in plain language, including several disclosures: (1) an explanation disclosing that OON providers may bill consumers the difference between a provider's billed charges and the sum of plan payments and copayments/coinsurance (balance billing), if balance billing is permitted under state law; (2) a statement that actual charges may vary from the estimate; (3) a statement that estimated cost sharing is not a guarantee of coverage; (4) disclosure of whether copayment assistance counts toward deductibles and out-of-pocket maximums; and (5) a statement that if the plan cannot determine whether the request is for a preventive or nonpreventive item or service, that the item or service may not be subject to cost-sharing if it is actually billed as a preventive item or service.

Plans and issuers must make this cost-sharing information available for the 500 items and services identified by the tri-agencies for plan years beginning on or after January 1, 2023 and for all items and services for plan years beginning on or after January 1, 2024.

In addition, plans and issuers must make the required information available, without a fee, in two ways: (1) through an Internet-based "self-service tool"; and (2) in paper form by mail upon a consumer's request. The self-service tool must provide real-time responses and be searchable by billing code, descriptive term, and provider identity. The tool must interact

with consumer input to deliver meaningful cost-sharing information depending on any tiering, network status, location of service, dosage, or other factors. The self-service tool also must permit the consumer to refine and reorder results based on geographic proximity of in-network providers and the amount of cost-sharing liability.

If a consumer requests information in paper form, the plan or issuer must mail the cost-sharing information in accordance with the same requirements applicable to disclosure using an Internet-based self-service tool no later than two business days after the request is received and may limit the number of providers included in the information to not less than 20. Plans and issuers may provide consumers the option to receive the information through other methods, such as by phone, face to face, fax, or email. Whichever method is chosen by a plan sponsor or issuer should be prudently documented.

Required public disclosure of negotiated rates and allowed amounts

Effective for plan years beginning on or after January 1, 2022, plans and issuers will be required to publish three machine-readable files—the first file is for in-network provider negotiated rates (Negotiated Rate File), the second for data outlining the historical allowed amounts for covered items or services provided by OON providers (OON Allowed Amount File), and a new third file for pricing information of prescription drugs (Rx Drug File). The files must be available to the public free of charge and *updated monthly*.

All three files must include the:

- Name or identifier for each plan option or coverage (employer identification number or Health Insurance Oversight System).
- Billing codes used to identify items or services (including CPT code, HCPCS code, DRG, or National Drug Code (NDC)).

The Negotiated Rate File must include the dollar amount of the negotiated or other applicable rate for each provider with the provider's National Provider Identifier (NPI), tax identification number (TIN), and Place of Service Code, and for bundled items and services, the rate by relevant code. The Transparency Rule added a requirement that plans or issuers indicate whether the rate is subject to an alternative payment arrangement (bundled payment arrangement). It also clarified that plans and issuers must include the underlying fee schedule rate used to determine provider reimbursement.

In a departure from the proposed version, the Transparency Rule requires the reporting of Rx drug pricing in a third, separate machine-readable file instead of as part of the Negotiated Rate File. Rx drugs that are reimbursed through a fee-for-service arrangement are required to be reported in the Rx Drug File. However, a bundled payment arrangement, inclusive of Rx drugs, remains a required criterion of the Negotiated Rate File.

The OON Allowed Amount File must include the dollar value of the historically allowed amount for each provider. Historical payments must have a minimum of 20 entries in order to protect consumer privacy. Additionally, this file must include each unique OON allowed amount for covered items or services provided by each OON provider during the 90-day period that begins 180 days before the date of the OON Allowed Amount File's publication.[4] Health plans must also disclose the aggregate actual amount that the health plan paid to the OON provider and the consumer's share of the cost.

The Rx Drug File must include the 10- or 11-digit NDC,[5] the proprietary and nonproprietary name assigned to the NDC, and the dollar amount of the negotiated rate for each in-network provider with the provider's NPI, TIN, and Place of

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[4] To publish a machine-readable file intended on July 1, a plan or issuer must detail each amount the plan calculated in connection with a covered item or service furnished between January 1 and April 1. To publish a machine-readable file intended on July 30, a plan or issuer would update the file with the appropriate amounts for services rendered from February 1 through April 1. On August 30, a plan or issuer would update the file to show such payments for services rendered from March 1 through May 1, and so on.

[5] 12 Requiring NDCs may signal that data will be reported at the strength/dosage/formulation level.

Service Code. The Rx Drug File must also include the dollar amount of historical net prices for each in-network provider for the 90-day period beginning 180 days before the date of the Rx Drug File's publication. In the Transparency Rule, "historical net price means the retrospective average amount a plan or issuer paid for [an Rx] 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 [Rx] drug."

Credit for "Shared Savings" in Medical Loss Ratio Calculations

Beginning with the 2020 medical loss ratio (MLR) reporting year, the Transparency Rule allows issuers to include shared savings payments made to a consumer—as a result of the consumer choosing to obtain health care from a lower-cost, higher-value provider—in the numerator of the issuer's MLR.[6] HHS believes that this favorable treatment will preserve the statutorily required value that consumers receive for coverage under the MLR program, while also incentivizing issuers to offer new or different value-based plan designs that support health care market competition and consumer engagement.

Next Steps and Implications of Transparency Rule

At first pass, compliance with the Transparency Rule in such a short time seems like a daunting task. However, careful review of the requirements and delegation among service providers will help plans to promptly achieve the requisite level of good-faith compliance. The following steps should help guide plan efforts:

- The first step is to get a basic understanding of what the Transparency Rule requires and how it works. While you are off to a good start, 2022 is just around the corner. For further reading, a DOL webpage has additional information about the Transparency Rule, including a fact sheet.
- Second, plan sponsors should inventory their health plans and determine which are subject to the Transparency Rule. At least for now, compliance is not required for excepted benefits (vision, dental, EAPs, FSAs, fixed indemnity hospital, and specified disease coverage), grandfathered plans, retiree medical plans, or certain account-based plans.
- Third, plan sponsors should deliberately assess which aspects of the Transparency Rule requirements it will undertake to assign to insurance issuers and third-party administrators and which (if any) it will address in house. Almost no employer plan sponsor will have access to the cost information required to satisfy the rule. Moreover, even with access, maintaining the required communication channels will undoubtedly prove to be a burdensome task. Early cooperation with insurers and TPAs (including PBMs) is a necessity.
- Fourth, plan sponsors should carefully document which parties are responsible for compliance with the Transparency Rule. Remember, an agreement with the insurer is required to absolve the plan sponsor from liability for insured coverage. Contracts with self-funded plan TPAs and PBMs should be revised to address Transparency Rule compliance. Federal agencies generally look to determine whether a health plan has assessed its compliance obligations and prepared a compliance plan. A deliberate compliance plan can demonstrate good-faith efforts and reasonable diligence. A compliance plan would be particularly important when there are multiple internal and external stakeholders required to commonly uphold their contractual obligations to secure compliance. Appropriate compliance representations/warranties and indemnification provisions should also be sought.
- Fifth, remember to set aside an adequate budget to address compliance with the Transparency Rule requirements. Issuers and TPAs will undoubtedly pass along their costs of compliance to their client plans.
- Finally, allow sufficient time for beta testing and participant communication. Plan sponsors should review operational conditions and determine any need to establish procedures to ensure that participants become and remain informed of how to use the required online tools.

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[6] An issuer's MLR is the percentage of a premium that an insurer spends on services that improve care quality, and insurers have to pay rebates if they don't meet a certain threshold. HHS aims to ensure that issuers would not be required to pay MLR rebates based on a plan design that would provide consumers with a benefit not currently captured in any existing MLR revenue or expense category.

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