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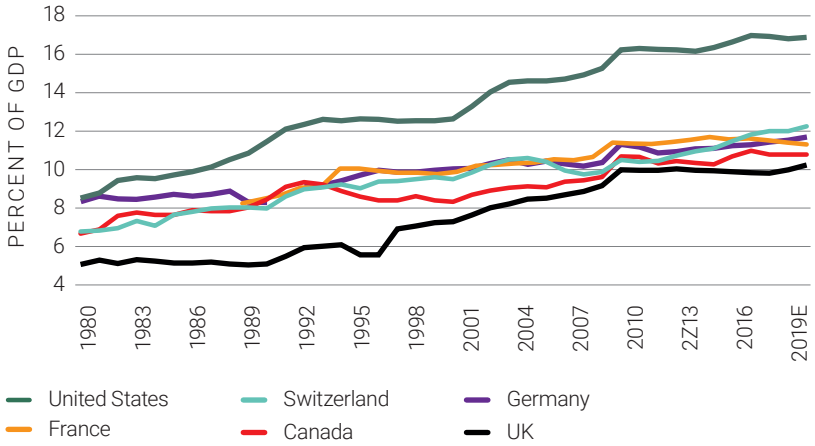
Healthcare and Life Sciences

WHAT DO YOU NEED TO KNOW ABOUT DRUG PRICE TRANSPARENCY IN THE UNITED STATES?

The issue of price transparency, including drug-pricing benefits, in the life sciences and healthcare industries, continues to be a critical one in the United States.

Price transparency has received increasing attention given the pandemic and the need to manage both patient care and the associated costs incurred by all US healthcare-system stakeholders. Some have estimated that the level of price transparency has led US healthcare spending to increase to an estimated 18% of GDP in 2020—almost double the percentage in other westernized nations such as France, at 11.3%; Germany, also at 11.3%; Canada, at 10.6%; and the United Kingdom, at 9.6%.[1] Those rising levels are clear signs that a structural change is necessary to control costs and improve healthcare quality. Most of the proposed price transparency changes will likely impose burdens on drug manufacturers and healthcare services providers alike, and like most system changes, the devil is in the details.

HEALTHCARE SPENDING AS A PERCENTAGE OF GDP



Source: OECD Health Data 2020

This article is the first in a series of three. This first article aims to talk about proposed legislation and issues raised around price transparency. The second and third articles will look at both sides of the price transparency problem from providers' and manufacturers' perspectives. In addition and to provide a complete view, we cannot discuss impacts on providers and manufacturers without discussing the pharmaceutical value chain.

Each side of the political aisle has proposed several initiatives to make pharmaceutical and healthcare prices transparent in the United States to prevent unexpected medical costs and lower prescription drug prices. The complexities that are built into US healthcare are difficult to understand because there are multiple moving parts among interrelated but disparate constituents.

President Trump has introduced five executive orders targeting price improvements. In June 2019, he signed the Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, which aims to "increase the availability of meaningful price and quality information for patients."[2] In July 2020, Trump issued three additional executive orders seeking to slash US prices to the lowest prices offered to developed countries and create a reimportation pathway.[3] More recently, on September 13, 2020, Trump issued an executive order addressing the pricing of drugs covered by Medicare Part B and Part D.[4]

1. World Bank. Current health expenditure (% of GDP) data by country. Accessed at https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?most_recent_year_desc=true on October 14, 2020.
2. President Trump. Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First. White House Presidential Actions, June 24, 2019. Accessed at https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/ on October 5, 2020.
3. President Trump. Executive Order on Access to Affordable Life-saving Medications, Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, and Executive Order on Increasing Drug Importation to Lower Prices for American Patients. White House Presidential Actions, July 24, 2020. Accessed at https://www.whitehouse.gov/presidential-actions/ on October 5, 2020.
4. President Trump. Executive Order on Lowering Drug Prices by Putting America First. White House Presidential Actions, June 24, 2019. Accessed at https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first/ on October 5, 2020.

Among the executive orders issued, one of the more controversial ones involves a requirement to match pharmaceutical costs available in several comparable nations.[5] Based on that executive order, it is estimated that Medicare would save around $17 billion in the first five years.[6] However, many healthcare stakeholders in the United States are worried that international reference pricing would reduce competition and innovation.[7]

It is essential to mention that an executive order is not immediately enforceable. However, drug price transparency is already a part of the ACA and in effect within the Obamacare marketplace[8]. Outside of the marketplace, it will be necessary to finalize regulations and go through follow-up procedural steps that could take months or even years, and in the meantime, each order may be challenged in court. In parallel with any legal developments, additional efforts will be made, such as the effort to force manufacturers to include drug list prices in television advertisements. Besides, list prices are somewhat misleading given certain rebates, discounts, service fees, and stakeholder cuts that significantly reduce the amounts manufacturers really receive as payment.

In his Presidential campaign, Joe Biden enumerated a list of drug-pricing priorities, including:

1 Repeal of the non-interference clause to permit Medicare price negotiation by the secretary of the Department of Health & Human Services.

2 Establishment of an independent review board to assess drug launch prices and then recommend prices based on prices in other countries.

3 Limitations on drug price increases to inflation, with penalties for noncompliance.

4 Permission for drug reimportation.

5 Ending of tax deductions for direct-to-consumer prescription drug ads.

6 Reform of patent laws to prevent delays in generic market entry.[9]

Both candidates cast drastically different visions of their healthcare agendas. Biden promotes the Affordable Care Act (ACA) law that Trump's administration wants to strike down. Parts of the ACA include drug price transparency clauses. Early indications from the US Supreme Court's November 10th hearing challenging the ACA's constitutionality is that the ACA will survive the court challenge. If the court decides to reverse the decade-old law and Congress cannot agree on how to replace it, disruption across the industry would be enormous.[10]

Many agree that the increasing costs of healthcare are not sustainable under our current system. According to the Organisation for Economic Co-operation and Development, the United States in 2015 had the world's highest per-capita pharmaceutical spending.[11] In 2018, the United States spent $3.6 trillion on healthcare, representing 17.7% of the US economy.[12] In the same year, Medicare spent $335 billion on prescription drugs (9% of total healthcare spending and 1.6% of GDP)—a 2.5% rise from the previous year and faster than the 1.4% growth in 2017.[13]

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5. Joshua Cohen. "Trump's Executive Orders on Drug Pricing Contain Caveats and Limitations." Forbes, July 25, 2020. Accessed at https://www.forbes.com/sites/joshuacohen/2020/07/25/trumps-executive-orders-on-drug-pricing-contain-caveats-and-limitations/#f6c914350011 on October 5, 2020.
6. Dan Best. Answering Your Questions about the IPI Drug Pricing Model." US Department of Health & Human Services, October 30, 2018. Accessed at https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html on October 5, 2020.
7. Jacqueline LaPointe. "Exploring International Reference Pricing for Pharmaceuticals." Pharmanews Intelligence, November 15, 2019. Accessed at https://pharmanewsintel.com/news/exploring-international-reference-pricing-for-pharmaceuticals on October 7, 2020.
8. "The Post-Election Future of Employee Benefit Policy: Health Policy Edition." American Benefits Council, November 6, 2020. Accessed at https://www.americanbenefitscouncil.org/pub/?id=34D9F74E-1866-DAAC-99FB-CDD9B2443372 on November 9, 2020.
9. John McManus. "Democratic and Republican Health Priorities In the Next Administration." Life Science Leader, September 9, 2020. Accessed at https://www.lifescienceleader.com/doc/democratic-and-republican-health-priorities-in-the-next-administration-0001 on October 5, 2020.
10. Rachel Cohrs. "Biden, Trump Offer Distinct Healthcare Agendas That Leave Some Questions Unanswered." Modern Healthcare, September 19, 2020. Accessed at https://www.modernhealthcare.com/politics-policy/biden-trump-offer-distinct-healthcare-agendas-leave-some-questions-unanswered on October 7, 2020.
11. President Donald J. Trump's Blueprint to Lower Drug Prices. White House Briefings & Statements, May 11, 2018. Accessed at https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/ on October 5, 2020.
12. Katherine Wilson. "Health Care Costs Accounted for 17.7 Percent of GDP in 2018." California Health Care Foundation, June 2, 2020. Accessed at https://www.chcf.org/blog/health-care-costs-accounted-17-7-percent-gdp-2018/ on October 14, 2020.
13. Historical NHE, 2018. Centers for Medicare & Medicaid Services National Health Expenditure Data, March 24, 2020. Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet on October 5, 2020.

Based on our experience in this industry, it won't be easy to define and gain agreement on which benchmark drug prices in the United States would be used to compare drug prices in other countries.

THE PRICE TRANSPARENCY EFFORT WOULD HAVE TO ANSWER THE FOLLOWING QUESTIONS:

1. Which price to choose, for which drug, in which country, using which pricing method? For example, in the United States, a drug price could refer to either average manufacturer price (AMP), wholesale acquisition cost (WAC), average selling price (ASP), estimated acquisition cost (EAC), actual acquisition cost (AAC), or usual and customary price (U&C). Pharmaceutical dead net pricing—although difficult to compute and compare across channels given the area's complexity—is one way to conduct an apples-to-apples comparison. In addition, when it comes to Medicare and Medicaid pricing, the government's various—and complicated—drug-pricing formulas determine the price the government will pay for a specific drug. Those pricing formulas are not comparable to the drug pricing that is in place in, for example, Canada or Germany.

2. Which countries and what number of countries would be the appropriate mix to designate a drug's objective pricing benchmark? This decision would need to be supported by sufficient statistical analysis evaluating the representation of sample size and correlation among the countries, and products in the basket of comparison. Also, deciding on the appropriate base year for comparison could significantly change the results of the statistical analysis.

3. Suppose it was proposed that reference drug pricing would use the lowest price for a particular drug in Canada. Could the manufacturer(s) of that drug change that drug's selling price in Canada to make manufacturer pricing more consistent globally? The model also needs to anticipate how often reference pricing should change. Using the same example, if the price of a drug at a specific formulation changes quarterly, should the reference pricing model change quarterly and can the infrastructure for reference pricing support price changes at the level of needed frequency?

An increasing number of drugs are tied to the procedures required for drug delivery, so will price transparency combine a drug's cost and the associated procedure? For example, if a particular drug is permitted to be administered only by intravenous drip by a physician in a clinic or hospital setting, would the drug's price include both drug price and procedure price? How would differences in the pricing of procedures across countries due to different healthcare standards and labor costs be handled? There are additional questions when it comes to companion diagnostics and how the change in a drug price would compare to the price of the companion diagnostic.

In light of all of the current initiatives, a challenging environment is in place that affects several sides of the industry, pharmaceutical manufacturing, pharmaceutical distribution, and pharmaceutical providers. Transparency initiatives affect all of those sides differently. The pass-through of 340B Program discounts, rebate reform, drug importation, and most-favored-nation status are only a few areas in which hospitals and manufacturers will be affected—and they will have to be prepared to adapt quickly to the potential changes.

If we assume there will be some change, regardless of where price transparency goes, we believe the life sciences and healthcare companies will (still) have to tackle the following issues.

Re-evaluation of global, regional, and local pricing. Take another look at strategies involving wholesale acquisition cost, rebates, chargebacks, and other pricing elements throughout the commercial and government channels.

Renegotiation of associated contracts with stakeholders in the value chain. If reference pricing is defined and implemented, the rebates provided down the value chain might be reduced or eliminated, requiring a change in contracts and business partners.

Pricing is only one component when it comes to supply and demand. Any changes in demand caused by pricing changes would require an understanding of capacity at different points across the supply chain.

Evaluate whether reference pricing can be applied to biologics and biosimilars. Given the various positions considering biosimilars' equivalency, this will be a key decision in the new normal.

Consider what to manufacture and where. When it comes to selling products in the market, it is possible that reference pricing would make it commercially unreasonable to sell certain products reference pricing. It will be essential to understand whether it will be commercially reasonable to sell through any government channel after applying government-pricing methodologies on top of reference pricing.

Health plans, providers, patients, and stakeholders down the healthcare value chain may be limited to obtaining products manufactured by a smaller number of companies that can produce at extremely low costs. If that is the case and the remaining companies have manufacturing issues, then manufacturing contingency plans will have significantly more importance from a market perspective.

The issues involving drug price transparency continue to develop as we speak; upcoming articles will explore the related issues.

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