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Drug Pricing Reform & The Trump Administration

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Background: The Drug Pricing Debate

Drug Pricing

- High and ever-increasing drug prices have become a top political and policy issue
- Providers, insurers, patient advocates and politicians from both parties have called for strong measures to curb drug costs
- There is broad concern among stakeholders regarding the lack of transparency with respect to brand-name drug prices
- Potential proposals could give the Secretary of Health and Human Services (HHS) the authority to:
  - negotiate prices with manufacturers,
  - require manufacturers to supply HHS with all cost and clinical data, as well as other information necessary to come to an agreement on price, and
  - implement transparency and reporting requirements.

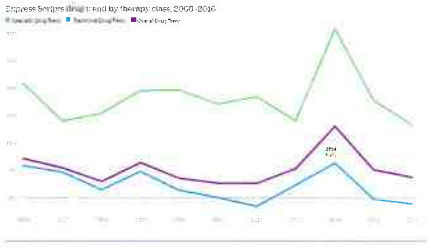
Background: The Drug Pricing Response?

- President Trump pledged during the campaign to address the rising cost of drugs his administration
- To date, there has been more rhetoric than action
- Thus far, steps in that direction include:
  - Newly appointed Food and Drug Administration (FDA) Commissioner Gottlieb indicating that he intends to take steps to make generic drugs more available on the market in an effort to address high drug prices
    - The FDA does not have authority to directly regulate drug pricing
  - The Trump Administration's leaked draft executive order on drug prices focuses on reducing the regulatory burden on drug manufacturers

Context: Specialty Pharmaceuticals Landscape

- Specialty drug spending is expected to increase by 361% from 2012 to 2020
- Drug manufacturers are actively pursuing "specialty" areas, instead of the traditional "blockbuster" model
  - Specialty drugs have gained regulatory approval at a faster rate than traditional drugs with the trend expected to continue
  - Six therapeutic areas account for approximately 2/3 of specialty drug spending in the US: **oncology**, rheumatoid arthritis, multiple sclerosis, HIV/AIDS, IVIG, and inflammatory bowel disease
- Specialty drugs often placed on "specialty tier" with prior authorization and higher patient coinsurance
  - Manufacturers have responded with extensive reimbursement assistance and generous copay assistance

Specialty drugs are a major driver of health spending



Source: Kaiser Family Foundation analysis of data from Express Scripts Drug Trend Reports, 2006 through 2016

Context: Biosimilars

- The Affordable Care Act (ACA) introduced an approval pathway for biosimilars
- Substitution requirements largely left up to the states
- Volume to date has been low but expected to increase significantly
  - 5 approvals through July 2017; 2 with the same reference product
  - 7 new biosimilar investigational new drug applications filed in FY 2016 and 3 filed through March in FY 2017
  - 66 enrolled in Biosimilar Biological Product Development Program through March 2017
  - Many more candidates not enrolled
- Biosimilars expected to account for 4% to 10% of the biologics market total by 2020

Trump Tackles Drug Prices

Trump Administration Inconsistent On Drug Pricing Reform

Time Magazine, December 2016:

Trump states he doesn't "*like what's happened with drug prices*" and that he will "*bring down*" the cost of prescription medication

Trump Administration Inconsistent On Drug Pricing Reform

Press Conference, January 11, 2017:

"*I think a lot of industries are going to be coming back. We have to get our drug industry coming back. Our drug industry has been disastrous. They're leaving left and right. They supply our drugs, but they don't make them here. To a large extent. And the other thing we have to do is create a new bidding procedures for the drug industry because they're getting away with murder. Pharma has a lot of lobbies, a lot of lobbyists and a lot of power. And there's very little bidding on drugs. We're the largest buyer of drugs in the world, and yet we don't bid properly. And were going to start bidding and were going to save billions of dollars over a period of time*"

Trump Administration Inconsistent On Drug Pricing Reform

Rep. Tom Price Confirmation Hearing, January 18, 2017:

"*Right now the PBM's are doing that negotiation. I think it is important to have a conversation and look whether there is a better way to do that. And if there is, I am certainly open to it*"

Price seemed to suggest that the policy would at least be considered, given Trump's outspoken support for it, but he expressed no enthusiasm for the proposal

Trump Administration Inconsistent On Drug Pricing Reform

President Trump Meeting with PhRMA, January 31, 2017:

President Trump met with big pharma's largest trade group and lobbying arm, the Pharmaceutical Research and Manufacturers of American (PhRMA), and signaled that he may be moving towards the conservative "*market-driven*" approach to lowering drug costs, only a few weeks after revisiting his unorthodox idea to allow Medicare to negotiate drug prices. Trump promised to slash regulations, get new treatments to market faster at the FDA, and increase international competition. Trump also promised to cut taxes on business and lure companies back to the U.S.

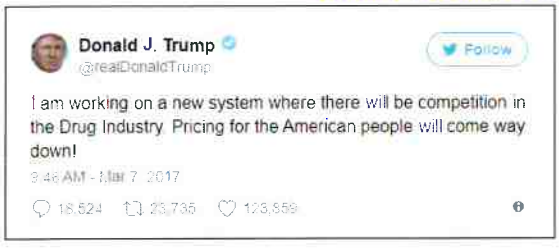
Trump Administration Messaging Starts to Focus

State of the Union, February 2017:

My administration and Congress should "work to bring down the artificially high price of drugs and bring them down immediately."

Trump Administration Messaging Starts to Focus (more)

Twitter, March 7, 2017:



Trump Administration Messaging…

Twitter, August 14, 2017:

Outlook: Potential Drug Pricing Policies

Potential Policy Changes For All Healthcare Markets

- In its FY 2018 Budget, the Trump Administration indicated that it plans to "clarify" barriers to manufacturers' ability to set up value-based arrangements
  - Potential barriers include Best Price, the Anti-Kickback Statute, FDA off-label promotion policy, and the Health Insurance Portability and Accountability Act (HIPAA)
- Allow pharmacies, wholesalers, and others to import drugs from abroad
  - Some ability for HHS to permit this under the Medicare Modernization Act of 2003 if the Secretary certifies to Congress that doing so will not create additional risk to the public health and safety and will reduce drug costs
- Federal Trade Commission (FTC) enforcement of "pay for delay" arrangements, in which manufacturers pay generic manufacturers to delay entry to the market (not a clear priority of the Administration)
- Potential legislative action on Risk Evaluation and Management Strategies (REMS)
  - Concern that manufacturers are using restricted distribution systems to delay or block generic competition
  - House Oversight and Government Reform Committee held a hearing on this issue in May

Potential Policy Changes For All Healthcare Markets

- Action plan on FDA review of drugs, including faster approval of generics, as advocated for by Commissioner Gottlieb, and reducing backlog of generic applications, among other measures
- Adopt regulatory limitations on direct-to-consumer advertising to reduce demand for higher cost drugs

Scott Gottlieb, M.D.
Commissioner of Food and Drug Administration

- Sworn into office on May 11, 2017
- Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and as a senior advisor to the FDA Commissioner
- Dr. Gottlieb was previously a Resident Fellow at the American Enterprise Institute, and a Clinical Assistant Professor at the New York University School of Medicine in Manhattan

Implications of Potential Changes For All Healthcare Markets

Health Insurance Coverage	Change in Essential Health Benefits to protect drug formularies and improve beneficiary access to drugs (unlikely given current fragility of exchanges)
340B Program	Modify 340B program through guidance to expand patient definition so that discounts must be offered for more patients (not binding as the Health Resources and Services Administration (HRSA) does not have much regulatory authority and generally can issue guidance only)

Potential Policy Changes May Affect Different Parts of Medicare

Part A	Part B	Part C	Part D
Hospital insurance benefits for the aged and disabled	*Supplemental Medical Benefits*	*Medicare Advantage, optional, alternative Medicare coverage through private plans that contract with the federal government*	*Optional Prescription Drug Benefits*
Generally covers inpatient hospital care, short-term skilled nursing facility care, post-institutional home health care, and hospice care	Services covered include physician services, hospital outpatient and ambulatory surgery center services, diagnostic tests, and durable medical equipment	Plans generally must provide at least the current Medicare benefits package and may provide additional services	Covers drugs not covered by Parts A or B
	Enrollment as of January 2017: 57,663,486		Enrollment as of January 2017: 42,327,569

CMS. Medicare Enrollment Dashboard *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html

Potential Policy Options in Medicare Part B and Part D

- If the Medicare growth rate is more than projected medical care spending, implement reforms to control rising drugs costs through the Independent Payment Advisory Board (IPAB)
  - If triggered, the IPAB must recommend changes in Medicare policy to Congress
  - If Congress fails to act, HHS is to implement the IPAB's policies anyway
  - If the IPAB fails to act, HHS can act in its place
  - Longstanding legislative efforts to repeal the IPAB
- Office of Inspector General (OIG) push back on the extent to which manufacturers can assist patients with out of pocket (OOP) expenses
  - Critics claim that when manufacturers do this it incentivizes patients to choose higher cost drugs
- CMS could publish more data on Part B and Part D drug spending to increase transparency (likely)

Potential Policy Options in Medicare Part B and Part D

- Permit the federal government to negotiate drug prices with manufacturers
  - Could be implemented initially through a Centers for Medicare & Medicaid Innovation (CMMI) model

Center for Medicare & Medicaid INNOVATION

- The Affordable Care Act (ACA) established CMMI
- CMMI models encourage health care providers to deliver high quality care more efficiently
- Shifting focus from short-term to longer-term costs and benefits
- Private payers implementing similar reforms at a much faster pace

Potential Policy Options in Medicare Part B

- Pay for more Part B drugs through bundled payments (likely)
- Use the CMMI to test alternatives to average sales price (ASP) plus 6 percent reimbursement and/or utilization management of drugs (may need to be mandatory to work, something that Secretary Price opposes)
- CMS could use its "inherent reasonableness" authority to adjust Part B items and services by +/- 15 percent or its "equitable adjustment" authority to modify rates under the outpatient prospective payment system (OPPS) (little used authorities)
- Consider cost in National Coverage Determinations and allow Medicare Administrative Contractors to consider cost in Local Coverage Determinations (unlikely)
- Test a Least Costly Alternative (LCA) policy through the CMMI (previous version of this policy which paid the lowest rate across similar Part B drugs struck down in court)
- Resurrect the Competitive Acquisition Program (CAP) or a modified version such as MedPAC's proposed Drug Value Program (DVP)

American Society of Clinical Oncology (ASCO) Position Statement

- ASCO Position Statement on Addressing the Affordability of Drugs Approved by ASCO's Board of Directors on June 1, 2017
- Recommendations:
  - Solutions to address the affordability of cancer drugs should be identified, evaluated, prioritized, and tested, including:
    - Defining value in cancer therapeutics
    - Ensuring high-value drug development
    - Testing different value-based pricing strategies
    - Encouraging development and use of generics and biosimilars
    - Limiting the financial burden that payer policies place on patients
    - Medicare negotiation of drug payments
    - Transparency of drug costs
    - Re-importation of drugs
  - The larger community must actively participate in any effort to develop policy solutions to address the affordability of cancer drugs
  - Congress and/or the Administration can play an important role in bringing together a diverse group of experts to identify, evaluate, and prioritize a series of demonstrations designed to test some of the solutions highlighted and, once tested, to recommend implementation for those that are successful. A high-priority effort of this group should be to propose a strategy for blending various value-based frameworks into a transparent and standardized approach to assessing value, and recommending drug pricing and reimbursement based on the value delivered.

Discussion Points

- Is the primary issue drug pricing or affordability for patients?
- Are you entering into value based arrangements (VBAs) with manufacturers?
- Have VBAs been successful in lowering cost and improving quality of care?
- Are VBAs more common for practices participating in the Oncology Care Model (OCM), Accountable Care Organizations, or other alternative payment models?
- Has participation in the OCM changed the way you prescribe or purchase drugs?
- Will having additional biosimilars and generic drugs on the market help ease drug pricing concerns?

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