# The Underlying Regulatory Landscape

Don't Get Lost in the New Normal!

July 16, 2020



## **Phia Group Consulting**



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#### **Overview**

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  - Contraceptive Mandate Ruling 0

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## **Today's Speakers**



Adam V. Russo, Esq. Chief Executive Officer



Ron E. Peck, Esq. **Executive Vice President** & General Counsel

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Jennifer M. McCormick, Esq. Sr. Vice President, Consulting Director, Legal Compliance

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Brady C. Bizarro, Esq. & Regulatory Affairs



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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.

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**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.

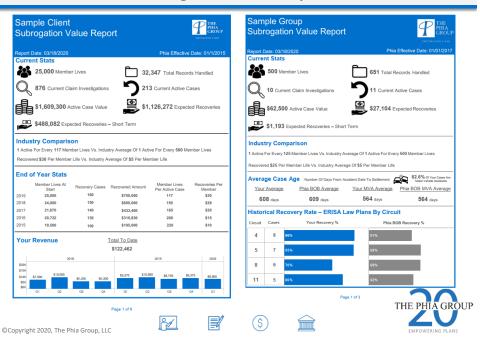
#### Please contact Michael Vaz at <u>mvaz@phiagroup.com</u> or 781-884-4971 if you are interested in learning more.





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#### **Subrogation Value Reports**

## **Introducing Phia's Client Success Team**

**Client Success** 

#### What Is Our Client Success Team?

- Centralized point of contact for all clients
- Relationship-focused client managers
- Align client and operations goals

#### What Will the Team Do for Me?

- Find out anything Phia is doing wrong, fix it, and ensure you are happy with our services
- · Identify any delays or roadblocks preventing us from doing our jobs
- · Deliver all reports and resolve any issues associated with them
- Fully analyze, utilize, and interpret Value Reports and other reporting tools
- Respond to routine file specific client questions (e.g., status on file #12345)
- Provide subject matter expert ("SME") assistance as needed



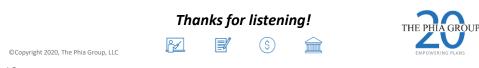
**Thanks for Listening!** 

Special Shout-Out to Hobson Carroll President MedRisk Actuarial Services, Inc.

# MEDRISK ACTUARIAL SERVICES, INC.

#### Hobson told us:

"I was traveling by train with a London broker to visit a client on the outskirts of Oxford, and as we rolled past a particularly picturesque meadow with a herd of cows grazing in it, my companion commented, "Oh, look at that bunch of black and white cows out there, quite a lot of them, eh?" I took a quick glance, and replied, "Well, they do appear to be black and white on the side we can see."



## Phia's New Louisville Location



## PGC Most Frequently Asked Questions

# **#1.** As employers begin to rehire displaced workers, how does that break in service impact ACA eligibility measurement?

- Two Issues to Consider
  - 1. Whether the employee was enrolled in your Plan before termination
    - Any returning ACA-eligible employee, who previously had been offered and enrolled in coverage before termination, must receive an offer of coverage upon return, and by the first of the following month at the latest
  - 2. Determination of the employee's ACA full-time status, which depends on when they return to work and how the employer counts their worked hours
    - Under the look back method, if an employee returns to work in less than 13 weeks from the termination date (26 weeks for employees in education), they must be treated as an ongoing employee, as if they never left your employment



### **PGC Most Frequently Asked Questions**

**#2.** Are we able to provide a retirement benefit plan to executives only? We heard there is an exception to the discrimination rules for retirees?

 26 CFR § 1.105-11(c)(3)(iii) provides a limited exception for benefits provided to retirees. It states (emphasis added):

(iii) Retired employees. To the extent that an employer provides benefits under a self-insured medical reimbursement plan to a retired employee that would otherwise be excludible from gross income under section 105(b), determined without regard to section 105(h), such benefits shall not be considered a discriminatory benefit under this paragraph (c). The preceding sentence shall not apply to a retired employee who was a highly compensated individual unless the type, and the dollar limitations, of benefits provided retired employees who were highly compensated individuals are the same for all other retired participants.

 Based on a review of 26 U.S.C. § 105 and accompanying regulations, it appears this structure may run afoul of Section 105(h)'s prohibitions against discriminating in favor of Highly Compensated Individuals ("HCIs"). Note that the penalties for this type of discrimination are limited to tax consequences

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## **Political Update**



As the 2020 presidential election heats up, most polls show Joe Biden, the presumptive Democratic nominee, with a significant lead over President Trump.

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## **An Election Unlike Any Other**

- COVID-19 Could Cause Chaos in November
  - Coronavirus response will be the #1 issue in the fall
  - Pandemic and economic disaster could put swing states in play 0
  - Trump cannot cancel or delay the election, but COVID-19 could decimate voter participation and threaten the legitimacy
- Biden Leads Most Polls, But So Did Hillary 4 Years Ago
- Top Five Healthcare Issues This Election Will Shape
  - 1. COVID-19 Response
    - Trump's approval #s here are slipping as cases explode in the southwest 0
  - 2. Fate of the Affordable Care Act
    - Biden "Unconscionable" for Trump to attack ACA in the middle of a pandemic

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- Biden expected to restore and expand the ACA 0
- 3. Public Option and the Slide Toward Medicare for All
- 4. Prescription Drug Pricing Reform
- 5. Medicaid Expansion

Biden Expected to Pick a Running Mate This Month ₽**∕∕** 

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House Passes a Bill to Expand the ACA

#### H.R. 1425 – The Patient Protection and Affordable Care Enhancement Act

- Passed largely along party lines, stands no chance in GOP-led Senate
- Would hike premium subsidies, expanding tax credits beyond individuals making more than 400% of the federal poverty line
  - Premiums for exchange plans would be capped at 8.5% of income
- Would allow federal health officials to negotiate price of drugs under Medicare • Trump used to support this idea but has turned against it
- Would rescind Trump rule which expanded short-term, limited-duration plans and revoke guidance on section 1332 waivers
- Congressional Budget Office estimates the bill would save \$582 billion over 10 years

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Includes several incentives to expand Medicaid •

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## **COVID-19 Stimulus #? This Month**

- Recall the House Passed the \$3 Trillion HEROES Act on May 15<sup>th</sup>
- HEROES Contained Provisions Which Would Impact Our Industry
  - o COBRA Subsidies
  - o COVID-19 Treatment Coverage
  - o Surprise Billing A blueprint for a bigger solution
- GOP-Led Senate Wants A New Bill Focused on 4 Areas
  - 1. Liability reform
  - 2. Getting kids back in school
  - 3. Jobs growth
  - 4. Healthcare
- More Details Have Crept Out
  - Stimulus Checks for Workers Making \$40,000 or Less
    - 5 Year Liability Shield For Businesses, Healthcare Providers, Universities, and Schools

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- Start in December 2019 and last through 2024
- Would not apply to acts of gross negligence

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• Time Is Running Out  $\rightarrow$  On July 31<sup>st</sup>, Expanded Benefits Expire



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#### **The New Normal**

#### What We Mean by "New Normal"

- Personal Life Change
  - Wearing masks
  - Social distancing
  - o Evaluating risk factors for life activities
- Workplace Changes
  - Back to work plans / safety measures
  - o Dealing with new surges and shutdowns
  - Increased remote work
  - Worker's compensation issues
- Healthcare Changes
  - COVID-19 testing/claims
  - o <u>Telemedicine</u>
    - It is not going away
    - Issue of virtual visits by INN providers

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Mental health

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Direct primary care



### Navigating the New Normal

- Keep Up with Legislation, Regulations, and Litigation
- Understand Your COVID-19 Related Obligations As Employers
- Review Employer Policies / Handbooks for Compliance
- Review and Update Plan Language Accordingly
- Protect Plan Assets Review/Negotiate Claims
- Avoid Costly Stop-Loss Mistakes



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## **Regulatory Updates You Need to Know**

#### **COVID-19 Public Health Emergency Will Be Renewed**

- Originally Declared on Jan. 31<sup>st</sup>, Renewed April 21<sup>st</sup>, Now Renewed Again
- Declaration Was Set to Expire on July 25th
- Prolongs the Emergency Designation by 90 days
- Maintains 20% Add-On Payment for Providers with COVID-19 Patients on Medicare

• Regulatory Freedom for Telehealth to Be Extended for the Duration

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- Direct Impact on Self-Funded Plans
  - Insurers Must Cover COVID-19 Testing Without Cost-Sharing for the Duration of the Emergency

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#### Federal Guidance for Employers on COVID-19 Testing

- Return to Work Testing
  - o Group health plans not necessarily required to cover these tests
  - General screening for COVID-19 may fall outside scope of FFCRA if performed for general employment purposes
  - Clinical decisions about testing are made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19
- Multiple Tests for the Same Individual/Asymptomatic Testing
  - A group health plan "...shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements..." for COVID-19 testing and related services
  - Plans cannot impose a limitation on the number of times an individual could be tested, as that would constitute a "medical management requirement"

#### • A Note on Medical Necessity

- o This is decided by the provider, and it is not required that it be the individual's PCP
- Must be determined according to "generally accepted medical standards"

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#### **Federal Rule on Copay Assistance Programs**

- Manufacturer's Coupons/Copay Cards
  - O Can Incentivize Employees to Choose Specialty Rx Over Cheaper Generics
- Excluding Patient Assistance Amounts from Patient's OOPM
  - O Earlier regulations appeared to indicate you could not do this
  - At the least, there was disagreement and ambiguity
- HHS Proposed Rule for 2020
  - Originally, Trump administration planned to permit the exclusion of patient assistance amounts only if patient was taking a brand name drug that had an appropriate generic alternative

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- O Face with criticism by insurers and employers, it reconsidered
- Final Rule Leaves the Decision Up to Employers
  - But state laws can supersede
  - 4 states have them AZ, IL, VA, WV
  - Effective 7/13
- <u>Review Your Plan Language and Internal Practices!</u>

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## **DOL/IRS Final Rule Extending Deadlines**

- Requires Plans to Disregard A Designated Period of Time with Respect to Deadlines
  - The "Outbreak Period" is from 3/1 until 60 days after the end of the Emergency Period or such date announced by the Departments
- Impacts
  - o HIPAA Special Enrollment
  - o COBRA Electing Continuation Coverage
  - COBRA Timely Payment of Premiums
  - o COBRA Notice of Qualifying Event
  - o Claims Filing Period
  - o Appealing an Adverse Benefit Determination
  - o Request for an External Review

#### <u>Be Careful When Reviewing Eligibility / Administering Claims</u>

- COBRA dates can be especially tricky
- Employers should not use the extension to defer sending out notices
- You could end up paying claims that were not the Plan's responsibility

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#### **Rule to Provide Greater Flexibility for GF Plans**

- Proposed rule would clarify that grandfathered group health coverage that is a high-deductible health plan ("HDHP") may increase fixed-amount cost-sharing requirements, such as deductibles, to the extent necessary to maintain their status as an HDHP without losing grandfather status
  - This change would ensure that participants and beneficiaries enrolled in that coverage remain eligible to contribute to a health savings account

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 Proposed rule provides an alternative method of measuring permitted increases in fixed-amount cost sharing that would allow plans and issuers to better account for changes in the costs of health coverage over time.

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• Comment Period Ends 8/14



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#### **IRS Expands Cafeteria Plan Midyear Election Changes**

- Section 125 Cafeteria Plans Are Required to Maintain Employee Pre-Tax Elections for Benefits Offered Through the Plan for the Full Plan Year, with Very Few Exceptions
- 5/12 IRS Released Notice 2020-29, Providing Increased Flexibility for Midyear Elections Under a Section 125 Cafeteria Plan During Calendar Year 2020 Due to COVID-19
- Applies to Cafeteria Plans that Offer Employer-Sponsored Health Coverage, FSAs, and DCAPs
- The Notice Permits an Employer to Amend its Cafeteria Plans to Allow Employees to Make or Revoke Certain Elections
- Cafeteria Plans Are Not Required to Adopt These Midyear Elections
- How Can Plans Make These Changes?
  - You Need a Plan Amendment for Any of the Above Midyear Election Changes

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Trump Administration Asks SCOTUS to Abolish the ACA

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- <u>California v. Texas (Texas v. United States</u> in Lower Courts)
- Quick Recap Who, What, When, Etc.
  - Argument No Mandate, No Payment...No Payment, No Tax!
  - o District Court No Longer a Tax, So Mandate Is Invalid
  - No Severability If One Part Is Illegal It's All Illegal
  - o 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
  - o Defendants Petitioned SCOTUS to Take Case Now, SCOTUS Disagreed
- 6/25, Trump Administration Submitted an 82-Page Brief Reaffirming Its Position

• SCOTUS Has Agreed to Consider 3 Legal Questions

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 1.) Whether Texas and two individual plaintiffs who have joined the suit have standing, 2.) whether Congress rendered the individual mandate unconstitutional, and 3.) if it did, whether the rest of the law must fall with it

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• Oral Arguments Will Take Place This Fall





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#### **SCOTUS Rules on Contraceptive Mandate Case**

- Little Sisters of the Poor v. Pennsylvania
  - Court ruled 7-2 that the ACA gives Trump administration broad authority to grant exceptions to a federal regulation requiring employers to provide birth control coverage to their employees
  - $\circ~$  Justice Clarence Thomas concluded a "plain reading" of the law gives the administration "virtually unbridled discretion" in this area
  - o This decision <u>reversed</u> a ruling by the Third Circuit Court of Appeals
  - In 2014, the Court had ruled that "closely held for-profit businesses" can raise religious objections and be exempt
- Case Involved a 2018 Regulation from HHS Exempting Any Employer with a Religious or Moral Objection to Contraception
  - o 17 states challenged that policy as arbitrary and capricious

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- Gov't estimated that between 70,500 and 126,400 women would immediately lose access to no-cost contraceptive services
- Impact on Employers
  - Objecting employers can simply decline to cover contraceptives for employees or students, with no accommodations process to make these services otherwise available

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#### **SCOTUS Issues Gender Discrimination Ruling**

- 6/12 HHS Issued Final Rule Revising Section 1557 of the ACA (eff. 8/18)
  - Repeals definition of discrimination "on the basis of sex" (Title IX)
  - Narrows the scope of "covered entities"
  - $\circ$  Section 1557 inapplicable to most self-funded and fully-insured group health plans
  - Eliminated provision that allowed individuals/entities to sue in federal court
- 6/25 U.S. Supreme Court Rules in Bostock v. Clayton County, Georgia
  - Court concludes that Title VII of Civil Rights Act prohibits employment discrimination against LGBT people
  - No direct impact on Final Rule on Section 1557, but OCR's decision to interpret "sex" solely as "biological sex" now called into question
  - Removal of gender identity from protections of 1557 will bring new lawsuits against the Final Rule

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#### What Should You Do?

- Determine if Section 1557 applies to you
- Plan members can still sue you for discrimination

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- Review your plan language for compliance
- Weigh the pros and cons of not adding benefits and/or adding a specific exclusion for transgender people to your plan

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## Looking Back at the Sutter Antitrust Case

#### Sutter Exposed Price Fixing, Resulting in a Historic \$575 Million Settlement

- The 2018 Complaint for Violations of the Cartwright Act
  - Since at least 2002, Sutter compelled PPO networks operating in Northern California to enter into unduly restrictive and anticompetitive agreements
  - o Sutter had the power to control prices and exclude competition
  - Sutter imposed prices for hospital services and ancillary services that far exceeded the prices it would have been able to charge in a competitive market
- Sutter Was Effectively a Monopoly
  - Sutter had absolute control over various geographic markets, where Sutter is the only facility in the area(s), such that it would be impossible to assemble a viable network in those markets without including those Sutter hospitals
- Sutter Paid \$575 to Settle the Case with the California Attorney General
- Not Legal Precedent
  - o But Strong Guidance That This Behavior Will Not Be Tolerated
  - Other state attorneys general will be watching their own health systems

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- Last June, Trump Signed Executive Order on Price Transparency, Directing Agencies to Pass Rules to This Effect
- HHS Drafted a Rule Requiring Hospitals and Insurers to Disclose Actual Prices (e.g., <u>negotiated rates</u>) for Common Tests and Procedures
- American Hospital Association Sued to Block the Rule

   Argued this was coercion and a violation of their First Amendment rights
- Administration officials said more price transparency would lead to lower and more predictable prices in an industry that has huge ranges in what insurers pay for services

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A simple blood test, for example, can cost \$11 or \$1,000

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Coronavirus tests show a similar variation, with prices from \$27 to \$2,315

- Rule Scheduled to Take Effect on 1/1/2021; the AHA Will Appeal
- Hospitals Asking for Delay Due to COVID-19



### Federal Court Strikes Down Rule on Rx Prices in TV Ads

- Rule Would Have Applied to Drugs Covered by Medicare/Medicaid
  - o Mfgs. were to list cost for a typical course of treatment (i.e., 30-day supply)
  - Rule set to take effect 7/9
- Why the Rule Was Struck Down

   HHS exceeded statutory authority (need Congress to act)
- What Could This Have Meant for the Industry?
- Prices May Be Beyond Your Control, But Your PBM Relationship Is Not

#### <u>Review Your PBM Contracts!</u>

- Many PBMs/TPAs/ASOs keep rebates who owns them?
- Some stop-loss carriers deny reimbursement for rebates issued to the Plan even if not received by the Plan

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- $\circ$   $\;$  Lack of ability to amend the formulary
- Arbitrary or nontransparent MAC pricing
- Prohibition on access to alternative sources
- Spread pricing

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Speaking of Drug Prices . . . Remdesivir

- Employers want to know pricing info, especially since many employers are <u>considering</u> covering this drug as a way to help get their workforce back to work. It's the most effective drug out there currently
- Gilead Sciences has set the price for COVID-19 treatment
- The drug maker Gilead has set the price for its coronavirus treatment Remdesvir at **\$390** per vial for the U.S. government and developed countries
- That puts the price of a five-day treatment course at \$2,340 per patient for people enrolled in federal health programs like Medicare and Medicaid — but private insurers will pay \$520 per vial, or \$3,120 for five days of treatment, the company said Monday. The U.S. is the only country for which Gilead has set tiered pricing



## Thank You!

## Join us for our next free webinar: August 18, 2020 at 1:00pm EDT

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