2019 Community Oncology Conference

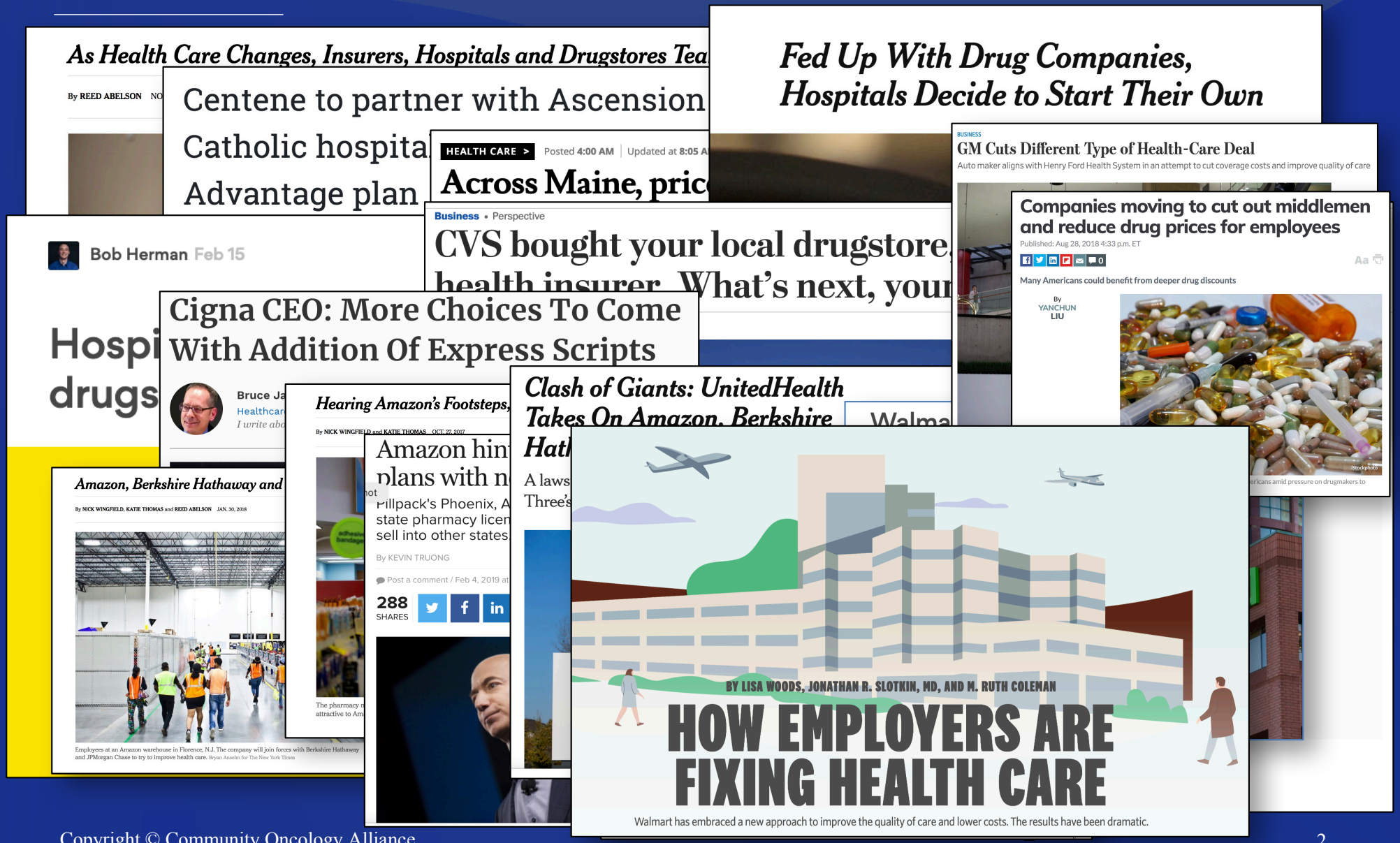
Ensuring quality, affordable & accessible cancer care

The Clash of DC Policy & Local Cancer Care

Politics vs. Reality

Ted Okon
Executive Director
Community Oncology Alliance

Healthcare Consolidation



Why This is Important

- Consolidation puts healthcare in the hands of big corporate for-profit and “nonprofit” entities
  - This takes medical decision making out of the hands of doctors and their patients
  - Costs have been shown to increase with consolidation, not decrease as promised
  - Healthcare becomes more “no nonsense” business rather than about people
- DC (Congress and the White House) trying to follow what is happening out there (away from the DC bubble)
  - This sets up a clash between DC politics and the reality of cancer care locally

What You Need to Know

- Healthcare changing like never before
  - Consolidation = profound impact on cancer care
  - Lines blurring between insurer and providers, especially pharmacy
- Lowering prescription drug prices (and costs) has become a political and media agenda – *like never before!*
  - Drug prices and companies in the crosshairs of Trump administration
  - Same holds true for Congress – both House (Democrat controlled) and Senate (Republican controlled)
- Need to score political victories can have a profound negative effect on cancer care
  - International Pricing Index (IPI) Model a perfect example
  - Giving insurers and PBMs more power to control medical decisions

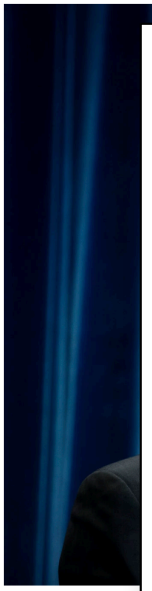
What is CVS???

- Medical Clinic
- Benefit Plan Sponsor
- PBM
- Insurer
- What Else?

- Specialty Pharmacy
- Drug Store
- Mail Order Pharmacy

Drug Prices in the Crosshairs

Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs

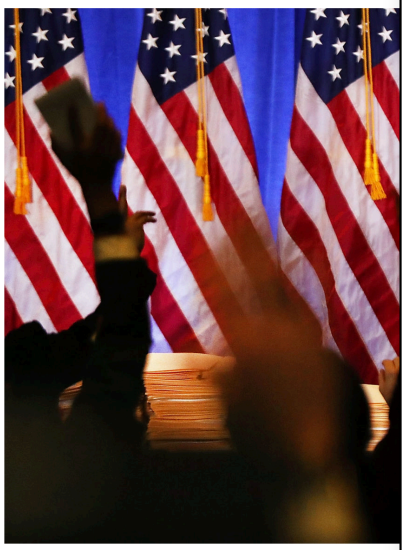


President Trump
and human servi

FIRST OPINION

Alex Azar: Why drug prices keep goin
up — and why they need to come dov

By ALEX M. AZAR II / JANUARY 29, 2019



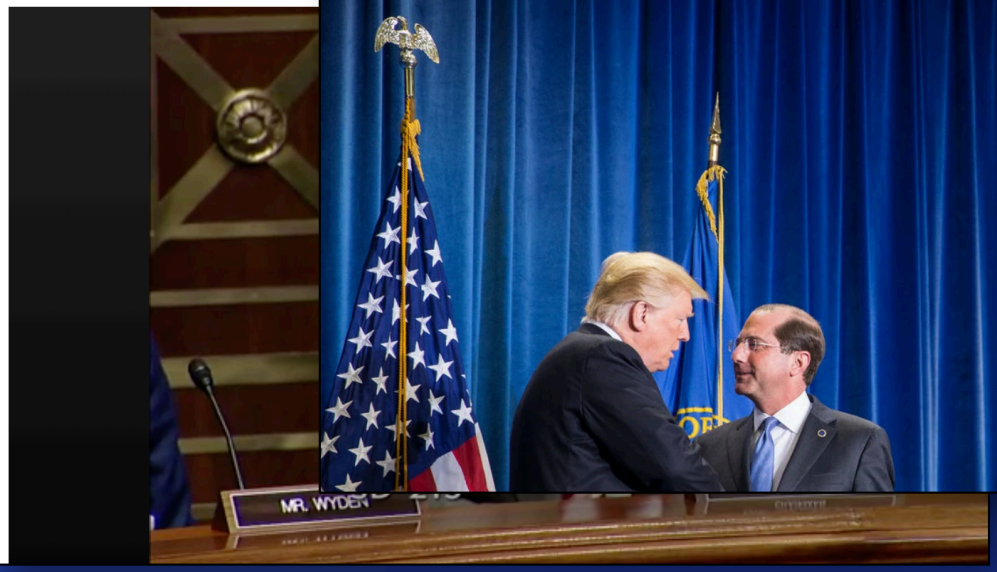
POLITICS

It's not just Democrats: In dueling drug pricing hearings, at least some Republicans slam pharma, too

By LEV FACHER @levfacher and NICHOLAS FLORKO @NicholasFlorko / JANUARY 29, 2019

Drug Pricing in Am

Date: Tuesday, January 29, 2019
Time: 10:15 AM
Location: 215 Dirksen Senate Office



The New York Times

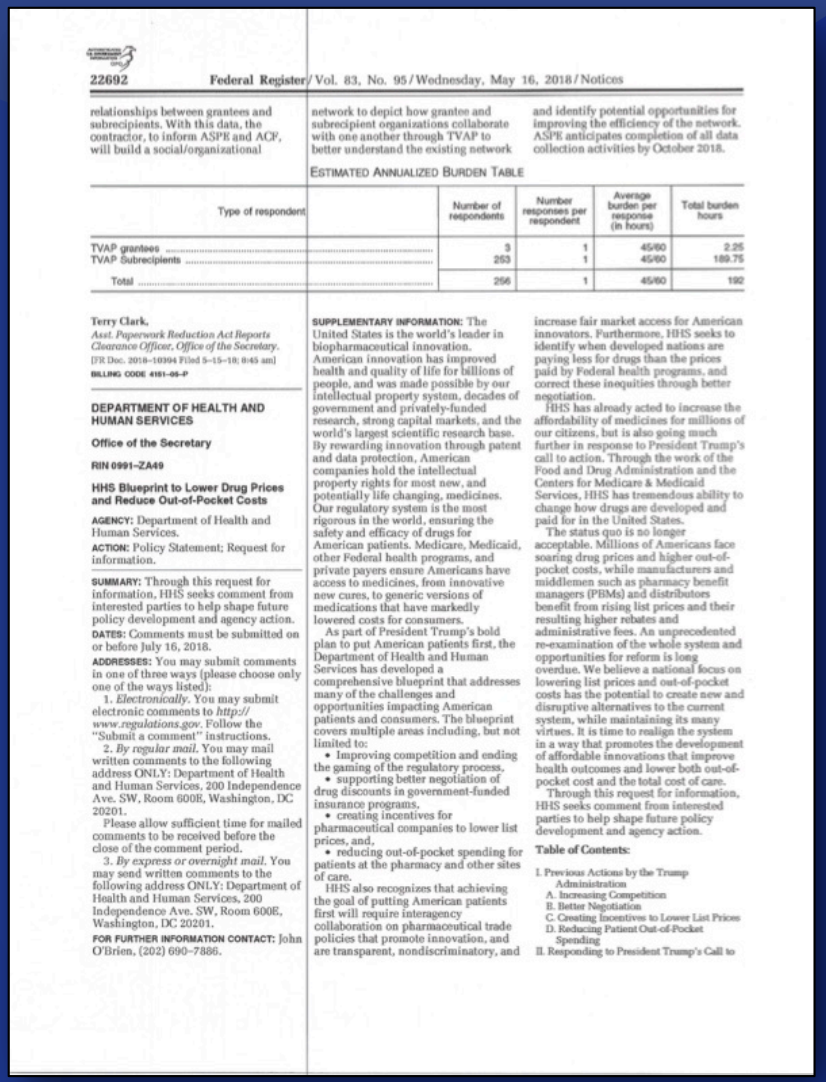
Trump Officials Move to Lower Drug Prices by Passing On Rebates to Patients

Where's the Drug Price Issue Going?

- Trump wants a "win" on drug prices and doesn't care about policy – *and I repeat this 3 times!!!*
  - So, HHS Sec. Azar needs a win on drug prices
- Medicare Part B is in the crosshairs like NEVER before – *and I repeat that 3 times!!!*
  - Giving MA plans ability to implement "fail first" (step therapy) and formularies
  - Back to "mandatory" demos — IPI is another Medicare Part B Experiment
  - Taking away protected classes
- Putting HUGE pressure on pharma companies
  - Both the administration and entire Congress
- Look for drug prices to be a HUGE election year issue

Trump Blueprint on Drug Prices

- Covered virtually every area of drug pricing except for direct government negotiating
- Posed 132 questions asking input on many aspects of drug pricing
- Regardless of media portrayal, pretty comprehensive



22692 Federal Register / Vol. 83, No. 95 / Wednesday, May 16, 2018 / Notices

relationships between grantees and subrecipients. With this data, the contractor, to inform ASPE and ACF, will build a social/organizational network to depict how grantee and subrecipient organizations collaborate with one another through TVAP to better understand the existing network and identify potential opportunities for improving the efficiency of the network. ASPE anticipates completion of all data collection activities by October 2018.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
TVAP grantees	3	1	45/60	2.25
TVAP Subrecipients	253	1	45/60	189.75
Total	256	1	45/60	192

Terry Clark,
Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
[FR Doc. 2018–10394 Filed 5–15–18; 8:45 am]
BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0991–ZA49

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

AGENCY: Department of Health and Human Services.

ACTION: Policy Statement; Request for information.

SUMMARY: Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

DATES: Comments must be submitted on or before July 16, 2018.

ADDRESSES: You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.
2. *By regular mail.* You may mail written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: John O'Brien, (202) 690–7886.

SUPPLEMENTARY INFORMATION: The United States is the world's leader in biopharmaceutical innovation. American innovation has improved health and quality of life for billions of people, and was made possible by our intellectual property system, decades of government and privately-funded research, strong capital markets, and the world's largest scientific research base. By rewarding innovation through patent and data protection, American companies hold the intellectual property rights for most new, and potentially life changing, medicines. Our regulatory system is the most rigorous in the world, ensuring the safety and efficacy of drugs for American patients. Medicare, Medicaid, other Federal health programs, and private payers ensure Americans have access to medicines, from innovative new cures, to generic versions of medications that have markedly lowered costs for consumers.

As part of President Trump's bold plan to put American patients first, the Department of Health and Human Services has developed a comprehensive blueprint that addresses many of the challenges and opportunities impacting American patients and consumers. The blueprint covers multiple areas including, but not limited to:

- Improving competition and ending the gaming of the regulatory process,
- supporting better negotiation of drug discounts in government-funded insurance programs,
- creating incentives for pharmaceutical companies to lower list prices, and,
- reducing out-of-pocket spending for patients at the pharmacy and other sites of care.

HHS also recognizes that achieving the goal of putting American patients first will require interagency collaboration on pharmaceutical trade policies that promote innovation, and are transparent, nondiscriminatory, and increase fair market access for American innovators. Furthermore, HHS seeks to identify when developed nations are paying less for drugs than the prices paid by Federal health programs, and correct these inequities through better negotiation.

HHS has already acted to increase the affordability of medicines for millions of our citizens, but is also going much further in response to President Trump's call to action. Through the work of the Food and Drug Administration and the Centers for Medicare & Medicaid Services, HHS has tremendous ability to change how drugs are developed and paid for in the United States.

The status quo is no longer acceptable. Millions of Americans face soaring drug prices and higher out-of-pocket costs, while manufacturers and middlemen such as pharmacy benefit managers (PBMs) and distributors benefit from rising list prices and their resulting higher rebates and administrative fees. An unprecedented re-examination of the whole system and opportunities for reform is long overdue. We believe a national focus on lowering list prices and out-of-pocket costs has the potential to create new and disruptive alternatives to the current system, while maintaining its many virtues. It is time to realign the system in a way that promotes the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care.

Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

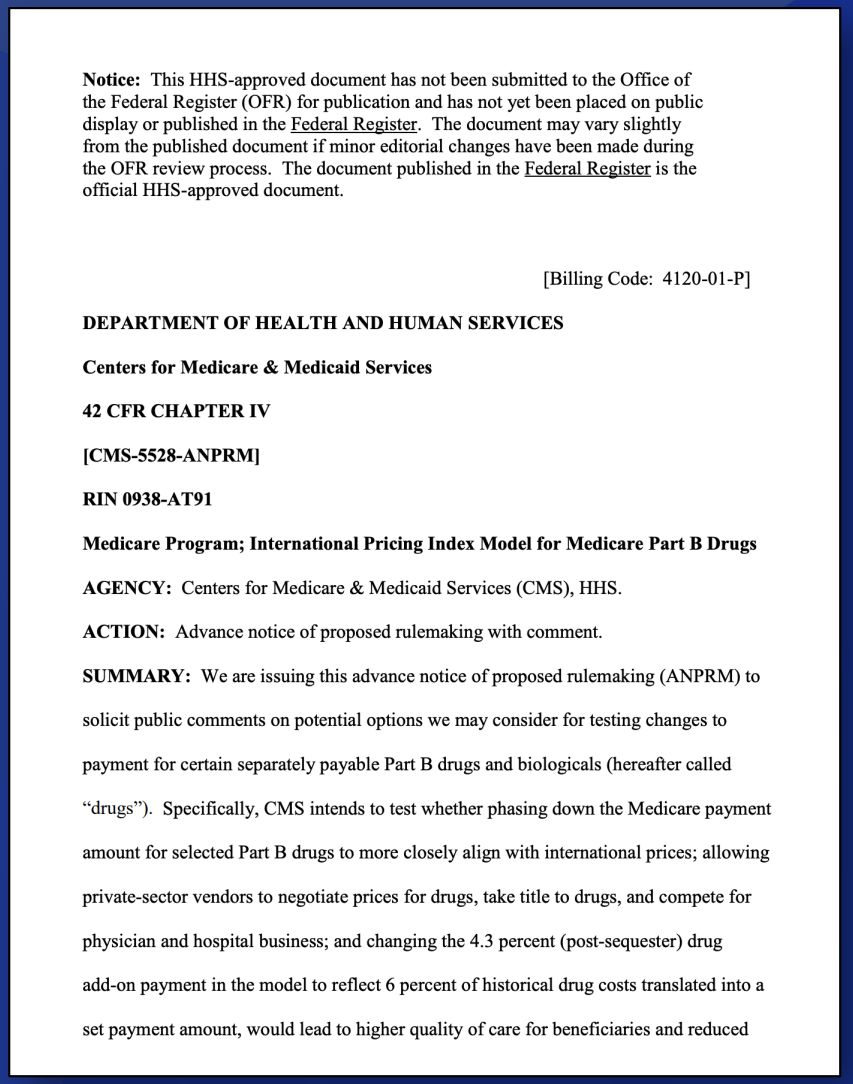
Table of Contents:

Blueprint Goals

- Increase drug competition
  - Speed generic, biosimilar, and brand approvals
- Fix “global freeloading”
- Change Medicare Part B
  - Move Part B drugs to Part D
  - Revive the Competitive Acquisition Program (CAP)
- Fix 340B
  - Move reimbursement closer to true drug acquisition cost
  - Tie 340B to charity care
- Reimburse MD practices and hospitals the same
- Address PBM situation, especially rebates
- Facilitate manufacturer value-based contracting
- Drug price transparency

International Pricing Index Model

- Index Medicare Part B drug prices to market basket of other countries
- CAP for 50% of the country in a mandatory CMMI demo
  - "Private sector" entities to negotiate with drug manufacturers and distribute drugs
- Add on of a flat fee equal to historical ASP + 6%



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[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR CHAPTER IV

[CMS-5528-ANPRM]

RIN 0938-AT91

Medicare Program; International Pricing Index Model for Medicare Part B Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Advance notice of proposed rulemaking with comment.

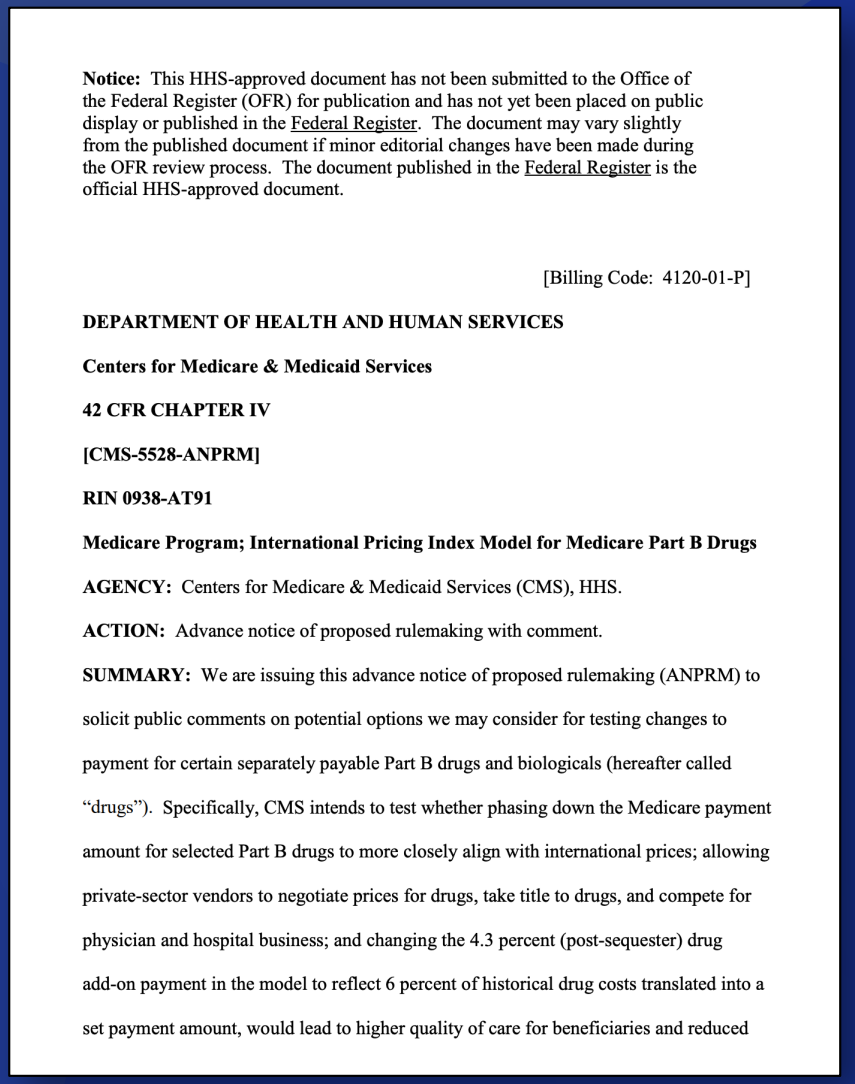
SUMMARY: We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals (hereafter called "drugs"). Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced

10

International Pricing Index Model

International Pricing Index Model

- Index Medicare Part B drug prices to market basket of 14 OECD countries
  - Target is a 30% decrease in Part B drug prices
  - Create a blend of the index target price and ASP
    - Starts at 80% of ASP and 20% of the index price moving towards 100% index after 5 years



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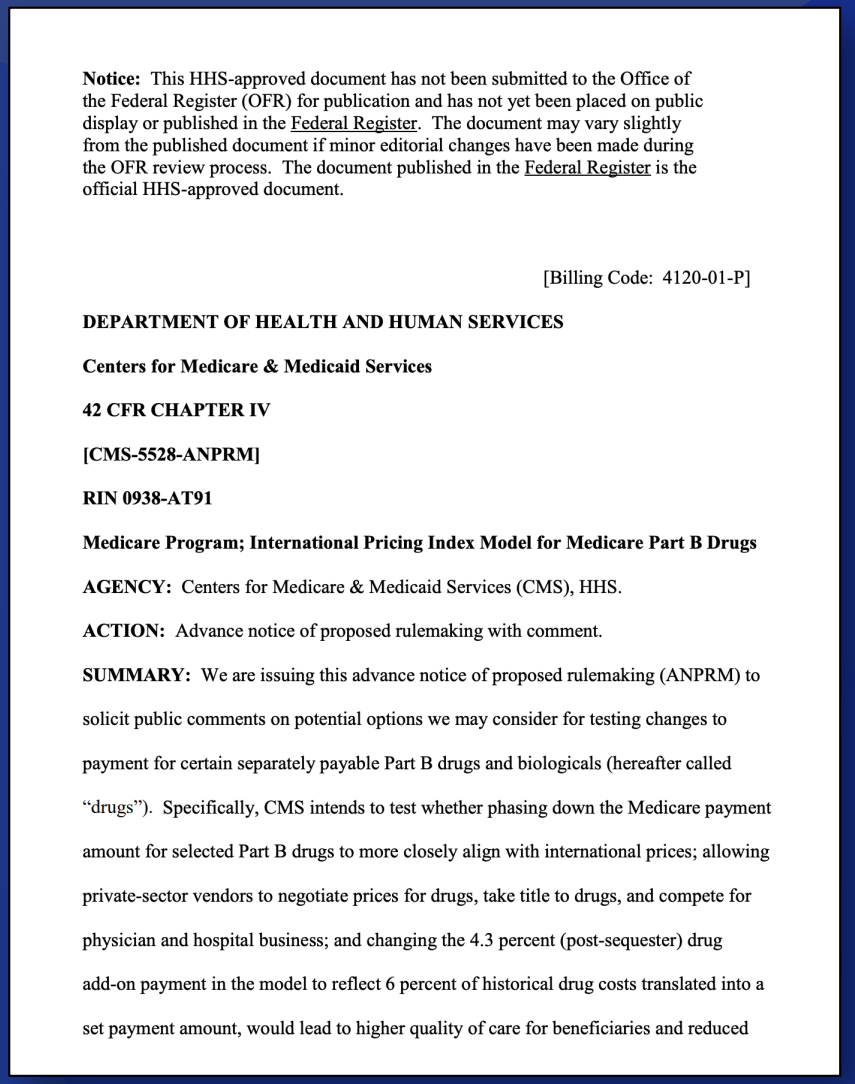
International Pricing Index Model

- Revive the previously-failed Competitive Acquisition Program (CAP)
  - Force physicians and hospitals to stop purchasing/billing drugs
  - Would have to deal with a CAP vendor(s)
  - CAP vendor would "negotiate" with drug manufacturers based on the ASP/index price
  - CAP vendor would bill Medicare for drug; providers would bill patients copay



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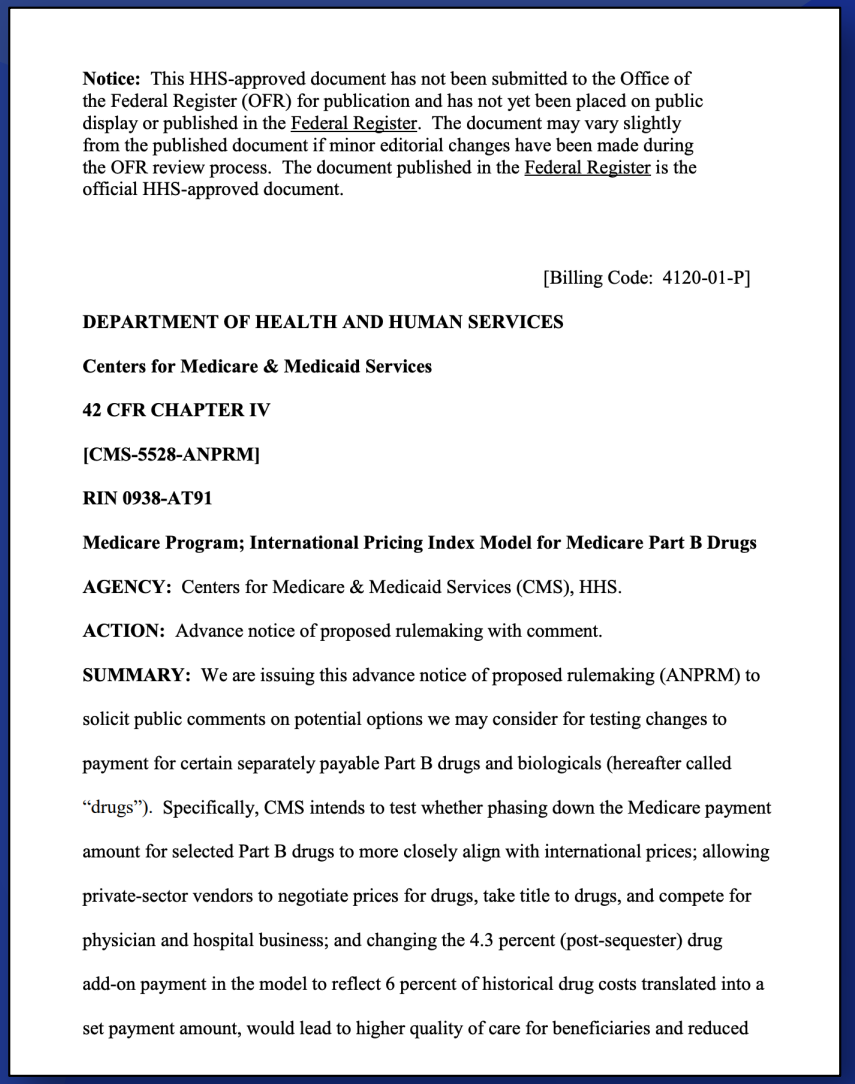
International Pricing Index Model

- Pay providers a flat fee based on the historical add-on to ASP
  - Providers would not take title to the drug but would still be responsible for collecting the 20% patient copay



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IPI: What's Wrong?

- Indexing U.S. drug prices to foreign prices sounds great on paper but how do you really do it without other countries playing games?
  - And more cancer drugs available here than in any other country
- Biggest problem is CAP
  - It would fundamentally change how cancer patients get their drugs
  - It would change from just-in-time delivery of chemotherapy to ordering and waiting for chemotherapy from some middleman
- Changing cancer drug reimbursement would put even more pressure on community oncology practices, forcing more closures and consolidation into hospitals

340B and Payment Site Neutrality

Public Health & Policy > Medicare

Site Neutral Payment, 340B Payment Cuts Raise Hospitals' Hackles

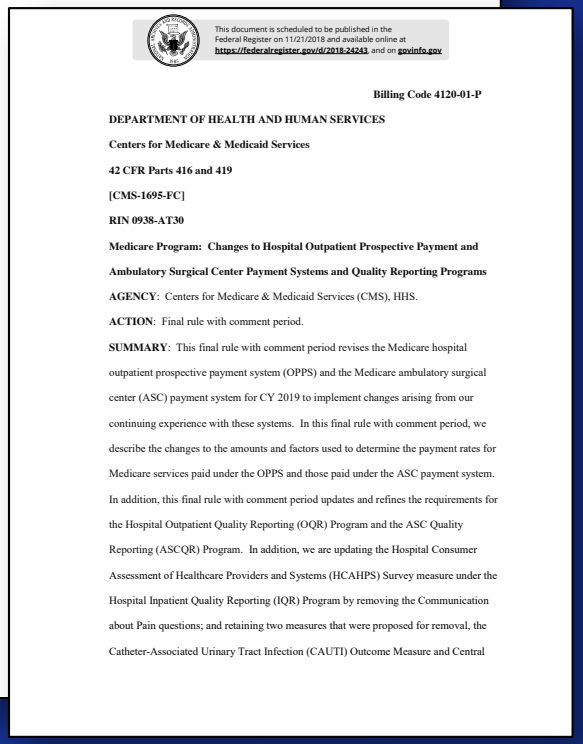
— Outpatient Prospective Payment System rule released Friday

by Shannon Firth, Washington Correspondent, MedPage Today

November 02, 2018

WASHINGTON -- The Centers for Medicare & Medicaid Services (CMS) released two final rules that aim to narrow the difference between payments rates for hospital outpatient services and those provided in ambulatory surgical centers. The agency said the proposed changes would spur competition, lower costs for seniors, and "create a level playing field for providers."

In the final Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (ASC) Payment Systems rules released Friday, CMS also increased 340B drug program cuts by expanding them to off-campus outpatient sites, triggering immediate threats of lawsuits.



This document is scheduled to be published in the Federal Register on 11/21/2018 and available online at https://federalregister.gov/d/2018-24243, and on govinfo.gov

Billing Code 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS-1695-FC]

RIN 0938-AT30

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

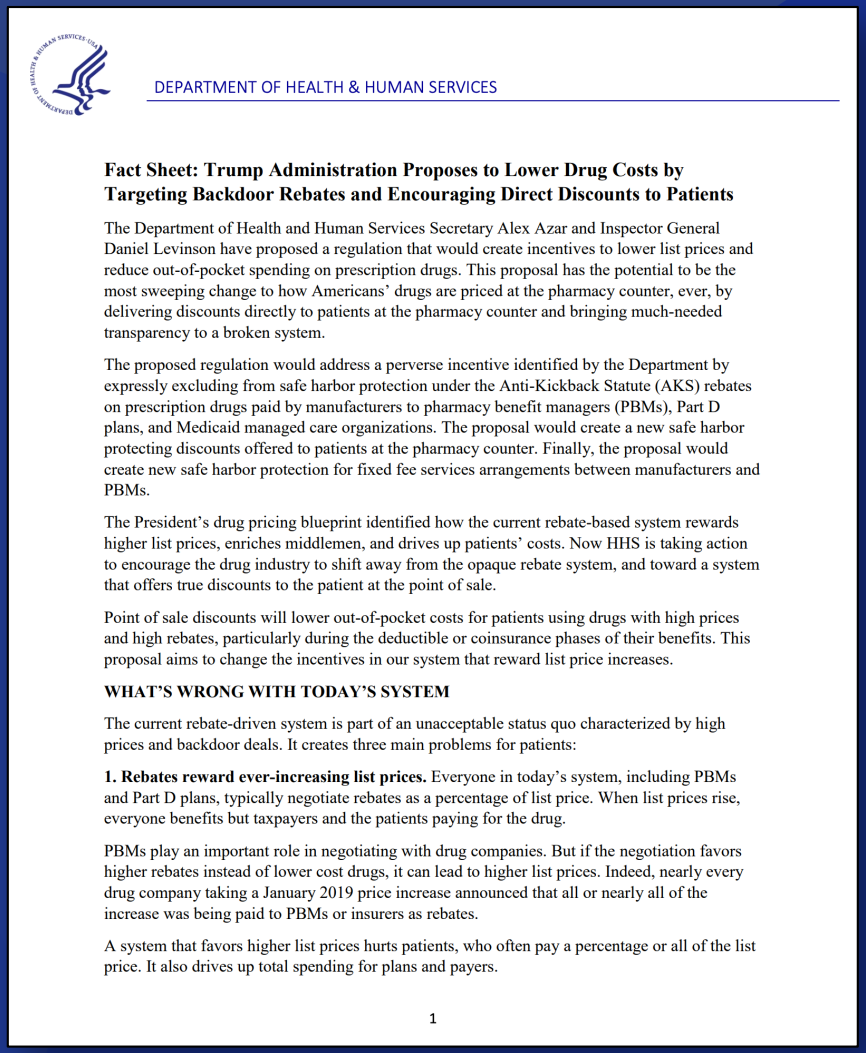
SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, we are updating the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by removing the Communication about Pain questions; and retaining two measures that were proposed for removal, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and Central

The Middleman Dilemma

- A “middleman” is just that – an entity that gets between doctor and patient
- Middlemen are insurance companies and pharmacy benefit managers (PBMs)
  - Insurers typically manage the “medical” benefit
    - Both commercial insurance and Medicare Advantage plans
  - PBMs manage the “pharmacy” benefit
  - Now, they are all merging!
- On one hand, the Trump administration wants to take away the PBM/insurer rebates that are fueling higher drug prices
- On the other hand, the Trump administration wants to give the PBMs/insurers more power over cancer care

Eliminate PBM Rebates

- Proposed rule would effectively eliminate PBM rebates from Medicare/Medicaid
- Manufacturers could provide discounts directly to patients
- Eliminates manufacturers' claim that rebates drive up list prices of drugs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients

The Department of Health and Human Services Secretary Alex Azar and Inspector General Daniel Levinson have proposed a regulation that would create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs. This proposal has the potential to be the most sweeping change to how Americans' drugs are priced at the pharmacy counter, ever, by delivering discounts directly to patients at the pharmacy counter and bringing much-needed transparency to a broken system.

The proposed regulation would address a perverse incentive identified by the Department by expressly excluding from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations. The proposal would create a new safe harbor protecting discounts offered to patients at the pharmacy counter. Finally, the proposal would create new safe harbor protection for fixed fee services arrangements between manufacturers and PBMs.

The President's drug pricing blueprint identified how the current rebate-based system rewards higher list prices, enriches middlemen, and drives up patients' costs. Now HHS is taking action to encourage the drug industry to shift away from the opaque rebate system, and toward a system that offers true discounts to the patient at the point of sale.

Point of sale discounts will lower out-of-pocket costs for patients using drugs with high prices and high rebates, particularly during the deductible or coinsurance phases of their benefits. This proposal aims to change the incentives in our system that reward list price increases.

WHAT'S WRONG WITH TODAY'S SYSTEM

The current rebate-driven system is part of an unacceptable status quo characterized by high prices and backdoor deals. It creates three main problems for patients:

1. Rebates reward ever-increasing list prices. Everyone in today's system, including PBMs and Part D plans, typically negotiate rebates as a percentage of list price. When list prices rise, everyone benefits but taxpayers and the patients paying for the drug.

PBMs play an important role in negotiating with drug companies. But if the negotiation favors higher rebates instead of lower cost drugs, it can lead to higher list prices. Indeed, nearly every drug company taking a January 2019 price increase announced that all or nearly all of the increase was being paid to PBMs or insurers as rebates.

A system that favors higher list prices hurts patients, who often pay a percentage or all of the list price. It also drives up total spending for plans and payers.

1

Step Therapy & Protected Classes

- MA plans given the authority to apply step therapy to Part B drugs
  - One goal is to reduce drug costs through “fail first” utilization of least expensive drug
  - Second objective is to give MA plans power to negotiate down drug prices
- “Fail first” drug is not necessarily the least expensive drug but the most profitable drug for the PBM/insurer
- Eliminating protected classes

Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs

Aug 07, 2018 | Leadership, Medicare Part C, Medicare Parts A & B, Prescription drugs

Share

Today, the Centers for Medicare & Medicaid Services (CMS) introduced much-needed competition and negotiation into the market for physician-administered and other Part B medications that will result in better deals and lower drug costs for patients. As part of the agency’s ongoing activities to deliver on President Trump’s promises outlined in his American Patients First Blueprint, CMS will provide Medicare Advantage plans the option of applying step therapy for physician-administered and other Part B drugs in a way that lowers costs and improves the quality of care for Medicare beneficiaries. Medicare Advantage (MA) plans will have the choice of implementing step therapy to manage Part B drugs, beginning January 1, 2019 as part of broader care coordination activities that include patient rewards and incentives. Currently, there are more than 20 million beneficiaries enrolled in MA plans.

What is Step Therapy?

Step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions. For example, using step therapy plans could ensure that a senior who is newly diagnosed with a condition begin treatment with a cost-effective biosimilar before progressing to a more costly drug therapy should the initial treatment is ineffective. By implementing step therapy along with care coordination and drug adherence programs in MA, it will lower costs and improve the quality of care for Medicare beneficiaries.

PBM Horror Stories

COA's Efforts

- Detailed meetings with CMS and HHS
  - Pushing back on IPI model
  - Providing alternatives
- Working with Congress to fix PBM issues
- Launching major campaign to highlight PBM abuses
- Working hard on oncology payment reform

Senate Hearing on PBMs

THE HILL

Senate panel to hear from pharmacy middlemen on drug prices

BY NATHANIEL WEIXEL - 03/21/19 12:44 PM EDT

15 COMMENTS

© Stefani Reynolds

The Senate Finance Committee said Thursday that it has secured commitments from executives of five major pharmacy benefit managers (PBMs) to testify next month about the high costs of prescription drugs.

Thanks!

- Ted Okon
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