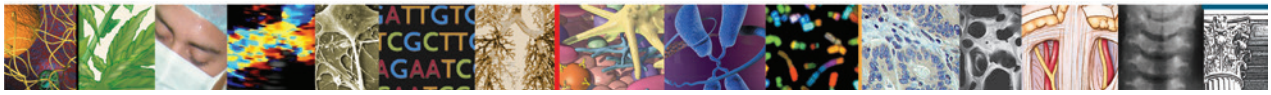

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

FEBRUARY 11, 2021

The Future of Drug-Pricing Transparency

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Prescription drug prices in the United States are opaque. Manufacturers set list prices, which are publicly disclosed, but then negotiate confidential rebates with insurers and pharmacy benefit managers (PBMs), often to secure preferred formulary placement. Because of warped incentives in the drug supply chain, rebates and other discounts have grown in recent years, driving "net" prices substantially below list prices for many brand-name drugs. The secrecy of negotiations means that patients and policymakers have no way of knowing the actual prices paid for prescription drugs.

The Trump administration occasionally criticized these private negotiations, advocating for marketplace transparency as a tool for lowering prices. More transparency, the administration argued, can provide insurers and PBMs with information to strengthen their negotiating positions with drug manufacturers and provide consumers with information to select cheaper insurance plans or buy medications directly without insurance. Conversely, payers argue that preserving confidentiality helps them negotiate lower prices and that transparency would allow manufacturers to obtain net prices even closer to the exorbitant list prices they now freely set.

Shortly before the 2020 election, the administration issued the "Transparency in Coverage" Final Rule, which addresses transparency throughout the health care system. For the pharmaceutical market, it requires that insurers disclose current list prices and historical net prices for prescription drugs in machine-readable files online and provide patients with real-time personalized estimates of cost sharing. Insurers and PBMs strongly oppose the rule, which they will almost certainly challenge in court.

This Final Rule was completed amid a barrage of scattered 11th-hour executive orders and rules targeting prescription drug prices, including initiatives to allow drug importation from Canada, eliminate rebates in Medicare Part D, and peg drug prices in Medicare Part B to prices abroad. But unlike other Trump drug-pricing proposals, many of which are likely to be abandoned by the Biden administration or overturned in court, efforts to promote health care pricing transparency may endure. Increased transparency enjoys bipartisan support, and Joe Biden himself has championed similar efforts.[1] Barring Congressional action, the Biden administration would also have less than a year to complete an entirely new rule-making process if it wanted to rescind the prescription drug re-

quirements in the Final Rule (which go into effect January 1, 2022).

Moreover, the rule will probably survive legal challenges. Two recent court rulings on other price-transparency policies shed light on the legal viability of this final transparency push. One decision invalidated a rule requiring drug manufacturers to reveal prices in advertisements[2]; the other upheld a rule requiring hospitals to disclose prices online.[3] Though seemingly at odds, these two decisions underscore how the Transparency in Coverage rule avoids prior pitfalls and relies on arguments that courts have found persuasive.

The issue in the first case, *Merck & Co., Inc., et al. v. U.S. Department of Health and Human Services et al.*, was whether the administration could require drug manufacturers to disclose list prices in television advertisements for drugs covered under Medicare and Medicaid.[2] The statutory basis for this requirement was a provision in the Social Security Act allowing the Department of Health and Human Services (HHS) to make rules necessary for the administration of Medicare and Medicaid. The U.S. Court of Appeals for the District of Columbia upheld a lower court ruling asserting that the link between this rule and its hoped-for trickle-down effect in Medicare and Medicaid was too tenuous. List prices, the court reasoned, do not reflect the actual prices paid by either the government or Medicare and Medicaid patients. The court concluded that HHS's construal of the statute was erroneous because it would give the agency seemingly unbridled power to institute any rule that could be linked, however distantly, to reducing Medicare or Medicaid spending.

The second case, *American Hospital Association et al. v. Azar*, considered disclosure of hospital prices in general. At issue was an Affordable Care Act (ACA) requirement that hospitals must establish and publicize "standard charges for items and services provided" through the ACA insurance exchanges.[3] The administration proposed expanding the definition of "standard charges" to include not only list prices but also payer-specific negotiated prices and discounted self-pay cash prices.

Unlike in *Merck*, the U.S. Court of Appeals for the District of Columbia upheld a lower court ruling that found this disclosure rule lawful because it did not exceed HHS's statutory authority. The hospitals challenging the rule had also maintained that it violated their First Amendment commercial speech rights. These rights have been interpreted to mean that the disclosure requirements must be "reasonably related" to the state's interest and not unduly burdensome. HHS put forward two key interests — assisting patient decision making and lowering costs — and the court agreed that price transparency was reasonably related to these interests. Knowledge of payer-negotiated prices, in particular, would help patients with high-deductible plans to anticipate costs and choose hospitals. Transparent prices would not, the court maintained, necessarily stifle negotiations, lead to anticompetitive practices, or drive up prices.

Though empirical data are sparse, the court found that the constitutionality of the disclosure rule does not depend upon definitive proof that transparency will help patients make decisions or lower prices but may instead rely on "simple common sense."[3] The common-sense analysis accepted by the court involved general economic principles of competition and some recent case studies, including a New Hampshire price-transparency website that reduced prices for medical imaging.[4] Counterexamples that the hospitals brought from outside health care — including a study showing that prices for concrete rose after the government of Denmark instituted transparency requirements — did not persuade the court that the disclosure requirement violated the government's common-sense analysis.[3] Finally, the court rejected the argument that the disclosure requirement was arbitrary and therefore invalid, finding instead that HHS had acknowledged conflicting data, articulated the evidence it found most compelling, and connected this evidence to the proposed rule.

Nearly one third of U.S. drug spending is for drugs dispensed in health care settings, so the *American Hospital Association* decision — unless overturned on further appeal — promises publicly available payer-specific negotiated drug prices for many drugs. Though this decision does not, by its terms, extend to retail prescription drugs, the Transparency in Coverage rule, which does, could be upheld on the basis of similar legal reasoning. The courts may not require direct evidence that transparency will actually reduce prices — an unanswered empirical question. Instead, the courts may well defer to the government's common-sense analysis and predictive judgment, as in the *American Hospital Association* decision.

Given such deference, the legal fate of the transparency rule may

ultimately rest on whether its statutory basis is sound. In promulgating the rule, the administration relied on an ACA requirement that private health plans publicly disclose certain data, including information on claims payment policies and practices, enrollment and disenrollment, out-of-network cost-sharing, and "other information as determined by the Secretary."[5] The courts traditionally interpret such catch-all phrases to mean that agencies may add to a list items that are sufficiently similar to ones already enumerated. Unlike the administration's errant argument in *Merck* linking disclosure requirements to distant effects in Medicare and Medicaid, the statutory basis invoked here, as in *American Hospital Association*, more directly relates to the regulatory action taken.

The exclusion of government payers such as Medicare from reporting requirements may attenuate the transparency rule's force. Since a separate rule eliminating confidential rebates in Medicare Part D may fail in court, net prices could remain unknown for a large swath of the drug market. Commercial insurers, moreover, may seek to undermine the transparency rule by misclassifying rebates and other discounts and thereby obscuring true net prices. Transparency itself offers some protection against misrepresentation, since outlier prices will be visible to stakeholders, but more coordinated or subtle misrepresentation could prove problematic. Sound measures to enforce reporting requirements will be critical.

An audio interview with Dr. Feldman is available at NEJM.org

Recent efforts by the Trump administration to alter the landscape of price transparency may resonate in the drug market for the foreseeable future. With a narrowly divided Congress in 2021, the Biden administration may face obstacles to achieving meaningful drug-pricing reform. Meanwhile, the Trump-era transparency initiatives will continue to be litigated. Amid inconclusive evidence about the effects of transparency, one thing remains clear: U.S. prescription-drug prices are too high under the current, opaque system, and a new approach is needed.

Disclosure forms provided by the authors are available at NEJM.org.

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This article was published on January 13, 2021, at NEJM.org.

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DOI: 10.1056/NEJMp2033734

BECOMING A PHYSICIAN

A Shared Evaluation Platform for Medical Training

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The medical education community has been debating the implications of a pass/fail scoring system for Step 1 of the U.S. Medical Licensing Examination (USMLE) since the March 2019 Invitational Conference on USMLE Scoring. The final conference report called for a multiorganizational panel to determine how to improve the transition from undergraduate medical education (UME) to graduate medical education (GME). Improving educational handoffs at each transition point will require consensus building among leaders from medical schools and residency and fellowship training programs. As part of this effort, we believe that fundamental flaws in these transitions should be addressed.

First, residency applications do not provide the relevant informa-