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Health Care & Life Sciences

CLIENT ALERT

New Health Care Transparency Requirements: Will They Lower Cost and Improve Quality?

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On November 12, 2020, the Trump administration published its final rule on price transparency (the "Final Rule") requiring affected entities to publicly release personalized information on out-of-pocket costs as well as certain negotiated rates, stating that transparency in health coverage requirements will improve competition and "strengthen America's health care system by giving health care consumers, researchers, regulators, lawmakers, health innovators, and other health care stakeholders the information they need to make, or assist others in making informed decisions about health care purchases."[1] Entities affected include most group health plans, including employer group health plans, and health insurance companies offering group and individual health coverage ("plans and issuers"). Additionally, the Final Rule makes certain changes to medical loss ratio ("MLR") calculations, to allow issuers to include as health care costs "shared savings" from efforts to encourage consumers to shop for services from lower-cost, higher-value providers.

The Final Rule was promulgated in response to the Trump administration's executive order on price transparency,[2] as well as to implement legislative mandates under the Patient Protection and Affordable Care Act ("PPACA")[3] and the Public Health Service Act ("PHSA"),[4] and to complement other federal price transparency initiatives being adopted for hospitals and in the context of prescription drug pricing. Critics of these price transparency rules have stated that, instead of promoting competition and lowering costs, requiring plans and issuers to reveal their negotiated rates will have the opposite effect and will undermine the contract negotiations and drive health care prices even higher.[5]

The Trump administration initially proposed, through the Office of the National Coordinator for Health Information Technology's proposed Interoperability and Information Blocking

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[1] The Final Rule was issued jointly by the U.S. Department of Health and Human Services, the Centers for Medicare & Medicaid Services, the U.S. Department of Labor, and the U.S. Department of the Treasury. Transparency in Coverage, Final Rule, 85 Fed. Reg. 72158 (Nov. 12, 2020), available at https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage.

[2] Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, 84 Fed. Reg. 30,849 (Jun. 27, 2019).

[3] PPACA § 1311(e)(3).

[4] PHSA § 2715A.

[5] Public Disclosure of Privately Negotiated Rates Will Lead to Less Affordable Health Care for Americans, AHIP Statement on Administration's Transparency Rule, October 29, 2020, available at https://www.ahip.org/public-disclosure-of-privately-negotiated-rates-will-lead-to-less-affordable-health-care-for-americans/.

Rule, that price information be made accessible through a patient's electronic health information provided via standardized application programming interfaces ("APIs"). However, the Final Rule adopts a more front-facing approach, requiring plans and issuers to establish a self-service tool on a website to enable individuals to obtain cost-sharing information for services by individual providers (and to provide such information in paper form, if requested). The Final Rule also requires that plans and issuers create and make publicly available three machine-readable files: one that discloses negotiated rates between plans or issuers and providers for all covered services, a second that discloses allowed out-of-network amounts, and a third that discloses rates for prescription drugs.

The MLR provisions also seek to promote competition and lower costs by allowing plans' and issuers' to share savings with enrollees that choose providers demonstrating higher value at a lower cost. The regulatory changes enable plans to "take credit" for the shared savings resulting from consumers shopping for services from lower-cost, higher-value providers.

The Final Rule will take effect in phases between January 2022 and January 2024. The machine-readable files must be produced for plan years beginning on or after January 1, 2022; cost-sharing information for 500 "shoppable" items and services identified by the applicable agencies will be required for plan years beginning on or after January 1, 2023;[6] and the same information for all items and services must be made available by January 1, 2024. Changes to MLR calculations will take effect beginning with the 2020 MLR reporting year (for reports filed by July 31, 2021).

Transparency Provisions

The online cost-sharing tool must function based on the input of a specific in-network provider along with a specific billing code or descriptive term (as well as other relevant factors, such as location of service). The tool must also provide the out-of-network allowed amount or other rate that will provide a reasonably accurate estimate of what the beneficiary using the tool will pay. The tool is not required to provide information or estimates regarding premiums, potential balance billing by out-of-network providers, or the cost of non-covered items or services. If reimbursement is paid through a bundled rate, the plan or issuer must disclose all of the items and services included in the bundled rate and a beneficiary's cost-sharing obligation for the bundle.

As to rates, plans and issuers must disclose, if applicable, the formula and the underlying fee schedule rate applicable to the formula (for example, if the reimbursement rate is 105 percent of the plan's internal fee schedule, the plan must disclose the 105 percent rate and the internal fee schedule). For prescription drugs, the plan or issuer must disclose the out-of-pocket cost as well as the negotiated rate for the drug. The disclosure need not disclose discounts, rebates, or price concessions. The disclosure of prescription drug costs apply even if the plan or issuer uses a pharmacy benefit manager ("PBM") or similar third-party administrator ("TPA") to obtain prescription drug coverage.

[6] A "shoppable" item or service is elective or planned in advance.

The Rule is intended to work together with the hospital price transparency rule issued in December 2019[7] to provide more complete price information to the consumer. For example, consumers looking to compare hospital prices will have both the hospital and plan data to look to, beginning in 2023. However, there are several key differences between the new price transparency rule for plans and issuers and the price transparency rule for hospitals, as outlined in the chart below.

Comparison of Hospital and Plan Price Transparency Rules

Requirements	Hospital Rule	Plan Rule
Services covered by rule	Hospital services only	All provider services, including prescription drugs
Rates required to be disclosed	• Negotiated (in-network) rates for all items and services with all plans • Gross charges • Discounted cash or "self-pay" prices • Minimum and maximum negotiated charges for all items and services	• Personalized out-of-pocket cost information for consumers • Negotiated (in-network) rates for all covered items and services with all providers • Out-of-network allowed amounts • Negotiated pharmaceutical prices and historical net prices for all covered drugs
Format for disclosure	• Machine-readable file for all rates • Consumer-friendly format for 300 "shoppable" services	• Three separate machine-readable files for all services in 2022 • Consumer-friendly format for 500 "shoppable" services in 2023 • Consumer-friendly format for the remaining services in 2024
Effective date of rule	1/1/21	Phased in 1/1/22, 1/1/23, and 1/1/24
Updates required for disclosures	Monthly	Monthly
Penalties for noncompliance under rule	$300/day	Generally subject to state enforcement[8]

[7] See the Epstein Becker Green Client Alert titled "Despite Issuance of Final Rule on Price Transparency, Are Health Care Rates Too Complicated to Be 'Consumer Friendly'?" available at https://www.ebglaw.com/news/despite-issuance-of-final-rule-on-price-transparency-are-health-care-rates-too-complicated-to-be-consumer-friendly/.

[8] These provisions are generally subject to state enforcement, with the federal government stepping in where it determines that the state has failed to substantially enforce a provision. Under federal enforcement, civil monetary penalties can be imposed up to $100 for each day for each individual with respect to which the failure occurs.

While a standards-based API format may be more consumer-centric by offering more accurate and timely price estimates for making more informed health care choices, the U.S. Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), the U.S. Department of Labor, and the U.S. Department of the Treasury recognized that the burden associated with health plans, issuers, and TPAs updating their existing internet-based self-service tool was a more reasonable first step. Therefore, the Final Rule does not require the implementation of standards-based APIs as the format for disclosing pricing information. Rather, HHS will monitor the implementation of the CMS Interoperability & Patient Access final rule to inform future rulemaking on the format for such disclosures.

Medical Loss Ratio

The Final Rule specifies that,

> beginning with the 2020 MLR reporting year, an issuer may include in the numerator of the MLR any shared savings payments the issuer has made to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider.[9]

While the preamble points to several state programs as examples of approaches for incorporating "shared savings" provisions into a plan design as a way to encourage enrollees to shop for and choose to obtain care from lower-cost, higher-value providers, the Trump administration declines to define "shared savings" as can be counted in the MLR. Rather, the Final Rule defers to state legislators to define the "shared savings" programs that they support, issue standards and criteria for the programs for their respective constituents, and decide in what form the savings can be made. The considerations left to the states include the operational details of any "shared savings" program, such as creating standards and definitions, developing acceptable payment methods, and addressing fraud concerns.

The Final Rule did make clear that "only actual payments made to enrollees can be included in an issuer's MLR calculation," seeming to rule out inclusion of plans' costs incurred to develop and administer the shared savings program (such as administrative fees paid to a vendor to operate the program). Further, HHS stated that "quality as well as cost" should be determinants of what qualifies for inclusion in any given issuer's "shared savings" program. Finally, the Final Rule clarified that whether "shared savings" payments to enrollees are taxable will vary based on specific facts and circumstances. Some forms of "shared savings" may be taxable; however, the Department of the Treasury will address the taxability of such payments as necessary.

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This Client Alert was authored by **Helaine I. Fingold, Jackie Selby, Lesley R. Yeung, Karen Mandelbaum,** *and* **Gregory R. Mitchell.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[9] 85 Fed. Reg. at 72310 (adopting new 42 C.F.R. §158.221(b)(9)).

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