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New Price Transparency Rules Finalized for Plans and COVID-19 Test Providers

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Increasing health care price transparency has been a stated strategic objective of the Centers for Medicare & Medicaid Services (CMS), which has now finalized rules regulating hospitals, health plans, and providers of COVID-19 tests.

In November 2019, CMS finalized requirements that hospitals post their negotiated rates online (see our summary here). Absent a court ruling in favor of hospitals challenging the rule, these requirements will take effect on January 1, 2021.

New COVID-19 Testing Price Transparency Requirements Effective Immediately

As part of an interim final rule, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," published on November 6, 2020, and effective November 2, 2020, CMS is requiring that any provider of COVID-19 diagnostic tests publish its cash price for COVID-19 testing. This implements a price transparency provision included in Section 3202(b) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

The rule adds a new 45 C.F.R. Part 182 that includes definitions of "provider of a diagnostic test for COVID-19" (or "provider"), "COVID-19 diagnostic test," and "cash price" and requirements for posting cash price information on the Internet, or upon request and through signage (if applicable). This rule also gives CMS discretion to provide a warning notice, seek compliance with a corrective action plan, or impose a civil monetary penalty for noncompliance with the COVID-19 testing price transparency requirement.

Transparency Requirements for Plans and Issuers Finalized for 2022 and 2023

Overview

To extend price transparency requirements to the full array of health care services, CMS, along with the Departments of Health and Human Services (HHS), Labor, and Treasury, finalized a rule in the November 12, 2020 *Federal Register*, "Transparency in Coverage."

This final rule includes significant new requirements for non-grandfathered health plans and issuers of non-grandfathered health insurance coverage in the group and individual markets:

- 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 500 "shoppable" services identified in the rule. For plan years beginning on or after January 1, 2024, this disclosure requirement will expand to all covered health care items and services, including encounters, procedures, medical tests, supplies, prescription drugs, medical equipment, and fees, including facility fees.
- For plan years beginning on or after January 1, 2022, plans and issuers must make publicly available, through standardized, regularly updated, machine-readable files:
  - Negotiated rates for in-network providers.
  - Historical allowed amounts for out-of-network providers.
  - Prices for prescription drugs.

The departments note that the final rule is intended to require information similar to what is generally required to appear on explanations of benefits (EOBs) and that only costs for anticipated items/services that a person could incur are covered by the final rule. In anticipation of challenges to the rule based on proprietary information arguments, the preamble asserts that because insurers and plans are required to supply this information after a beneficiary receives the services, preemptively requiring the same information in advance of receiving the services should not elevate the risk of releasing proprietary information.

The final rule provides relief to prevent unnecessary duplication of disclosure in the case of fully insured group health plan coverage. Under this relief, a group health plan satisfies the final rule if the plan requires the issuer offering the coverage to provide the required information pursuant to a written agreement between the plan and the issuer. In such a case, if the issuer fails to provide the required information, the issuer, but not the plan, would be in violation of the rule. The same relief does not, however, apply in the case of other third parties that a plan may contract with to provide required information. For example, a self-funded plan could contract with a third-party administrator (TPA) or a pharmacy benefit manager (PBM) to provide required disclosures, but if the required disclosures are not made, the plan will be in violation.

The final rule does not alter existing privacy and security requirements. Nothing in the final rule is intended to alter or otherwise affect plans', issuers', and other entities' privacy and security responsibilities under HIPAA or other applicable state and federal laws.

The final rule is subject to the same enforcement structure as other Affordable Care Act (ACA) requirements. 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. 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 Department of Labor also has enforcement authority over group health plans subject to ERISA. The final rule provides some relief for certain types of errors. For example, a plan or insurer will not be in violation merely because the plan or issuer, acting in good faith and with reasonable

diligence, makes an error or omission that is corrected as soon as practicable. The final rule also addresses specific situations that do not result in a violation, such as certain situations in which the plan's or issuer's website is temporarily unavailable.

The final rule does not apply to grandfathered health plans, plans providing only excepted benefits (e.g., vision, dental, and specified disease policies), or retiree-only health plans. The final rule also does not apply to short-term limited-duration insurance (STLDI). The final rule does, however, apply to so-called grandmother (or transitional) plans, which are non-grandfathered individual and small group market plans that are not subject to certain ACA requirements in accordance with CMS guidance and state law.

Disclosure of information to enrollees

Effective for plan years beginning on or after January 1, 2023, plans and issuers will be required to provide the following information to participants, beneficiaries, or enrollees:

- **Estimated cost-sharing liability:** The consumer's share of the cost of an item or service under the plan or coverage.
- **Accumulated amounts:** The consumer's 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:** The in-network provider payment amount for an item or service. Note that the final 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:** The maximum amount a plan would pay an out-of-network provider for a covered item or service.
- **Items and services content list:** 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, or other medical management requirement.
- **A "disclosure notice":** Must include the following information in plain language: (1) an explanation disclosing that out-of-network 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 preventive service may not be subject to cost-sharing if the plan cannot determine whether the request is for a preventive or nonpreventive item or service.

Plans and issuers must make cost-sharing information available for 500 items and services identified by the departments 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. The list of 500 items and services is available in the final rule, Table 1.

Plans and issuers must make 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, be searchable by billing code, descriptive term, and provider identity, and 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 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 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.

Public disclosure of negotiated rates and allowed amounts required

Effective for plan years beginning on or after January 1, 2022, plans and issuers will be required to publish three machine-readable files—one for in-network provider negotiated rates (In-Network Rate File), the second for data outlining the historical allowed amounts for covered items or services provided by out-of-network providers (Allowed Amount File), and a new third file, as added by the final rule, for pricing information for prescription drugs (Prescription Drug File). The files must be available free of charge and *updated monthly*. All three files must include:

- 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 In-Network Rate File (referred to in the proposed rule as 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 final rule adds a requirement to note whether the rate is subject to an alternative payment arrangement. The final rule also clarifies that plans and issuers must include an underlying fee schedule rate when one is used to determine cost-sharing liability when that amount differs from the negotiated rate (or comparable derived amount) used to determine provider reimbursement.

In a departure from the proposed rule, the final rule requires the reporting of prescription drug pricing that was proposed to have been included in the In-Network Rate file in a third, separate machine-readable file. Prescription drugs reimbursed through a fee-for-service arrangement are required to be reported in the Prescription Drug File. However, prescription drugs included in a bundled payment arrangement must still be included in the In-Network Rate File.

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

The Prescription Drug File must include the 10-digit or 11-digit NDC (meaning that data will be reported at the strength/dosage/formulation level), the proprietary and nonproprietary name assigned to the NDC, and the dollar amount of the negotiated rate for each in-network provider (including in-network pharmacies or other prescription drug dispensers) with the provider's NPI, TIN, and Place of Service Code. The Prescription 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 Prescription Drug File's publication. In the final rule, "historical net price means the retrospective average amount a plan or 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."

Credit for "shared savings" in medical loss ratio calculations

Beginning with the 2020 medical loss ratio (MLR) reporting year, the 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. HHS believes that this favorable treatment of shared savings payments for MLR purposes will encourage issuers to offer new or different plan designs to support competition and consumer engagement.

Responses to requests for information

The final rule does not require plans to provide information through a standards-based application programming interface (API), but CMS has indicated that they may consider such requirements in future rulemaking.

The final rule also does not include provisions related to how health care quality information is shared, even though the proposed rule requested information on how provider quality measurements could be leveraged to complement price transparency in consumer tools.

Hospital Price Transparency Litigation Update

Following the release of the hospital price transparency final rule by CMS, the American Hospital Association (AHA) filed a lawsuit in the U.S District Court for the District of Columbia seeking to vacate the rule. Specifically, the AHA argued that the final rule exceeds the agency's statutory authority, violates the First Amendment, and is arbitrary and capricious under the Administrative Procedure Act. The crux of this case hinges on Section 2718(e) of the Public Health Service Act (PHSA), enacted as part of the ACA, which requires hospitals to make public a list of "standard charges" for items and services provided by the hospital.

The AHA first argued that the final rule exceeds CMS's statutory authority, claiming that "standard charges" is an unambiguous term that can only refer to a hospital's chargemaster charges and cannot be expanded to include negotiated charges with third-party payers. (Of note, the newly finalized transparency in coverage rule relies on a different statutory authority imposing reporting and disclosure requirements for health plans, which does not use the term "standard charges").

The AHA also argued that the final rule compels speech in violation of the First Amendment and that the final rule is arbitrary and capricious, arguing that the agency failed to adequately consider the costs and implementation burdens imposed on hospitals.

On June 23, 2020, the district court rejected each challenge and denied the AHA's motion for summary judgment. On July 17, 2020, the AHA appealed this decision to the U.S. Court of Appeals for the District of Columbia Circuit, restating and elaborating upon the arguments made to the district court.

The D.C. Circuit held oral argument in the case on October 15, 2020. The three-judge panel expressed skepticism for the AHA's arguments. Notably, the judges appeared to agree that the standard chargemaster charges are not helpful for patients and seemed perplexed that these "misleading charges" are the only knowable charges that can be provided to patients. In addition, the circuit court focused much of the questioning on the "workability" of the final rule and burdens the requirements place on hospitals.

The D.C. Circuit generally issues rulings in argued cases by the end of the following August. Although there is no way to know with certainty whether the court will rule before the regulation's January 1, 2021 effective date, the court typically tries to rule before the effective date in a case like this, and both parties have urged the court to do so.

Next Steps and Implications

With the hospital price transparency final rule effective date now less than two months away, and additional price transparency requirements now slated to take effect a year later, significantly more pricing data will need to be provided to consumers and third parties.

Alston & Bird has formed a multidisciplinary response and relief team to advise clients on the business and legal implications of the coronavirus (COVID-19). You can view all our work on the coronavirus across industries and subscribe to our future webinars and advisories.

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