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BLOG

Departments Issue Transparency in Coverage Final Rule

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On November 12, 2020, the Departments of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively, the Departments) published the "Transparency in Coverage" final rule (Final Rule), imposing new requirements on group health plans and health insurers in the individual and group markets to disclose cost-sharing information, in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information. The Final Rule also amends HHS' medical loss ratio (MLR) program rules to allow issuers offering coverage to receive credit in their MLR calculations for savings they share with enrollees.

The Final Rule **does not apply** to grandfathered health plans; account-based group health plans, such as HRAs, including individual-coverage HRAs; or health FSAs, healthcare-sharing ministries, or short-term limited duration insurance plans.

Background

The Final Rule stems from President Trump's Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, issued on June 24, 2019, and the Hospital Price Transparency final rule, issued November 15, 2019. The executive order directed the Departments to issue an advance notice of proposed rulemaking on health care price and quality transparency, but the Departments, instead, issued a full and final rule.

The Departments' authority for these rules is derived from reporting and disclosure requirements added to the Employee Retirement Income Security Act (ERISA), the Internal Revenue Code (Code), and the Public Health Services Act by the Affordable Care Act (ACA).

Winston Takeaway: *The fate of the ACA is uncertain, as the law is currently being challenged in California v. Texas, brought by Republican state officials asserting that the ACA became unconstitutional when Congress reduced the individual mandate penalty to zero in the Tax Cuts and Jobs Act. If the U.S. Supreme Court determines that the entirety of the ACA must be overturned, these Final Rules would also be invalidated. However, based on comments recently made by a majority of U.S. Supreme Court justices at oral arguments, this outcome appears unlikely.*

According to the Departments, the purpose of the Final Rule is to (i) provide necessary information for consumers to make more-informed health care spending decisions, (ii) strengthen stakeholders' ability to support customers,

(iii) reduce the potential for surprise billing, and (iv) increase competition and contain costs.

The Final Rule's two main disclosure requirements are to occur in separate phases. The first phase includes requiring insurers and plans to make disclosures specific to participants, beneficiaries, and enrollees (collectively, participants) upon request of the participant. This will be phased-in with respect to 500 items and services identified in the final rule, beginning with plan or policy years on or after January 1, 2023, and will be fully implemented beginning with plan or policy years on or after January 1, 2024, for all items and services. The second phase requires insurers and plans to make public disclosures in separate machine-readable files for information regarding in-network providers (for each covered item or service), out-of-network (historically allowed amounts and billed charges for covered items or services), and prescription drug prices for in-network providers. This requirement is effective beginning with plan or policy years on or after January 1, 2022.

Lastly, the Final Rule amends the MLR program to recognize the special circumstances of different and newer types of plans for purposes of MLR reporting, and calculations for plans that share savings with consumers who choose lower-cost, higher-value providers.

Requirements for Disclosing Information to Participants Upon Request

Information Required to be Disclosed to Participants.

Under the Final Rule, a plan or issuer offing group or individual insurance must disclose the following, upon the request of a participant who is enrolled in a plan or coverage:

- The participant's estimated cost-sharing liability (i.e., the amount a participant is responsible for paying, such as deductibles, coinsurance, and copayments) for a requested item or service covered under the terms of the plan or coverage. The estimate does not include premiums, balance billing amounts charged by out-of-network providers, the cost of non-covered items or services, or costs for any unanticipated items or services the participant may incur.
- Accumulated amounts (i.e., the amount of financial responsibility that a participant has incurred at the time the request for cost-sharing information is made, with respect to a deductible and/or an out-of-pocket limit). This includes accumulated amounts for a cumulative treatment limitation that reflects the status of the participant's progress toward meeting the limitation, but does not include any individual determination of medical necessity that may affect coverage for the item or service.
- The in-network rate with a contracted in-network provider applicable to the plan or insurer's payment model. The in-network rate includes:
  - The negotiated rate with the in-network provider for the requested item or service, which must be expressed as a dollar amount; and
  - The underlying fee schedule rate used to determine the cost-sharing liability, but only if it is different from the negotiated rate.
- The out-of-network allowed amount and any cost-sharing liability, based on the allowed amount that the participant would be responsible for paying if the provider is an out-of-network provider.
- A list of the individual items and services covered, if the requested item or service is subject to a bundled payment arrangement.
- A notice of any prerequisites to coverage, which capture medical management techniques that apply to an item or service that require action by the participant before the plan or issuer will cover the item or service.
- A disclosure notice that communicates, in plain language, the following statements: (i) actual charges may be different from those described in a cost-sharing liability estimate; (ii) an out-of-network provider may bill the participant and that the cost-sharing information does not include such amounts (only required if state law permits

balance billing); (iii) the estimated cost-sharing liability for a covered item or service is not a guarantee that coverage will be provided for such item or service; (iv) whether the plan counts copayment assistance or other third-party payments in the statement of cost-sharing liability or an out-of-pocket maximum; and (v) preventive items may not be subject to cost-sharing liability in certain specified instances. *Note: this disclosure notice is in addition to the information that plans and issuers are currently required to publish on their websites.*

Winston Takeaway: *Since these disclosure requirements apply equally to self-insured group health plans (or third-party administrators acting on their behalf), some plans may not currently have access to the information that would be required to calculate a participant's cost liability, due to such information being confidential and/or proprietary. We recommend plan administrators review their existing contracts with issuers, TPAs, or providers to consider whether such contracts need to be amended with respect to accessing such information.*

Required Methods for Disclosing Information to Participants

The Final Rule requires the information above be made available through an Internet website and other means for participants without access to the Internet through (1) a self-service tool that meets certain standards, and (2) in paper form:

- **Internet-based self-service tool** – The self-service tool must allow users to search for cost-sharing information by billing code, name of in-network provider, and other factors that affect cost-sharing liability, such as location of service, facility name, or dosage. The tool must also allow participants to search for an out-of-network allowed amount, by billing code, name of an item or service, the geographical location of the provider, or percentage of billed charges.
- **Paper form** – A plan or issuer must also furnish, at the request of the participant, and without a fee, all of the information required to be disclosed through the self-service tool in paper form. A plan or issuer may, however, limit any results for a paper request to 20 providers per request. The paper form must be mailed to the participant, within two business days after receipt of the request, unless the participant agrees that the disclosure be made by phone or email.

Winston Takeaway: *To the extent coverage under a plan consists of fully insured group health insurance coverage, the plan may satisfy the requirements of the Final Rule (and no longer be liable) if the plan requires the issuer offering the coverage to provide the information pursuant to a written agreement between the plan and issuer. While self-insured plans can contract with TPAs to provide the information and include indemnification provisions in such contracts, the plans still must monitor TPAs because such plans ultimately remain liable for the disclosure requirements.*

The Final Rule does allow some time for plans or issuers to implement the requirements related to participant disclosures. As mentioned above, plans or issuers have until plan or policy years beginning on or after January 1, 2023, with respect to 500 items and services the Final Rule lists, to post on a publicly available website, while all covered items and services must be made publicly available by plan or policy years beginning on or after January 1, 2024.

Requirements for Public Disclosure

The Final Rule also requires plans and issuers to disclose to the public certain information regarding covered items and services, including in-network negotiated amounts, out-of-network allowed amounts, and negotiated rates and historical net prices for prescription drugs.

The Departments determined that public disclosure of this pricing information is important to uninsured consumers and insured consumers who need to access out-of-network benefits to make informed health care decisions, to allow consumers to evaluate their options for group or individual coverage, to increase competition among health care providers (with the hope that this could potentially lower health care costs), to allow employer plan sponsors access to data that could allow them to negotiate for lower prices for their participants, and to assist health care regulators in carrying out health insurer oversight responsibilities, and in designing and sustaining public health care programs.

These public disclosures are required to be made publicly available on an Internet website, in three separate machine-readable files (i.e., digital representations of data or information in files that can be imported or read by a computer system for further processing without human intervention), free of charge, and without restrictions (e.g., passwords, credentials).

Required information to include in all three machine-readable files.

The following information must be included in each of the machine-readable files for each coverage option (e.g., PPO, POS, HMO, etc.):

- The name and health insurance oversight system (HIOS) identifier, if available, for each coverage option offered by a plan or issuer.
  - If an HIOS identifier is not available, then the employer identification number is required.
- A billing code (i.e., the code used by the plan or insurer or provider to identify items or services for purposes of billing, adjudicating, and paying claims, such as a CPT code, HCPCS code, DRG, NDC or another common payer identifier), and a plain language description for each billing code.
  - A plan or issuer is permitted to choose its own indicator or other method to communicate to the public when there is no corresponding code with the covered item or service.
  - Note, however, only an NDC may be used for prescription drugs.
- The NPI, TIN, and Place of Service Code of each in-network and out-of-network provider associated with the covered item or service.

Specific required information to include in each machine-readable files.

The Final Rule also requires specific information to be included in each of the three machine-readable files: in-network rate, allowed amount, and prescription drug.

- **In-network rate file** – For each coverage option, this file must include all applicable rates that apply to each covered item or service that is associated with the last date of the contract term or the contract expiration date for each provider as identified by NPI, TIN, and Place of Service Code. These rates may include one or more of the negotiated rates, the underlying fee schedule rates, or derived amounts (the price assigned to an item or service for purpose of internal accounting, reconciliation with providers, or submission of data).

  This file may contain prescription drug information only to the extent the prescription drug is part of a bundled payment arrangement. The applicable rate for each covered item (including prescription drugs) and service must be reflected in a dollar amount. The file must identify rates where an arrangement other than a standard fee-for-service model—such as a capitation or bundled payment arrangement—applies.
- **Allowed amount file** – This file must include each unique combination of allowed amounts and billed charges with respect to covered items and services (including prescription drugs) provided by each out-of-network provider during the 90-day time period that begins 180 days prior to the file's publication date. For example, a file published on June 30, 2022, should include data for a 90-day period beginning on January 1, 2022.

  To address health privacy concerns, the file must omit this information, however, if the out-of-network allowed amounts are in connection with fewer than 20 different claims under a single plan or coverage.
- **Prescription drug file** – This file must include prescription drug pricing information, reflected as a dollar amount, for in-network providers, including in-network pharmacies and other prescription drug dispensers. The information must be coded using the applicable proprietary and nonproprietary name assigned to the NDC by the FDA for each prescription drug under a coverage option.

  Plans and issuers must disclose two amounts for prescription drugs in the file: (i) the negotiated rate and (ii) the historical net price (i.e., the retrospective average amount paid for a prescription drug, inclusive of any rebates,

discounts, chargebacks, fees, and any additional price concessions received, associated with the 90-day time period beginning 180 days prior to publication of the file for each provider-specific historical net price).

Winston Takeaway: *For plans that provide outpatient prescription drugs through a separate pharmacy benefit manager (PBM), prescription drug pricing information will have to come from both the PBM (for outpatient drugs obtained from a retail or mail order pharmacy) and the medical plan TPA (for drugs obtained as an inpatient or administered in a doctor's office).*

Each file must clearly indicate the date of its most recent update. The Departments are developing technical implementation guidance, which will be available on GitHub (a website and cloud-based service that helps developers store and manage their code, as well as to track and control changes to their code), to assist plans and insurance issuers in developing the required machine-readable files.

Winston Takeaway: *The Final Rule also allows some time for plans or issuers to implement the requirements related to public disclosures. Plans or issuers have until plan or policy years beginning on or after January 1, 2022 to comply with the above public disclosure requirements. However, once implemented, the information required to be included in the machine-readable files must be updated monthly.*

Similar to the participant disclosure requirements above, fully insured and self-insured plans may satisfy the public disclosure requirements via a written agreement with an insurance issuer, TPA, or other third-party vendor; however, a self-insured plan will remain ultimately liable for the public disclosure requirements.

Amendment of MLR Program Rules

The Department of Health and Human Services also finalized changes to the MLR program intended to encourage insurance issuers to offer new plan designs that support competition and consumers' engagement in their health care. The MLR is the proportion of premium revenue spent on clinical services and quality-improvement activities. The ACA requires an insurance issuer to provide annual rebates to enrollees if its MLR falls below specified standards (generally, 80% for the individual and small-group markets, and 85% for the large-group market).

The Final Rule amends the MLR program rules to allow insurance issuers to receive credit in their MLR calculations for savings they share with enrollees that result from the enrollees shopping for, and receiving care from, lower-cost, higher-value providers. **Shared savings payments made by an issuer to an enrollee will be factored into an issuer's MLR numerator, beginning with the 2020 MLR reporting year.**

Winston Takeaway: *Plan administrators and issuers should be aware that the Final Rule does not provide definitions for "shared savings" or "lower-cost, higher-value." Rather, the Departments defer to state legislators and regulators to work with issuers to develop standards and criteria for shared-savings programs for their respective constituents*.

Next Steps

Plan sponsors will need to work with their TPAs, PBMs, insurance carriers, and providers to comply with these transparency rules. Service contracts will have to be amended to require vendors to provide the information needed for reporting. Plan sponsors will need to contract with one or more vendors to provide the disclosures required under the Final Rule. Since in-network and prescription-drug pricing information has historically been considered confidential and proprietary information of TPAs and PBMs, changes will be needed to the confidentiality provisions of those service agreements. Since the plan sponsor of a self-insured plan remains responsible for compliance with the Final Rule, plan sponsors should also ensure that indemnification and liability limits are appropriate for the vendors who will provide these disclosure services. Plan sponsors could be subject to potential penalties and excise taxes under ERISA, the Code, and the Public Health Services Act for failure to comply with these requirements.

Please contact a member of the Winston & Strawn Employee Benefits and Executive Compensation Practice Group or your Winston relationship attorney for further information.

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