





The 2018  
Community Oncology Conference:  
**KEEPING PATIENTS AT THE CENTER**

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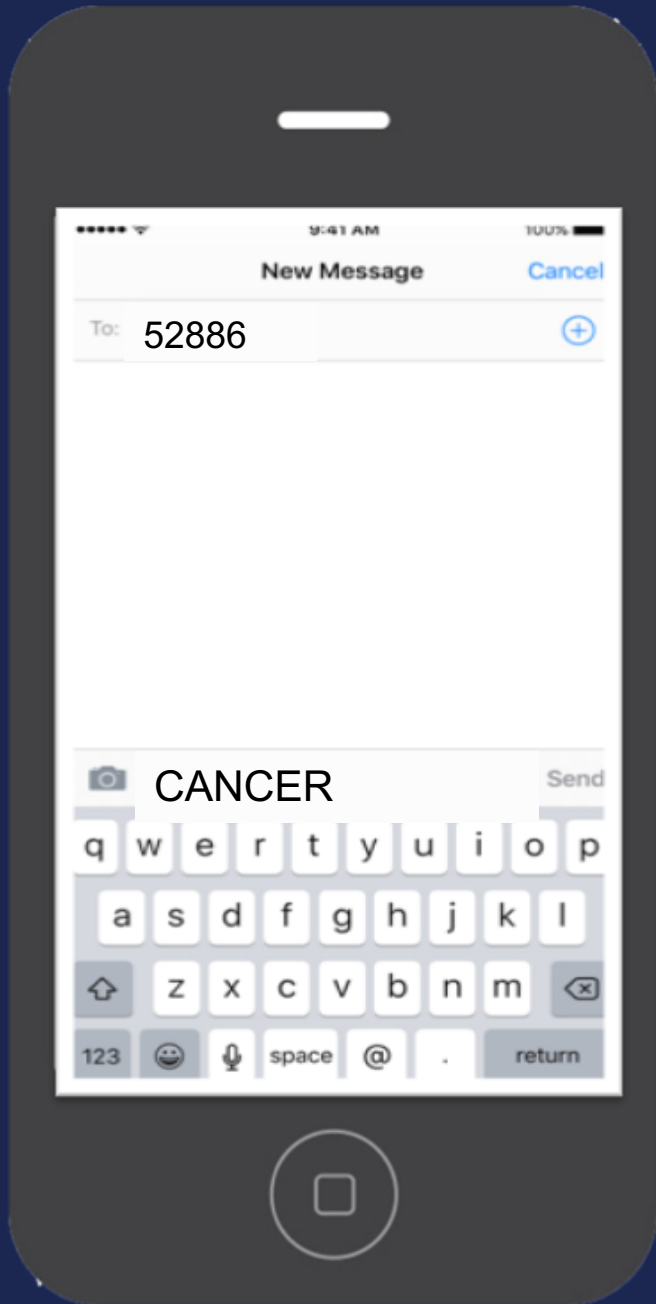
April 12–13 | National Harbor, MD

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# 2018 State of Community Oncology

# Overview of the State of Community Oncology & COA Initiatives

Ted Okon  
Executive Director  
Washington, D.C.  
February 7, 2018

*Innovating and Advocating for Community Cancer Care*





# State of Community Oncology?

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- **Surviving**
  - Significant consolidation into hospitals since the MMA
  - But the most recent trend is consolidation among practices
- **Thriving (by Fighting Back!)**
  - Stopped regressive payment policies, including Part B (Model) Experiment and additional sequester cut
  - Exposing abuses in the 340B drug discount program and PBM intrusions
    - And how 340B discounts and PBM rebates/DIR Fees are fueling drug prices
- **Innovating**
  - Doing more to advance payment reform – *while enhancing patient care* – than any other single area of medicine
  - Working with payers and employers in thinking outside of the box about cancer care



# It's All About People (We Call Patients)

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# But Challenges Abound!!!

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- Push/pull pressures constantly on community oncology practices
  - Push of ratcheting down reimbursements and restrictions; increasing insurer and PBM hurdles in blocking patient care; “tired” work force
  - Pull of hospitals to “merge or perish” by drying up referrals
    - ***Cancer care has become really, really big business!!!***
- PBMs are out to capture and control the flow of an increasing pipeline of (expensive) oral cancer drugs
  - And vertically integrate into capturing and controlling injectables
- Cancer drugs are increasingly more expensive
  - And a constant focus in the press and on Capitol Hill





2018

# COA Priorities

- Stopping application of the sequester on drugs
  - Existing 2% Medicare sequester being wrongly applied
- Fixing the broken 340B program so it helps patients, not hospital profits
  - Introducing transparency & accountability
  - COA supports 340B HELP ACT & PAUSE ACT
- Pushing to end PBM abuses hurting patients/practices
  - Stopping PBM stall tactics that impede patients from getting their cancer drugs
  - Curbing “DIR Fees”
- Making meaningful, effective oncology payment reform a reality
  - Making the OCM successful
  - Advancing the OCM 2.0 – with a “drug” component



2017

# Fighting for 340B Reform



- The only cancer organization pushing for real reform of 340B
- 2.8 million Americans reached by COA 340B advocacy in 2017



2018

# Studies Keep Coming...

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

## Consequences of the 340B Drug Pricing Program

- Bombshell study in NEJM released 2 weeks ago
- Conducted independently by Harvard & NYU researchers, and funded by HHS agency! (Health Resources and Services Administration)
- Found that 340B program associated with:
  - “hospital–physician consolidation in hematology–oncology”
  - “more hospital-based administration of parenteral drugs in hematology–oncology”
  - No “clear evidence of expanded care or lower mortality among low-income patients”



2018

# ... And Coming!

## New Study: Most Hospital's Payments Will Rise in 2018, Despite 340B Cuts



- COA commissioned study by Avalere, released last week
- 85% of hospitals will see a net payment increase after recent 340B & Medicare payment changes
- Rural hospitals benefit the most, with much greater than average payment increases for 2018
  - Majority of hospitals will see 1.5% net increase
  - Rural hospitals will see 2.7% net increase



2017

# Shaping the Future of Oncology Payment Reform



- Hosted another successful Payer Exchange Summit on Oncology Payment Reform as part of COA's commitment to oncology payment reform
- Helping 80% of OCM practices succeed in a support network
- Developing the OCM 2.0 model as future of oncology payment reform



2017

# Hosted the Largest Community Oncology Conference Ever



- Nearly 1,300 attendees joined us in 2017  
— *May hit 1,500 this year!*
- Join us this year, outside of DC on April 12-13, 2018 [www.COAConference.com](http://www.COAConference.com)



2017

# Stopped a New Medicare Sequester



- Threat of new 4% sequester cut to Medicare during budget negotiations
- COA coordinated massive emergency effort to warn Congress & Administration of impact to cancer care
- Emergency DC fly in to meet with policymakers, conducted extensive media outreach, coordinated with allies



# 2017 Fought Growing Presence & Negative Impact of Pharmacy Benefit Managers (PBMs)



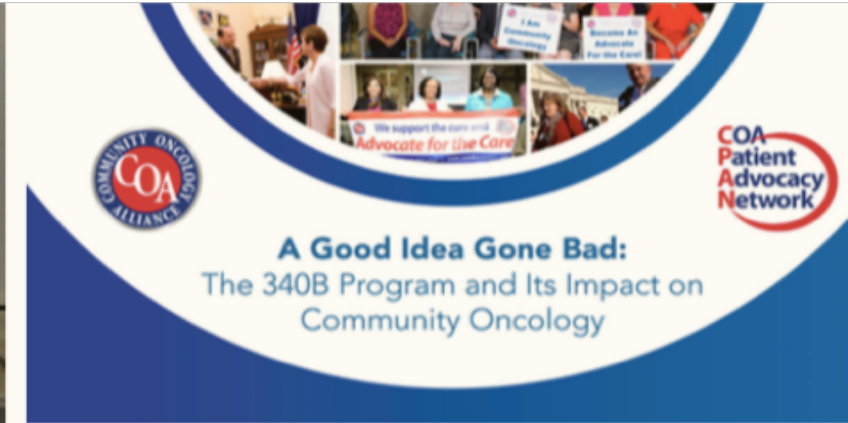
- PBMs are harming patient care and hurting practices
- Murky PBM “direct and indirect remuneration” fees (commonly known as “DIR Fees”).
- In 2017, COA released 4 studies, 3 white papers, 2 videos, 1 legal paper on PBMs





2017

# Unprecedented Expansion of Patient Advocacy via CPAN



- COA Patient Advocacy Network (CPAN) chapters in practices
- Our grassroots advocacy army
- In 2017, the number of CPAN chapters nearly doubled. New chapters in Texas, New England, New York, Washington State, and more!



2017

# Helped Patients & Practices in Puerto Rico Devastated by Hurricane Maria

## Puerto Rico Hurricane Cancer Patient Assistance Fund



- Started fund solely dedicated to helping cancer patients in Puerto Rico, in partnership with CancerCare
- Have raised nearly \$500k from individual & corporate donors
- 1,000+ cancer patients received assistance
- Thanks to BMS, BI, Celgene, Foundation Medicine, Merck, Tesaro, and ASCO!!!



2017

# Launched COA Fellows Initiative

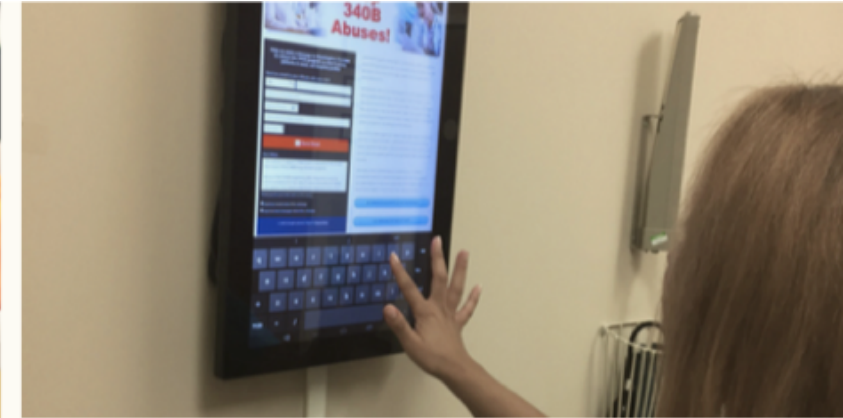
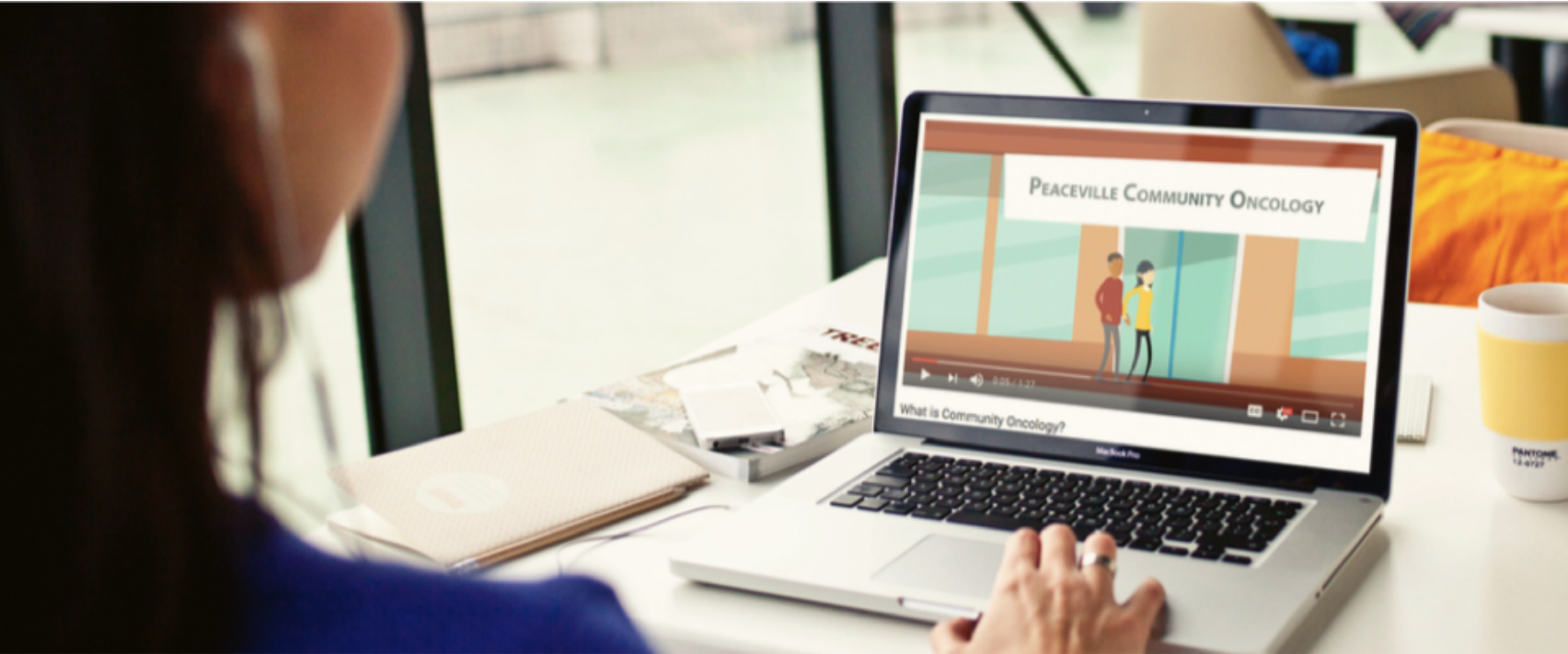


- Educating future generations of community oncologists
- Host interactive educational events & dinners across country
- Includes job board for practices & grants for fellows to attend COA events



2017

# Launched *I AM Community Oncology*



- Educate, engage, activate the public on the value of community oncology
- Developing educational resources (waiting room materials, videos, web content), hosting local events, and more
- Highlight: COA TV waiting room network. Now live in 240+ practice locations with 1,000+ providers in 27+ states!



2018

# Providing Professional Resources & Support



- COA Administrators' Network (CAN)
- Community Oncology Pharmacy Association (COPA)
- COA Advanced Practice Providers (CAPP) network
- Oncology Care Model (OCM) support network



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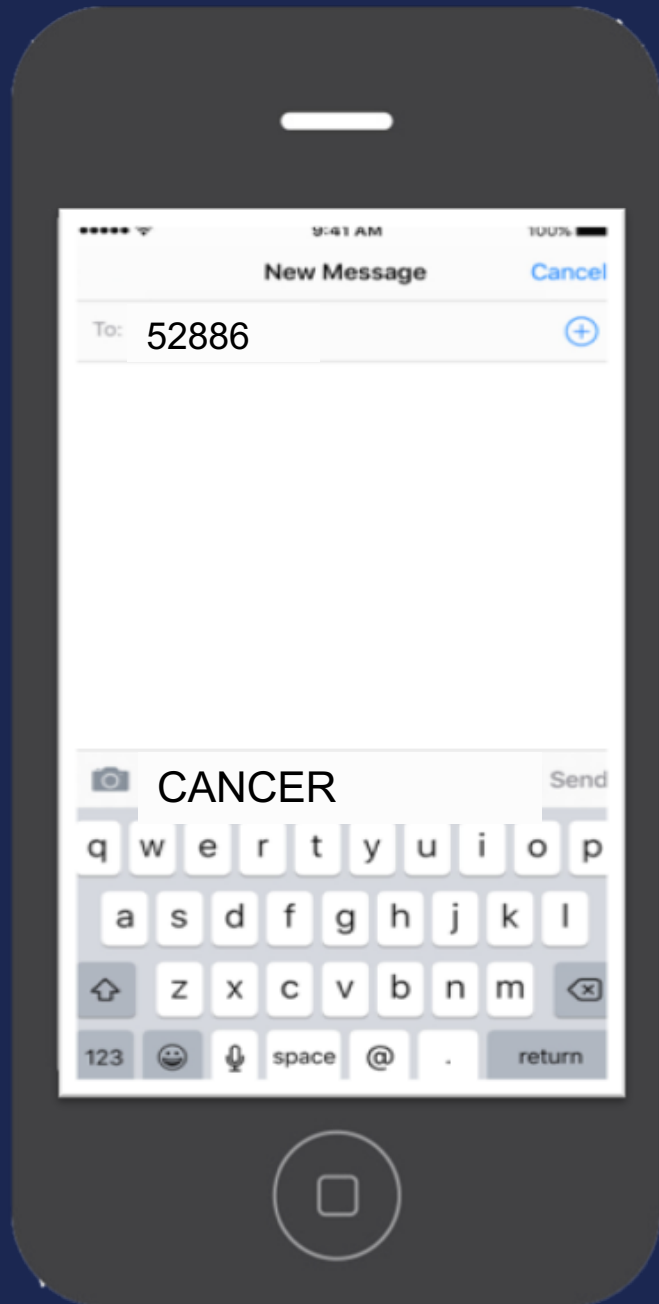
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# Oncology Site of Care Cost Differences & Solutions

Lucio Gordan, MD

Medical Director, Division of Informatics & Quality

Florida Cancer Specialists & Research Institute

February 7, 2018

*Innovating and Advocating for Community Cancer Care*





# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Barriers to high-quality cancer care:**
  - Limited Oncology Workforce
    - Aging population; retiring physicians; rural settings
  - Access to Affordable Healthcare Coverage
    - Premium increases, disappearance of preferred provider organizations, unavailability of public health exchanges
- **Economic Strain:**
  - Escalating costs, shifting payment models, practice consolidation, administrative and regulatory challenges



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **2008-2016 (source: COA Milliman Study)**
  - 121% increase in community-based practice closures
  - 172% increased in **community-based** practice acquisition by **hospitals**
    - Significant increase in volume of chemotherapy claims (Vandervelde 2014)
    - Higher cost of care (Winfield 2017)
- **Mean per member per month cost of care 20-39% lower for those receiving chemotherapy in the community (Hayes 2015)**



# Facts & Complexities of Cancer Care

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- 2011-2016: 68 new molecules approved with 22 indications
  - 640+ drugs in the pipeline
  - 87% are targeted therapies (small molecules, mAbs, b-mAbs, genetic-based)
- 2004-2013:
  - Mortality rate compound annualized reduction by nearly 2% (France, USA, Japan, Spain, Italy, Germany, UK)
  - Prostate, lung, colorectal, and breast cancer 2-3%

QuintilesIMS, ARK R&D Intelligence, Feb 2017; WHO Cancer Database, Mar 2017;  
QuintilesIMS Institutes, Mar 2017



# Facts & Complexities of Cancer Care

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- 2011-2016: Number of patients on continued therapy for melanoma has increased by 2.5 fold
- Duration of lines of therapy in lung cancer
  - 1<sup>st</sup> line: increased by 50%
  - 2<sup>nd</sup> line: increased by 15%
  - 3<sup>rd</sup> line: increased by 50%

QuintilesIMS Institutes, Mar 2017



# Facts & Complexities of Cancer Care

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- Increased utilization of biomarkers
- Complexity of clinical trials
- COST
  - Cost of new drugs
  - Supportive care
  - Diagnostics
  - **Site of care**

QuintilesIMS Institutes, Mar 2017



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- White Paper: September 2017
  - Authors
    - Marlo Blazer, PharmD, BCOP (XCENDA)
    - Lucio N. Gordan MD (Florida Cancer Specialists)
  - Acknowledgments
  - Submitted for publication – JOP January 2018.



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- Study Design:
  - Matched analysis of patients treated in the **community** or **hospital** setting for breast, lung and colorectal cancer
  - Evaluation of differences in cost, emergency department (ED), and inpatient care





# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- Data Source:
  - 10% random sample of medical and pharmacy claims – IMS LifeLink database
    - Includes longitudinal, integrated, patient-level medical and pharmaceutical claims for > 80 million patients for 70 health plans
    - Paid and charged amounts
    - 80% commercial, 3% Medicaid, 1.7% Medicare risk, other



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Sample Selection:**

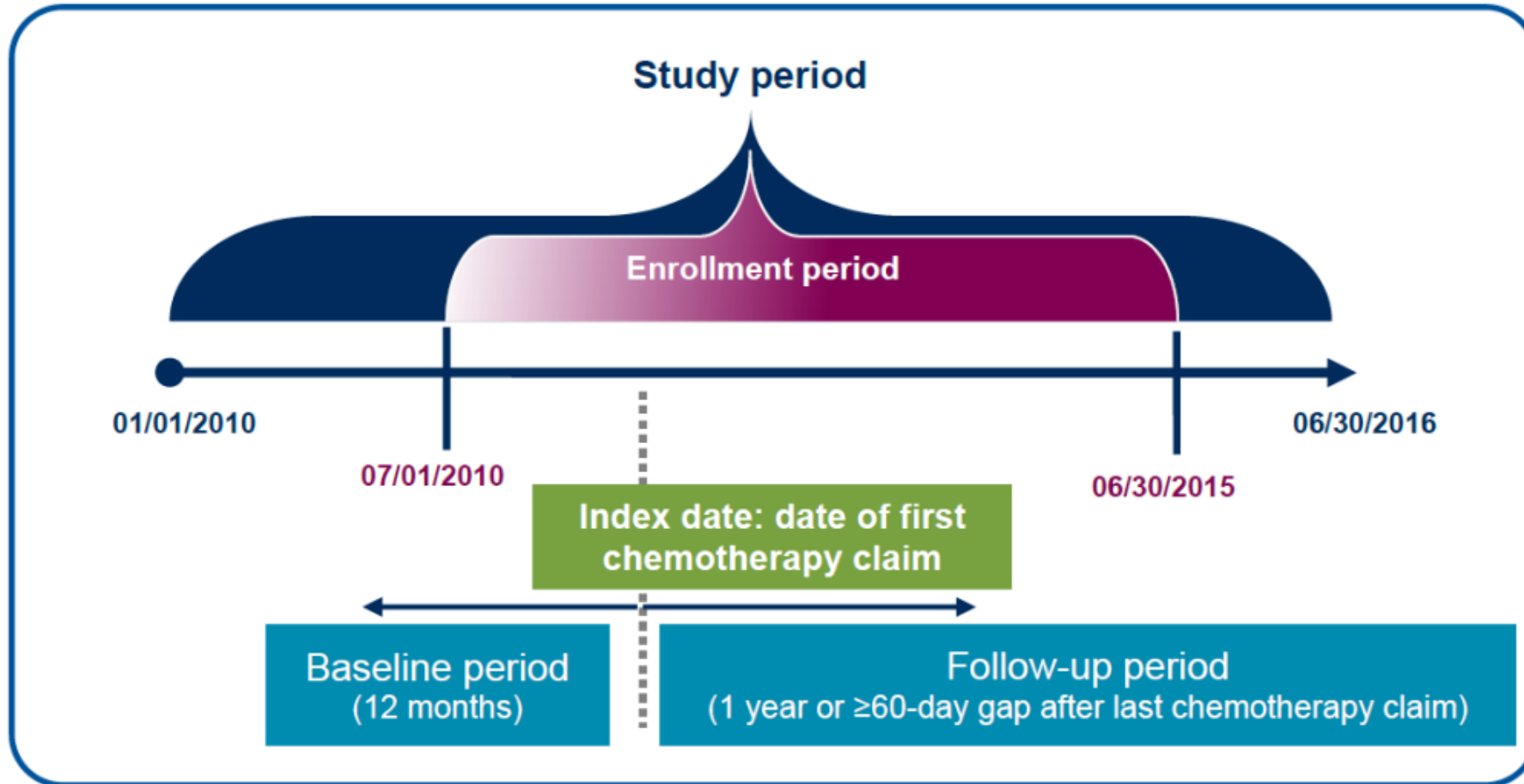
- Patients receiving chemotherapy, radiation, and/or surgery for breast, lung, or colorectal cancer between July 01, 2010 and June 30, 2015
- First date of chemotherapy served as the index date for each patient
  - Required to have continuous eligibility for 6 months in the pre-index period through the end of follow-up
  - Chemotherapy all in the **community** or **hospital**
  - Patients were followed for up to 1 year post-index date or till discontinuation of first-line chemotherapy (60-day period with no record of chemotherapy administration)



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

Figure 1. Study Timeline





# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- Matched Analysis of **community** versus **hospital**-based practice
  - 2:1
  - Cancer type (breast vs colon vs lung)
  - Specific chemotherapy regimen received
  - Receipt of radiation therapy during treatment
  - Presence of metastatic disease (Y/N)
  - Gender
  - Surgery
  - Geographical region: East/Midwest versus South/West



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Outcomes of Interest:**

- Cost differentials between patients treated in the community clinic vs hospital clinic setting
- Quality of care outcomes differences
  - Rate of hospitalization within 10 days of chemotherapy visit and ED visits occurring within 72 hours after each chemotherapy visit and within 10 days after each chemotherapy visit.

# Results

Table 1. Patient and Disease-related Characteristics of All Matched Patients (N=6,675)

Characteristic	Community Practice (CC Cohort) N=4,450	Hospital-based Clinic (HC Cohort) N=2,225
Female gender, n (%)	3,606 (81%)	1,803 (81%)
Mean age, years (SD)	56 (10)	54.9 (10)
Age group in years, n (%)		
<25	12 (0%)	3 (0%)
25–34	91 (2%)	54 (2%)
35–44	435 (10%)	303 (14%)
45–54	1,418 (32%)	662 (30%)
55–64	1,714 (39%)	885 (40%)
65–74	624 (14%)	261 (12%)
75–84	156 (4%)	57 (3%)
Geographic region, n (%)		
East	898 (20%)	627 (28%)
Midwest	1,716 (39%)	680 (31%)
South	1,584 (36%)	748 (34%)
West	252 (6%)	170 (8%)
Cancer type, n (%)		
Breast	2,996 (68%)	1,498 (68%)
Lung	952 (21%)	476 (21%)
Colorectal	502 (11%)	251 (11%)
Presence of metastatic condition, n (%)	2,468 (55%)	1,234 (55%)
Surgery during pre-index period, n (%)	2,378 (53%)	1,189 (53%)
Radiation treatment during pre-index period, n (%)	667 (15%)	323 (15%)
Surgery during post-index period, n (%)	34 (1%)	16 (1%)
Radiation treatment during post-index period, n (%)	504 (11%)	252 (11%)
Required inpatient service, n (%)	504 (11%)	252 (11%)
Required ED service, n (%)	449 (10%)	292 (13%)
Mean Charlson comorbidity index, n (SD)	4.7 (2.3)	4.8 (2.4)
Mean unique drugs prescribed at baseline, n (SD)	4.4 (3.8)	4.3 (3.7)
Mean chemotherapy agents filled at baseline, n (SD)	7.9 (5.5)	9.1 (6.1)
Mean eligible days at baseline, n (SD)	180 (0)	180 (0)
Mean paid medical cost at baseline, n (SD)	\$4,604.10 (\$4,406.00)	\$5,278.40 (\$4,868.80)
Mean allowed medical cost at baseline, n (SD)	\$5,434.00 (\$4,803.80)	\$6,038.30 (\$5,126.80)
Mean duration of therapy, days (SD)	99.6 (61.0)	95.7 (57.0)
Mean total cycles of treatment, n (SD)	5.2 (4.2)	4.8 (4.4)

Key: ED – emergency department; SD – standard deviation.

# Results

**Table 2. PPPM Total Costs in Community Practice vs Hospital-based Practice**

	Community Practice N=4,450		Hospital-based Practice N=2,225		P-value
	Mean	SD	Mean	SD	
Mean Total Costs	\$12,548	\$10,507	\$20,060	\$15,502	<0.0001
Total Medical Costs	\$12,103	\$10,504	\$19,471	\$14,559	<0.0001
Chemotherapy	\$4,933	\$4,983	\$8,443	\$10,391	<0.0001
Branded agents only	\$6,674	\$5,046	\$10,900	\$10,712	<0.0001
Generic agents only	\$2,936	\$2,585	\$5,134	\$6,306	<0.0001
Combination regimen <sup>a</sup>	\$11,080	\$5,889	\$19,412	\$13,869	<0.0001
Physician visits	\$765	\$1,607	\$3,316	\$4,399	<0.0001
Radiation	\$1,095	\$4,153	\$1,430	\$4,904	<0.0001
Inpatient	\$1,178	\$6,229	\$1,498	\$7,193	0.0095
ED visits	\$121	\$501	\$168	\$620	<0.0001
Outpatient	\$3,838	\$3,681	\$3,912	\$5,698	<0.0001
Other	\$174	\$2,405	\$704	\$3,353	<0.0001
Total Pharmacy Costs	\$445	\$1,239	\$589	\$1,934	0.2708

<sup>a</sup>Combination = chemotherapy regimen contained both branded and generic drugs.

Key: ED – emergency department; PPPM – per patient per month; SD – standard deviation.

# Results

**Table 4. PPPM Total Costs in Community vs Hospital-based Practice Settings for Breast, Lung, and Colorectal Patients**

	Community Practice N=4,450		Hospital-based Practice N=2,225		P-value
	Mean	SD	Mean	SD	
<b>Breast Cancer Patients</b>	<b>N=2,996</b>		<b>N=1,498</b>		
Mean Total Costs	\$11,599	\$8,129	\$19,279	\$14,358	<0.0001
Total Medical Costs	\$11,139	\$8,139	\$18,667	\$14,403	<0.0001
Chemotherapy	\$4,671	\$4,577	\$8,206	\$9,719	<0.0001
Branded agents only	\$5,608	\$4,273	\$9,279	\$7,805	<0.0001
Generic agents only	\$2,982	\$2,275	\$5,084	\$5,591	<0.0001
Combination regimen <sup>a</sup>	\$11,511	\$5,647	\$21,240	\$13,356	<0.0001
Physician visits	\$820	\$1,813	\$3,499	\$4,564	<0.0001
Radiation	\$378	\$1,305	\$440	\$1,493	0.0561



# Results

	Community Practice N=4,450		Hospital-based Practice N=2,225		P-value
	Mean	SD	Mean	SD	
<b>Breast Cancer Patients</b>	<b>N=2,996</b>		<b>N=1,498</b>		
Inpatient	\$735	\$4,230	\$874	\$3,804	0.0415
ED visits	\$120	\$516	\$162	\$638	0.0045
Outpatient	\$4,318	\$3,835	\$4,735	\$6,322	0.2696
Other	\$97	\$718	\$752	\$3,461	<0.0001
Total Pharmacy Costs	\$461	\$1,361	\$612	\$1,699	0.1084

# Results

**Table 5. Rates of Hospitalizations and ED Visits Among Patients Treated in the Community vs Hospital-based Setting Within 72 Hours and 10 Days of Each Chemotherapy Visit**

	<b>Community Practice N=4,450</b>	<b>Hospital-based Practice N=2,225</b>	<b>P-value<sup>a</sup></b>
<b>72 hours</b>			
ED visits	2.6%	3.6%	0.0055
<b>10 days</b>			
Hospitalizations	7.0%	7.3%	0.6198
ED visits	7.9%	9.8%	0.0022

<sup>a</sup>McNemar's test was used for testing the difference in frequencies.

Key: ED – emergency department.



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **CONCLUSIONS:**

- Validation of previous studies
  - Winfield 2017, Hayes 2015, Fitch 2013, COA study
- Cancer treatment for patients with breast, lung, colorectal cancer treated in **community oncology is:**
  - **\$8,000.00 less expensive PPM**
  - **Lower costs of chemotherapy and physician visits**
  - **28% less ED visits in 72h post chemotherapy**
  - **18% less ED visits at 10 days post chemotherapy**
  - **Less multiple ED encounters**



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Our study:**
  - Large patient population, randomly selected
  - Matched analysis 2:1
  - Comorbidity scores were equal
  - Breakdown of extensive data by tumor type
  - Emergency room visits at 72h and 10 days
  - Hospitalization rates



# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Concerns**

- Rapid shift from community-based oncology to **hospital-acquired** practices = explosion of **cost**
- 2014-2015
  - 75% of acquired **community-oncology** practices by hospitals with 340B drug discount pricing
  - Evidence shows that payers and patients are **paying more** and not **less** in these **hospital-based** settings

- **REAL world-data to payers and health systems, oncology workforce, US Congress, and tax payers**

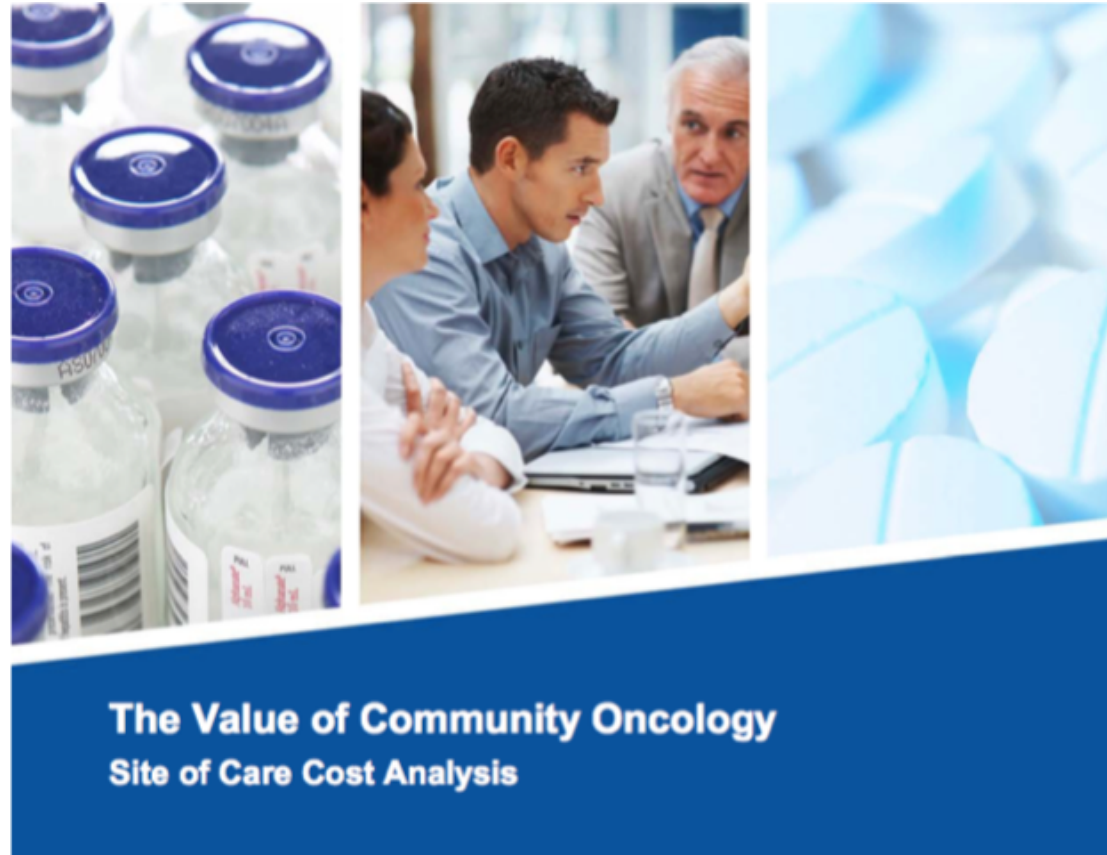


# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- Download the full study at: <http://bit.ly/siteofcarestudy917>





# Site of Care Cost Analysis 2018

## The Value of Community Oncology

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- **Future presentations of ongoing studies**
  - **Immunooncology and Site of Care Cost Analysis - April 2018**
  - **Coordinated-dispensing of oral oncolytics (community oncology practices) versus non-coordinated dispensing (PBM's)**
  - **Quality efforts and results in value-based care contracting**
    - Cost control and improved outcomes at Florida Cancer Specialists







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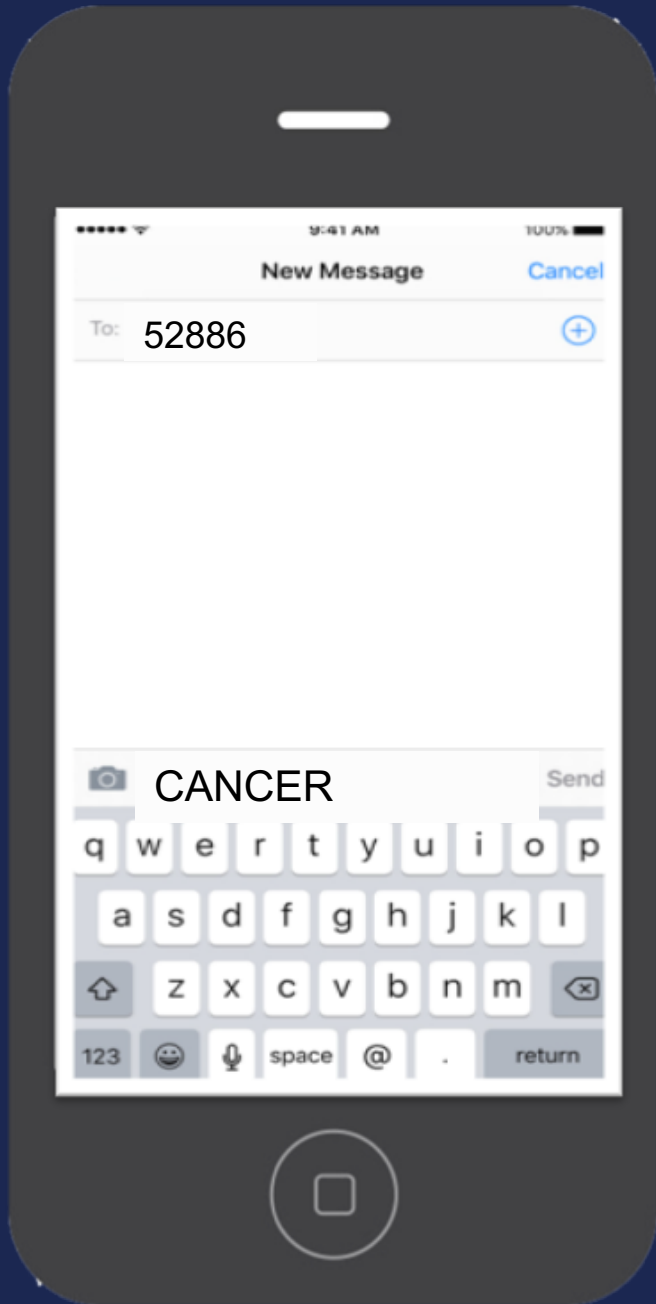
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# **“OCM 2.0” The Journey Ahead**

## **OCM 1.0 to OCM 2.0 Lessons Learned and Applied**

Basit Chaudhry, MD

Bruce Gould, MD

Kavita Patel, MD

Bo Gamble

February 7, 2018

*Innovating and Advocating for Community Cancer Care*





# OCM – Simple Form

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- Practice redesign
  - IOM care plan
  - Navigation
  - Guidelines
  - ER/Hospital avoidance
- Monthly Episode Oncology Services payments (MEOS)
- Measures and reporting
- Actuals compared to targets = Performance Based Payment (PBP)



# OCM Annual Report by Abt as of February 2017

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- *“Beneficiaries receiving care in OCM practices had a slightly higher number of comorbidities and cancer-relevant comorbidities, as well as slightly higher Hierarchical Condition Category (HCC) scores (an alternative indicator of severity and comorbidities), than did those in comparison TINs...*
- *...More than 80 percent of OCM and comparison patients were enrolled in Medicare Part D drug plans. Despite high enrollment, there were undoubtedly episodes that did not “trigger” for model purposes because the prescribed drugs were not covered under Part D...*
- *...Episodes attributed to OCM practices averaged higher total cost of care (including standardized Parts A and B, and [non-standardized] Part D) with \$27,400 at OCM practices and \$26,200 for the comparison group....*
- *...However, OCM practices’ patients used more services, including more high acuity/high cost services at the end of life (emergency department [ED], hospital, and intensive care unit [ICU] care), than did patients in the comparison group.*
- *...These results highlight factors that will be taken into account in future analysis (e.g., for risk adjustment), and suggest some relevant subgroup analyses, especially by cancer bundle, and practice size and affiliation...”*



# How We Developed OCM 2.0

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- Close involvement with OCM 1.0
- Interviews with
  - Patient Groups
  - Providers
  - Payers/Employers
  - Federal/State/Local Officials
  - Manufacturers
- Participation in
  - 2015, 2016, 2017 COA Payer Summits
  - 2015, 2016 COA Annual Meetings
  - 2016, 2017 COA State of the Union
- Focus groups
- Thought leader input: Dr. Bruce Gould, Dr. Mark Fendrick
- Literature review



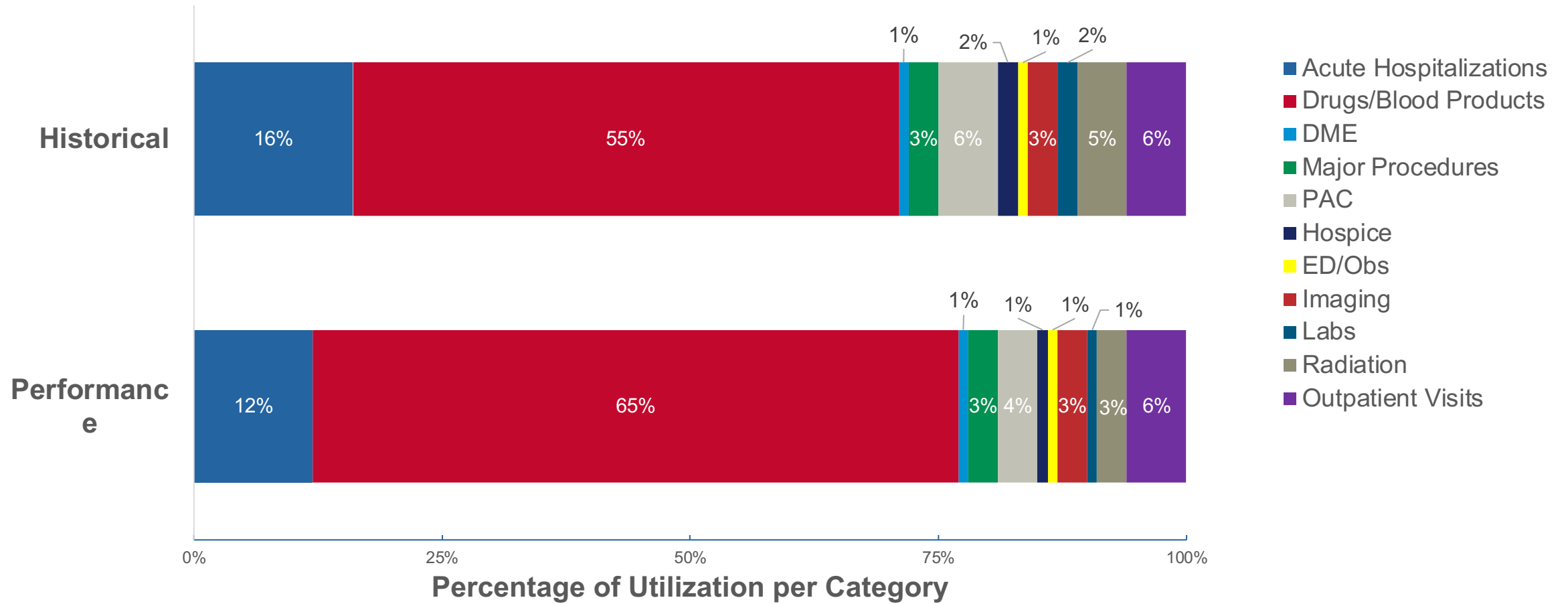
# Care and processes in OCM 2.0

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- Collaborative OMH effort
  - Team
    - ASCO
    - COA
    - IOBS
    - NCQA
  - Joint Principles
  - Goals
    - Appropriate and meaningful standards
    - Narrow set of meaningful measures
    - Measures to be proof of completed OMH standards
    - Only measures where the numerator and denominator can be automatically extracted
- Separate project underway with the above components and care processes tailored for employers



A policy simulation shows that pharmaceuticals have increased from ~55% of costs in the historical baseline period to ~65% of costs in the first four quarters of the performance period.







# Drugs in OCM 2.0

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- Inclusion of oral meds
- Inclusion of claims data in a timely manner (particularly 3rd party plans, PBMs, etc.)
- Emphasis on Health Economics and Outcomes
- Greater pressure on
  - Manufacturers
  - Immunotherapy drugs
  - Biosimilars
  - Outcomes or indication based pricing
  - CDK4/CDK6 inhibitors



# Value Based Insurance Design (VBID) & OCM 2.0

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- Goals
  - Lower or remove financial barriers to essential, high-value cancer care.
  - Identify discrete treatment regimens that do not offer any additional value or could even pose potential risks to patients
  - Consensus, evidence-driven benefit design with element of clinical nuance
- Potential VBID ideas for drugs
  - Eliminate copays for oral chemotherapeutics
  - Emerging data illustrating lack of adherence at higher copay rates
    - Overall 18% abandonment rate, with higher rates in greater OOP categories:
    - 10.0% for ≤ \$10 group
    - 13.5% for \$50.01 to \$100 group
    - 31.7% for \$100.01 to \$500 group, 41.0% for \$500.01 to \$2,000 group
    - 49.4% for > \$2,000 group
  - E.g. Tarceva in EGFR+ in patients with no response after 3 months  
(Armstrong et al. *Journal of Clinical Oncology* - published online before print December 20, 2017)



# Components of OCM Payment Models

Elements For Consideration	OCM 1.0	OCM 2.0
Attribution	Practice/TIN	Practice/TIN
Network Design-whats in and whats out	Medical Oncology (primarily)	Community-based medical oncology
Episode Definition	Trigger based on Chemotherapy	Trigger based on therapy choice
Clinical Trials	Not included (without non trial trigger) but risk adjusted	Inclusion
Metrics/Accountability	Mix of Claims, Practice Reporting, Survey	Flexible
Level of Risk	Flexible- 1 or 2 sided	Flexible
Oral Drugs	Included with part of claims	Included with VBID Component
Financial Gains	MEOS + PBP	PMPM+ Shared Savings

(Armstrong et al. *Journal of Clinical Oncology* - published online before print December 20, 2017)



# Lessons Learned for OCM 2.0

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- The greater the complexity of the model/ methodology the greater the need for communication and clarity
- Early stake holder engagement with feedback and prototyping is critical e.g. risk adjustment model, measures
- Attribution is foundational and complex in oncology, particularly when orals are involved
- Accounting for new therapies, particularly in modeling target prices is a central and growing concern
- Turn around time on when data is sent to participants has a major impact on feasibility



# Sensitive Touchpoints

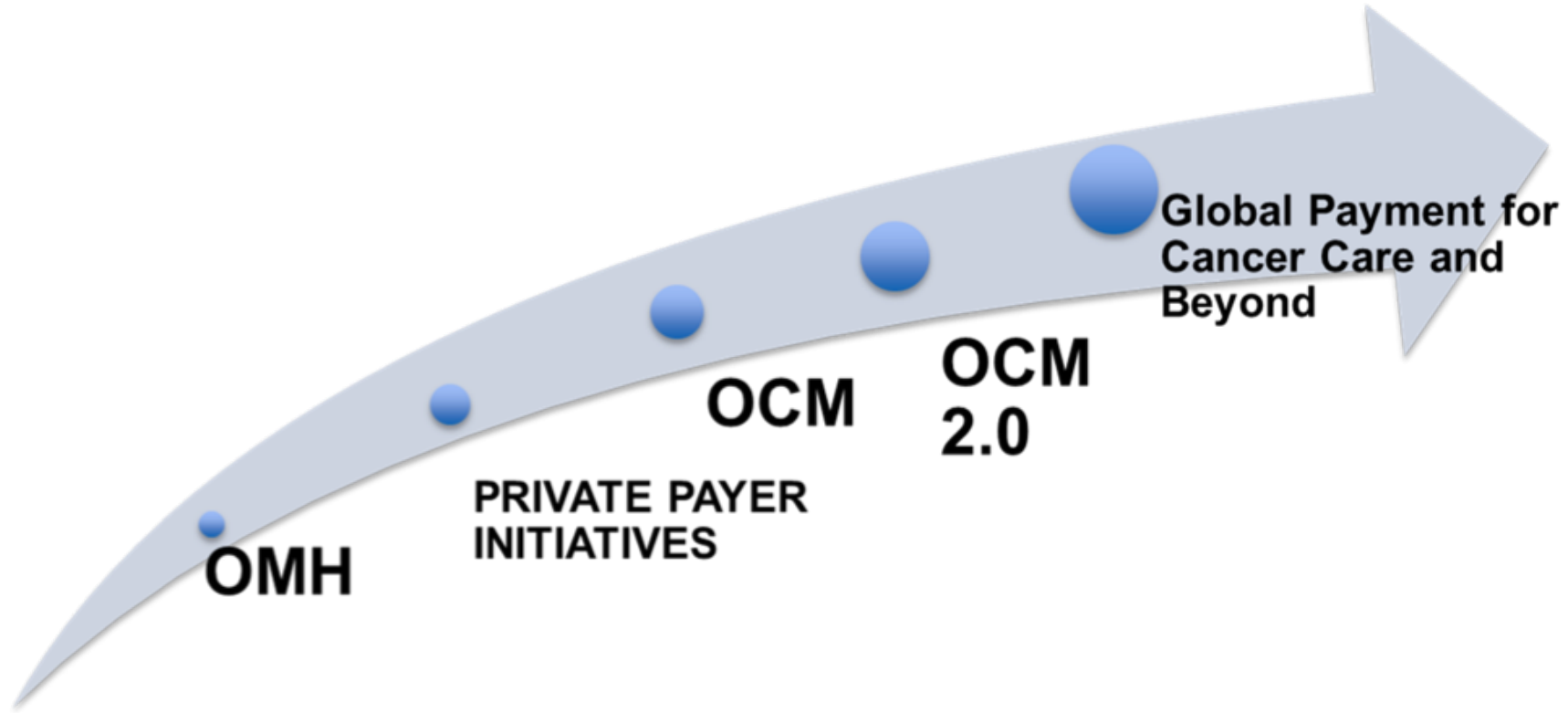
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- Transformation is hard and costly (not just infrastructure dollars, but labor)
- Inclusion of almost all cancers may not be best initial approach
- Issues with understanding data
- Triggers and end dates
- Plurality and attribution
- Commercial payers and employers require simplicity and clarity also



# The Journey: Looking Back and Ahead

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# Discussion

*Innovating and Advocating for Community Cancer Care*





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The 2018  
Community Oncology Conference:  
**KEEPING PATIENTS AT THE CENTER**

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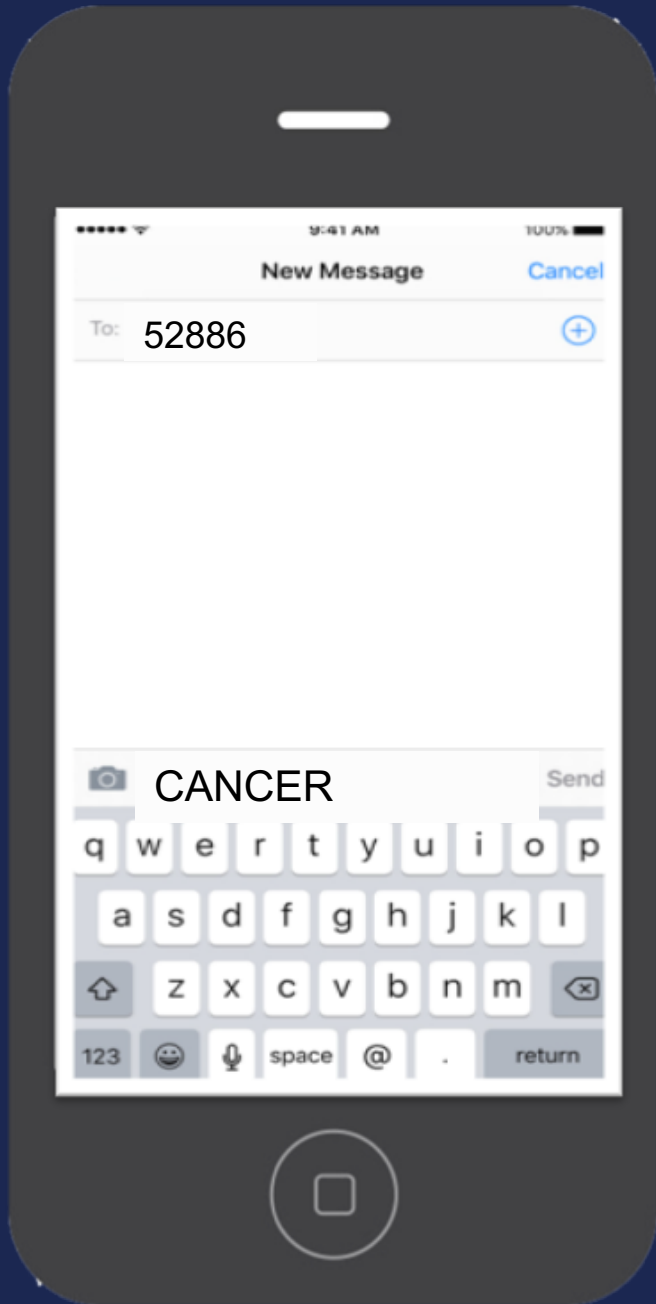
April 12–13 | National Harbor, MD

**Agenda & faculty list now available.**

**Join us for two packed days of learning & networking.**

**Discount room block is 60% sold out.**

[www.COAConference.org](http://www.COAConference.org)



**REGISTER AS A COA  
ADVOCATE!  
TEXT: CANCER  
TO: 52886**

# How are PBM's Impacting Cancer Care

Ricky Newton, CPA

Treasurer & Director of Financial Services & Operations

Washington, DC

February 7, 2018

*Innovating and Advocating for Community Cancer Care*

















# COPA Board & Membership

- COPA officially started on March 17, 2015
- Currently over 465 members representing over 280 practices

## Co-Chairmen

					
<p><b>Josh Cox, Pharm.D., BCPS</b>  <i>Director of Pharmacy</i>            Dayton Physicians Network</p>	<p><b>Todd Murphee, Pharm.D.</b>  <i>Manager of the Dispensing Pharmacy</i>            Clearview Cancer Institute</p>	<p><b>Howard Levine, Pharm.D.</b>  <i>Director of Pharmacy</i>            Queens Medical Associates</p>	<p><b>Jeff Lombardo PharmD, BCOP</b>  <i>Research Assistant Professor</i>            UB School of Pharmacy and Pharmaceutical Sciences  <i>Associate Director</i>            Empire State Patient Assurance Network</p>	<p><b>Stacy McCullough, Pharm.D.</b>  <i>Senior Vice President, Pharmacy</i>            Tennessee Oncology</p>	<p><b>Matt Williams, Pharm.D., RPh</b>  <i>Clinical Pharmacist</i>            Comprehensive Cancer Centers</p>

## COPA Board members

					
<p><b>Ray Bailey, RPh</b>  <i>Director of Pharmacy</i>            Florida Cancer Specialists</p>	<p><b>John Clagg, RPh</b>  <i>Director of Pharmacy and Admixture Services</i>            The Center for Cancer and Blood</p>	<p><b>Steven D'Amato, BS Pharm, BCOP</b>  <i>Executive Director</i>            New England Cancer Specialists</p>	<p><b>Jonas Congelli, RPh</b>  <i>Director of Pharmacy Services</i>            Hematology-Oncology Associates of CNY</p>	<p><b>Christine Pfaff, RPh</b>  <i>Director of Pharmacy</i>            The Zangmeister Center</p>	<p><b>Ginger Blackmon, Pharm.D.</b>  <i>Pharmacy Manager</i>            Cancer Specialists of North Florida</p>



# COA Press Releases Creating COPA

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## COMMUNITY ONCOLOGY ALLIANCE ANNOUNCES LAUNCH OF NATIONAL ORGANIZATION FOCUSED ON ORAL CANCER DRUGS

### *Commercial Interests Threaten to Interfere with Critical Physician-Patient Bond Essential to Quality Cancer Care*

**WASHINGTON, D.C. – March 17, 2015** – The Community Oncology Alliance (COA), a not-for-profit organization dedicated to preserving access to community cancer care, announced today the formation of the Community Oncology Pharmacy Association (COPA). COPA is a non-profit, non-commercial organization, under the direction of the COA Board of Directors, dedicated to addressing a variety of pharmacy issues, all in the sole interest of patient care. COPA will establish

“Due to the increasing costs of cancer drugs, there are commercial interests, such as specialty pharmacies, attempting to separate oral cancer therapy from the point of care and oncologist control, thus interfering with the physician-patient relationship,” said Ted Okon, COA executive director. “COPA was created to provide support to practice-based pharmacies while preserving the physician-patient relationship that is the fundamental basis of quality cancer care.”



# ACHC Accreditation & Tools

- COPA Board in 2015 Partnered with Accreditation Commission for Health Care (ACHC)
- Created Additional Accreditation over Existing Specialty Standards
- Oncology Accreditation standards finalized by early 2016
- Josh Cox, Pharm.D., BCPS & Todd Murphree, Pharm.D. were first practices to achieve dual accreditation
- Created tools on COPA website

## ACHC SPECIALTY PHARMACY ACCREDITATION



ACHC and COPA have partnered to provide members with a customized suite of specialty pharmacy accreditation offerings, including discounts on educational resources and accreditation programs. ACHC was the first accrediting body to offer specialty pharmacy accreditation. By undergoing ACHC accreditation pharmacies demonstrate their commitment to providing the highest quality service by complying with stringent national regulations and industry best practices.

ACHC's Accreditation University offers a full suite of accreditation resources to help pharmacies achieve and maintain accreditation. [Click here to learn more >>](#)

Preferred Partner Discount Code: COAS86

COPA members may use the discount code provided above to receive a \$250 discount on the final accreditation fee (applied at time of final payment, not deposit). Please contact Lindsey Holder at 855-937-2242 with any questions.

[Visit ACHC / COPA Partner Site](#)

[View Partnership Pricing](#)  [View ACHC Standards](#) 

**Audit Tools**

[ACHC - Contents Survey](#) [Patient Record Audit](#) [Personnel Files Audit](#) [Potential Interview Questions](#) [Plan of Correction](#)

**Standards**  
The table below provides the ACHC Specialty Pharmacy Accreditation standards released February 1, 2014. Refer to Customer Central for most current standards.


Standard	Downloads	Requirements	Explanation
DRX1-1A		Copy of all current applicable licenses/permits	Organizational Bylaws/Articles/Business License
DRX1-1B		Copy of all current applicable licenses/permits	Pharmacy permit/pharmacist and technician licenses
DRX1-2A	 	Written policies and procedures/Board of Directors Minutes/List of Governing Body/Ownership Members/Orientation to each Governing Member	- Bylaws/organization chart/Board minutes showing board review of pharmacy services - Legal document showing structure of organization and BOD - Stock certificates/List of governing body - Confidentiality agreement/BOD minutes showing that each member was oriented to pharmacy operations meeting each portion of standard
DRX1-3A		Conflict of interest and disclosures	Employee Handbook/HR policy that shows that business ethics are observed and employees do not engage in conflicts of interest
DRX1-4A	 	Role of Director/Secondary Director	1) Company Organizational Chart 2) Pharmacy technician application/job description 3) Pharmacy technician training checklist 4) Interview evaluation form 5) 30, 60, 90 day evaluation forms 6) Annual evaluation form 7) Pic/Resume/App



# Patient Stories and Assistance

April 2017

Delay, Waste, and Cancer Treatment Obstacles:  
**The Real-Life Patient Impact of Pharmacy Benefit Managers**



Over 15 Years of Making a Difference in Cancer Care

There is growing awareness of the problems and pitfalls with Pharmacy Benefit Managers (PBMs) in the United States health care system. Contracted by insurance carriers to negotiate on their behalf with pharmaceutical companies, these 'middle men' corporations have quietly become an unavoidable part of our nation's health care system. Controlling at least 80 percent of drug benefits for over 260 million Americans, PBMs have the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned specialty pharmacies.

However, while the role PBMs play in the U.S. health care system is complex and under scrutiny by policymakers and the public, with much of the debate focusing on economics, little discussion takes place of the impact PBMs have on patients.

This paper is the first in a series that will focus on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

### AN AVOIDABLE DEATH?

Derek, a young husband, was diagnosed with advanced melanoma with brain metastases. Prognosis was grim, yet a ray of light appeared in the form of a new drug prescribed by his doctor. Proven to have the potential of significantly extending life, the drug offered Derek and his wife real hope. Located in his doctor's office was the clinic's pharmacy, where this potentially life-prolonging medication was simply waiting on the pharmacy shelf—but not for Derek. Derek's PBM mandated that Derek purchase his meds from one of their own mail-order specialty pharmacies. The clinic immediately faxed to the PBM all the necessary information for receiving

\$1,000 co-pay, an amount they were unable to afford. Derek's wife now began arranging co-pay assistance, but she had to deal with the matter on her own at this point, because Derek had been admitted to the ICU. Several days later, she received approval for co-pay assistance, and forwarded the information to the PBM's pharmacy, which then FedExed the drug to Derek. The medication finally arrived—only there was no one to take them. By this time, Derek could no longer swallow pills, and sadly, shortly after, he died.

*The most common and devastating issue that cancer patients face with PBMs is the fact that they must wait*

- PBM horror stories volume 1 was released in April 2017
- PBM horror stories volume 2 was released in May 2017
- PBM horror stories volume 3 was released in September 19, 2017
- Papers with stories are found at [www.coapharmacy.com](http://www.coapharmacy.com) under Studies and Publications
- Please continue to email stories from patients and practice to [rnewton@coacancer.org](mailto:rnewton@coacancer.org)
- Stories used by Ted on hill to open up discussions all the time

May 2017

Unaccountable Benefit Managers:  
**Real Horror Stories of How PBMs Hurt Patient Care**



Over 15 Years of Making a Difference in Cancer Care

There is no shortage of horror stories associated with the increasingly large role that Pharmacy Benefit Managers (PBMs) play in the United States' health care system. With their numerous offshoots and service lines, PBMs have managed to take on an oligopolistic presence that adversely impacts patients receiving treatments, their health care providers, and everyone else in between.

Originally created to lower prescription drug costs, it has become clear that these multibillion dollar PBM corporations have transformed into gargantuan and almost completely unaccountable arbiters of the care that cancer patients receive. As this story series demonstrates, the dangerous combination of PBM unaccountability, opacity, and lack of oversight have resulted in benefit managers that are focused on their profits and not patient care.

This paper is the second in a series from the Community Oncology Alliance (COA) that focuses on the serious, sometimes dangerous, impact PBMs are having on cancer patients today. These are real patient stories but names have been changed to protect privacy.

### PBM KNOWS BETTER THAN THE DOCTOR?

A community oncology and hematology clinic in Pennsylvania was being forced to use a specific PBM specialty pharmacy for their patients' oral chemo prescriptions, despite the practice having its own in-office dispensary. They had actually applied to the PBM two years earlier for the right to dispense drugs; however, approval was still "pending."

Frank was one of the clinic's patients battling rectal cancer. His oncologist prescribed an appropriate medication and submitted it to the PBM specialty pharmacy for filling. Soon after, the PBM called the clinic and announced that approval was denied for the submitted diagnosis, however if the oncologist were to change the diagnosis to one of several other cancers, they would then approve it. The clinic responded by noting that this would be a fraudulent change that they refused to comply with, and would

and instructions. This was done despite the fact that a pharmacy is forbidden to change prescription instructions without the approval of the prescribing physician. To make matters even worse, the quantities sent to Edward were incorrect, even for the adjusted regimen.

Chris was another patient at the practice battling with rectal cancer and prescribed the same medication with the same dosage. He too found that his prescription had been changed by the PBM specialty pharmacy—from seven days per week to five days per week. When the PBM specialty pharmacy called Chris to schedule shipment he refused because the instructions were different from those he'd been given at the doctor's office. At this point, the PBM specialty pharmacy called the patient's physician, who had to reinstate the original prescription.



# Impact of PBM's on Patient Care

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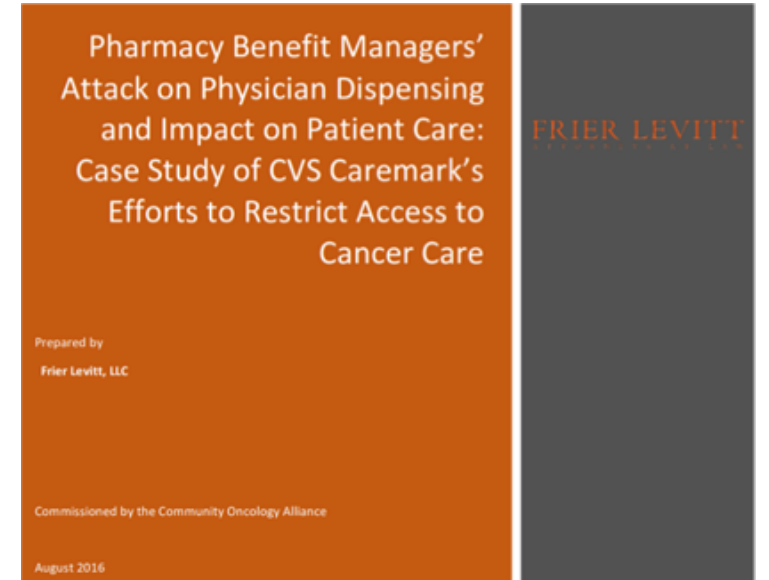
- Treatment Delays sometimes leading to patient death or outcomes that would have been avoided with timely treatments
- Medication Denials
- Switching Medications different from what physician prescribed
- Drug Waste
- Patients and providers get runaround trying to get drugs
- Less Compliance
- Less patient education





# CVS/Caremark History

- April 15, 2016 CVS/Caremark Declared No Physician Dispensing Pharmacies allowed in network as of January 1, 2017
- COA hired Frier Levitt
- Decision overturned by CVS except that any new physician dispensing pharmacies would not be allowed into network
- CVS opened up their networks as of July 1, 2017 to physician dispensing pharmacies
- First practice approved as of October 15, 2017
- 3 Urology practice pharmacies have been approved January 2018





# 2016 Express Scripts Decisions

Network Pharmacy Weekly

March 10, 2016



Starting November 15, 2016, your Express Scripts patients taking Imbruvica® or Venclexta® must fill these limited distribution drugs through either Avella Specialty Pharmacy or Diplomat Specialty Pharmacy. Prescriptions for these drugs currently at Biologics, Onco 360 or select other pharmacies will not process after November 15, 2016, for the following patients:

## Oncology Drug Program Update (Continued from page 1)

Members may need to get a new prescription from their physicians. If the prescriber pursues a clinical exception and it is approved, the prescription may need to be filled through Accredo.

The top 25 oncology medications included in this program are listed below.

Oncology Drug Name	
AFINITOR	SUTENT
ERIVEDGE	TAFINLAR
GILOTRIF	TARCEVA
GLEEVEC	TASIGNA
IBRANCE	TEMOZOLOMIDE
INLYTA	THALOMID
JAKAFI	VOTRIENT
LUPRON DEPOT	XALKORI
MEKINIST	XTANDI
NEXAVAR	ZYTIGA
POMALYST	LENVIMA
REVLIMID	INTRON A
SPRYCEL	

If you have any questions, please call us at 800.922.1557.

EXPRESS SCRIPTS PATIENT	DRUG NAME
-------------------------	-----------

This was for Imbruvica. MM

### What You Need to Do

We know how important it is that your patients receive their drugs on time. To prevent a delay in your Express Scripts patients' specialty prescriptions, **you must help your patients transition their prescriptions to one of the pharmacies listed below.** You may need to send a new prescription to the pharmacy of choice.

PHARMACIES THAT CAN FILL YOUR PATIENTS' DRUGS	
<b>Avella Specialty Pharmacy</b> Patient questions: 844.841.5499 Prescription fax line: 877.546.5780 Physician line: 844.841.5499 Pharmacy hours: 7 a.m. to 7 p.m. Central, Monday through Friday; 10:30 a.m. to 1:30 p.m. Central, Saturday Cutoff time: 4 p.m. Central	<b>Diplomat Specialty Pharmacy</b> Patient questions: 877.977.9118, Opt. 4 Prescription fax line: 800.550.6272 Physician line: 877.977.9118, Opt. 3 Pharmacy hours: 7:30 a.m. to 8 p.m. Central, Monday through Friday; 7:45 a.m. to 4:15 p.m. Central, Saturday Cutoff time: 1 p.m. Central

Prescriptions received by the cutoff time can be shipped for next day delivery.

If you have any questions, feel free to contact Express Scripts at 800.282.2881. Thank you for your prompt attention to this matter.

Sincerely,

Express Scripts

\* Changes not applicable to Medicare Part D beneficiaries. Additional pharmacy options may be available to TRICARE beneficiaries.



# Express Scripts Credentialing Requirement (2017)

## ESI Specialty Provider Credentialing

The following are frequently asked questions (FAQs) related to the Specialty Provider Questionnaire.

**Q. Will the provider have to pay a fee for the Specialty credentialing process?**

**Yes.** A processing fee of \$1,500 is required with the completed credentialing application. After documentation has been approved, a mandatory onsite audit of the provider must take place. An additional fee of \$2,000 is associated with this inspection.

**Q. What happens if the provider does not take required action?**

**Providers that do not complete the Specialty credentialing requirement will be considered in breach of contract and may be restricted from filling Specialty drugs for Express Scripts members and/or subject to termination.**

**Q. Why is additional insurance required?**

**Given the complexities of Specialty therapies, which treat chronic, rare and complex disease states and frequently require special handling and patient monitoring, Express Scripts requires Specialty providers that dispense such therapies to carry higher insurance coverage.**

**Q. The provider has applied and is in process of accreditation. Is that acceptable?**

**Yes.** However, the provider must let Express Scripts know the provider's estimated date of completion of the accreditation, as well as provide proof that the provider has started the accreditation process with one of the accreditation bodies identified in the credentialing application. The provider must update Express Scripts on accreditation status every 6 months after starting the application process, via a letter from the accreditation body demonstrating that the provider is still in process. Formal accreditation must be obtained within 24 months of receiving Express Scripts Specialty Provider credentialing.

**Q. What if the provider was previously accredited but the accreditation has lapsed?**

**The provider will be required to obtain current accreditation status with one of the accreditation bodies identified in the credentialing application.**

**Q. What if the provider does not have accreditation?**

**If the provider does not have one of the accreditations identified in the credentialing application, the provider must begin the application process within 60 days of receiving Express Scripts Specialty Provider credentialing. The provider must obtain said accreditation within 24 months of receiving Express Scripts Specialty Provider credentialing, and will update Express Scripts on accreditation status every 6 months after starting the application process, via a letter from the accreditation body demonstrating that the provider is in process.**



# PBM Trolling Template Letter

[Insert Physician Letterhead]

[Insert date]

By Regular Mail  
[Name of PBM]  
[Address 1]  
[Address 2]  
[City, State Zip]

**Re: Violations of the Health Insurance Portability and Accountability Act (“HIPAA”) and Other Laws**

Dear Sir/Madam:

Please accept this letter from [Provider] (hereafter, “Provider”) a dispensing oncology practice that serves as an in-network provider within [PBM’s] network. Recently, Provider has learned of facts that suggest there has been a misappropriation and/or unlawful disclosure of Protected Health Information (“PHI”) that Provider provided to [PBM] in connection with the treatment of one of Provider’s patients, as well as improper steering of that patient by [PBM] to its related entity, [PBM-owned Pharmacy]. This conduct is wholly improper, as [PBM] is obligated to strictly maintain the confidentiality of any PHI received in the course of its duties, and may not inappropriately utilize PHI to steer patients toward its wholly-owned pharmacies. As a result, and as further explained below, Provider has reported [PBM] to the proper authorities in connection with [PBM’s] conduct which violates a host of federal and state laws, including HIPAA.

From what we have learned, the facts reveal that [PBM] has engaged in the misappropriation, diversion and unlawful disclosure of PHI. Specifically, [PBM], on at least one occasion, unlawfully disclosed PHI in the following fashion: [Include details of the misappropriation/patient steering here including name of patient, drug name, original prescription number, date of submission, and what PBM did to make use of the PHI for its own gain].<sup>1</sup> Most importantly, [PBM’s] conduct has many adverse consequences to patient care, such as unnecessary delays in treatment, decreased adherence rates to treatment regimens, and an inherent disconnect in oncological treatment between treating physician and patient. Thus, not only does [PBM’s] conduct violate federal and state law, but it unnecessarily jeopardizes patient safety.

As [PBM] is no doubt aware, HIPAA prohibits the disclosure of PHI by covered entities, such as [PBM]. 45 C.F.R. § 164.502. Moreover, even if [PBM-owned Pharmacy] were a “business associate” of [PBM], [PBM] could only have lawfully disclosed PHI to its wholly-owned pharmacy if it were done in furtherance of the patient’s treatment or legitimate payment for

<sup>1</sup> By way of general background, [Provider] forwards a prescription (and sometimes preauthorization request) for a given patient covered by [PBM]. Such transmissions obviously contain PHI. [PBM] receives the PHI and, in its fiduciary capacity as the PBM, *should* then simply process the claim by authorizing [Provider] to fill the prescription. Instead, [PBM] communicates unlawfully to its related entity, [PBM-owned Pharmacy] and thereafter grants the pre-authorization. Once [PBM] grants the pre-authorization to have the medication filled at [PBM-owned pharmacy], [PBM] informs the patient and informs [Provider] of same via facsimile.

such treatment – not for obtaining business opportunities. See, generally, 45 C.F.R. § 164.502(a); 45 C.F.R. § 164.506. Thus, [PBM’s] transmission of PHI for the purpose of steering the patient away from [Provider] and toward [PBM-owned Pharmacy] is blatantly violative of HIPAA. HIPAA provides, in addition to substantial civil penalties, criminal sanctions for the use of PHI in this way. 42 U.S.C. § 1320d-6. Specifically, where a HIPAA violation is made with the intent to sell, transfer or use PHI for commercial advantage or personal gain, that person “shall be fined not more than \$25,000 [or] imprisoned not more than 5 years, or both[.]” HIPAA further provides that where a reasonable belief exists that PHI has been compromised, notice must be given to the Secretary of the U.S. Department of Health & Human Services. See 45 C.F.R. § 164.408.

[PBM’s] conduct does not only render it liable under HIPAA, but also a host of other federal and state laws. For starters, CMS guidance specifically prohibits Part D Plan Sponsors and PBMs from steering patients toward their wholly-owned pharmacies by way of the pre-authorization process. See Section 30.2.2.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. Further, State and Federal kickback laws similarly outlaw patient steering practices, as the practice has one entity referring a patient to another entity in exchange for remuneration. Additionally, the Medicare Any Willing Provider Law disallows patient steering, as the conduct effectively precludes a qualified provider from participating in the PBM’s network. Not only does patient steering violate numerous federal laws, but the conduct is impermissible pursuant to a number of common law causes of action, including unfair competition, breach of contract, breach of the implied covenant of good faith and fair dealing, interference with prospective economic advantage, and fraud.

As a result, please be aware that Provider has relayed [PBM] and [PBM-owned pharmacy’s] improper patient steering practices to the Office of Civil Rights and the appropriate Board(s) of Pharmacy. Further, Provider hereby asserts any and all non-retaliatory protections afforded by applicable state and federal law, and reserves the right to file suit should [PBM] and/or [PBM-owned Pharmacy] take any measures against Provider. Finally, please be advised that Provider hereby expressly reserves all applicable rights and remedies under federal and state law. Provider expects that these unlawful practices will not occur again in the future, but should [PBM] continue to engage in this (or similar) conduct, Provider will assert any and all rights available to it under the Provider Agreement, the Provider Manual and applicable law, and will seek any and all remedies available therein.

Sincerely,

[Provider]



# Template Letter Regarding Egregious PBM Conduct

[Insert Physician Letterhead]

[Insert date]

By Regular Mail  
[Name of PBM]  
[Address 1]  
[Address 2]  
[City, State Zip]

**Re: Reporting Inadequate Patient Care to Board of Pharmacy**

Dear Sir/Madam:

I write this letter as a licensed dispensing oncologist, currently treating a patient with prescription benefits managed by [PBM]. Recently, one of my patients experienced some truly objectionable conduct at the hands of [PBM-owned Pharmacy], [PBM's] wholly-owned specialty pharmacy. As described in greater detail below, this conduct has ineffectively and improperly treated my patients. By way of this letter, please be advised that I have reported these incidents to the appropriate Boards of Pharmacy and Medicine, and I further demand that this type of impermissible and inappropriate conduct immediately cease.

Specifically, [Describe the egregious PBM conduct in detail, including any harm to the patient, delay to therapy, and additional costs/waste (e.g., "On August 1, 2017, a representative from CVS Caremark contacted my office and indicated that it would not approve a prescription for Sutent unless my office changed the patient's actual diagnosis to one of multiple other diagnoses, none of which were proper for the patient. Upon my office informing CVS Caremark that changing the correct diagnosis would be illegal, CVS Caremark immediately approved the prescription with no change in diagnosis having to be made. This resulted in a five-day delay to therapy for this patient" or "On August 1, 2017, Accredo and/or Express Scripts singlehandedly modified the treatment regimen I had prescribed for [Patient] receiving Capecitabine 1650 mg twice a day, 7 days a week for 5 weeks, and changed the instructions for [Patient] to take 1650 mg twice a day, for 5 days a week. Accredo/Express Scripts essentially changed my instructions to an alternate treatment regimen without any notification or approval. Upon receiving the medication that was not in line with my treatment plan as I had discussed with the patient, the patient returned the medication to Accredo and was forced to wait an additional seven days until they received the correct medication. This cost patient and the plan sponsor extra money due to the wasted medication, and created the real possibility of the patient taking the wrong doses or prolonged courses of the medication"). Not only did these actions illegally seek to usurp the authority to practice medicine vested in me, the prescriber and treating physician for this patient, but this type of conduct literally puts my patients' lives at risk, and completely jeopardizes the success of their oncological treatment.

Moreover, with respect to [Patient], [PBM-owned Pharmacy] is the only specialty pharmacy [PBM] has chosen as an in-network provider to provide [Drug] to [Patient]. [PBM] has chosen to exclude all other providers – including this office (despite being a duly-licensed

dispensing oncology practice) – from providing this service to the patient. As a result, I have extremely limited options but to refer all oncological patients with their prescription drug benefits managed by [PBM] to [PBM-owned Pharmacy] for oncological medications like [Drug]. Were I not forced – by virtue of [PBM's] virtual monopoly – to send these prescriptions to [PBM-owned Pharmacy], this all could have been avoided.

As a result of this egregious and unprofessional conduct, please be aware that I have notified the appropriate Board(s) of Pharmacy and Board of Medicine of the impermissible and improper treatment practices utilized by [PBM] and [PBM-owned Pharmacy], including what amounted to the unlicensed practice of medicine. Any further similar conduct will result in additional notifications being sent by this office to the appropriate Board(s) of Pharmacy and Medicine. Please be aware that Provider hereby asserts any and all non-retaliatory protections afforded by applicable state and federal law.

Sincerely,

\_\_\_\_\_  
[Physician], M.D.



# Exclusion of Pharmacy from Network

- Any Willing Provider State Laws
- Employer Plans (Employee Retirement Income Security Act or ERISA)
- Frier Levitt to represent practices when ESI or other PBM's exclude you from network
  - Discounted fee of \$500
  - FL will contact PBM by telephone
  - FL will write letter to PBM

FRIER LEVITT  
ATTORNEYS AT LAW

Jonathan E. Levitt, Esq.  
direct: 973.852.8351  
jlevitt@frierlevitt.com

August 7, 2017

Via Email Only ( )

INSERT HERE

Re: Legal Representation

Dear [REDACTED]

Thank you for offering to retain the firm of Frier & Levitt, LLC. Pursuant to New Jersey rules, we must present you with an engagement agreement outlining the terms of our engagement. The intent of this letter is to serve that purpose, and its focus is to outline the terms, scope and costs associated with our performance of legal services on your behalf. Upon affixing an authorized signature to the end of this letter and returning it to our office along with the advance payment of \$500.00, we will be engaged and will begin work on the Flat Fee Project as described in Exhibit A. For your convenience, we do accept credit card payments.

You and [REDACTED] (Collectively, "You" or "Your") have requested legal representation with respect to a Flat Fee Project relating to Your exclusion from being reimbursed for one or more claims submitted to [REDACTED]'s pharmacy networks. We have offered to perform this service (described fully in Exhibit A) on a Flat Fee Basis for a total flat fee payment of \$500.00 upon execution of this agreement. I want to emphasize that these policies, procedures, and advice are proprietary to Frier Levitt and are strictly confidential. They are not to be shared with anyone outside your organization.

For all work performed beyond the scope of the Flat Fee Project, you will be billed at our normal hourly rates. Often times, our clients have other companies with overlapping ownership. The Firm and You agree that at times, you may ask us to provide legal services to another entity with overlapping ownership or control, not formally listed on this engagement letter. The Firm and You agree that all of the terms and conditions of this Engagement Letter shall cover the Firm's relationship with such additional entities. My billing rate for all time spent working on your matters will be \$570.00 per hour. The billing rates of other attorneys at Frier & Levitt range from \$160.00 to \$570.00 per hour and our legal assistants bill at \$115.00 - \$145.00 per hour. These rates include, but are not limited to, all travel time and time spent during telephone consultations. We will also bill for expenses related to excessive photocopying, filing fees, travel expenses (e.g., tolls, parking) over-night postage that is not the result of a delay on our part, messenger service, online legal research expenses and other significant out-of-pocket expenses. We reserve the right to raise our fees in the future.

You are responsible for paying all expenses in connection with our Frier & Levitt's legal representation. These expenses include, but are not limited to costs associated with serving subpoenas and complaints, retaining experts, and court reporting expenses. When we receive these vendor invoices, we will promptly send them to you for payment. You agree to be contractually obligated to pay the vendors directly.

Because we charge by the hour, our fees will depend on the amount of work we do. We bill for all time we spend on your behalf, including, but not limited to, telephone consultations. You will be billed in intervals of 1/10 of an hour, and our bills will specifically itemize the services provided and the time spent. You will be



# Subsequent Fills Pushed Elsewhere Tool

- Frier Levitt to represent practices when PBM/Plans only allow you to dispense initial fills
- Discounted fee of \$500
- FL will contact PBM by telephone
- FL will write letter to PBM

FRIER LEVITT  
ATTORNEYS AT LAW

## EXHIBIT A

### Flat Fee:

For the flat fee of \$500.00, Frier Levitt will prepare and submit a Demand Letter on Your behalf, challenging Express Script's denial of You from filling [insert particular drug]. The Demand Letter will include reference to State and Federal "any willing provider" laws, contract and manual provisions, and other applicable laws. The \$500.00 Flat Fee will include the drafting a Demand Letter and participating in one (1) telephone call with Express Script's aimed at resolving the denial. All work thereafter will be performed on an hourly basis subject to our normal hourly rates.



# Prime Therapeutics & MedImpact

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- Prime Therapeutics

“Starting January 29, 2018, Prime Therapeutics (“Prime”) will no longer be accepting PSAO additions with a pharmacy type of Dispensing Physician. Prime is no longer seeking new pharmacies with this dispensing classification. This change will be effective for the PSAO addition week beginning on **January 29, 2018**. If you have any questions regarding this notification, please send your questions to [primecredentialing@primetherapeutics.com](mailto:primecredentialing@primetherapeutics.com) or call 1-888-277-5510, option 3.”

- MedImpact stated that they would no longer be allowing dispensing physicians pharmacies to be in network in 2018





# Direct and Indirect Remuneration Fees (DIR)

- Caremark was charging nominal DIR fees 2012 to 2015
- Caremark started charging a percentage in 2016 ranging from 3.5 to 5.5% using a Star Quality system measuring
  - Diabetes Adherence
  - Statin Adherence
  - GAP Therapy (Statins)
  - ACE/ARB Adherence
- Humana charging \$5 flat DIR fees
- 2017 - Cigna/OptumRx/Catamaran 7/9% or preferred network 9/11% DIR fees





# DIR fees Legislation

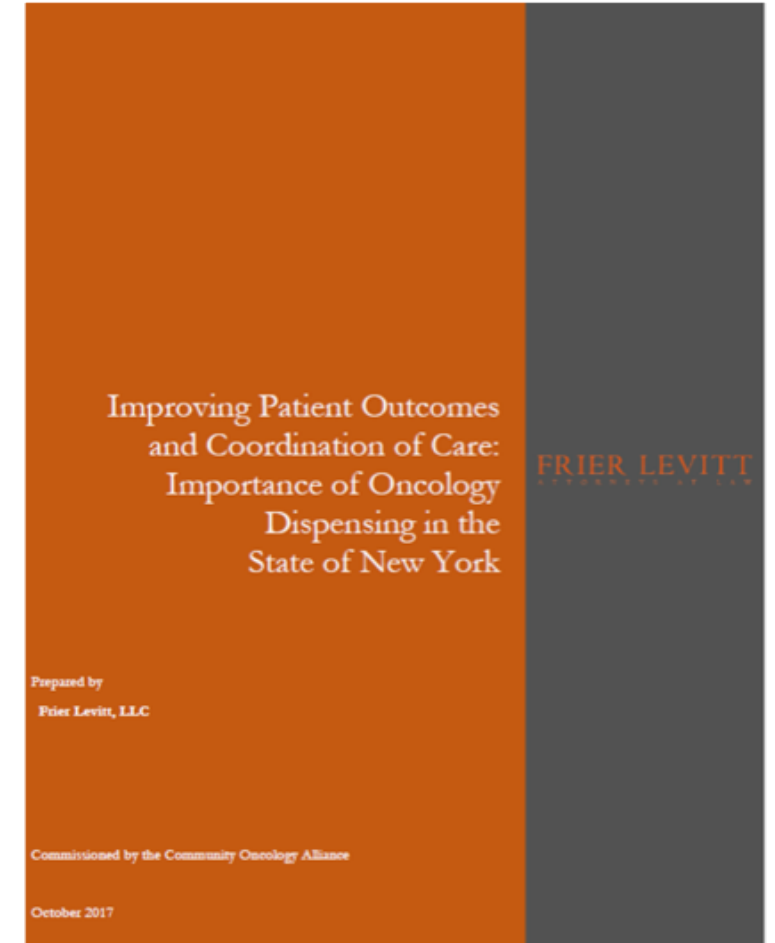
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- H.R. 1038 (Griffith Bill) and S.413 – Attempt to eliminate DIR fees but based on Frier Levitt research could actually do the opposite
- HR 1316 “Prescription Drug Price Transparency Act” Rep Collins (GA) – Does not allow a PBM that owns a distribution arm to close the network down to only their own distribution arm
- COA is working on a quality measures bill
  - Have positive and negative payment adjustments for quality metrics
  - Quality measures would be applied based on the drugs being prescribed
  - Be communicated at the claim level
  - Be communicated as to how to understand your score and how to improve on it



# Policy Paper by Frier Levitt on Oncologist Dispensing

- Based around the laws of New York but can also be used in other states
- White paper released October 2017
- Topics include
  - Introduction
  - Why Physician Dispensing is Critical
  - Legal Analysis of Healthcare Laws and How Physician Dispensing is Compliant
  - Important to Open All Pathways to Allow Oncologists to dispense to Their Patients
  - World Without Dispensing Oncologists





# Medicare Advantage and the Prescription Drug Benefit Program

- COA submitted comments to CMS on at the deadline of January 16, 2018
- Summary
  - Price transparency at point of sale
  - Clarify definition of “mail-order” pharmacy
  - Modify definition of “network pharmacy” to make sure it includes all providers licensed and authorized to dispense medications
  - Require plan sponsors and PBM’s to disseminate contract terms when requested by providers within a set time period
- <https://www.communityoncology.org/blog/2018/01/16/january-16-coa-submits-formal-comments-on-medicare-advantage-and-the-prescription-drug-benefit-program/>



**COMMUNITY ONCOLOGY ALLIANCE**  
Innovating and Advocating for Community Cancer Care

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(202) 756-2258 | [communityoncology.org](http://communityoncology.org)

Electronically submitted to: <http://www.regulations.gov>

January 16, 2018

The Honorable Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4182-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Re: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P, Federal Register, Vol. 82, No. 227, at 56336-56527)**

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), I am submitting this comment letter regarding the Center for Medicare & Medicaid Services’ (“CMS”) proposed *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program* as set forth in CMS-4182-P, Federal Register, Vol. 82, No. 227, at 56336-56527 (the “Proposed Rule”).

**Background on COA and the Community Oncology Pharmacy Association (“COPA”)**

COA is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities. For more than fifteen (15) years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care, as well as to advocate for public policies that benefit patients with cancer. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees.

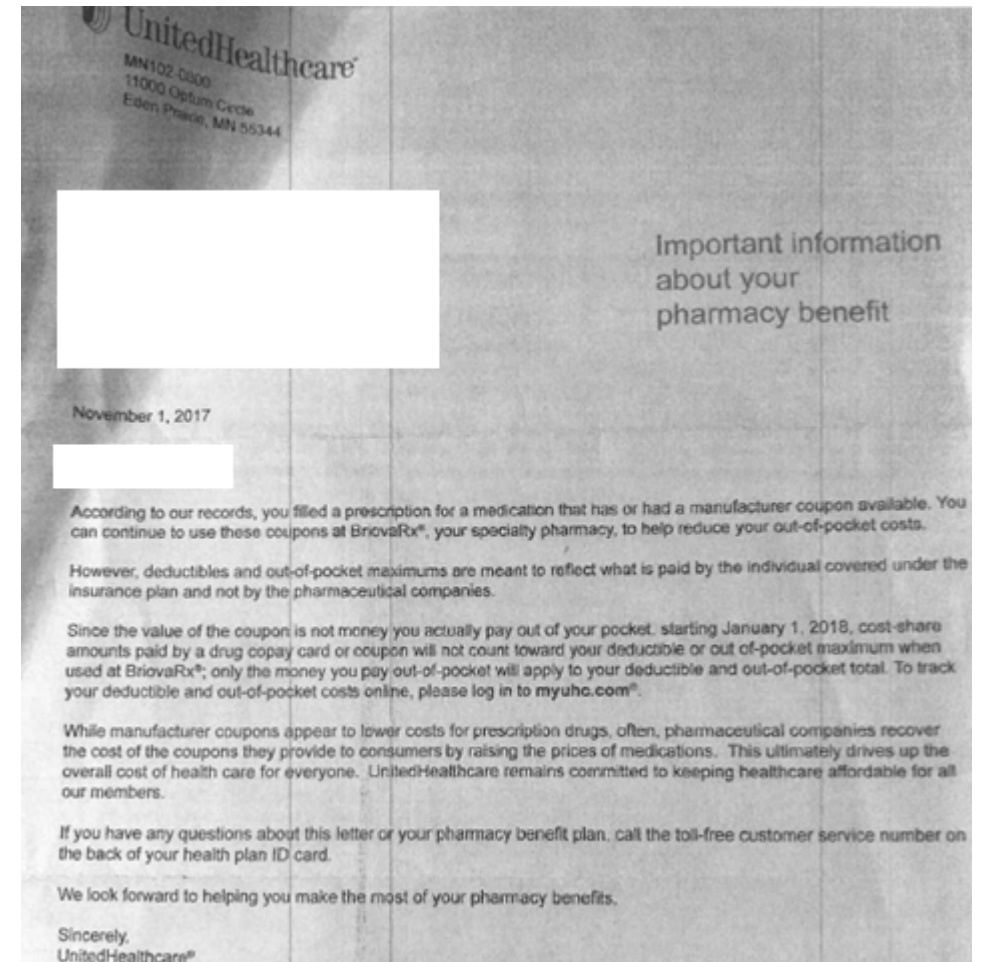
Several years ago, COA formed COPA in response to the increasing number of community cancer practices providing oral cancer drugs and ancillary therapies at the site-of-care. Given the increased availability of cancer drugs in oral formulations, which in many cases provide meaningful therapeutic benefits versus injectable formulations, it is critical that practices provide these oral drugs at the site-of-care, closely integrated with their treatment. This is especially important given the non-compliance problems cited extensively in the literature with oral cancer medications versus the certainty of injectable drugs administered at the site-of-care. Teams of oncologists, mid-level providers, oncology nurses, pharmacists, and ancillary staff have to be diligent in educating patients about oral medications, potential drug side effects, and the importance of compliance, as well as helping to overcome patient financial and insurance issues that often are barriers to oral cancer drug compliance.

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Virginia



# Copay Accumulators

- Manufacturer payment assistance will no longer apply to patient's deductible or out-of-pocket maximum
- Assistance still applies to copay of drug on day patient gets prescription
- Unless patient gets to deductible or out-of-pocket maximum then manufacturer will have to give assistance for every prescription throughout entire treatment for year
  - Are manufacturer's going to continue to provide assistance with these costs increasing significantly this year?
  - How does assistance provided by copay assistance credit cards from manufacturer factor into this?





# Thanks to our Financial Partners

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- Amerisource Bergen, Cardinal Health, McKesson have financially supported COPA and worked closely together on all projects
- UROGPO financially and actively supports COPA on all issues
- Work with NASP and MHA on DIR fees issues
- Communication opening back up with HOPA
- Thanks to the following manufacturers Apobiologix, Astellas, Exelixis, Incyte Corporation, Janssen Pharmaceuticals, Regeneron, Spectrum Pharmaceuticals, Taiho Oncology, Takeda Pharmaceuticals that have financially supported COPA



# How Can Our Partners Help

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- Allowing Physician pharmacies to be able to dispense drugs from manufacturer
- Speak to payers about value of dispensing from community oncology pharmacy (Compliance, education, less waste, etc.)
- Not limiting distribution to only 1 or 2 pharmacies nationwide
  - Tesaro, Astra Zeneca, Pharmacyclics and Gilead done great job at limiting distribution to specialty pharmacies but open to all physician dispensing pharmacies
  - Limit access to pharmacies that take away choice from patients and providers i.e. PBM owned pharmacies
- Meet with Pharmacists and Oncologists for input on new orals coming to market that have pharmacies
  - Helps alleviate concerns by manufacturers over issues on dispensing
  - Manufacturers can learn prior to exposing themselves to issues that could have been avoided
  - Pricing and price increases







The 2018  
Community Oncology Conference:  
**KEEPING PATIENTS AT THE CENTER**

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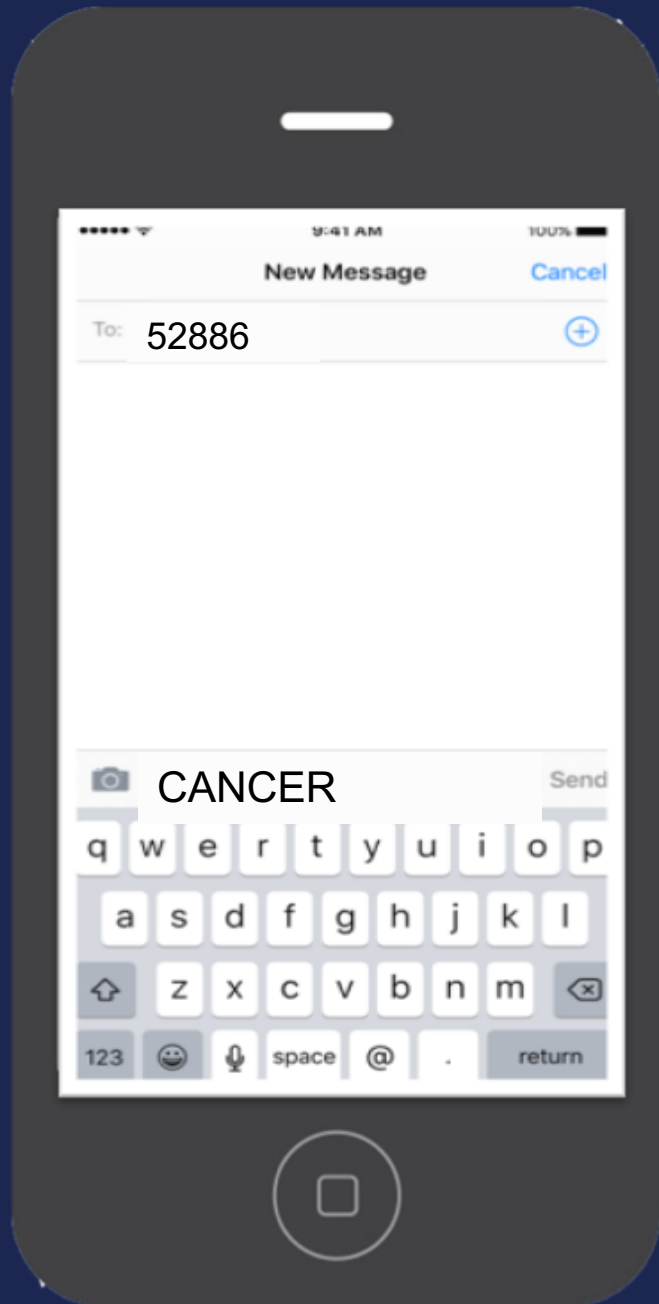
April 12–13 | National Harbor, MD

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[www.COAConference.org](http://www.COAConference.org)



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