



EMPOWERING PLANS SINCE 2000



## A Dose of Savings

Addressing Drugs, PBMs, and the Controversies Surrounding Them

January 21, 2020



## Overview

- The Future Is Now
- PGC FAQs / ICE Meltdown
- Political Update
- The Cigna R.I.C.O. Case & Implications for PBMs
- Specialty Drugs – 2020 Trends & Pricing
- Cost Containment
  - Exclusion
  - Importation
  - Drug Rebates & Patient Assistance Programs
  - Other Strategies – Pharmacogenomics
- Right to Try – A Reminder
- Stop-Loss Treatment of Specialty Drugs

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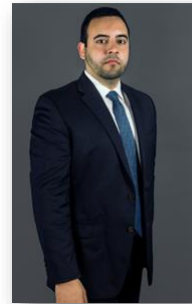
## Today's Speakers



**Adam V. Russo, Esq.**  
Chief Executive Officer



**Jennifer M. McCormick, Esq.**  
Sr. Vice President, Consulting



**Brady C. Bizarro, Esq.**  
Director, Legal Compliance  
& Regulatory Affairs

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## What Motivates Us?

**The Problem** – **Health Care Costs Too Much** and The Price is Increasing; Employers are Forced to Offset Costs Through Higher Co-Pays and Deductibles

**Our Purpose** – To **Make Health Benefits Affordable** for Employers and Employees

**Why?** – Because **Hard Working Americans Deserve Access** to High Quality, Affordable Healthcare

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## So Little Can Do So Much!

<https://secure.qgiv.com/event/directcare/>



RIP  
MEDICAL  
DEBT

RIP Medical Debt leverages each dollar to abolish \$100 in medical debt. Donate today.



Gold Direct Care's Campaign against MA Medical Debt

RIP Medical Debt (a national 501(c)(3) nonprofit organization) uses donations to purchase bundled medical debt portfolios. It targets debt incurred by people facing financial hardship and then forgives it. On average, \$1 is leveraged to abolish \$100 in medical debt. **Donations totaling \$90,000 will abolish all medical debt for people facing financial hardship in Massachusetts.** Please join us in the fight to abolish \$9 MILLION of medical debt for those in need!

Please visit [www.ripmedicaldebt.org](http://www.ripmedicaldebt.org) for more information and to donate today!

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*Thanks for listening!*

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## Podcast Topics

We Want YOU to Choose the Topic of Our Next Podcast!

**Which of today's webinar topics deserves a deeper dive?**

1. Drug Importation – Latest Guidance
2. Drug Carveout Strategies
3. Stop-Loss Treatment of Specialty Drugs
4. Executive & Legislative Proposals
5. Non-ERISA Claims Against PBMs

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## PACE® Certification

The PACE® Certification program will educate you using 3 distinct chapters of information:

### Chapter One

Explore the ins and outs of self-funding while learning about its risks and rewards. This chapter will transform any individual into a self-funding pro.

### Chapter Two

Take a deeper dive into the laws that apply to self-funded plans. We cover it all, from federal preemption to adverse benefit determinations and appeals.

### Chapter Three

Explain what PACE is, what PACE does, and how it's obtained, implemented, and utilized.



**UPDATE!** 75% of PACE Certified TPAs are reporting the tools provided have already increased their PACE plan-adoption rate, resulting in increased revenue for the TPA, and more employers being protected.

Please contact Michael Vaz at [mvaz@phiagroup.com](mailto:mvaz@phiagroup.com) or 781-884-4971 if you are interested in learning more.

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Thanks for Listening!

Special Shout-Out to Anne Gustafson  
of



Anne told us:

*"I'm a Brady Bizarro fan. I think he has the best slides of each presentation. His fame will only skyrocket in the 2020 political season...Also, I'm from Colts country so I rather enjoyed seeing the Patriots go down in defeat to the Titans. Still trying to come to grips with the retirement of Luck."*

Thanks for listening!



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A Great Past – A Bright Future



**2020 Ushers In the 20<sup>th</sup> Year of The Phia Group's Existence**  
Stay Tuned for a Year of News and Events Celebrating 20 Years of Empowering Plans!



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## The Future Is Now

### New for 2020 – Free Health Benefits

- Employees Enrolled in Plan for 5+ Years Will Have their Contribution Requirement Waived
- Coverage for Employee, Spouse, and Dependents is Provided Free-of-Charge
- As Long as Costs are Contained, the Rewards Will Flow

say “ ”  
what.

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## The Future Is Now (cont.)

### New for 2020 – Free Health Benefits

- Offer is Contingent Upon Continuous Plan Membership and Attending Mandatory Open Enrollment Meeting
- Mandatory Open Enrollment Meeting
  - Not “Just” About How to Enroll
  - Not “Just” About How the Plan Works
  - Not “Just” About What’s Covered and What’s Excluded
  - We Address:
    - Top Cost Drivers For Our Plan & In General
    - Trends in the Nation and Commonwealth of Massachusetts
    - Existing & New Cost Containment Programs
    - Using Cost & Quality Data to Make Smart Choices
    - ... and What YOU Can Do to Contain Plan Costs!

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## PGC Most Frequently Asked Questions

### #1 – If a plan provides for two levels of appeal, do the claim regulations require that each level be granted a 180 day window from denial in which to appeal?

- Regulations are not clear
- In general - plans must “establish and maintain reasonable procedures governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefit determinations...”
- Do these provisions mean that every appeal must be granted a 180 day window for filing?
- Court treatment & the 60-day window for a second-level appeal

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## PGC Most Frequently Asked Questions (cont.)

### #2 – How can we protect the plan against charges incurred in connection with a paid surrogacy arrangement?

- When the surrogate is NOT the Participant
  - Well-drafted Plan language should suffice
- When the surrogate is the Participant
  - Pregnancy Discrimination Act (“PDA”)
  - Limitations that don’t relate exclusively to pregnancy are permissible
- Third-Party Liability Angle
  - A well-drafted plan should be able to go after these funds (e.g. from the adoptive parents or the surrogacy agency)

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## ICE Meltdown

### Inquiry – What happens to an Employer’s group health plan if they are acquired by another entity?

#### • Brief Facts

- The Sponsor of a Group Health Plan was in talks to be acquired by another entity
- The Sponsor wasn’t sure what effect the transaction would have on employee benefits and how to best approach the transaction from an employee benefits perspective



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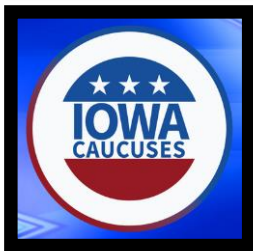


#### • PGC Response

- There are a lot of considerations for group health plans when entering into a potential M&A transaction
- What is the legal form of the transaction?
  - Asset sale
  - Stock sale
  - Merger
- COBRA implication
- Inadvertent creation of a MEWA
- Special Rules for FSAs

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## Political Update



*Senate Impeachment Trial – January 21<sup>st</sup>*

*Iowa Caucuses – February 3<sup>rd</sup>*

*State of the Union Address – February 4<sup>th</sup>*

*8<sup>th</sup> Democratic Debate – February 7<sup>th</sup>\**



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## Drug Pricing Front & Center at Democratic Debate

### Candidates' Plans to Lower Drug Costs



- Senator Warren (D-MA)
  - Doubled down on pledge to lower drug prices on day 1
  - Executive action to make it easier for generic drug makers to move in on brand-name drugs that were created using federally-funded research
    - Gov't Manufacture: EpiPens, HIV/AIDS drugs, insulin, Humira, and naloxone
- Senator Klobuchar (D-MN)
  - In favor of drug importation, something for which the Trump administration already has a plan
- All Candidates Agree on Medicare Negotiation
  - A bill that would allow this passed the House at the end of last year, but it seems unlikely that the Senate will take it up
  - For leverage in the negotiations, use intellectual property rights
  - Sens. Warren & Sanders - "March in Rights" & "Compulsory Licensing"

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## Update on Obamacare Case

### What Will SCOTUS Do?

- Texas v. United States (2018)
  - Quick Recap – Who, What, When, Etc.
  - Argument - No Mandate, No Payment...No Payment, No Tax!
  - District Court - No Longer a Tax, So Mandate Is Invalid
    - No Severability
    - If One Part Is Illegal – It's All Illegal
  - 5th Circuit – ACA's individual mandate is unconstitutional
    - Remanded the case back to the district court to determine whether any part of **Obamacare** can remain in light of the mandate's unconstitutionality
  - Defendants Petition SCOTUS to Take Case Now
  - Trump Administration Asks SCOTUS to Delay
  - The Politics At Play & What It Means for You

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## CIGNA Faces RICO Case



- A “Brazen Scheme” Against Self-Funded Plans
  - CIGNA is accused of violating RICO, defrauding patients, healthcare providers and plans
  - 150-Page Complaint Filed on New Year’s Eve
- The Scheme
  - CIGNA accepts OON provider’s claims at full billed charges and requests that amount from the plan. Then, instead of paying the provider or member, CIGNA hires a Repricing Company to try and negotiate a reduction
  - If the provider refuses to negotiate, CIGNA pays the claim at an exorbitantly low level but appears to keep the difference between what was removed from the self-insured health plan and what was paid to the medical providers
- Implications Are Huge
  - These are **non-ERISA Claims**
  - They are being brought against **PBMs** too

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## Specialty Drugs – The Trends

- Specialty Drugs Expected to Account for 50% of Total U.S. Drug Spend by 2020
  - Only 1-2% of Americans use them
- 61% of Employers Report Managing Specialty Drug Costs Is Their #1 Priority
- In the Next 15 Years, the Cost to Employers of Providing Healthcare Benefits Is Expected to Exceed Wages Largely Due to Specialty Drugs
- For Members Using Specialty Drugs, the Average Annual Cost of a Single Specialty Drug Already Exceeds Wages

**\$52,486**  
AVERAGE TREATMENT

vs.

**\$48,665**  
MEDIAN WAGE

The average annual cost of treatment with a single specialty drug was \$52,486 in 2015.<sup>1</sup>

Median wage in 2016 was \$48,665,<sup>1</sup> and median household income in 2016 was \$57,617.<sup>2</sup>

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## Specialty Drugs – 2020 Pricing

### New Drugs / Outrageous Pricing

- Gene therapy drug - **Zolgensma** (\$2.125m)
  - The most expensive drug ever approved by the FDA
- Cancer drug - **Zaltrap** (\$132k/year)
- Hepatitis C drug - **Sovaldi** (\$1k per pill: \$4 per pill [generic] in India)



### New in 2020 – Pay-Over-Time Programs

- AveXis has partnered with Accredo® to offer a pay-over-time option of up to 5 years to help ease possible short-term budget constraints, especially for states, small payers and **self-insured employers**



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## Cost Containment: Exclusion

- Excluding Specialty Drugs from the Plan Design
- What Are the Risks?
- Preventive Drug Coverage Requirement
- Discrimination Concerns
  - Treatment vs. disease
- Timing of the Plan Change
- Notice Requirements and Impact on “Minimal Value”



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## Cost Containment: Importation

- Importing Specialty Drugs from Abroad (Medical Tourism)
  - Is It legal?
  - Is It safe?
- Law on Importing Drugs
  - From enforcement discretion to warning and back
- Plan Exclusions: The Plan Must Allow It!
- Manufacturing and Safety Standards
- Provider Liability Laws
  - Medical malpractice considerations

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## The Latest Drug Importation Guidance

### May 2019

- FDA Issued Warning to Major Broker Regarding Drug Imports

### December 2019

- Trump Administration Released plan that would green-light the importation of certain drugs from Canada and potentially other foreign countries

### Hurdles for the Trump Plan

- Regulations could cut into cost savings
- Drugmakers might not cooperate
- Canada might not cooperate
- Experts seem skeptical



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## Patient Assistance Programs – Good or Bad?

- More Than 300 Drugs Are Associated with PAPs and Mfgs. Spend Nearly \$4 Billion Per Year on Them
- Assistance Programs Are Marketed As Reducing the Financial Impact on Patients → Great Public Relations Benefits
- How Do Patient Assistance Programs Impact Plan Spend?
  - They can increase the demand for specialty drugs, even when generic alternatives are available, resulting in a huge cost to the health plan.



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## Copay Assistance – The Latest Guidance

- Manufacturer's Coupons/Co-Pay Cards
- What Are They?
  - A few examples...
- They Can Incentivize Employees to Choose Specialty Rx When Cheaper Generics Exist
- Many Plans Are Not Counting Assistance Amounts Toward Patient's OOPM
  - Regulations appear to indicate that is currently illegal
- HHS Proposed Rule for 2020
  - Non-Generic drugs and drug mfg. coupons could be excluded from the OOP limit in some cases



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## Other Cost Containment Strategies

- Carve-Outs for High-Cost Drugs
  - Generic only?
- Vendor Programs to Help Reduce Costs or Avoid Needless Spend
  - Manufacturer assistance
- Promoting Use of Lower-Cost Drugs
- Specialty “Tiers” and Member Incentives (or Disincentives)
- General Health and Wellness Programs
- **Pharmacogenomics**
  - Pharmaco(logy) + genom(e): effect of genes on drug responses



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## Right to Try – Don't Forget!

### What the Law Does

- Allows terminally ill patients with physician approval to request access to experimental drugs which have completed Phase I clinical trials
- Protects mfgs. and physicians from liability from such use
- Allows mfgs. To bill patients for the cost of the drugs

### What the Law Does Not Do

- The law DOES NOT require a mfg. to provide any drug or require any payer/insurer to cover any drug or side effect



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## Right to Try – Don't Forget! (cont.)

### Why Consider Covering These Drugs?

- Consider a terminally ill patient taking a regimen of approved drugs that the plan HAS to cover at or close to 100% of the cost. An E&I drug accelerates healing, so the amount of covered treatment could be limited, leading to savings

### Recommendations for Covering These Drugs

- Review covered benefits section and add a benefit for drugs obtained via RTT by an eligible individual
- Review the schedule of benefits
- Discuss this with your UR management company to investigate the clinical aspects
- **Carriers and Plans should discuss coverage options!**

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## Stop-Loss Treatment of Specialty Drugs

### Most Important Definitions & Exclusions

- **Experimental & Investigational**
  - FDA approval
  - Off-label use
  - Language **example**: “[T]he chosen method of care cannot be lawfully marketed without the approval of the U.S. Food and Drug Administration for the particular condition and approval for marketing for the particular condition has not been given at the time such care is provided.”
- **Medically Necessary**
  - SPDs and Policies Can Differ
    - Ex. What about frequency of treatment?
  - Plan Ideal: The Policy Does Not Mention This, Instead Deferring To the SPD (*But Watch Out For Interpretation*)

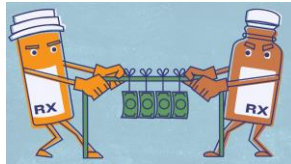
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## Stop-Loss Treatment of Specialty Drugs (cont.)

- Mirroring Endorsements Are Helpful, But Not A Guarantee
- Conduct Medical Reviews When Necessary
- Communicate with Your Carrier Early On!
- Two Examples:
  - Don't Assume Your PBM Is Handling Everything
  - Be Clear About What Guidelines Are In Use



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## THANK YOU!

**Join us for our next free webinar:  
February 12, 2020 at 1:00pm EDT**  
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