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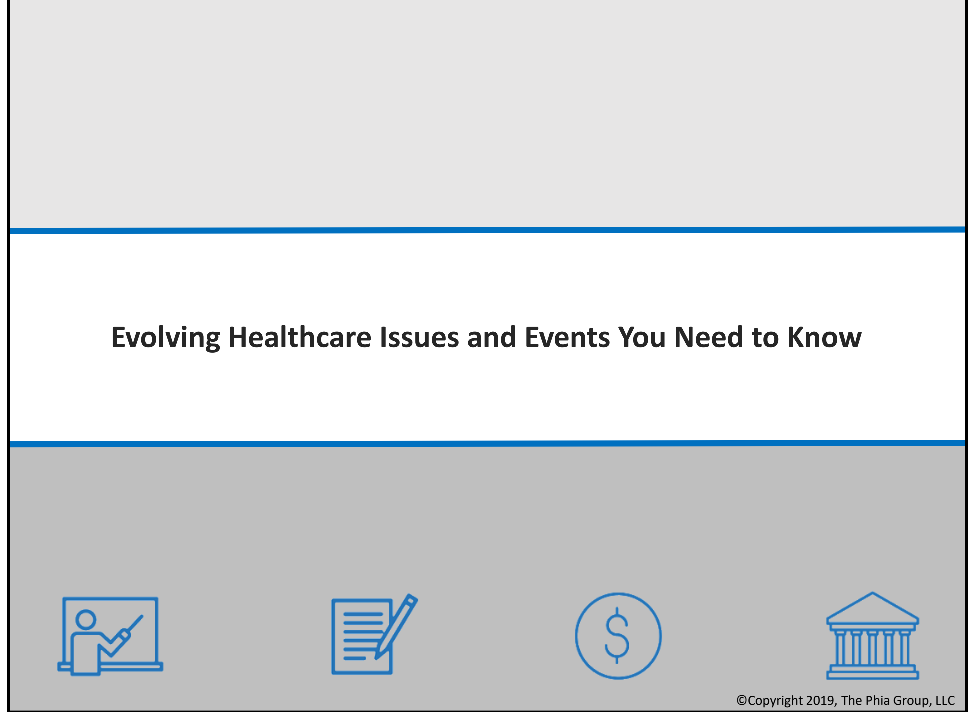
Evolving Healthcare Issues and Events You Need to Know
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Today's Speakers

Adam V. Russo, Esq.
Chief Executive Officer

Ron E. Peck, Esq.
Senior Vice President
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Vice President, Consulting

Brady C. Bizarro, Esq.
Director, Legal Compliance
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A Special Shout-Out!

Special Shout-Out to Dr. Michael Tremblay

of

Dr. Tremblay is an avid fan of our webinars and podcasts!

Thanks for listening!

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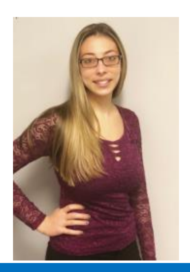
Faces of Phia

Boris Senic, Chief Business Architect – As Chief Business Architect, Boris maintains the space in which The Phia Group's client data is analyze for subrogation purposes. Recognizing that data analytics is the key to identifying cost-containment opportunities, Boris helps The Phia Group deveop and sustain processes to allow The Phia Group to save money for its clients as efficiently as possible. Boris excels at finding ways to use data to help our clients save money on a daily basis.

Maya Tamhankar, Director, Project Management – Maya oversees The Phia Group's Project Management team. Her team currently performs business analysis, assists with client implementation, and provides both internal and external training regarding The Phia Group's service offerings. The quality of any ervice is partially measured by how well it is managed by the service provider; Maya excels at creating and maintaining dependable processes for The Phia Group's clients to utilize our services as effectively and efficiently as possible, and in turn continue to provide low-cost, high-quality healthcare.



Amanda Grogan, Team Leader, Senior Recovery Team, Attorney Tier – Amanda leads efforts in which recovery specialists reach out to external entities. The correspondence serves to verify that these entities are put on notice of the plan's interest in all settlement matters. Amanda works to ensure that the plan receives reimbursement whenever an opportunity is identified. Amanda's dedication allows plans to recuperate funds and eliminate waste.

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Overview

- Problem, Purpose, Process
- Last Month's PGC FAQs
- Political Update
  - PBM Hearings
- Evolving Issues and Events:
  - FDA Warning Regarding Canadian Drug Importation
  - ACA Contraceptive Mandate Case – What Now?
  - HHS To Conduct Random HIPAA Compliance Testing
  - Federal Judge Strikes Down AHP Initiative
  - Federal Judge Blocks Some Medicaid Work Requirements

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Problem, Purpose, Process

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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Last Month's PGC FAQs

- **Can an HDHP-enrolled individual over 65 still utilize an HSA?**
  - Hinges on (1) coverage under HDHP, (2) no other health coverage (…with exceptions), (3) non-enrollment in Medicare, and (4) tax dependent status
- **Can a plan limit dialysis treatment by number of visits?**
  - The underlying question: does this impermissibly differentiate between individuals with and without ESRD, or take into account Medicare enrollment?
  - Federal regulations apparently allow this:
    - "A plan is not prohibited from limiting covered utilization of a particular service as long as the limitation applies uniformly to all plan enrollees. For instance, if a plan limits its coverage of renal dialysis sessions to 30 per year for all plan enrollees, the plan would not be differentiating in the benefits it provides between plan enrollees who have ESRD and those who do not." 42 CFR § 411.161
- **How does a plan's reference-based-pricing program interact with stop-loss?**
  - *(How much time do we have?)*

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Trending Now: Specialty Drugs
SPECIALTY DRUGS CARRY A HIGH PRICE TAG
From 2012 to 2020, spending on specialty drugs is expected to increase by 361%.
Specialty drug spending in US dollars billions
$87
$192
$402
2012
2016
2020
Source: PwC's Health Research Institute: Behind the Numbers 2015 and analysis of CVS Caremark data.
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Drug Pricing In America: The Committee Hearings
COMMITTEE ON FINANCE
HEARING ROOM
This room is equipped with an assistive listening system.
Please silence all electronic devices before entering.
SD 215
• Executives from the five largest PBMs appeared before the Senate Finance Committee on Tuesday, April 10th.
• Executives from the three makers of insulin and of CVS Health, OptumRx, and Express Scripts appeared before the House Committee on Energy & Commerce on Wednesday, April 11th.
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The House Hearing – Key Takeaways

Hearing Title - "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin"

- Insulin Prices Are the Case Study; Driving Broader Price Reform Efforts
  - Question → Why Do List Prices Keep Increasing?
  - Answer → ______
- **The Committee**
  - Was Visibly Irate - "***I don't know how you people sleep at night****...your days are numbered*" Rep. Jan Schakowsky (D-Ill.).
  - Believes Insulin Prices Prove the Free Market Isn't Working
  - Believes Drug Makers Can (But Won't) Lower Prices
  - Threatened to Set List Prices; Threatened to End the Rebate System
  - Suggested that PBMs Should Be Put Out of Business

- **Manufacturers & PBMs**
  - Blamed Each Other; Defended the Current Market Structure
  - Claimed A Drastic Reduction of List Prices Would Threaten Access to Medications for People Currently Depending on PBMs
  - Highlighted Patient Assistance & Charity Programs to Data Showing "Net" Prices Keep Dropping
  - Want the Rebate System to Stay In Place

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The Senate Hearing – Key Takeaways

Hearing Title - "Drug Pricing in America: A Prescription for Change, Part III"

- Focus on PBMs, PBM Consolidation & Rebates
  - CVS Health, OptumRx, Express Scripts (together control 71% of Medicaid Membership & 86% of the Private Market), Humana & Prime Therapeutics
  - Reminder → What Is A PBM & What Does It Do?
- **The Committee**
  - "Did PBMs ever persuade drug companies to set a higher list price so the PBM could have more flexibility to negotiate a rebate?" Answer → No.
  - "Are there any other egregious anti-consumer practices in your industry you'd like to highlight?" Answer → Silence
  - Signaled A Focus on Transparency Rather Expanding Proposed Ban on Rebates for PBMs
  - Was Unimpressed by Pre-Emptive Action by Cigna & Sanofi
- **PBMs**
  - Insisted That Consolidation Helps Take Better Care of Patients
  - Claimed Ending Rebates Would Lead to Premium Increases
  - Claimed Transparency In Negotiations Won't Solve Problem; Instead, Advocated for More Competition (So, They Blamed Drugmakers)
  - Highlighted Their Pre-Emptive Regulatory Actions (Sanofi, Cigna, CVS "Guaranteed Net Cost PBM Model")

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A Closer Look: Rebates

Example:

A manufacturer originally prices a drug at $100. A health plan hires a PBM that negotiates that price down to $80. A pharmacy purchases the drug from a wholesaler and the PBM pays the discounted rate to the pharmacy. The pharmacy also pays a fee to the PBM for the negotiating service. Because this fee is based on a percentage of the drug's list price ($100) instead of the discounted price ($80), the PBM earns an extra profit. The PBM may then charge the insurer a higher price ($90) for the drug, even though it reimburses the pharmacy at the negotiated price ($80). The PBM also earns a rebate directly from the drug manufacturer for placing their drug on the PBM formulary.

Because the negotiated discount is kept secret, we have no idea how large PBMs' profit margins are for the fees they charge.

When the patient obtains the drug from the pharmacy, they are charged a copay amount based on the list price ($100) rather than the negotiated price ($80). This co-payment is often higher than the cash price, and pharmacists used to be prohibited by PBM contracts from informing patients about this potential cost-saving opportunity.

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A Closer Look: Patient Assistance Programs

- More than 300 drugs are associated with PAPs, and manufacturers spend nearly $4 billion per year on these programs
- Assistance programs are marketed as reducing the financial impact on patients, which has 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.

Example:

A specialty drug's list price is $10,000. A generic alternative is available that has a list price of $2,000. The health plan imposes a $500 copay for specialty drugs when generics are available and a $100 copay for generics. In this case, however, the specialty drug manufacturer offers the patient a $450 copay card. For the patient, the out-of-pocket cost for the specialty drug is $50 cheaper than the copay for the generic alternative. The patient chooses the specialty drug, and the health plan pays $9,500. Had the patient selected the generic alternative, the plan would have only paid $1,900.

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What Action(s) Could Be Next?

- Manufacturers & PBMs Likely to Continue Announcing New Programs / Price Discounts to Try to Preempt Regulation
- Trump Administration Rule On Rebates Takes Effect on 1/1/2020
- Still Awaiting Clear Legislative Direction
  - Congress Is Not Going to Directly Set Drug Prices
  - Medicare Negotiation and Competitive Licensing Act → allow Medicare to negotiate drug prices with possibly of stripping patents
- Bipartisanship Might Actually Lead to Real Legislative Action
  - Powerful Committee Chairmen & Ranking Members Have Made Addressing High Drug Prices A Main Priority
    - Chairman Chuck Grassley (R-IA)
    - Ranking Member Ron Wyden (D-OR)
    - Chairman Frank Pallone, Jr. (D-NJ)

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FDA Warning Regarding Canadian Drug Importation

- FDA warns of “unapproved” and “misbranded” drugs
- 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
- Initial indications are that many groups – especially municipalities – have no plans to change their utilization

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Texas v. United States (Update)

- **DOJ announced that it will no longer defend the ACA!**
  - Previous position: individual mandate, guaranteed issue, community ratings provisions may be "invalid" – but the rest of the ACA was severable and should be upheld
- DOJ now agrees that the Fifth Circuit Court of Appeals should uphold the ruling that the entire ACA is invalid
- Oral arguments set for early July. Only time will tell…

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HHS To Conduct Random HIPAA Compliance Testing

- Covered Entities to receive random audits!
- In April 2019, nine (?) health plans and clearinghouses will be chosen at random, followed by periodic random audits
- But… "Covered entities found to be noncompliant will be given the opportunity to take actions to correct issues and achieve compliance."
  - So, a free chance to correct HIPAA compliance before any actual enforcement will take place
- Be aware* of random audits!

*…but if you're found to be noncompliant, HHS wil apparently let it slide as long as you *become* compliant)

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Federal Judge Strikes Down AHP Initiative

- Many view the AHP initiative as a victory for self-funding – effectively enabling small businesses to join an AHP and self-fund when they previously would not have been able
- Court: “The Final Rule was **intended and designed to end run the requirements of the ACA**, but it does so only by **ignoring the language and purpose of both ERISA and the ACA**. DOL unreasonably **expands the definition of “employers” to include groups without any real commonality of interest** and to bring working owners without employees within ERISA’s scope **despite Congress’s clear intent that ERISA cover benefits arising out of employment relationships**.”

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Federal Judge Blocks Some Medicaid Work Requirements

- Trump administration gave states the power to impose work requirements on Medicaid enrollees
- Administration has approved eight states; seven more pending – but in the meantime:
- HHS-approved work requirement “is arbitrary and capricious because it did not address … how the project would implicate the ‘core’ objective of Medicaid: the provision of medical coverage to the needy.”
- Judge criticized HHS for approving, and essentially giving in to republican Kentucky governor’s threats of scrapping the state’s Medicaid expansion unless those rules stuck

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The Evolving Contraceptive Coverage Rules

- The Hobby Lobby Case & Religious Objections
- How to Obtain A Religious Exemption
- How to Obtain a Religious Accommodation
- New Trump Administration Rules
  - Exemptions for Religious Beliefs (CMS-9940-F2)
  - Exemptions for Moral Conviction (CMS-9925-F)
- Impact on TPAs
  - Optional Accommodation Process
  - Accommodation vs. Exemption

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Contraceptive Coverage Rules Blocked – An Update

- The New Rules Are Currently Blocked
  - Rules Set to Take Effect on 1/14/2019
  - Federal Judges Granted Requests for Injunction
  - Pennsylvania Federal Judge Blocked Rules Nationwide
- Trump Administration Appeals the Injunction
  - Brief Filed 3/28/2019
  - Argument Over Standing → Has Harm Occurred Yet?

- What Do Plans & TPAs Do Now?
  - Employers not permitted to rely on the two final rules to requests accommodations to the ACA's contraceptive mandate
  - Churches, religious groups & closely-held for-profit companies are still permitted to opt-out
  - Employers must decide if the meet requirements for accommodations
  - Employers that have obtained an accommodation should not seek an exemption under the new rules

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Massachusetts Paid Family Medical Leave Law (PFML)

- Contributions start 7/1/2019
- As of 1/1/2021, employees eligible for 12 weeks of paid family leave and 20 weeks of paid medical leave
  - Eligible for combined max of 26 weeks per year
- Continuation of medical coverage is required
- Other states may follow suit!
- **Your to-dos:**
  - **HR**: make sure to update employee handbooks and materials;
  - **SPD Drafting**: make sure the SPD reflects the continuation;
  - **Stop-Loss**: make sure carrier is aware and on the same page!

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