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March 20, 2019
116th Congress Party Split

House

235 Democrats; 197 Republicans; 3 Vacancies

Speaker of the House: Nancy Pelosi (D-CA)
Minority Leader: Kevin McCarthy (R-CA)

Senate

53 Republicans; 45 Democrats; 2 Independents

Majority Leader: Mitch McConnell (R-KY)
Minority Leader: Chuck Schumer (D-NY)
# 116th Congress - House Committee Leadership

<table>
<thead>
<tr>
<th>Committee</th>
<th>Democrat</th>
<th>Republican</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intelligence</td>
<td>Rep. Adam Schiff (CA)</td>
<td>Rep. Devin Nunes (CA)</td>
</tr>
<tr>
<td>Transportation &amp; Infrastructure</td>
<td>Rep. Peter DeFazio (OR)</td>
<td>Rep. Sam Graves (MO)</td>
</tr>
<tr>
<td>Veterans’ Affairs</td>
<td>Rep. Mark Takano (VA)</td>
<td>Rep. Phil Roe (TX)</td>
</tr>
<tr>
<td>Ways &amp; Means</td>
<td></td>
<td></td>
</tr>
</tbody>
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### 116th Congress - Senate Committee Leadership

<table>
<thead>
<tr>
<th>Committee</th>
<th>Republican</th>
<th>Democrat</th>
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</thead>
<tbody>
<tr>
<td>Agriculture</td>
<td>Sen. Pat Roberts (KS)</td>
<td>Sen. Debbie Stabenow (MI)</td>
</tr>
<tr>
<td>Armed Services</td>
<td>Sen. James Inhofe (OK)</td>
<td>Sen. Jack Reed (RI)</td>
</tr>
<tr>
<td>Banking, Housing &amp; Urban Affairs</td>
<td>Sen. Mike Crapo (ID)</td>
<td>Sen. Sherrod Brown (OH)</td>
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<tr>
<td>Commerce, Science &amp; Transportation</td>
<td>Sen. Roger Wicker (MS)</td>
<td>Sen. Maria Cantwell (WA)</td>
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<td>Health Education</td>
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<td>Sen. Lamar Alexander (TN)</td>
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<td>Labor &amp; Pensions</td>
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<td>Sen. Patty Murray (WA)</td>
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<tr>
<td>Judiciary</td>
<td>Sen. Lindsey Graham (SC)</td>
<td>Sen. Dianne Feinstein (CA)</td>
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<tr>
<td>Select Committee on Intelligence</td>
<td>Sen. Richard Burr (NC)</td>
<td>Sen. Mark Warner (VA)</td>
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<tr>
<td>Special Committee on Aging</td>
<td>Sen. Susan Collins (ME)</td>
<td>Sen. Bob Casey (PA)</td>
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116th Congress Agenda

- ACA
  - Real vs 2020 election spin

- Health IT/Telemedicine
  - On the rise but how much

- Drug Pricing
  - Congress
  - Administration
  - Industry efforts

- Hospitals
  - Offensive vs. Defensive issues
Future of the ACA: The Lawsuit

The Basics:

- 20 Republican state attorneys general filed suit challenging the ACA after the individual mandate was effectively eliminated in last year’s tax bill
- A TX judge found the ACA unconstitutional in December 2018
- Democratic state attorneys general will appeal with support from House Democrats
- **The law is still in effect while pending appeal**
- If affirmed by higher courts, entire ACA would be repealed including popular provisions like pre-existing condition protections
Future of the ACA: The Lawsuit

States that have joined Texas v. Azar

Source: Politico Pro Datapoint
Future of the ACA: Congress

- Senate HELP may again take up stabilization compromise
- We may see legislative action to protect pre-existing conditions
  - Energy and Commerce Hearing
- Bipartisan permanent repeal of “Cadillac tax” and medical device tax
  - Sens. Amy Klobuchar (D-MN) and Pat Toomey (R-PA) permanent repeal
    - $10B over 10 years
- Will the House see a vote on Medicare for all?
116th Congress Agenda: Health IT and Telemedicine

- In 2018, CMS continued the trend of expanding reimbursement and pilot projects for telehealth services – expect this to continue
  - Medicare Advantage
  - Removal of geographic and originating site restrictions
  - Nursing homes and senior care
  - Expanded broadband – especially into rural areas
  - Telebehavioral health
  - Interoperability
    - CMS released proposed rule, 2/22/19
    - Increase accessibility of patients to health information
    - Applies to providers, Medicaid, CHIP, MA, MCOs
Drug Pricing: Administration

- Trump Administration’s Blueprint to Lower Drug Prices released May of 2018 identified four strategies:
  1. Improved Competition
  2. Better Negotiation
  3. Incentives for Lower List Prices
  4. Lowering Out-of-Pocket Costs

- Other Trump Administration approaches to drug pricing include:
  - Proposed demonstration to lower Part B prices
  - International Pricing Index
  - Drug reimportation under consideration at FDA
  - Antikickback Reg.- Guts PBM model
Drug Pricing: Congress

- One of the few areas of bipartisan interest, drug pricing is a priority in the 116th Congress

- Turf war and finger pointing
  - Pharma, AAM, Insurers, PBMs, Providers, Hospitals
  - Look for “bad actor” scapegoat companies
  - Pharmacy Benefit Managers will continue to be focus
  - 340B cuts and lawsuit impact pricing
  - Medicaid misclassification by pharmaceutical companies
  - Incentives to increase competition and generic drugs including sample-blocking
March 15, 2019

Drugs with Single Manufacturer Drive Medicaid, Medicare Spending

BY JANIE BOSCHMA, SARAH KARLIN-SMITH AND SARAH OWERMOHLE, POLITICO PRO

Drugs for which there is only one manufacturer are responsible for the biggest spending increases in Medicare and Medicaid even when a range of treatments are available for a particular disease, according to updated data CMS released this week. The figures raise questions about why there is not more price competition among branded products, a solution commonly embraced by Republicans and some Democrats in Congress.

Source: CMS drug spending data

Note: CMS data do not include the number of manufacturers per drug for Part B. The CMS data include the amount paid by Medicare or Medicaid as well as beneficiary payments, government subsidies or any other third-party payer payments. In Part D and Medicaid, the spending does not take into account any manufacturer rebates or price concessions.
Average annual growth rate of Medicare, Medicaid drug spending, 2013 to 2017:

- Medicare Part B: 10.0%
- Medicare Part D: 10.6%
- Medicaid: 14.8%
Drug spending increases by percentage with single manufacturer

INCREASES IN AVERAGE SPENDING PER DOSE, 2016-17

- **Drugs with single manufacturer**
  - Drugs for which average spending per dose increased by at least $35: 94%
  - Drugs for which average spending per dose increased by less than $35: 79%
  - All Medicaid Drugs: 71%

- **More than one manufacturer**
  - Drugs for which average spending per dose increased by at least $35: 21%
  - All Medicaid Drugs: 29%
Drugs for which average spending per dose increased by at least $35: 99%
Drugs for which average spending per dose increased by less than $35: 78%
ALL PART D DRUGS: 71%
Feb. 12, 2018

HHS Proposes Ban on Drug Rebates

BY POLITICO PRO DATAPoint STAFF

The Trump administration is calling for an ambitious overhaul of the drug purchasing system — banning drugmaker rebates that it says incentivize higher prices — in its latest bid to lower drug costs.

In the proposed rule, HHS would end an exception to a federal anti-kickback law that currently allows drugmakers to pay rebates to insurers and benefit managers.

The rule would only apply to federal programs — HHS Secretary Alex Azar has asked Congress for legislation extending the idea to the broader market.

Sources: HHS; Lexology; America’s Health Insurance Plans
How prescription drug rebates can alter the flow of drugs and money

1. Pharmacies pay the full price for drugs

   Pharmacies purchase drugs from manufacturers at the “list price” — the full price without any rebates applied.
   When a patient gets their prescription filled, the pharmacy will charge them this list price plus an additional fee for the pharmacist.
   The patient will then split this bill with their insurer, depending on their copay and deductible arrangements.

2. Drugmakers pay rebates to insurers based on sales

   To encourage sales, some manufacturers offer to pay a rebate to insurers if their enrollees purchase a certain volume of the drug.
   These rebates are typically based on a percentage of the list price — more expensive drugs often come with larger rebates attached.
   A drug’s price with a rebate applied is known as the “net price.”
How prescription drug rebates can alter the flow of drugs and money

3 Benefit managers take a cut and set drug lists

An insurer typically delegates the administration of their prescription drug benefit to a pharmacy benefit manager. The PBM negotiates for rebates and sets up a drug formulary — the list of drugs that will be covered by the insurer.

PBMs profit by keeping a portion of the rebate. HHS argues that PBMs seek bigger rebates by giving priority on the formulary to more expensive drugs.

4 Savings are passed to enrollees via premiums

After the PBM and insurer take a cut of the rebate, the remaining savings are passed on to enrollees in the form of reduced premiums. Since premiums are decreased across-the-board, all enrollees on the plan benefit. As a result, rebate savings are not necessarily targeted at the specific enrollees who purchased the drug.
HHS will allow two new types of manufacturer payments

While the proposed rule would eliminate most existing rebate arrangements, HHS has outlined two types of payments that drug manufacturers will be allowed to make if they choose to maintain some existing business practices.

1. **Manufacturers can offer discounts that go entirely to the consumer**

   If a drugmaker opts to negotiate a discounted price with an insurer or pharmacy benefit manager, HHS will only allow it if the consumer receives the full value of the discount at the point-of-sale.

   Manufacturers could pay pharmacies directly for the portion being discounted using chargebacks. These discounts would apply to the price paid by the consumer at the pharmacy, and must be reflected in any copays or deductible payments.

   Manufacturers can use these discounts to compete for priority on a PBM’s drug formulary, but the PBM will not be able to take a cut.

2. **Manufacturers can pay fixed fees in return for various drug services**

   Currently, some drugmakers give PBMs extra rebate amounts in exchange for certain services.

   For example, a PBM might perform a review of how a drug is being utilized by an insurer’s enrollees so that the drugmaker can tailor their business accordingly.

   The proposed rule would continue to allow such arrangements, but the payment would not be tied to rebates. Instead, drugmakers could pay a flat fee that does not vary with drug prices.
Importation

- WHO estimates 10% of medicines are counterfeit
- Basic arguments: Safe and Effective; lower costs?
- Basic principle of follow the medicine
- Who guarantees safety?
- Sounds like a good and easy policy…..but remember the MMA
Hospitals

The ways in which hospitals and providers are compensated are always of interest to lawmakers:

- Surprise medical bills and “balance billing”
- Executive compensation: Relive Sen. Grassley’s Not-for-Profit scrutiny
- Stark Law Reform on the Horizon
- The 340B cut and lawsuit continue to be big news in 2019
  - 30% cut went into effect in 2018
  - Court sided with hospitals
    - Budget Neutral provision – how to hand the money
Surprise Billing

- Has jumped to a top-tier Congressional items
- Legislative vs. Industry self-imposed oversight
- Provider Price caps tied to Medicare rates?
- Average billed charges lead to cap price
  - Creates skewed charges due to out-of-network vs in-network
Ratio of list prices to Medicare payment rates, by type of physician

For calendar year 2016 (source: USC-Brookings Schaeffer Initiative for Health Policy)

- **All physicians**: 239%
- **Emergency & ancillary physicians**:
  - Anesthesiology: 403%
  - Emergency medicine: 551%
  - Diagnostic radiology: 402%
  - Pathology: 343%
- **Other specialist physicians**:
  - Cardiology: 227%
  - Orthopedic surgery: 259%
  - General surgery: 248%
- **Primary care physicians**:
  - Family practice: 203%
  - Internal medicine: 203%
Reforming the Physician Self-Referral “Stark” Law

- HHS Deputy Secretary Eric Hargan spoke on administration’s efforts to modernize the Physician Self-Referral Law
- Regulatory reform is aimed at “impeding coordination among providers that can provide better, lower cost patient care”
- HHS plans to issue rule guidance this year to better accommodate health care delivery and payment changes that have taken place since the legislation’s passage.
Cannabis

- Only two countries (Uruguay and Canada) are legalized
- Canada is to the World what Colorado is to the US – has the sky fallen?
- Hemp paving the way to legalization?
- CBD for pain and ingredient in food….what will the FDA do?
Dramatis Personae

HHS
- Tom Price
- Alex Azar

FDA
- Scott Gottlieb
- Ned Sharpless

CMS
- Seema Verma

Administration
- Mike Pence
BALANCE OF POWER
### Scott Gottlieb

**Experience**
- ✔️ FDAer
- ✔️ Industry
- ✔️ Agent Provocateur
- ✔️ Finance
- ✔️ Policy
- ✔️ Patient

**Communications**
- ✔️ Twitter
- ✔️ Speeches

### Norman "Ned" Sharpless

**Experience**
- ❏ FDAer
- ❏ Industry
- ❏ Agent Provocateur
- ❏ Finance
- ❏ Policy
- ❏ Patient

**Communications**
- ❏ Twitter
- ❏ Speeches
Areas of Interests

Competition
- Generics
- NDAs

Technology
- Devices
- IT Linkage
INITIATIVES

- Offices of Excellence
- Opiate Task Force
- Inspectorate
- Clinical Trials Evolution
  - New methods/models
  - Real World Evidence
  - Big Data
  - Artificial Intelligence
Thank you

Questions?

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