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Healthcare Alert

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Latest executive order signals increased healthcare price transparency enforcement

By Jonah D. Retzinger, Whitney Phelps, and Vidaur Durazo

President Trump's latest EO aims to enhance healthcare price transparency and ensure that hospitals and insurers comply with transparency requirements.



What's the impact?

• Industry stakeholders should prepare for further rulemaking and increased enforcement regarding hospital price transparency and health plan transparency requirements.

On February 25, 2025, President Donald Trump signed an executive order to enhance healthcare price transparency requirements, and to ensure hospitals and certain health plans and insurers (including health benefit plans covered under ERISA) improve regulatory compliance.¹ The

¹ Exec. Order No. 14221, Making America Healthy Again By Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information, 90 Fed. Reg. 11005-6 (Feb. 28, 2025).

executive order builds on President Trump's efforts to increase healthcare price transparency, which he initiated in 2019 with Executive Order 13877.²

The newly published executive order directs federal agencies to rapidly implement and enforce the healthcare price transparency regulations issued at the end of President Trump's first term.³ The executive order also instructs federal agencies to ensure that the prices disclosed constitute the actual prices for the services rendered—rather than estimates. Moreover, President Trump ordered federal agencies to update their enforcement policies to ensure hospitals and payors comply with regulatory requirements.

Hospital price transparency requirements

The Hospital Price Transparency Final Rule, which was issued by the US Department of Health & Human Services (HHS) in 2019 and took effect in January 2021, requires hospitals to publicize their prices. Hospitals are required to disclose their standard charges, including gross charges, payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges, for all items and services in a machine-readable file (MRF). The rule also requires hospitals to display online in a consumer-friendly manner the standard charges for 300 shoppable services that can be scheduled in advance by consumers.

When the rule was published, the American Hospital Association (AHA) and other hospital groups challenged the rule on various statutory and constitutional grounds, arguing that the definition of "standard charges" was overly broad and that the rule imposed undue burdens on hospitals. However, the AHA's challenge was rejected, both by the district court and on appeal.⁵

When the Centers for Medicare and Medicaid Services (CMS) conducted initial compliance assessments in 2021, CMS determined that compliance with the Hospital Price Transparency Rule was very low. In response, effective January 2022, CMS increased the civil monetary penalty (CMP) for noncompliance from \$300 per day to a maximum of \$5,500 per day, depending on the hospital's size. CMS issued its first notices of impositions of CMPs for violations of hospital price transparency requirements in June 2022 to two hospitals in Georgia.

⁶ 86 Fed. Reg. 63458, 63941-57 (Nov. 16, 2021).



² Exec. Order No. 13877, Improving Price and Quality Transparency in American Healthcare To Put Patients First, 84 Fed. Reg. 30849-52 (Jun. 27, 2019).

³ See generally 45 CFR 147.210 et seq. (Transparency in Coverage; 45 CFR 180 et seq. (Hospital Price Transparency).

⁴ 84 Fed. Reg 65524-606 (Nov. 27, 2019); 45 CFR 180 et seq.

⁵ See Am. Hosp. Ass'n v. Azar, 983 F.3d 528 (D.C. Cir. 2020).

In April 2023, <u>CMS took action</u> to: (i) shorten timeframes for the completion of corrective action plans (CAPs) for noncompliant hospitals; (2) impose CMPs earlier and automatically; and (3) streamline the compliance process for wholly noncompliant hospitals.

In November 2023, to increase standardization, CMS amended its regulations to require hospitals to display their standard charge information by conforming to a CMS template layout, data specifications, and data dictionary by July 1, 2024.⁷ Hospitals were further required to include additional new data elements (i.e., estimated allowed amounts, drug units of measurements, drug types of measurement, and modifiers) in MRFs by January 1, 2025.

CMS also implemented requirements to automate access and real-time centralization of hospital MRF and standard charge data, including by mandating that a hospital provide a link to its MRF on the hospital's homepage. The revised regulations require a hospital to affirm that its MRF, to the best of its knowledge and belief, includes all applicable standard charge information in accordance with regulatory requirements and that the information displayed is true, accurate, and complete. CMS further modified its regulations to improve its enforcement capabilities and increase transparency by requiring hospital officials to certify the accuracy and completeness of MRF data and take notice of CMS warnings and agency actions to address noncompliance.

CMS publishes online a list of <u>CMP notices issued by CMS</u> to noncompliant hospitals. CMS has issued 18 total CMP notices to noncompliant hospitals since CMS began enforcing hospital price transparency requirements, only four of which were issued after January 1, 2024.

Health plan transparency requirements

Health plan transparency requirements were set forth by federal agencies in 2020 in the Transparency in Coverage Final Rule.⁸ Initially applicable for plan years beginning on or after January 1, 2022, the Transparency in Coverage Final Rule requires most health plans and issuers to disclose information about their coverage and costs to the public. The rule requires plans to disclose in-network provider rates, historical out-of-network allowed amounts and billed charges, and negotiated rates and historical net prices for covered prescription drugs through MRFs posted online. The rule also requires plans and issuers to disclose cost-sharing information and pricing details to participants, beneficiaries, or enrollees, including an estimate of their out-of-pocket costs for covered items and services from a particular provider, through internet-based price comparison tools (for plan or policy years beginning on or after January 1, 2024, for all covered items and services).

In August 2021, <u>federal agencies issued guidance</u> providing that they would exercise enforcement discretion and defer enforcement of transparency in coverage MRF requirements

⁸ 85 Fed. Reg. 72158-310 (Nov. 12, 2020); 45 CFR 147.210 et seq.



⁷88 Fed. Reg. 81540, 82079-121 (Nov. 22, 2023).

until July 1, 2022, and further defer enforcement of prescription drug pricing MRF requirements indefinitely pending further rulemaking. Additionally, in April 2022, in light of challenges encountered by payors relating to disclosure of in-network rates, federal agencies <u>issued further guidance</u> providing for an enforcement safe harbor when plans and issuers were unable to determine applicable rates in advance due to alternative reimbursement arrangements, or were otherwise unable to disclose specific dollar amounts according to technical guidance issued by federal agencies. In September 2023, however, federal agencies <u>rescinded their general policy</u> of deferring enforcement of prescription drug MRF requirements, and issued guidance providing that they would not be maintaining an enforcement safe harbor with respect to transparency in coverage MRF requirements.

To date, federal agencies have not published information regarding their enforcement of health plan transparency requirements, though CMS's <u>webpage devoted to health plan transparency</u> currently provides that "as of July 1, 2022, most group health plans and issuers of group or individual health insurance are posting pricing information for covered items and services. This pricing information can be used by third parties, such as researchers and app developers to help consumers better understand the costs associated with their health care."

Prepare now to comply with price transparency regulations

President Trump's February 25, 2025, executive order directs his cabinet, within 90 days of the date of his order, to take all necessary and appropriate action to: (a) require the disclosure of the actual (rather than estimated) prices of items and services; (b) issue updated guidance or proposed regulatory action ensuring pricing information is standardized and easily comparable across hospitals and health plans; and (c) issue guidance or proposed regulatory action updating enforcement policies designed to ensure compliance with the transparent reporting of complete, accurate, and meaningful data.⁹

Accordingly, interested stakeholders should prepare for rulemaking and increased enforcement attention and activity regarding hospital price transparency and health plan transparency requirements. The proposed rules may require close collaboration between payors and hospitals when publishing price information to ensure alignment and consistency between these stakeholders.

Additionally, while not specifically referenced in Trump's most recent executive order, all healthcare providers and payors should anticipate renewed attention to, and increased enforcement of, the No Surprises Act (NSA). The NSA, enacted during President Trump's first term, contains broad, sweeping requirements designed to protect patients from surprise medical bills and balance billing. However, there has been little enforcement of the NSA since its

⁹ Exec. Order No. 14221, supra Note 1.



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enactment, as federal agencies never finalized their proposed rule relating to enforcement of NSA requirements. 10

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Jonah D. Retzinger

213.629.6131

<u>jretzinger@nixonpeabody.com</u>

Whitney Phelps

518.427.2659

wphelps@nixonpeabody.com

Vidaur Durazo

213.629.6066

vdurazo@nixonpeabody.com

¹⁰ 86 Fed. Reg. 51730 (Sep. 16, 2021).

