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HOUSE DEMOCRATIC POLICY COMMITTEE

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House of Representatives
COMMONWEALTH OF PENNSYLVANIA

HOUSE DEMOCRATIC POLICY COMMITTEE HEARING
Topic: COVID-19 Testing Challenges
G-50 Irvis Office Building – Harrisburg, PA
August 11, 2020

AGENDA

2:00 p.m. Welcome and Opening Remarks

2:10 p.m. Panel from the Pennsylvania Department of Health:
- Sarah Boateng
  Executive Deputy Secretary
- Dr. Wendy Braund
  COVID-19 Response Director

2:20 p.m. *Questions & Answers*

2:40 p.m. Brian O'Neill
Executive Chairman and Founder,
GENETWORx, Recovery Centers of America, Testing Centers of America, The Discovery Labs MLP Ventures

3:00 p.m. *Questions & Answers*

3:20 p.m. Panel Two:
- Dr. Monica Taylor
  Vice Chair
  Delaware County Council
- Zach Shamberg
  President and CEO
  Pennsylvania Health Care Association
- Anne Henry
  Senior Vice President and Chief Government Affairs Officer
  LeadingAge PA

3:50 p.m. *Questions & Answers*

4:10 p.m. Closing Remarks

GENETWORx
Your Partner in Personalized Medicine™

Testing Centers of America

August 11, 2020

Testimony of Brian O'Neill
Before the
Pennsylvania House Democratic Policy Committee

We are Pennsylvania Companies

- I am born and raised in Pennsylvania
- King of Prussia headquarters
- 600 employees in Pennsylvania today
- 2,200 nationwide
- Hiring 2,000+ Pennsylvania employees in 2021-2022
- Investing $600 million in Pennsylvania in 2021-2022
- We produce test results in 72 hours or less

Introduction

- Thank you for the opportunity to explain the mission and the work of Testing Centers of America and its partners GENETWORx and Nucleus. We appreciate the opportunity to explain how we can assist the Commonwealth of Pennsylvania meet its testing needs.

- We have current capacity to process 125,000 tests per day and plan to reach 870,000 tests per day backed by a platform technology for large population and sample management.

- We provide PCR testing – the gold standard for accuracy and high volume – with turnaround time within 48 hours.

Introduction to Our Companies

GENETWORx (Gx) is a complex molecular testing laboratory that is building capacity to conduct 120,000 COVID-19 tests per day. It expects to reach that volume in August 2020. The company provides testing services to schools, universities/colleges, state health agencies, healthcare providers, and employers across many industry sectors.

Testing Centers of America (TCA) is building massive COVID-19 testing capacity at our mega-site in King of Prussia, Pennsylvania to process 100,000 tests per day by September 2020 and 750,000 tests per day by December 2020. This will be one of the largest COVID-19 testing facilities in the country.

Nucleus Healthcare (Nucleus) is the creator of Aura, a Population Management and Sequential Workforce Testing and Compliance Program. Aura software, running on desktops and iOS/Android mobile devices, drives sequential testing, monitoring, and reporting on large population groups including municipalities, large companies, healthcare facilities, academic institutions, schools and other organizations to maintain ongoing COVID-19 safety and certification.

GENETWORx, Testing Center of America, and Nucleus are all owned and managed by Brian O'Neill and operate in a network of healthcare companies founded by Brian O'Neill that include The Discovery Labs and Recovery Centers of America.

Our Goal

Testing Centers of America

GeneTworx

Provide Managed and Administered Large-scale Sequential Workforce Testing and Compliance Program for Large Populations by Processing Over 870,000 COVID-19 Tests per Day

Our Mission

Testing Centers of America

GENETWORX

Reenergize the Economy, Build Confidence and Reduce the Spread of COVID-19 through Large-scale Testing and Sample Management

Testing Centers of America is based in The Discovery Labs, a One Million Square Foot Life Science Facility set on 200 Acres in King of Prussia, Pennsylvania .
One of the largest stand-by fully operational BSL2 lab and manufacturing facilities in the world.

Testing Centers of America and Genetworx are Solving the Two Greatest Issues Facing America - **COMPLIANCE AND CONFIDENCE**

1. Testing Centers of America (TCA) and Genetworx (Gx) are providing large-scale COVID-19 testing for large-scale populations to safely get America back to work and back to school.

2. The TCA and Gx offering drives **compliance** with testing protocols and instills **confidence** in specified populations within predefined perimeters by providing a large-scale population management sequential and frequent testing platform and a reporting and contact tracing system for a fully-certified workforce and student body.

3. Going back to school/work will be impossible without ensuring confidence in the population.

4. Individuals are foregoing essential services and engagement out of fear.

5. The general public is refusing to engage due to fear of getting sick.

6. TCA and Gx are building the largest and only global compliance and confidence platform including large scale testing capacity for up to 870,000 COVID-19 tests/day, scalable to 1.5 million tests/day, and Aura, a Nucleus developed proprietary platform, that will ensure compliance with customer pre-programmed testing protocols. 100% compliance will ensure populations can get safely back to school.

The Need for Expanded Testing to Control the COVID Pandemic in the U.S.

- Over the most recent 30-day period, test volumes have been in the range of 700K to 900K tests per day.
- Public health and other experts recommend dramatically increasing testing capacity:
  - NIH / RADx: 2% of population / 6 million tests per day
  - Rockefeller Foundation: 5-30 million tests per week
  - Tom Frieden, MD, former CDC director: ~1.5 million tests/day
  - Harvard Center for Ethics: “increase to 20 million tests per day by mid-summer to fully re-mobilize the economy”
- We are currently testing 711,000 per day
- TCA/Genetworx is scaling to 870,000 per day

The United States is Focused on Testing Symptomatic Patients

- While testing symptomatic patients is crucial, asymptomatic patients pose the greatest risk to society.
  - Silent spreaders
  - 40% of people with COVID-19 have no symptoms
  - 1.3% of all people showing COVID-19 symptoms die
  - 0.01% of all people showing flu symptoms die

COVID-19 has Shutdown America

The Coronavirus has triggered the sharpest economic decline in US history - 32.9% in three months. GDP declined 30% in three years in the Great Depression.

- Nearly 16 million Americans are unemployed and rising daily
- Retailers are facing bankruptcy and uncertain futures
- Supply chain disruptions have resulted in shortages
- Consumer activity is reduced across all categories including healthcare
- 90% fewer passengers flying than 2019
- 163,000 Americans have died
- 5.06 million cases have been reported – 48,000 per day
  - 55,000 GIs lost their life in Vietnam

"Regular testing on a global scale, across all industries, would both help keep people safe and help get the economy back up and running."

– **Jeff Bezos, CEO of Amazon**

Reducing the Spread of COVID-19 Across Various Populations

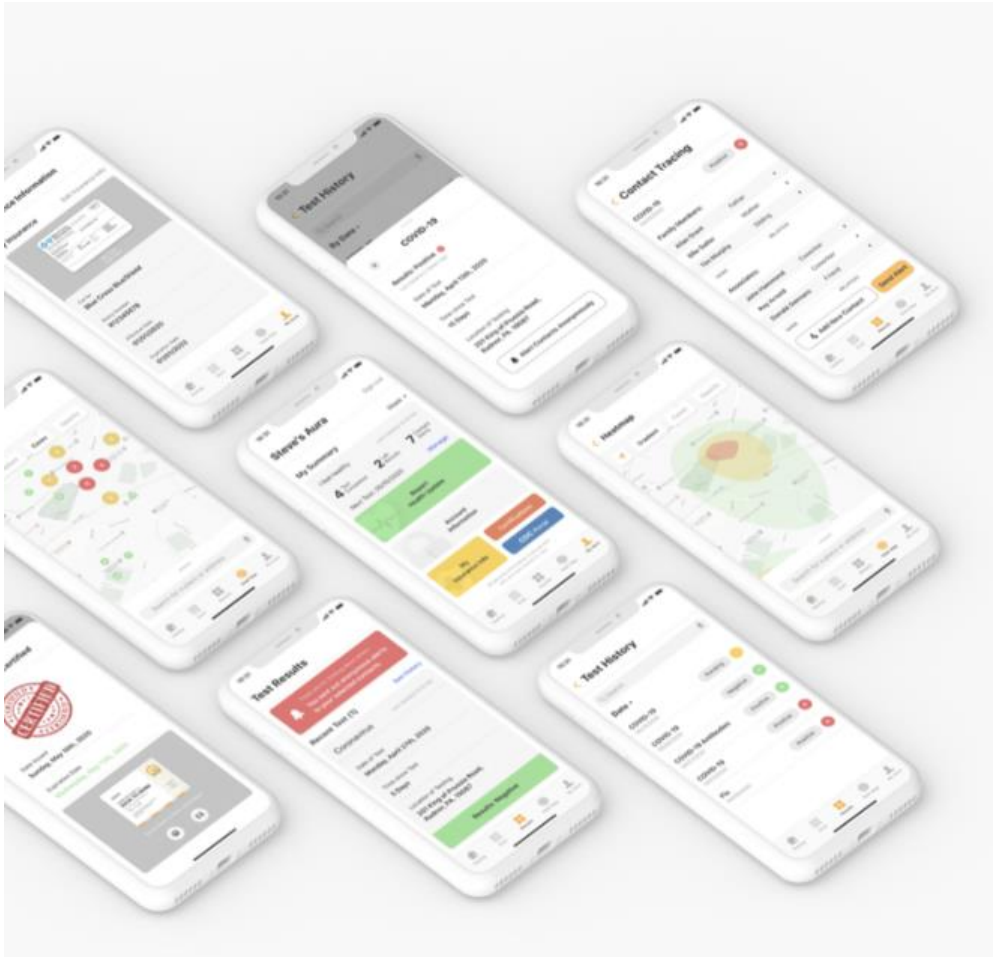
- Back to work
- Back to school (universities, colleges, public and private schools)
- Nursing homes and healthcare facilities
- Game day
- Inner city
- Municipalities – Currently, the government drop ships tests and allows the various municipalities to fend for themselves; there is no management program; TCA/Gx can eliminate the bottlenecks including testing queues and wait times for results

Testing Initiatives Need to be Managed

- Our Aura app captures important population data, creates a pipeline indicator prior to test site arrivals, expedites testing, eliminates paperwork and provides sample tracking with faster turnaround times
- Wait time in a TCA/Gx managed testing line is 60 seconds. Unmanaged test line wait times can be 6+ hours
- Our Aura symptom tracker and alert system identifies symptomatic and asymptomatic individuals prior to testing providing refined data for local, state and federal health officials
- Our dashboards manage sequential testing to ensure compliance in high risk populations such as nursing homes and assisted living facilities

Large-scale Health Initiatives

- African Americans, Hispanics, and Native Americans are 2.6x – 2.8x more likely to contract COVID-19 and nearly 5x more likely to be hospitalized.
- African Americans are 2.1x more likely to die from COVID-19.
- The inner city is not being tested.
- TCA/Gx can manage large-scale health initiatives providing crucial data, sequential protocols, symptom tracking, contact tracing, sample tracking and government reporting all in one.



Aura
Infectious Disease Tracker

TCA Cloud-based Comprehensive Software for Quick Results and Convenient Population Management

The TCA Aura software app tracks sequential testing results and provides dashboards, accurate reporting, and important health data reflecting the COVID-19 status of your entire population maintaining compliance with all governmental regulations even as they evolve over time.

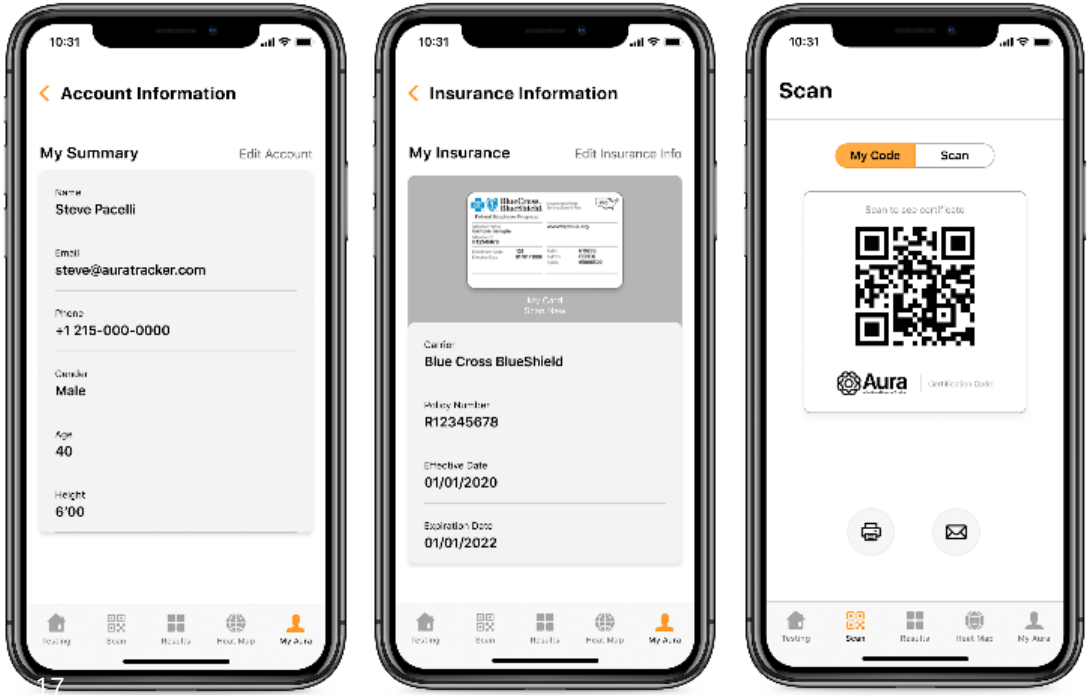
Testing Centers of America and GENETWORx Platform for Efficient and Effective Population Management – Nucleus Aura App

Our global population and workforce management platform with tracking software for global population knowledge.

- Testing - molecular and serology tests including blood, nasal swab, and saliva tests
- Contact tracing – Identifies heat maps of COVID-19 positive and negative diagnoses through GPS tracking
- Population Variance Reporting – Provides daily update on those tested versus global population.
- QR Code Trackers and TCA/Gx Preferred Access (stadiums)
- Provide 100% safe certification for the workforce.
- Massive Volumes – The Discovery Labs/Genetworx can test up to 870,000/day and expandable to 1.5 million/day

Aura Reduces Bottlenecks in the Testing Process

25% - 45% increased throughput on sample collection due to elimination of registration procedures while at the test site – more capacity without spending a nickel

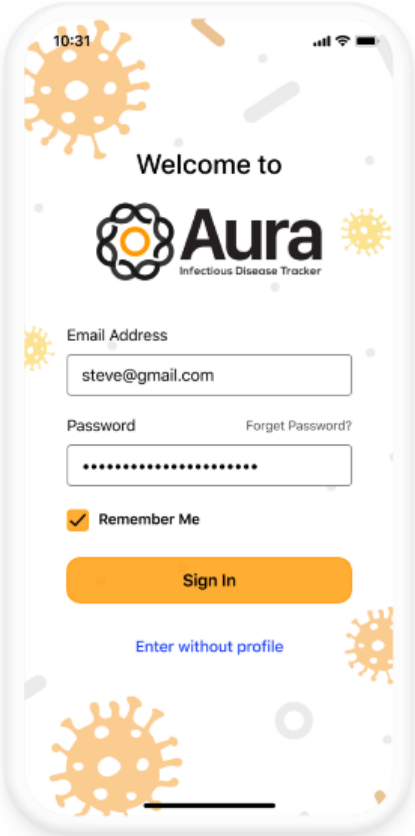


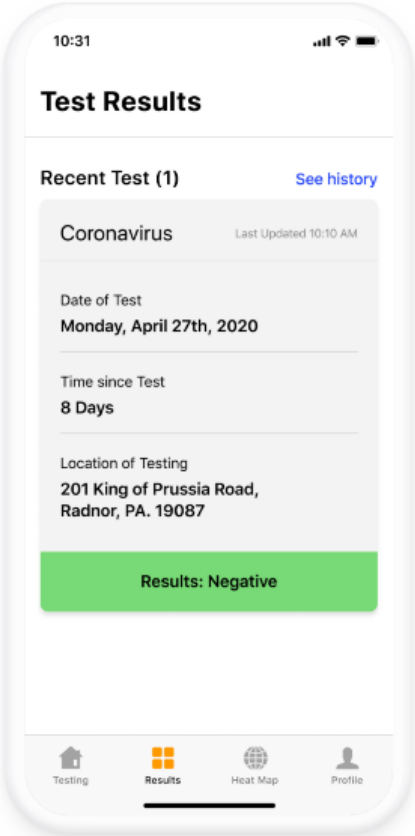
Users Preregister at home, providing all demographic and insurance information.

Capacity based scheduling technology ensures there are no long lines

Users check in via app at testing site

No paper required. In and out.





This software enables large populations to be placed on routine sequential testing protocols and to allow or prevent access to facilities based on the confirmed COVID-19 status of the user.

Aura ties to QR-code readers at all entry points to your campus allowing easy access to all certified students, faculty and staff, and denying access to those who have tested positive.

This software enables rapid registration in the field at collection sites and preauthorizes insurance coverage. The software rapidly reports results to the user and management dashboard and provides digital monitoring, and anonymous contact tracing through optional GPS location services.

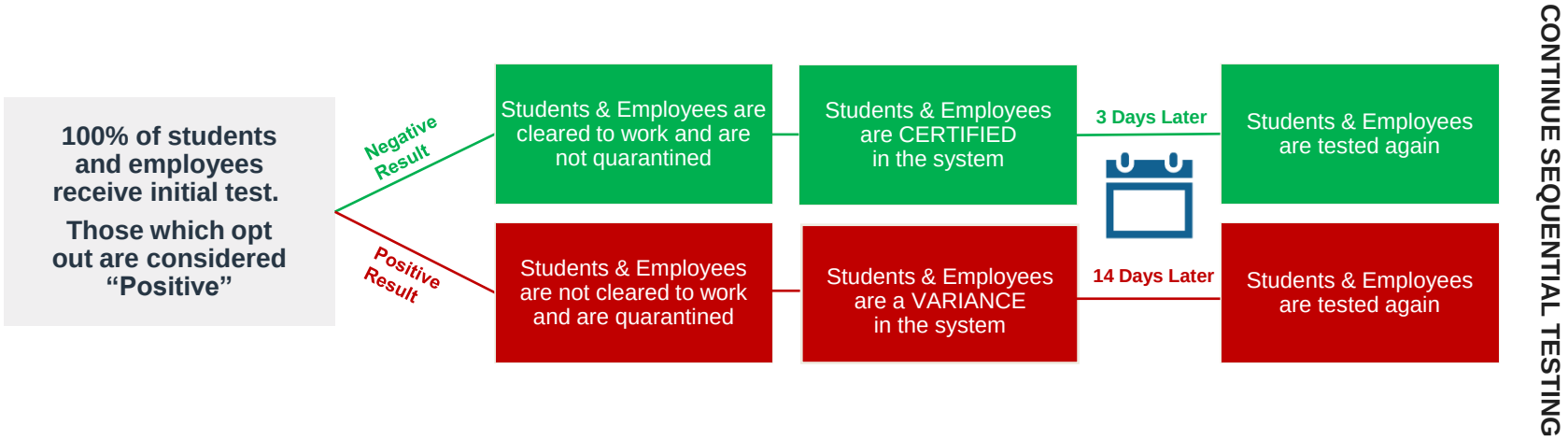
Aura enables individual COVID-19 testing status certification. Based on the most recent COVID-19 test, an individual is granted access to or restricted from buildings or locations via QR code. QR codes can be scanned from the Aura smartphone app or traditional ID badge.

Why Sequential Testing

- Silent Spreaders are a major problem in the spread of COVID-19
- 40%+ of all infected people are asymptomatic
- The only way to ensure a safe student body, workforce and consumer is consistent, sequential testing to identify and quarantine the silent transmitters from the general population
- A sequentially tested population contains the virus spread and restores confidence in US citizens
  - 70% of the nations largest school districts are opting to go all-remote this fall
  - 66% of school districts nationwide are virtual in the fall

TCA Sequential Testing for Population Management

By sequentially testing 100% of your population on regular intervals and receiving test results within two-three business days, populations can continue engagement all while reducing the spread of COVID-19



Daily Reporting on the status of 100% of a population via our Aura proprietary software

Platform Technology Streamlining Testing and Optimizing Turnaround Times

- We are currently the only company that combines digital monitoring, contact tracing, GPS location, COVID-19 status, sample tracking and testing in the world.
  - Consumer notification drives testing and compliance.
  - Testing is managed and maintained on a sequential and frequent basis.
  - Location administration provides for efficient sample collection and logistics coordination.
  - Sample tracking and prioritization of processing provides for turnaround time optimization.
  - Our digital backbone provides for efficient testing and timely reporting with executive dashboards.

- The TCA Mega Site in King of Prussia and the GENETWORx lab process tests within 24-48 hours and communicate test results in seconds via email, text, and application interface.

- Our offering includes software, hardware and logistics with a digital backbone to accurately manage, administer and report on tests with a solution that eliminates all the bottlenecks.
  - Our offering is automated and data-driven with person-to-person customer service.
  - Instant executive reporting via dashboard interface.

- We have secured machines, robotics, operating software, reagents and test kits through an ultra-aggressive sourcing effort to perform these volumes from multiple vendors for redundancy and price efficiency.

Testimony

Submitted on Behalf of Delaware County

Public Hearing COVID-19 Testing Challenges

Before the: House Democratic Policy Committee

August 11, 2020

Submitted by:

Dr. Monica Taylor

Vice Chair County Council

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Media PA 19063

610-891-4000

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Chairman Mike Sturla, Representative Mike Zabel and esteemed members of the Pennsylvania the House Democratic Policy Committee:

Thank you for this opportunity to highlight the challenges experienced by county governments with COVID-19 testing. My name is Dr. Monica Taylor and I am the Vice Chair of Delaware County Council having assumed office in January 2020 only to be thrust into the COVID -19 Pandemic a few short months later. Delaware County faces unique challenges in responding to COVID-19, as it is the largest county in Pennsylvania and the United States without a county health department. While the Pennsylvania Department of Health worked to serve the needs of the county, it became apparent as the Pandemic spread that Delaware County with a population of over 560,000 people in a densely populated area bordering Philadelphia, would need additional supports to respond to COVID-19. Fortunately, the neighboring county of Chester felt that its health department had the capacity to assist Delaware County in its COVID-19 response. In March, the Pennsylvania Department of Health and Governor Wolf approved the temporary transfer of COVID-19 response in Delaware County to Chester County Health Department (CCHD.) This context is important as it frames some unique challenges that Delaware County has faced and is still facing with COVID-19 testing as well some solutions that may be useful to other counties.

One of the first pressure points that Delaware County faced in testing was in late February and early March as the hospital systems operating in our county were having difficulty testing the surge of patients in their emergency rooms. Adding to this complication was the beginning of shortages of testing supplies, including test kits, reagents to run the tests and lab capacity as only a few labs were approved to process COVID-19 PCR tests. Many hospitals and healthcare

entities were also experiencing severe shortages of personal protective equipment (PPE) which hampered the ability to do larger scale testing in an effort to preserve PPE for healthcare professionals. As a county we faced challenges of helping to coordinate the health systems in delivering testing, responding to the public who wanted the county to offer public testing sites and responding to a growing crisis in the Long-Term Care facilities that was partially rooted in the inability to do widespread testing of staff and patients. Frustratingly, the early failures of the federal government around testing and supplies exacerbated the inability of effective local responses. We would like to note that the Pennsylvania Department of Health and PEMA were helpful resources for information and linkages to PPE supplies, particularly in the first five months.

Limitations of Testing

When CCHD took over responsibility for Delaware County COVID-19 response, one of the first priorities was to assess how to maximize testing, utilizing the existing infrastructure in the county. Fortunately, Delaware County has three major hospital systems operating in the Crozer Keystone Health System, Main Line Health System and Trinity Health, who were willing to expand testing to the general public, as well as within their health system. Through coordinated weekly calls with CCHD we were able to constantly assess their testing capacity as well as keep track of problems with PPE and testing supplies, which were being supported through the Delaware County Department of Emergency Services and PEMA.

In mid -April, Delaware County had approximately 7,500 tests performed in the county which was inadequate for a county our size with increasing positivity and death rates. Unfortunately,

this was a problem not only in Pennsylvania but along the Northeast corridor as lab testing was still limited by the number of approved labs, test kits and now reagent shortages. Counties in Southeast Pennsylvania began experiencing extremely long turnaround times for test results sometimes up to 10 to 12 days, making contact tracing and case investigation even more difficult for CCHD. This caused difficulty with data analysis as we would receive large batches of results sometimes reflecting a week's worth of testing, skewing what was really happening in that week's positivity rates. Like other counties in Pennsylvania, the numbers were continuing to increase in positivity with the hot spot of long-term care facilities increasingly becoming a major concern and with very limited ability to do testing in those facilities it was nearly impossible to stem the tide of the outbreaks.

CCHD began ordering testing supplies from multiple outlets to support hospitals and long -term care facilities that were having difficulty obtaining testing supplies. CCHD created documents to support testing, including FAQ about testing, explanations for contact tracing and information in multiple languages on what a positive and negative test result meant in preparation for additional testing in the county.

Expanding Testing

Delaware County, in consultation with CCHD began to plan for larger scale public testing as it was becoming obvious that many communities, particularly black and minority communities were not having the same access to testing as other wealthier areas of the county. With the assistance of Delaware County Department of Emergency Management, Delaware

County Department of Intercommunity Health, the Delaware County Medical Reserve Corps, and CCHD the County was able to organize a large testing event in Upper Darby for three days. The County soon realized however that this large-scale event was not sustainable and was taxing on resources including manpower. Challenges included identifying a lab that could provide complete services to meet the large-scale needs of the county, processing patient billing, making notifications of results to the patient and the reporting of positive and negative cases to the PADOH Reporting System all for a reasonable cost as Delaware County would be footing the bill for all uninsured residents.

At the same time testing was being expanded by private organizations including the Black Doctors Consortium, which conducted testing in the City of Chester and Yeadon, as well as some pharmacies being contracted by HRSA to do testing in Delaware County.

The County revised its testing strategy to develop a mobile unit that could travel to higher risk communities across the county to expand the reach of testing. The mobile testing unit has been in operation for several weeks, however the stress points of maintaining and moving testing sites around the county and relying primarily on 120 volunteers a week from Delaware County's Medical Reserve Corps is simply not sustainable. By mid-July, Delaware County had approximately 55,000 people tested for COVID-19, utilizing a variety of public and private testing sites. The logistics of billing, registration, supplies and difficult weather conditions are all causing the County to reassess the testing plans for the fall, including the potential purchase of a mobile testing RV.

Policy Recommendations

The COVID-19 pandemic is presenting a constantly changing environment for counties' public health response for testing. If counties are going to have a long-term response to COVID-19 testing than several things will need to be implemented by the state. Counties will need funding for full-time staff to support testing, including specialty staff of pediatric nurses to perform pediatric testing which has been up to now not a priority. Counties need access to reliable labs that have capacity to meet the large-scale needs of counties doing thousands of tests. Back up supplies of test kits, reagents and PPE should be available to counties. Logistic support of tents, RV's or other structural supplies should be available to counties. Training videos for staff would be helpful. Standardized communication materials for testing sites including large scale banners and signs would eliminate some of the costs and resource commitments from counties.

Sadly, one of the critical points of testing in our state has been the limited coordination and recognition of vulnerable population's access to testing. Better data on the populations being tested, the death rates in minority communities and tracking of testing of essential workers in grocery stores, pharmacies and healthcare facilities will protect more Pennsylvania residents and allow our economy to continue to get back on the right track.

Written Testimony of

Delivered by

Zach Shamberg

President and CEO

For a
Public Hearing on
COVID-19 Testing Challenges

Delivered Virtually

Before Representative Mike Zabel
and members of the
House Democratic Policy Committee

August 11, 2020

Representative Zabel, Chairman Sturla and members of the House Democratic Policy Committee,

Good afternoon, and thank you for the opportunity to testify and share this important story.

I'm Zach Shamberg, and I am the president and CEO of the Pennsylvania Health Care Association, better known as PHCA.

We're a statewide advocacy organization representing both non-profit and for-profit long-term care, including nursing homes, personal care homes and assisted living communities.

We also represent the most vulnerable population in Pennsylvania: senior citizens. In our long-term care facilities, residents are generally 80 years of age or older, require around-the-clock care, and often have co-morbidities and underlying conditions.

In other words, we also represent and care for *the* most vulnerable population to the novel Coronavirus, or COVID-19.

And by now, you surely know the numbers: nearly 70% of all COVID-19-related deaths have occurred in long-term care facilities, and more than 800 of our facilities statewide have reported at least one positive case.

There is no cure. There is no vaccine. There is no way to stop this virus in its tracks.

So as long-term care providers fight to *mitigate* and *contain* the spread of COVID-19, there are two essential elements they need to be successful: PPE, or personal protective equipment, and **testing**.

And that's why we're here today, to focus on testing. And to share the challenges that still exist for the nearly 2,000 long-term care facilities across the Commonwealth.

Now, you might think back to late July, when our Department of Health celebrated the fact that all of Pennsylvania's 695 nursing homes had completed a mandated baseline, universal test for their residents and staff. In all, tens of thousands of Pennsylvanians in nursing homes were tested from early June to late July to adhere to this mandate.

And it was a cause for celebration.

But let me tell you what's been made clear since the dust from that exercise has settled:

More testing, from a financial standpoint, for an industry that has been underfunded by our state's Medicaid program for the better part of the last decade, is simply unsustainable.

Given increased demand and limited capacity at labs here in Pennsylvania, turnaround times for testing results have ballooned from two days to longer than one week. Sometimes up to 12 days.

Partnerships that the state has entered into for help with testing have been anything but helpful.

And the recent creation of the Regional Response Health Collaborative Programs, or RRHCPs, has yet to yield any real support for the chief reason they were designed and awarded $175 million in federal CARES Act dollars: to help long-term care facilities **test** their residents and staff.

This is all important because our state's nearly 1,200 personal care homes and assisted living communities are currently working to meet their own universal testing mandate, with a deadline of August 31st.

Additionally, nursing homes will have to re-test – and they should. One universal test simply paints a single picture in time. Recurring testing will yield trends, and it's the best way to ensure asymptomatic staff don't continue to transmit the virus to their patients. It's also an essential tool in cohorting COVID-positive residents in a facility.

Ultimately, we must address these challenges so that long-term care providers have access to the critical testing they need to keep residents and staff safe.

First, one universal, baseline test for every resident and staff member in Pennsylvania's long-term care facilities costs approximately $34 million. While Medicare and Medicaid cover most of these costs for residents, providers are being forced to absorb the remaining costs for staff members, especially as private insurance companies refuse to cover a test that they deem 'medically unnecessary'. Furthermore, many of these providers are self-insured and pay these increased costs directly.

Multiple states across the country have already funded testing in long-term care, including Massachusetts, New Hampshire, Maryland, Rhode Island and West Virginia. That's why we – in conjunction with LeadingAge PA and PMDA – sent a joint letter to Governor Wolf on July 31st that urged the administration to direct additional funding to long-term care providers for the purpose of future testing efforts. We've also shared that letter with the members of this committee.

Second, results are simply taking too long. A test for a long-term care resident or staff member that comes back in seven days or longer is a worthless test – they've already likely spread the virus by then. We need more lab capacity, we need to forge better, stronger public-private partnerships with outside groups and companies, and we need more rapid testing from the federal government.

Third, while the Department of Health has implemented programs with CVS Health and Eurofins to provide additional testing support to our long-term care providers, those partnerships have – unfortunately – fallen short.

Many of our members were unable to receive support from CVS until a week before the testing deadline. And others eventually declined support from CVS after multiple attempts to schedule testing and longer turnaround times. In short, they preferred to pay for their testing with a lab than get it for free from CVS.

Finally, the Regional Response Health Collaboration Program, or RRHCP, which received $175 million in CARES Act funding as a part of Act 24, was created specifically to enhance testing capabilities for long-term care providers.

But our members are already being told that these RRHCPs don't have the capacity to test. In fact, they're simply referring them to the same laboratories providers could find on their own.

Is that the best $175 million can buy?

Recent independent research has indicated that community spread of COVID-19 equals spread in our long-term care facilities. As the number of positive cases increase across Pennsylvania, we remain concerned these outbreaks may lead to a dramatic increase in cases in nursing homes, assisted living communities and personal care homes as well.

As we look ahead at the fall months and a potential Phase II of the virus, it is more critical than ever to bring long-term care providers to the table to collaborate and work together to overcome these challenges.

We must make long-term care the priority.

We must ensure providers have access to every resource necessary.

And that must begin with testing.

Thank you.

July 31, 2020

The Honorable Tom Wolf
Governor of the Commonwealth of Pennsylvania
508 Main Capitol Building
Harrisburg, PA 17120

Dear Governor Wolf,

As the fight to mitigate and contain the spread of COVID-19 persists across the Commonwealth, Pennsylvania's long-term care providers, including skilled nursing facilities, assisted living residences and personal care homes continue to care for and protect our most vulnerable residents.

In late June, your administration and the general assembly directed nearly $300 million in federal CARES Act funding to long-term care, and your investment has enabled providers to care for their residents, acquire personal protective equipment (PPE) for staff and maintain their operations. We could not be more grateful for your support.

Issues remain, however, and chief among them is **testing**. In early June, your Department of Health mandated universal, baseline testing for all nursing facilities, and a testing mandate for all personal care homes and assisted living communities followed shortly thereafter.

While we have advocated for testing supplies and accessibility since the COVID-19 pandemic began, this initiative does not come without a cost to our providers.

One universal, baseline test for every resident and staff member in Pennsylvania's long-term care facilities will cost approximately $34 million. While Medicare and Medicaid cover most of the testing cost for residents, providers are being forced to absorb the remaining costs for staff members, especially as private insurance companies refuse to cover a test that they deem 'medically unnecessary'. Furthermore, many of these providers are self-insured and must pay these increased costs directly.

Simply put, even with investments from the CARES Act and the HHS Provider Relief fund, widespread testing has become an unsustainable cost, especially as providers look to implement recurring testing to reopen visitation and cohort residents.

Recent independent research by Harvard Medical School, Brown University's School of Public Health and the University of Chicago has indicated that higher community spread of COVID-19 equals a greater chance for outbreaks in our long-term care communities. As the number of positive cases continues to increase across Pennsylvania, we remain concerned these outbreaks may lead to a dramatic increase in cases in nursing homes, assisted living communities and personal care homes as well.

We urge you to allocate emergency state and federal funding to long-term care providers to support these rising testing costs. Additionally, we understand that up to $175 million was available in Act 24

for testing in long-term care, but only $20 million has been utilized. We would appreciate understanding why more funds are not available and how the $20 million is to be dispersed for testing of long-term care caregivers and their residents.

Multiple states across the country have already funded testing in long-term care, including Massachusetts, New Hampshire, Maryland and Rhode Island. We urge Pennsylvania to join these other states to help protect our seniors.

Thank you for your consideration of this request. We look forward to working with you to protect our most vulnerable residents.

Sincerely,

Zach Shamberg
President and CEO
Pennsylvania Health Care Association

Adam Marles
President and CEO
LeadingAge PA

Brian B. Kimmel, DO, CMD,
President
Pennsylvania Society for Post-Acute
and Long-Term Care Medicine

Dillard Elmore, DO, CMD, MBA
Chair, Public Policy Committee
Pennsylvania Society for Post-Acute
and Long-Term Care Medicine

House Democratic Policy Committee
Virtual Hearing

Testimony on COVID-19 Testing

Anne Henry
Senior Vice President Chief Government Affairs Officer
LeadingAge PA

August 11, 2020

Good Afternoon Chairman Sturla and members of the House Democratic Policy Committee. Thank you for inviting LeadingAge PA to participate in this discussion about COVID -19 testing in Pennsylvania. I would be remiss to not also thank you for the work you do to protect seniors in Pennsylvania. I am grateful to be here and discuss the great work our members do every day to ensure the health, safety and wellbeing of long-term care facility residents across the Commonwealth.

I am Anne Henry, Senior Vice President and Chief Government Affairs Officer of LeadingAge PA, which represents more than 360 not-for-profit providers of senior housing, health care, and community services across the Commonwealth. These providers serve more than 75,000 older Pennsylvanians and employ over 50,000 dedicated caregivers, all of whom are affected by the crisis caused by the coronavirus pandemic, whether or not they live or work in a community with positive cases of COVID-19.

I am sure you have heard there are over 2,000 long-term care facilities across Pennsylvania serving over 100,000 residents. Statistics help paint the picture, but each of those residents has a face, a history, and hopefully a family. I am part of the family to one of those statistics - one of those residents. My mom has been a resident of a nursing home in York, near where I grew up, for four years. Prior to the Coronavirus Pandemic, I visited my mother regularly, enjoying her company, and fulfilling her shopping lists of essential sweets. Part of those visits also included checking in with staff to see how she was doing.

Since COVID, I have been Face Timing one time a week and have had one brief window visit with my Mother. I can assure you, seeing her on an IPad or through panes of glass just isn't the same. We are approaching five full months living in a world with coronavirus. That means five months with facilities enforcing visitation restrictions as outlined by the Centers for Disease Control & Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS) and the Pennsylvania Department of Health (DOH). I have worked in long-term care for more than 30 years. I understand the precautions. I respect them. But that doesn't make the separation any easier. I look forward to holding my mom's hand, combing her hair, and thanking the staff who have been caring for her. We can't forget as we make policy decisions how they will affect people, who are longing for familial contact, the restoration of group activities and communal dining.

As we have heard Secretary Levine say on numerous occasions, this is a "novel" Coronavirus. In the beginning of the pandemic, testing for COVID-19 was reserved solely for individuals exhibiting specific symptomology - elevated temperature, coughing, and difficulty breathing. Weeks later, a stuffy nose, gastrointestinal symptoms and a loss of taste and/or smell were added to the list. By mid-April, we had learned that there was significant research showing community spread through asymptomatic individuals. This remained a problem. We knew spread was happening among our populations by asymptomatic carriers, but we were still only allowed to test individuals with clinical symptomology.

The members of LeadingAge PA have been supportive of testing to understand baseline infection rates and inform infection control and mitigation protocols from the beginning. As you know in early June, the Department of Health (DOH) mandated testing for all nursing facility staff and residents to be completed prior to July 24. The mandate came while testing availability was sparse in some geographic areas of our commonwealth. Providers did their best to schedule testing with labs and coordinate local specimen collection. This was done in addition to the ongoing compassionate care they continued to provide to every resident every day. Testing result turnaround times stretched from a day or two to

sometimes as much as 10 days or beyond. These turnaround times rendered results all but useless - though the price to providers didn't come with a zero dollar price tag. Fortunately, Medicare and Medicaid cover the cost of resident testing but insurance coverage for testing asymptomatic staff is nearly nonexistent. The average cost is $100 per person. If the facility is testing weekly because of positive residents and/or staff, the financial implications are thousands of dollars per week. While providers appreciate the additional funding of Act 24, most providers used these funds to cover expenses that were already incurred. Ongoing testing continues to drain the pocketbooks of our providers.

DOH has provided some assistance to help nursing facilities meet the testing mandates. Partnerships have been announced with CVS and Eurofins to assist with testing access, specimen collection, and result delivery. While many of our members had conducted and paid for these rounds of testing before the 'free' option was available from CVS, footing the bills themselves - others were grateful for the CVS partnership. As with so many efforts that are stood up in short order, this program faced the same challenges of privatized testing. The process was outlined in which facilities could schedule on-site testing with CVS. In multiple instances, facilities received cancelation notices from CVS at or after mid-night the morning in which CVS was to be onsite to begin testing early the next morning. This left facilities reeling and forced staff to stand in lines for hours to be tested through alternative methods. For communities that successfully scheduled and had specimens collected, result turnaround sometimes lagged more than a week, stretching to 10 days. These results become useless as the data rendered is now nearly 2 weeks old, and tells nothing about the current scope of infection within a facility.

On June 24th, DOH mandated testing for all residents and staff in personal care homes and assisted living residences by August 31. For proactive facilities that had completed baseline testing of residents and staff prior to June 12, they are required to retest all staff and residents. Both mandates have been updated to require recurring testing for all staff and residents if a positive case is identified within the staff or resident population.

We were hopeful that the Regional Response Health Collaborative Program (RRHCPs), established by Act 24 at the end of May would be a great help in the testing process. Unfortunately, the RRHCP program was not formally announced until the end of July – much too late to offer assistance with the required nursing home baseline testing. We also have concerns about the effectiveness of the program for the personal care home/assisted living baseline testing. We have heard from members that the RRCHPs may not have capacity for testing by the August 31 deadline or if they do, they will not be assuming any of the cost of testing even though they have been provided with $175M for this program. Act 24 also included additional funding for testing of up to $175M however even after discussion with the administration, we have not been about to ascertain the exact amount of money available or how providers can obtain these funds if they don't have funds available to pay for the very expensive testing of asymptomatic staff.

Ongoing testing is used as a point of reference or gatekeeper for facilitates to begin reopening and re-engaging families in onsite visitation for residents. Our residents need to be protected from COVID, but they also need to see relief from the isolation they are experiencing under the mandates and guidance of DOH, CMS and the CDC.

The policies and decisions to limit 're-opening' based on testing results continue to be a challenge. We have members questioning the validity of testing results, while academic research also rates the validity of the popular PCR (polymerase chain reaction) tests to render 95-99% accurate results. One might assume that false positive results do nothing more than lead to an abundance of caution, but the implications are significant. Individuals may test positive- maybe the only positive in a community- maybe falsely. Per DOH, this person would be placed in isolation, further isolation from their already room-bound reality. They receive the necessary attention to ensure they receive any additional care that they need. But, that single positive result has much bigger effects. That positive result means that the facility must continue to test ongoing on a weekly basis. This repeated testing is physically uncomfortable for staff and residents, prompts the stress of waiting for the test result, and adds to the growing weariness that COVID is disproportionally foisting upon our long-term care residents and staff.

Of utmost importance, this single positive test result halts or reverts any possible steps towards reopening, dashing the hopes of residents and their families of in-person visits, and imposing on residents a longer quarantine from one another. It is no secret that infection from the coronavirus is dangerous, but isolation can lead to depression and cognitive decline in residents who were previously very sharp and very engaged. Depression and isolation was shown prior to the pandemic to cause detrimental health effects equal to that of lifelong cigarette smoking. My experience in this field tempers my desire to see my mom, given my understanding of infection control and safety- but it doesn't make my heart hurt any less. It doesn't relieve the suffering of every other family member of a long-term care resident or the residents themselves. We need to consider ways to balance the risks, while assuring providers are protected from frivolous lawsuits and predatory attorneys.

As we think about next steps- conversations have been swirling about vaccinations. The trauma, isolation, and stress that residents and staff have endured through the pandemic is leaving them in tremendously fragile positions. We need to show our commitment to these residents and staff by prioritizing access to early and likely limited supplies of COVID vaccinations.

In closing, please know that limiting activities and creating physical distance has been emotionally taxing for all of us. Testing continues to add to the stress and potentially, to the time before the next visit with our loved ones. For residents in our senior communities and the people taking care of them, we need to do more, and we need your help. We need funds to cover the cost of testing. We need continued research into the sensitivity of tests so that residents are not excluded from visitation and activities by a false positive result. We request that in updates to their testing requirements, policymakers recognize the difficult balance between the emotional and social needs of residents and the steps needed to ensure their safety. Additionally, providers, like our members, who have done their utmost to protect residents and staff need protection from lawsuits related to the continually evolving science, policy and resource availability of this pandemic.

Our field is unique, with opportunities to really get to know the people in each community. The residents living in long-term care facilities are our heroes of years past and present – our fathers and mothers, my mother. Each of our member organizations becomes a microcosm of what we wish our society reflected more often: outward generosity, care for one another, engagement, and compassion.

Thank you for the opportunity to offer comments on the status of COIVD-19 in our communities and for allowing me to share our members' needs. On behalf of our membership, thank you for the work you do to support and protect seniors and senior service providers across Pennsylvania. I look forward to

working with the committee to forge a meaningful and supportive path forward for our Commonwealth's long-term care providers.

August 11, 2020

Representative Mike Sturla, Chair and Members
Pennsylvania House Democratic Policy Committee

Re: Public Hearing on COVID-19 Testing Challenges

Mr. Chairman and Committee Members:

Thank you for the opportunity to provide written testimony to the committee. My name is Bryan Lowe; I am the Regional Director for State and Local Government Relations for the Mid-Atlantic Region for Walgreens. I am sorry I am unable to testify in person today, but want to highlight a few issues that Walgreens is experiencing in Pennsylvania regarding COVID-19 testing.

Walgreens has tested over 500,000 patients throughout the country, with 86 testing locations in 49 states and Washington D.C. Unfortunately, Walgreens only has one testing location in Pennsylvania (Darby, PA). This is due to the inability for Walgreens to attain a waiver for a pharmacist to utilize a point-of-care testing model. Since launching the testing site in Darby in mid-July, we tested 1,300 patients to date at that one location.

There are two types of tests performed around the country at Walgreens locations. Many pharmacy chains use a "collection" model, where a patient collects their own sample. That sample is then shipped to a laboratory partner for testing. This is the model where patients are experiencing delays in receiving test results. The other type of testing is "point-of-care" where patients collect their own samples. Here the pharmacy has the ability to put that sample directly into the testing equipment on site for a rapid result.

While Walgreens does utilize both types of tests throughout the country, the point of care test is the preferred method for receiving timely results. The point of care test allows Walgreens to provide the patient with results within 48 hours, and in most cases are delivering results in less than 24 hours. This is important, as it allows patients peace of mind, and the ability to continue either to self-quarantine in the event of a positive test result or to resume normal activities such as returning to work. Also, because there has been significant delays in getting results back from laboratories, Walgreens is moving forward with more point of care testing model in many states and has slowed the expansion of collection sites until laboratories can ensure turnaround times are reasonable for patients to change behaviors (3-5 days). If Walgreens were to have expanded in Pennsylvania it would be contributing to the existing delays that high throughput laboratories are experiencing.

Pennsylvania goes beyond the federal baseline to require a pharmacist to have worked in a traditional laboratory for 2 years or more to perform simple Clinical Laboratory Improvement Amendment-waived (CLIA) tests. This antiquated requirement, adopted in state law in 1952 before point-of-care tests were invented, is a barrier for registered pharmacists and Doctors of

Pharmacy from being approved as a lab director, thus preventing pharmacies from providing the point-of-care testing model which provide patients with much faster results. Pharmacists are already educated and trained to perform point of care tests. Walgreens urges the legislature to consider legislation to permanently remove the two year lab experience requirement for a CLIA-waived test.

Walgreens has over 60 point of care testing locations throughout the country including the neighboring states of Delaware, New Jersey, New York, Ohio, and Virginia, and have not experienced any significant issues with our point-of-care testing model. If point-of-care testing were to be available for pharmacy use, Walgreens has highlighted cities such as Reading, York, Lancaster, Pittsburgh, and others for possible testing expansion.

Walgreens urges the committee and the State to waive the two-year lab experience requirement for qualified and trained health care professionals to perform simple point-of-care COVID-19 tests. This would tremendously increase testing capacity in the state and reduce self-quarantine time for patients. Today, the Commonwealth has more than 2,600 pharmacies, including 119 Walgreens stores, located in every community including underserved urban and rural settings. The pharmacy administered testing program includes training on performing point-of-care tests. In short, the lab director's experience requirement poses an unnecessary barrier that prevents Pennsylvania's citizens from taking advantage of convenient, safe, and fast COVID-19 testing.

Thank you again for the opportunity to testify today, please feel free to reach out to me with any questions or follow ups the committee may have.

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