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Sunlight on Drug Prices Negotiated by Health Plans: The "Transparency in Coverage" Final Rule

On October 29, 2020, the Department of Health and Human Services ("HHS"), the Department of Labor ("DOL"), and the Department of the Treasury ("DOT") jointly released the "Transparency in Coverage" final rule (the "Final Rule"). The Final Rule requires group health plans and health insurance issuers to make available certain pricing information regarding health care items and services to participants, beneficiaries, or enrollees (collectively referred to herein as the "participants"), as well as the public. While the Final Rule addresses pricing transparency requirements for health care services and items more generally, this Alert focuses on the Final Rule's requirements impacting drug pricing transparency.[1]

Background

President Trump has voiced strong opposition to high prescription drug prices and has taken certain actions to try and reduce drug prices. In the wake of President Trump's May 2018 American Patients First strategy to address prescription drug prices, many drug companies delayed mid-year price increases.[2] These results, however, proved to be short-lived, as most companies followed through on increases at the end of 2018 and in the years since.[3]

Other Drug Pricing Legal Actions Under the Trump Administration

The administration has issued several proposed administrative rules related to curbing drug pricing. In fall 2018, the Centers for Medicare & Medicaid Services ("CMS") issued a highly controversial proposed rule that would, among other things, tie Medicare reimbursement for drugs to their generally lower prices in other countries and require plans and pharmacy benefit managers ("PBMs") in the Medicare and Medicaid markets to pass through manufacturer rebates to beneficiaries at the point of sale.[4]

Also tied to the administrative process, this summer the President issued four executive orders, three of which directed HHS to revive the rulemaking process for 1) international reference pricing for Medicare Part B, 2) rebate pass-through to beneficiaries at the point of sale, and 3) importation of drugs.[5] And, on June 17, 2020, CMS issued a proposed rule that would substantially alter current Medicaid Drug Rebate Program regulations relating to manufacturer drug price reporting and, in certain respects, likely increase manufacturer liability under the Medicaid and 340B programs.[6] On the whole, legal and political obstacles have forced CMS and the Trump administration to delay or abandon these proposals. As Ropes & Gray has previously reported, there is widespread skepticism that most of the executive orders will have any significant impact.[7]

The administration's efforts with regard to drug price transparency have similarly fallen flat, up until this point. The administration's most noteworthy transparency initiative to date—an HHS final rule published on May 8, 2019, requiring drug makers to disclose the list prices of drugs covered by Medicare and Medicaid in television advertisements[8]—was struck down in federal district court in July 2019 as exceeding the agency's authority.[9]

On the legislative front, Congress has taken certain action to increase transparency of drug prices, under the theory that making price information more widely available will incentivize manufacturers to lower prices. For instance, at the end of 2018, Congress enacted new laws that restrict plans and PBMs from imposing so-called "gag clauses" that prohibit pharmacists from informing customers when they would save money if they purchased a drug out of pocket, as opposed to with their insurance benefit.[10]

Health Plan Drug Pricing Transparency: The Final Rule

Against this backdrop of delayed or abandoned proposals, the Final Rule is significant, and it represents a culmination of a year-long rulemaking process. The process originated with an Executive Order President Trump issued on June 24, 2019, entitled "Improving Price and Quality Transparency in American Healthcare to Put Patients First," calling for third-party payors to make pricing information, including negotiated rates, available to participants.[11] In response, DOL, DOT, and HHS jointly issued the proposed version of the Final Rule on November 27, 2019.[12] With the publication of the Final Rule, HHS, DOL, and DOT have introduced cost transparency requirements for all health care services offered by health plans and insurers, with an expectation that price transparency will lead to price competition.

Parties Affected by the Final Rule

The Final Rule applies to group health plans and health insurance issuers in the individual and group markets, as well as to insured and self-insured group health plans and ERISA plans (collectively, "Payors"). The Final Rule does not apply to "grandfathered plans" under the Affordable Care Act,[13] nor does it directly apply to PBMs. Given the role of PBMs in the negotiation of drug prices, their exclusion may seem surprising. However, the Final Rule restates the view of DOL, DOT, and HHS that it is health plans and issuers that decide how the cost of a prescription drug is passed along to a plan enrollee, and, as such, those entities are in a position to disclose (or obtain from their contracted PBM and then disclose) the negotiated rate for a drug. As a practical matter, PBMs likely would play a key role in collecting this information and sharing it with plans, given that PBMs generally negotiate for rebates and discounts in connection with drug utilization. Also of note, PBMs that administer pharmacy benefits for Medicare Part D and qualified health plans are subject to distinct drug pricing-related reporting requirements under the Affordable Care Act.[14]

Requirements of the Final Rule

The Final Rule imposes two requirements on Payors relating to drug pricing. First, Payors must make certain drug pricing information publicly available through machine-readable files. Second, upon the request of a participant, a Payor must make available certain pricing disclosures to the individual participant at the participant's request.

1. Public Disclosure of Prescription Drug Prices.

With regard to drug pricing transparency, the Final Rule requires affected Payors to disclose to the public on an Internet website a prescription drug price information file reflecting the negotiated rate for the drug, as well as a historical net price for a drug. The term "negotiated rate" is defined as the dollar amount that the Payor has contractually agreed to pay for a covered item or service (whether directly or indirectly through a third-party administrator or PBM) to an in-network provider for the related covered drugs. Further, the negotiated rate for a drug must be made publicly available for each in-network provider contracted with the health plan or insurer, as identified by the National Provider Identifier of such provider.

The historical net price is defined as the retrospective average a plan paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any other additional price concessions received by the Payor with respect to the prescription drug or prescription drug service. The relevant period for a historical net price extends over the 90-day period that began 180 days before the date a particular prescription drug file is published (, the prescription drug price from January through March for a prescription drug file publication made in June). Notably, CMS expressly declined to permit Payors to disclose aggregate or otherwise-summarized pricing information.

The Final Rule does not specify where on a Payor's website the information must be posted, or otherwise impose accessibility requirements. Compared to the public disclosure required under the Medicare Shared Savings Program, for example, it is unclear how CMS will ensure the required disclosure is made easily accessible to the public and ensure that the goal of increased transparency is achieved. On the flip side, pharmaceutical manufacturers and other stakeholders are likely to strongly object (on legal and policy grounds) to making net drug prices publicly accessible in any manner, given that rebate and discount information is regarded as highly confidential and proprietary information and historically has

been protected under various federal laws. For instance, in stark contrast to the Payor-related drug price-reporting requirements under the Final Rule, PBM reports under the Affordable Care Act are made to HHS, are made at the aggregate level, and are subject to confidentiality protections.

These public disclosure requirements will apply for plan or policy years beginning on or after January 1, 2022. The plan or insurer must update the files on a monthly basis and may contract with a third party to meet these requirements.

2. Disclosures to Participants upon Request.

The Final Rule also requires that Payors disclose, upon the request of a participant, certain cost-sharing information broken down into seven elements. The cost-sharing information elements are designed around the typical "explanation of benefits" document received after health care services are performed, and include (i) estimated cost-sharing liability, calculated based on in-network rates, out-of-network allowed amounts, and individual-specific accumulators like deductibles;[15] (ii) the amount of financial responsibility that a participant has incurred at the time a request for cost-sharing information is made with respect to a deductible or out-of-pocket limit; (iii) in-network rates; (iv) the maximum amount a Payor would pay for a prescription drug furnished by an out-of-network provider; (v) the items and services content list, for which cost-sharing information is disclosed for items or services subject to a bundled payment arrangement (, ESRD drugs); (vi) a notification informing the requesting participant that a specific drug may be subject to a prerequisite for coverage; and (vii) a plain-language disclosure notice addressing several items, such as the fact that out-of-network providers may balance bill, as well as that the estimated cost-sharing liability for a given drug is not a guarantee that coverage will be provided for the drug. In the case of non-covered prescription drugs, price information is not required to be disclosed, with the Final Rule noting that Payors may not have information regarding the cost of such drugs.

Payors must make available the aforementioned information to participants via a self-service tool available on the plan or insurer's website. Alternatively, participants may request that the Payor supply the required information via mail; the mailing must be sent to the participant within two days after the Payor receives the participant's request. In the occasion that the participant requests the information through a paper form, the Payor may limit the information to twenty providers per request.

The disclosure requirements will come into effect over the course of two phases of implementation, with Payors providing information on 500 items and services identified in the Final Rule for all plan or policy years beginning on or after January 1, 2023, and providing information on all covered items and services for plan or policy years beginning on or after January 1, 2024.

Legal Challenges to Implementation

In the preamble to the Final Rule, the agencies appear to anticipate the potential for litigation. First, commenters expressed a concern that the Final Rule's mandated disclosure of negotiated rates constitutes compelled commercial speech in violation of the First Amendment. This was one of the arguments advanced in the prior drug pricing disclosure rule, but the court did not reach the issue since it found the rule exceeded the agency's authority.[16] Second, commenters also commented that the Final Rule would exceed the agency's authority. For the Final Rule, it seems that there could be a stronger chance of survival on the authority claim given the more specific nature of the cited authority – an argument similar to the one made in connection with the prior drug pricing disclosure rule. The court found that DOL, DOT, and HHS did not have the proper authority to promulgate the prior drug disclosure rule, which was based on DOL, DOT, and HHS's general authority to publish rules that "may be necessary to the efficient administration" of the Medicare and Medicaid programs. The court noted, for that prior rule, that there is no "actual and discernible nexus between the rule and the conduct or management or Medicare and Medicaid programs."[17] The Final Rule, on the other hand, derives its authority from the Affordable Care Act's requirement that group health plans and health insurance issuers seeking certification as qualified health plans make accurate and timely disclosures to HHS and the public, including claims payment policies and practices, information on cost-sharing and payment with respect to any out-of-network coverage, and other information as determined appropriate by HHS.[18] While an argument could be made that the requirement's

catch-all provision is still too broad to bolster the authority of the Final Rule, the open-endedness and intent of the provision does seem to indicate a closer nexus between the authorizing provisions and the Final Rule's intent to provide consumers with important information as they are shopping for health plans. Lastly, commenters also argued that the mandated disclosure of rates constitutes an unlawful taking of trade secrets without just compensation in violation of the Fifth Amendment. While DOL, DOT, and HHS rejected the merits of each of these legal theories in its response to the comments, they are representative of the potential legal challenges that the Final Rule may face in the future.

Conclusion

As with prior Trump administration actions on prescription drug pricing, the Final Rule faces substantial challenges in the next year before it is to become effective. In addition to the above-mentioned likely litigation, to date, Congress has lacked sufficient support for particular proposed strong drug pricing measures.[19] If the Senate remains in Republican hands in the coming administration, the prospect looms of action to reverse the Final Rule in a bill that represents bipartisan (and therefore more modest) consensus. Furthermore, a Biden administration could reinterpret the underlying statute in a manner contrary to the Trump administration. Health plans (and PBMs) would be well advised to watch this issue closely, since the administrative work to get ready for the Final Rule would be substantial.

If you have any questions about this Alert, please contact your usual legal advisor at Ropes & Gray.

1. As a general matter, the Final Rule sets forth two requirements on health plans and insurance issuers: (1) making certain pricing information regarding covered health care items and services publicly available on a website; and (2) making available certain pricing disclosures to the participant at the participant's request, including the cost for covered items and services.

   With regard to (1), the health plan or issuer must make available pricing information on covered items and services in three machine-readable files, including an in-network provider negotiated rate file, a historical out-of-network allowed amount file, and, as explained further in this Alert, a prescription drug pricing information file.

   With regard to (2), a health plan or issuer must provide certain pricing disclosures to requesting participants either via a self-service or in paper form, if so requested by the participant. The information required to be disclosed includes the cost-sharing liability for the furnishing of a covered item or service by a particular provider or providers; the amount of financial responsibility that the participant has already accumulated with respect to a deductible and/or an out-of-pocket limit as of the moment of the participant's request; the in-network rate (negotiated rate and/or underlying fee schedule) for an in-network provider as applicable to the plan or insurer's payment model; the out-of-network allowed amount for the requested item or service; if the item or service is subject to a bundled payment arrangement, the list of items or services included in the bundle; any applicable prerequisites for coverage (, prior authorization, concurrent review); and an accompanying notification of disclaimers.

2. American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, U.S. Dep't Health and Hum. Servs. (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf; Tom Bulleit & Kristen Mayer, , Law360 (May 17, 2018), https://www.law360.com/articles/1043394/a-look-inside-trump-s-4-point-plan-for-curbing-drug-prices.
3. Video, , Ropes & Gray (June 20, 2019), https://www.ropesgray.com/en/newsroom/alerts/2019/06/Trending-Video-Drug-pricing-initiatives-during-the-Trump-presidency.
4. Tom Bulleit & Scott Falin, , Law360 (Jan. 14, 2020), https://www.law360.com/articles/1232594/drug-pricing-what-happened-in-2019-what-to-watch-in-2020.
5. Fact Sheet, , White House (July 24, 2020), https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-lower-drug-costs-ensure-americans-access-life-saving-medications/.
6. 85 Fed. Reg. 37,286 (June 19, 2020).

7. Tom Bulleit at al., , Law360 (Sept. 25, 2020), https://www.law360.com/articles/1312963; Tom Bulleit et al., , Law360 (July 31, 2020), https://www.law360.com/articles/1297011/surveying-drug-pricing-reform-the-latest-federal-activity.
8. Kellie Combs et al., , Law360 (Oct. 24, 2018), https://www.law360.com/articles/1095398.
9. , 385 F. Supp. 3d 81 (D.D.C. 2019), 962 F.3d 531 (D.C. Cor. 2020); Tom Bulleit & Scott Falin, , Law360 (Jan. 14, 2020), https://www.law360.com/articles/1232594/drug-pricing-what-happened-in-2019-what-to-watch-in-2020.
10. Patient Right to Know Drug Prices Act, S. 2554, 115th Cong. (2018) (enacted); Know the Lowest Price Act, S. 2553, 115th Cong. (2018) (enacted).
11. Executive Order, , White House (June 24, 2020), https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/.
12. 84 Fed. Reg. 65464 (Nov. 27, 2019). https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-25011.pdf.
13. A "grandfathered plan" is a health plan that was in existence as of the date of the enactment of the Affordable Care Act on March 23, 2010. 26 C.F.R. § 54.9815-1251; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140. It is worth noting that, practically speaking, there are few grandfathered plans that remain at this point. Gary Claxton et al., , Kaiser Fam. Found. 207 (2019), http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019 (stating that, in 2019, only thirteen percent of covered workers are enrolled in a grandfathered health plan).
14. Social Security Act § 1150A, 42 U.S.C. § 1320b-23; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6005, 124 Stat. 119, 698 (2010).
15. Notably, the Final Rule allows for the cost-sharing information disclosure requirement to be met through the use of a third-party tool, such as one provided by a PBM.
16. , 385 F. Supp. 3d 81 (D.D.C. 2019), 962 F.3d 531 (D.C. Cor. 2020).
17. , 962 F.3d at 537-38; 42 U.S.C. §§ 1302, 1395hh.
18. Public Health Service Act § 2711, 26 U.S.C. § 9815(a)(1); Patient Protection and Affordable Care Act § 1311(e)(3)(A)(ix), 42 U.S.C. § 18031(e)(3)(A)(ix).
19. Tom Bulleit et al., , Law360 (July 31, 2020), https://www.law360.com/articles/1297011/surveying-drug-pricing-reform-the-latest-federal-activity.