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Double Dose

Revisiting Rx Drugs &
Answering Your Questions

February 12, 2020



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Overview

- The Future Is Now
- PGC FAQs / ICE Meltdown
- Political Update
- Two Approaches to Drug Pricing Reform
- Lightning Round – Your Questions Answered
- Utah Goes to Mexico
- Importation & Medical Tourism – Liability?
- Record FDA Approvals – Impact on Plans
- Experimenting with the Experimental
- Stop-Loss Considerations
- PBM Contracts & Rebates

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Today's Speakers



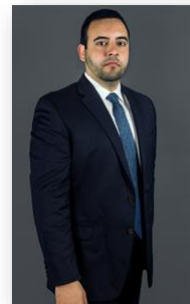
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What Motivates Us?

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 (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 for more information and to donate today!

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Follow Us!

Looking to stay updated on the latest health insurance industry news?





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Or...

Go to LinkedIn and search for *The Phia Group, LLC*


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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 & Medical Tourism
2. How to Safely Exclude Specialty Drugs
3. Stop-Loss Treatment of Specialty Drugs
4. Legislative Proposals on Drug Pricing
5. PBM Contracts & Rebates

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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 or 781-884-4971 if you are interested in learning more.

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Thanks for Listening!

**Special Shout-Out to
Kristy Lor-Ly**
Registered Nurse, Senior Clinical Consultant, Lockton



LOCKTON[®]

Lockton Dunning Benefits

Kristy told us:

"I can find a medical claim problem in reports better than I can find a vein to start an IV." She added, "Some nurses are just made differently I guess."

Thanks for listening!

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A Great Past – A Bright Future



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2020 Ushers In the 20th 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 – How should we handle charges incurred outside of the U.S.? What are our options?

Three Approaches to Consider

- Expenses incurred outside the U.S. are eligible just like any expenses
- Expenses incurred outside the United States are eligible unless travel was for the sole purpose of receiving treatment
- Expenses incurred outside the United States are excluded

There Is No Right Option

Check for PD & SL Gaps!

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PGC Most Frequently Asked Questions (cont.)

#2 – Is a self-funded plan required to offer dependent coverage for domestic partners?

The Short Answer Is No

The Longer Answer

- Many states recognize domestic partnership as a legitimate, defined legal status, but even if they don't, a plan is free to offer this coverage under its own terms
- A state requirement for dependent coverage of same-sex spouses would not impact a private, self-funded ERISA plan due to preemption

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ICE Meltdown

Inquiry – What is 10 U.S.C. § 1095, and how does it affect my self-funded group health plan?

- **Brief Facts**

- Plan denied claims from a military hospital for untimely filing
- Provider responded on DOD letterhead citing this statute and saying they have 6 years to appeal, regardless of the Plan language



- **The Takeaway**

- Special rules sometimes apply

- **PGC Response**

- This statute gives DOD the “right to collect” reimbursement from health plans for the reasonable cost of care provided to military retirees and dependents
- Limited arguments a plan can make against a military hospital in this circumstance
- Very little case law on this
- Stop loss is unlikely to reimburse

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The State of the Union's Health



On February 4, President Trump delivered his third State of the Union address before a joint session of Congress.


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The State of the Union's Health

<u>2019 Honorable Mentions</u>		<u>2020 Honorable Mentions</u>
<ul style="list-style-type: none"> • Prescription drug prices ✓ • Price transparency • End to "surprise" billing ✓ • Nationwide paid family leave • Legislation to protect those with pre-existing conditions ✓ • Repeal of the ACA's individual mandate ✓ • Right to Try legislation ✓ • Deregulation 		<ul style="list-style-type: none"> • Prescription drug prices • Price transparency • Legislation to protect those with pre-existing conditions • Expand association health plans • Offensive against Medicare-for-All proposals • Boost funding to fight childhood cancers & kidney disease • Eradicate HIV & the opioid epidemic

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The State of the Union's Health

- “New Plans with Premiums Up to 60% Less Expensive – And Better”
 - Refers to expansion of short-term plans, which don't need to cover EHBs, can exclude those with pre-existing conditions, and can have huge deductibles and copays
- “Hospital & Insurer Price Transparency Rules Will Save Families Massive Amounts of Money”
 - Rules go into effect January 2021
 - Just 7% of out-of-pocket spending is on “shoppable services”
 - Potential gains are modest
- “Last year, for first time in 51 years, the cost of prescription drugs actually went down”
 - That was 2018 for existing drugs, over 90% of which are generic
 - In 2019, prices actually rose 3%, not counting the astronomical prices for new medicines like Zolgensma



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Two Approaches to Drug Pricing Reform

- The State of Affairs
 - Trump has low approval with drug pricing efforts (54% disapprove, 30% approve, rest are neutral)
 - Source: KFF Health Tracking Poll (conducted January 16-22, 2020)
- House Bill H.R.3 - The Elijah Cummings Lower Drug Costs Now Act
 - Allow HHS to directly negotiate prices for up to 250 drugs per year
 - CBO projects \$450b savings to Medicare over 10 years
 - 8 fewer drugs (out of 300) would come to market over 10 years
 - Trump threatened to veto the plan, calling it “government price controls” and saying it would “limit access to medicine”
 - Dead on arrival in the Senate → Maj. Ldr. McConnell (R-KY) has no interest
- Chuck Grassley’s (R-IA) Senate Bill
 - Narrower set of reforms
 - Moved out of Finance Cmte. last fall, stuck there now
 - Achieves pricing reform through a mix of technical changes to rebates as well as provisions to cap out-of-pocket costs for seniors

UNITED STATES SENATE
COMMITTEE ON FINANCE

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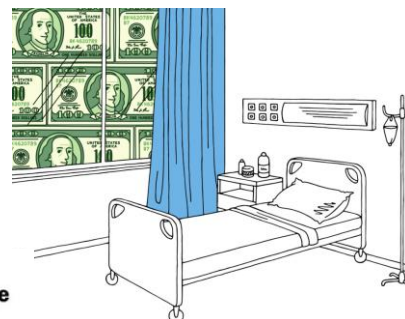
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What About Hospital Pricing Reform?

- Hospitals receive \$1 out of every \$3 spent on health care
- United States was projected to spend about \$1.3 trillion for hospital care alone in 2019 (compare to \$370b for prescription drugs)
- Collectively, hospitals boast a margin of 8%, a level higher than margins in the pharmacy industry or the insurance industry
- Why aren’t politicians talking about this?

“People don’t like their insurance companies, they like their doctors and their hospitals.”

Senator Bernie Sanders (D-VT)



A majority of U.S. adults say medical doctors care about their patients’ interests all or most of the time

% of U.S. adults who say the following about medical doctors



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Lightning Round – Your Questions Answered

- Question: What are some different options in regards to specialty drug coverage?
 - Can dollar limits be placed on specialty drugs?
 - What about EHBs?
 - Will our PBM allow us to play around with coverage?
 - Is there a distinction between limiting coverage for a treatment, and limiting coverage for a disease?

- Question: If a health plan's prescription coverage does not include specialty drugs, can the medical plan also exclude coverage for specialty drugs?
 - What about preventative drugs?
 - Can the change be made mid-year?
 - How does §1557 factor in?



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Lightning Round (cont.)

- Question: PBMs have told me that excluding any drug for which there is no alternative therapy is illegal under the ACA. Is this true?

- Question: Can I make a specialty drug out-of-network to eliminate the annual maximum out-of-pocket?

- Question: Can a plan have a maximum “per script” reimbursement in the plan?
 - Not an annual cap but simply a maximum reimbursable amount per script



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Utah Goes to Mexico

- **Utah Isn't Waiting Around**
 - Utah is paying public employees to travel to Mexico to fill prescriptions
 - Medical tourism isn't new, but this is the first major health insurer to deploy this kind of program
- **How Utah's Gov't Employee Program Works**
 - Patients taking one or more of 13 specialty drugs are eligible to participate
 - They can travel to Vancouver, Canada, or Tijuana, Mexico, to buy their prescriptions
 - They still make their usual copayments only
 - The state health insurance plan covers the cost of their airfare, transportation to and from the airport, and lodging if necessary
 - The state will also pay the patients \$500 cash for making the trip
 - State contracts with a Mexico-based specialty pharmacy to arrange purchases and coordinate travel
 - A rep. from the pharmacy never leaves the employee's side



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Utah Goes to Mexico (cont.)

Should Plans Consider This Kind of Program?

- **The Results**
 - Saved \$225k so far
 - Of 160,000 state and local EEs covered by the insurer, less than 400 are eligible
 - Only 10 patients have actually made the trip
- **The Risks**
 - This is not a sustainable model for drug pricing reform
 - The medications could be unsafe for patients



What Are Other States Doing?

- California is considering launching its own generic-drug label. Louisiana has a Netflix-style program for hepatitis C drugs, where the state negotiated a deal to pay a flat fee rather than for each prescription.

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Importation & Medical Tourism – Liability?

- Law on Importing Drugs
 - From enforcement discretion to warning and back
- Plan Exclusions: The Plan Must Allow It!

Are Plans/Employers Liable If Plan Participants Are Injured?

- Manufacturing and Safety Standards
 - FDA: Drugs “may have different dosage strengths or be manufactured by companies different than the FDA-approved drug. They may be from different regions and they may be counterfeit.”
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632360.htm
- Notably, however, the FDA has acknowledged that they have no reports of anyone harmed by these programs

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Record FDA Approvals – Impact on Plans

- In 2019, FDA approved 1,171 generic drugs, an all-time record
- FDA will evaluate more than 150 new approvals this year
 - 64 applications submitted to the agency with likely approval in 2020
- According to OptumRx, 11 of those drugs are set to be “blockbuster” products with over \$1 billion in U.S. sales
- “Orphan” Status & Fast Track Approval – Plan Impact
 - Designating “orphan” status allows mfgs. to charge more
 - Often limited supporting evidence for long-term or curative benefits, yet drug companies start pushing for treatments right away
 - How does stop-loss address fast-track approved drugs?
- Plans must strike a balance between access and cost-containment



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Experimenting with the Experimental

- **The Problem**
 - Plan has EE undergoing cancer treatments
 - EE just completed bone marrow transplant (BMT)
 - EE might be candidate for CAR T-cell therapy depending on the response to BMT
 - CAR T-cell therapy has been deemed experimental
 - If BMT does not work, the Plan wants to be able to cover the treatment
- **The Answer & Ongoing Risks**
 - Plan language that caveats to experimental and investigational treatment
 - Alternative care and alternate course of treatment language
 - Regarding stop-loss, no concrete solution here → ultimately a business decision must be made
 - Transparency is key with the TPA and stop-loss carrier
 - Explain the situation and put them on notice that the claim is being investigated and request that the claim be held open. This will help prevent proof of loss issues



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Stop-Loss Considerations

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 & 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*)



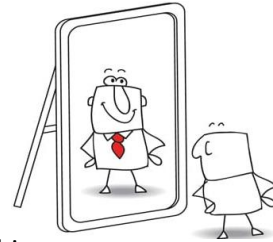
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Stop-Loss Considerations (cont.)

- 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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PBM Contracts

Valuable Services PBMs (Sometimes) Provide:

- Development of a Formulary
- Access to Quality Drugs & Steerage to Generics
- Discounted Rates
- Negotiation & Administration of Rebates
- Programs to Improve Health
- Minimum Discount Guarantees



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PBM Contracts

Things to Look Out For:

- Confidentiality of Manufacturer Agreements
- Arbitrary or Nontransparent MAC Pricing
- Lack of Ability to Amend the Formulary
- Prohibition on Access to Alternative Sources
- Lack of Rebate Transparency
- Spread Pricing



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PBM Rebates – Who Owns Them?

- Why Is This A Problem?
 - Many PBMs/TPAs/ASOs keep a portion of rebates



Medical Drug Rebates: [x] shall retain rebates it receives directly from pharmaceutical manufacturers for Claims for Prescription Drugs administered by [x] and covered under the medical benefit portion of the Plan(s) ("Medical Drug Rebates") for its own use and as reasonable compensation for its services.

- Many stop-loss carriers deny reimbursement for rebates issued to the Plan, even if not received by the Plan. Language isn't always clear

We may elect to reduce or deny any reimbursement which may be payable to You, to the extent that a payment may be made by another insurer, another Plan or any other party, to either the Plan or the Covered Person.

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THANK YOU!

**Join us for our next free webinar:
March 10, 2020 at 1:00pm EDT**
www.phiagroup.com/media/webinars

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