

What's Up With Drug Pricing?

Mark E. Thompson, M.D. Medical Director for Public Policy, COA

Ohio Hematology Oncology Society Annual Meeting October 11, 2019

Let's Frame the Issue



- Increasing drug prices for antineoplastic drugs are rapidly escalating and unsustainable
- New and more effective agents are expanding in use and expensive
- Consolidation in health care is rapidly occurring with increasing costs
- Cancer care is now moving from a localized service-based business to "BIG" business
- PBMs and rebates are driving up the costs of drugs
- 340B growth is driving up drug costs

Oncology Drug Cost Trends



- In 2018, two-thirds of the growth in U.S. oncology costs in the previous five years could be attributed to the uptake of innovative medicines launched since 2013 (2018 IQVIA)
- Oncology immunotherapy costs are projected to increase 231% from 2016 to 2021 (2018 Magellan)
- Oncology accounted for 35% of commercial medical pharmacy spend in 2016 (2018 Magellan)
- Commercial market per-member, per-year spend for oncology drugs increased by 18.1% from 2017 to 2018, making oncology the therapy class with greatest cost increase (2018 Express Scripts)
- Oncology agents accounted for 10 of the top 25 drugs by spend in the commercial medical benefit in 2017 (2018 Magellan)
- Oncology and oncology support accounted for 43% of the medical benefit drug per-member, per-month spend in the commercial market in 2017 (2018 Magellan)

Drug Prices/Costs in Perspective

NUTY ON COLOCY

- New drugs launched in the last five years now account for more than 20% of global oncology spending (2017 Quintiles)
- While total cancer care costs increased about 60% for commercially insured cancer patients between 2004 and 2014, spending on cytotoxic and biologic chemotherapies grew by 101% and 485% (2016 Milliman)

 "Increased spending is the result of higher drug prices, greater use of high-priced drugs, and an increase in the proportion of chemotherapy infusions being done in hospital outpatient settings, which is generally more expensive than administering drugs in physicians' offices." (President's Cancer Panel)

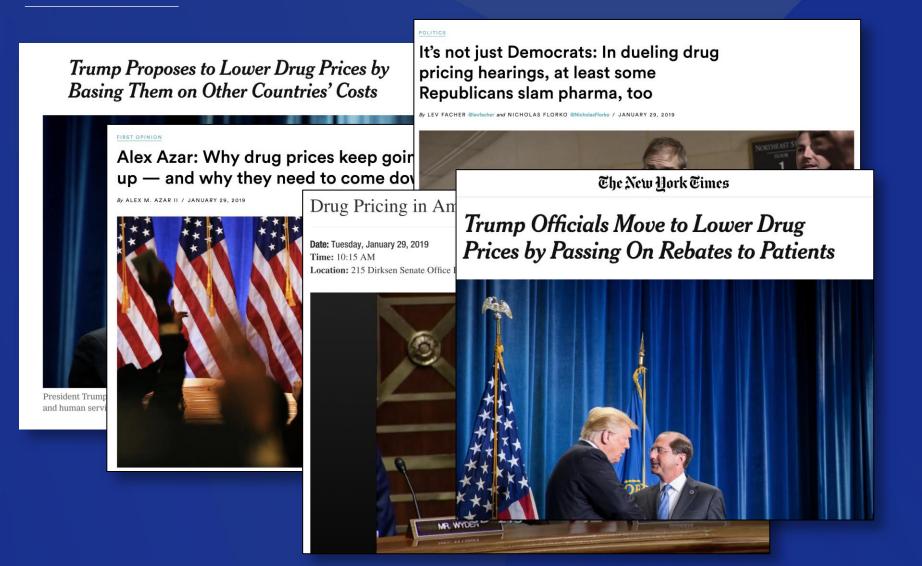


Here's the Environment!

- Health care is 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

Drug Prices in the Crosshairs







So What's Up in D.C. Regarding Drug Prices?

- There are currently more than 20 bills in Congress regarding drug pricing issues
- The President's Blueprint for drug pricing has influenced the environment
- The proposed IPI Model remains looming, yet not finalized
- Both Republicans and Democrats have an appetite to enact meaningful legislative fixes
- It is likely given the current D.C. climate that NOTHING of substance gets legislated this year



What Does the Legislation Look Like?

- S2543 Prescription Drug Pricing Reduction Act of 2019 -Senate Finance proposal
- HR 3 Lower Drug Costs Now Act of 2019 House Democrat's proposal - May pass the House
- S1227- Prescription Pricing for the People Act of 2019 -Senate Judiciary Committee - everyone wants a piece
- REFUND Act of 2019 Senators Portman & Durbin's Bill
- Various bills regarding PBM's and rebates

Politics Versus Reality



Bipartisan interest in tackling drug prices

- Progressive Dems want "Medicare For All" and complete negotiation of drug prices vs moderates
 - Ironic in that Republicans want to do something but split among Democrats may stop getting something done
- Democrats starting to spar with each other that and ideological split makes moving forward tough
- Big focus right now among the Democrats is impeachment
 - Makes working with the Republicans harder
- The closer we get to 2020 a major election year Congress will likely grind to a halt

Where's the Drug Price Issue Going in D.C.?

- Trump wants a "win" on drug prices and doesn't care about policy. Democrats want a "win" as well. Neither want to credit the other in this space.
 - So, HHS Sec. Azar needs a win on drug prices
- Medicare Part B is in the crosshairs again a theme that never quits
 - Giving MA plans ability to implement "fail-first" (step therapy) and formularies
 - Using "mandatory" demos under the Medicare "Innovation Center" to change reimbursement
 - Proposed taking away protected classes (cancer is one of six protected classes)
 - But backed away from it!
- Recently passed (out of committee) Senate Finance drug pricing bill puts price inflation caps on Part B and D drugs, among other provisions
- Speaker Pelosi's HR 3 drug pricing Bill in the House also has caps
- 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 negotiation of drug prices in Medicare
- Posed 132 questions asking input on many aspects of drug pricing
- Regardless of media and political portrayal, most comprehensive blueprint ever



American Patients First

The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

MAY 2018





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 physician practices and hospitals the same
- Address PBM situation, especially rebates
- Facilitate manufacturer value-based contracting
- Drug price transparency

relationships between grantees and subrecipionts. With this data, the contractor, to inform ASTE 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 ESTIMATED ANNUALIZED BURDEN TABLE		and identify potential opportunities for improving the efficiency of the network. ASPR anticipates completion of all data collection activities by October 2018.			
Type of respondent		Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours	
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Where's the IPI Model?



Waiting for the final rule from CMS/HHS

- CMS/HHS moved it to OMB for a "possible" August 2019 release of the proposed rule that never came to be
- Some speculate it may not be released anytime soon, or at all
 - Lots of pushback on the indexing of drugs to international prices (can it even be operationalized?)
 - Apparently, not a lot of takers on CAP (at least in a version that doesn't totally disrupt providers' operations)
 - ASP flat add-on fee being looked at by Congress, possibly as part of bipartisan drug pricing legislation, however the recent Senate Finance package failed to tackle this piece

IPI Model: 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?
 - Problem comparing other countries' net prices to U.S. list prices
 - More cancer drugs available here than in any other country
- CAP- a big problem
 - 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

"Old School" Strategies/Tactics Not Working

- NUTY ON COLOCY
- Using middlemen PBMs, insurers, etc. to "manage" cancer care drug spending through centralized decision making and rationing
 - Prior authorizations
 - Formularies
 - "Fail-first" step therapy
 - Copayment tiers
- Largely focused on drugs, leaves out other drivers of cancer care costs
- Not patient-centric and not focused on value (quality delivered for the cost)

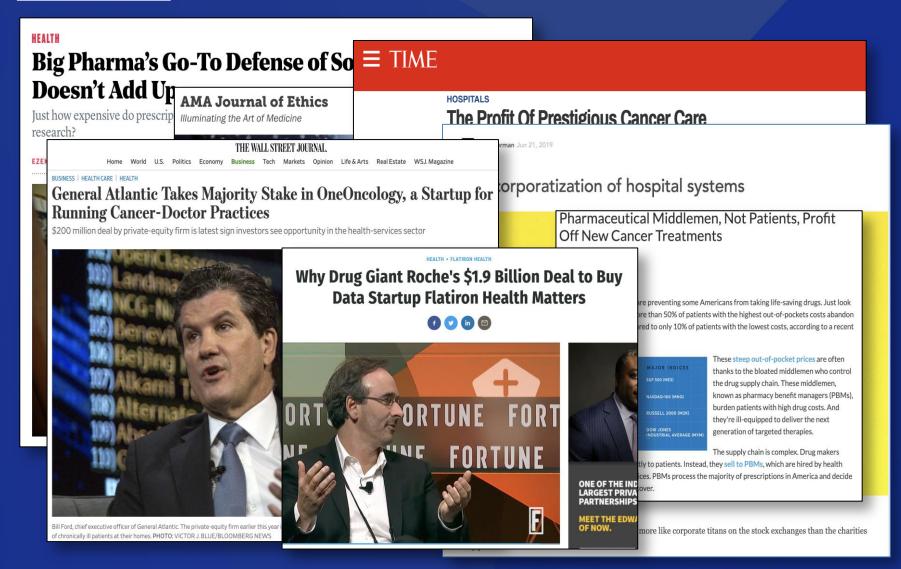


Let's Look at Some Drivers of Drug Pricing

- Health care consolidation
- Pharmacy Benefit Managers (PBMs)
- 340B Drug Pricing Program

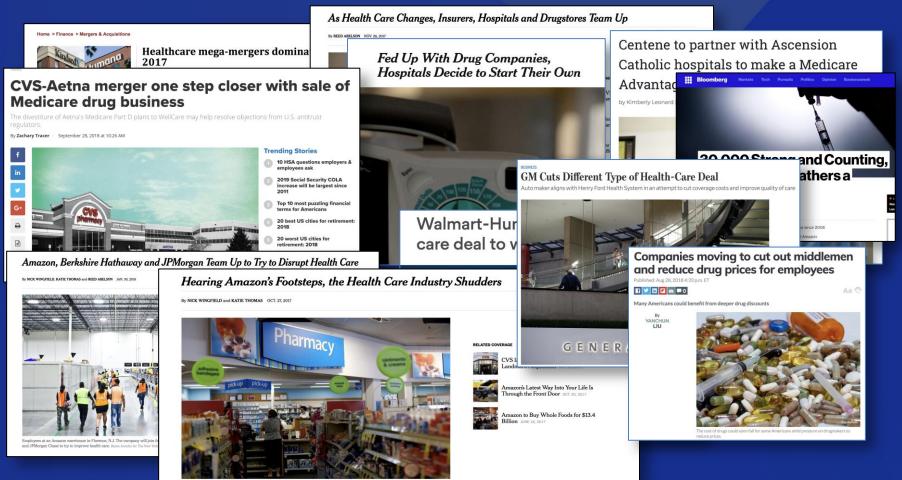
Cancer is Big Business!





Health Care Consolidation





The pharmacy market, with huge amounts of consumer spending and frustrating inefficiencies, could be attractive to Amazon. Mario Amazoni/Reuters

The Site of Cancer Care Matters



PROGNOSIS PROFITS Prices soar as hospitals dominate cancer market ALEXANDER, KAREN GARLOCH & JOS<u>EPH NEEE - AALEXANDER@CH</u>ARLOTTEORSERVER CO KGARLOCH@CHARLOTTEOBSERVER.COM HEALTH CARE > Posted 4:00 AM Updated at 8:05 AM APRIL 22, 2015 12:14 AM, UPDATED APRIL 23. Across Maine, prices for the often staggeringly different Large nonprofit hospitals in No drugs at a time when they are c Low patient volumes and scarce competition among pro-THE NEW HEALTH CARE Observer and The News & Obs for health care in the U.S. Hospital Mergers Improve Health? The newspapers found hospital BY I. CRAIG ANDERSON STAFF WRITER **Evidence Shows the Opposite** over cost. Some markups are fa Share 🚹 У 😚 🛅 🗹 🛱 It's happening as hospitals incr offer better care. more - sometimes much more Asked about the findings, hosp **By Austin Frakt** more for some services to make shifting. Feb. 11. 2019 you live and work. does so as well.

COSTS & SPENDING

By Zack Cooper, Stuart Craig, Martin Gaynor, Nir J. Harish, Harlan M. Krumholz, and John Van Reenen

Hospital Prices Grew Substantially Faster Than Physician Prices For

The New Hork Times

The claim was that larger organizations would be able to harness economies of scale and

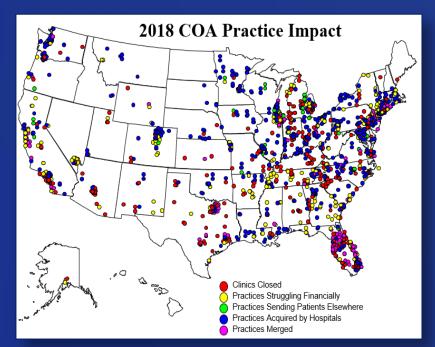
Many things affect your health. Genetics. Lifestyle. Modern medicine. The environment in which

But although we rarely consider it, the degree of competition among health care organizations

Markets for both hospitals and physicians have become more concentrated in recent years. Although higher prices are the consequences most often discussed, such consolidation can also result in worse health care. Studies show that rates of mortality and of major health setbacks grow when competition falls.

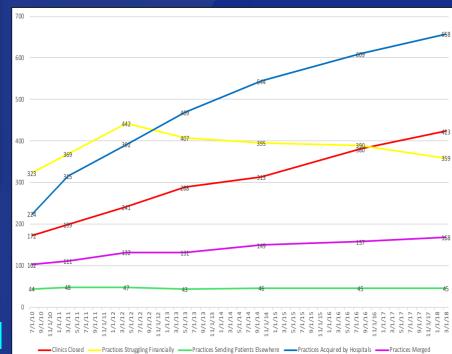
Cancer Care Consolidating



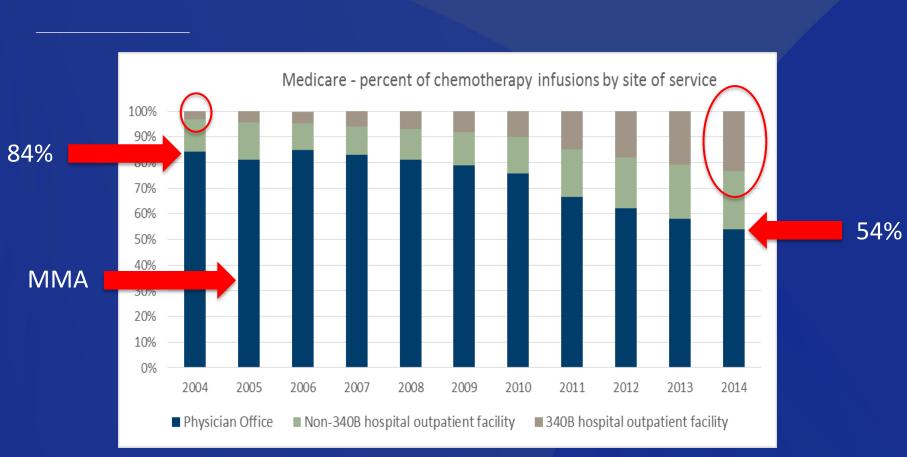


- 11.3% increase in closings, 8% increase in consolidations since 2016 report
- Full report: CommunityOncology.org

1,654 clinics and/or practices closed, acquired by hospitals, merged, report financial struggles from 2008-2018



Shifting Site of Cancer Care Delivery



Percent of chemotherapy administered in community oncology practices decreased from 84.2% to 54.1%

Percent of chemotherapy administered in 340B hospitals increased from 3.0% to 23.1% (670% increase)

340B hospitals account for 50.3% of all hospital outpatient chemotherapy administrations

Source: Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014, Milliman, April 2016



The PBM Problem

- PBMs have a vested interest to use <u>the most profitable drug for</u> <u>them</u>, even if it's the highest priced drug
 - Rebates are based on drug list prices (higher the better)
 - DIR fees (and similar pharmacy concessions) are based on drug list prices (the higher the better)
 - Documented increasing gap between list and true net drug prices
- Problem is that rebates (and pharmacy concessions) may not be passed onto payers and beneficiaries (paying off of list prices)
- PBMs increasingly narrowing networks and requiring use of corporate specialty/mail pharmacies
 - Delays, denials, mistakes & waste increasing

The PBM Problem (continued)

PBMs driving up drug and insurance prices, critics

Invisible Middlemen Are Slowing Do

PBM and hiring Express Scripts to act in its place.

Pharmacy benefit managers under scrutiny for their role



UnitedHealthcare Network Bulletin May 2019

Table of Contents

Front & Center

Updates to Requirements for Specialty **Medical Injectable Drugs for UnitedHealthcare Commercial and Community Plan**

We're making some updates to our requirements for certain specialty medications for many of our UnitedHealthcare commercial and Community Plan members. These requirements are important to provide our members access to care that's medically appropriate as we work toward the Triple Aim of improving health care services, health outcomes and overall cost of care. These requirements will apply whether members are new to therapy or have already been receiving these medications.

What's Changing for UnitedHealthcare **Community Plan**

Spravato[™] has been added to the Review at Launch Drug List for UnitedHealthcare Community Plan. This list is located at UU s-protocols/ mmedicaid-policies/medicaid-co -policies.html through the Review at Laur Market Medications drug policy.

What's Changing for UnitedHealthcare **Commercial and Community Plan Members**

Clinical Policy and Prior Authorization Updates

Effective July 1, 2019, our White Blood Cell Colony timulating Factors medical drug policy will be updated clude preferred product coverage criteria. Prefe requage will be added as follows: prod

· Use of Net sta® vial prior to the use of Fulphila™ and Udenyca™

In addition to the preferred product changes to the drug policy, UnitedHealthcare commercial plans will be expanding the current prior authorization requirements on these medications to include use for any diagnosis:

 Neulasta Onpro/Neulasta, Fulphila, and Udenyca currently require prior authorization when used to treat a cancer diagnosis.

 On July 1, 2019, for UnitedHealthcare commercial plans (including affiliated plans for Oxford, UMR and Neighborhood Health Partnership) use of these medications for all diagnoses will require prior authorization with this policy change.

 On Aug. 1, 2019, for UnitedHealthcare affiliate plans UnitedHealthcare of the Mid-Atlantic and UnitedHealthcare of the River Valley, use of these medications for all diagnoses will require prior authorization.

For both UnitedHealthcare commercial and Community Plan members, current authorizations will be honored through their end date. Upon authorization renewal, the updated policy will apply. Care providers are encouraged to begin using the preferred Colony Stimulating Factor products.

If you administer any of these medications without first completing the notification/prior authorization process, the claim may be denied. Members can't be billed for services denied due to failure to complete the notification/prior authorization process.

Health Care Nurses spend 16 hours patients suffer as they w OLGA KHAZAN APR 9, 2019 Iune 10, 2019 Marion Bradley, 57, filling a p is the lead pharmacist and co

HEALTH

choose what drugs are determine co-pays for and decide how much

HEALTH :: by CHRISTOPI

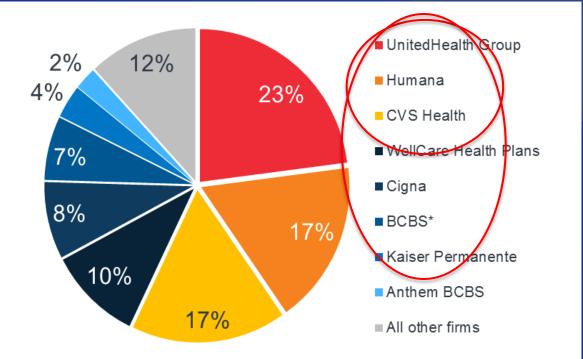


8 | For more information, call 877-842-3210 or visit UHCprovider.com.



Consolidation in Medicare Part D





Three companies control almost 60% of Medicare Part D

Six companies control over 80% of Part D

Total Part D Enrollment in 2019 = 44.9 million

Source: KFF analysis of Centers for Medicare & Medicaid Services 2019 Part D plan files

PBMs Impacting Real Lives



LOCAL

Cancer patients are being denied drugs, even with doctor prescriptions and good insurance

BY CARMEN GEORGE

managers

AUGUST 02, 2019 06:40 AM, UPDATED AUGUST 0

Smith's story is "an example of how bad things can get" for cancer patients who require different medications than what pharmacy benefit managers consider standard protocol.





Cancer patient Norma Smith and husband Ro Specialty Pharmacy in trying to secure prope

"My husband would call and be on the phone for five and six hours trying to advocate for me," Smith said, "trying to find out how he could work the system so he could get the needed drug for me so that I would live.

"I'm a human being. I'm not a used car. I have feelings. I'm a person. I want to live. I want to spend time with my grandchildren. I want to quilt. I want to do things. I want to live."

The 340B Problem



- About one-third of all outpatient volume for certain types of cancer treatments is now at 340B hospitals (2017 Berkely Research Group)
 - 30% of Medicare Part B reimbursements were at 340B hospitals in 2017 (2017 Berkely Research Group)
 - In 2017, 340B covered entities purchased more than \$19 billion in drugs, a 114% increase since 2014 (2017 Berkely Research Group)
- 340B discounts increasing in both scope and magnitude
 - Incentives for 340B hospitals to consolidate cancer care to the more expensive setting
 - Drives up the cost of cancer care
 - Pharma/bio companies' factor 340B discounts into launch prices
 - Discounts are so large in scope and magnitude that they fuel drug prices
 - Discounts don't typically get passed on to patients or shared with payers

340B: Higher Cancer Care & Drug Costs

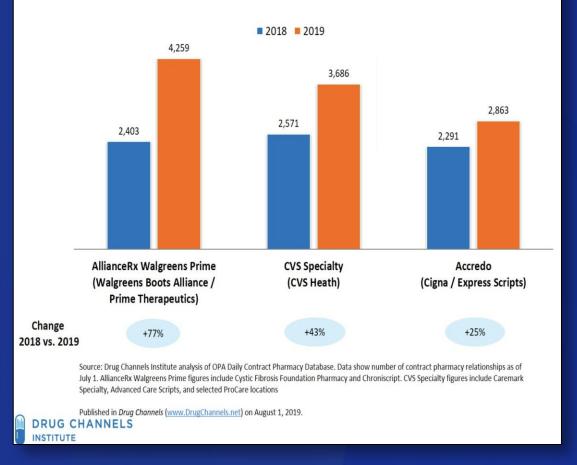




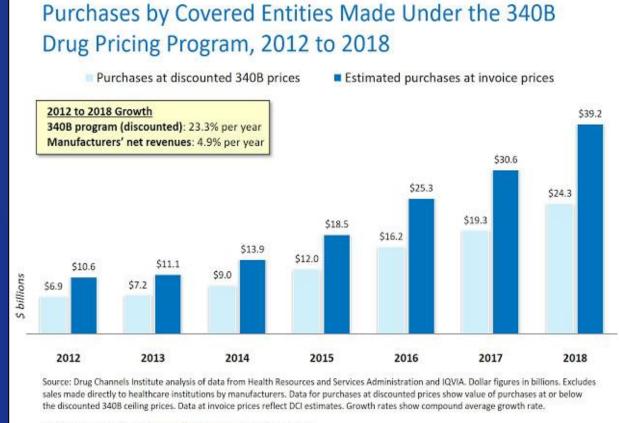
Source: The Oncology Drug Marketplace: Trends in Discounting and Site of Care, Berkeley Research Group, December 2017

PBMs More Active in 340B Covered Entities

Contract Pharmacy Relationships with 340B Covered Entities, by Specialty Pharmacy, 2018 vs. 2019



340B: Increasing Scope & Magnitude



Published on Drug Channels (www.DrugChannels.net) on May 14, 2019.

DRUG CHANNELS

Source: 340B Program Purchases Reach \$24.3 Billion—7+% of the Pharma Market—As Hospitals' Charity Care Fluctuates, Drug Channels, May 2019

ALLIANCE

What Happens Overall in 2019?

- PROBABLY NOTHING of substance in 2019!!!
- Likelihood of more bills relating to drug pricing/costs passing Congress
 - Not likely given the current environment and focus on impeachment
- There is increasing focus by Congress on PBMs
 - More bills coming but not clear what can pass
 - Think greater focus will be at the state level which could influence federal policy

The closer we get to 2020 – a major election year Congress will likely grind to a halt

COA's Efforts



Detailed meetings with CMS & HHS

- Pushing back on IPI Model
- Providing alternatives
- Working with Congress to fix PBM problems
- Suing the government over the sequester to drug reimbursement
- Working hard on oncology payment reform
- Only advocacy organization solely devoted to community based cancer care





COA's Efforts (cont'd)



PBM Abuses Campaign (www.PBMAbuses.org)

- OCM 2.0 CMMI demonstration project
- Continued advocacy on key issues
- Regularly scheduled Hill Days as well as ad hoc days when needed
- Creation of a standing Government Affairs and Policy Committee
- Creation of Position Statements to highlight COA's position on key issues - available on COA's website (CommunityOncology.org)

ALLIANCE

COA's Efforts (cont'd)

 Comment letters on MPFS, HOPPS, Mandatory Radiation Oncology Payment Model

- Comments on "Patients over Paperwork" RFI
- Community Oncology Pharmacy Association (COPA)
- Continued Advocacy track through COA Patient Advocacy Network (CPAN)
 - Senate Finance Committee Bill and patient assistance programs advocacy

Thanks!



- Mark E. Thompson, M.D.
 - Medical Director of Public Policy
 - Community Oncology Alliance (COA)
 - Cell: (614) 561-7972
 - Email: mthompson@COAcancer.org
 - Web: www.CommunityOncology.org