Committee on Energy and Commerce

Hearing on
"Oversight of the Trump Administration's Response to the COVID-19 Pandemic"

June 23, 2020

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U.S. Department of Health and Human Services

The Honorable Frank Pallone, Jr. (D-NJ)

1. The COVID-19 public health emergency has triggered distress for many Americans, such as experiencing the loss of family or community members, loss of employment, insurance, or other supports.

   It was reported early on that the Disaster Distress Helpline, which is supported by the Substance Abuse and Mental Health Services Administration (SAMHSA), saw an 891 percent increase in call volume in March 2020 compared to March 2019. Close to half of Americans say that their mental health has been negatively affected due to worry and stress over the virus

   a. What actions are the Administration taking to address the mental health effects of the coronavirus pandemic? Is there a coordinated response among the agencies? If so, who is leading interagency efforts?

      Response:
      As SAMHSA became aware of COVID-19's impact on operations for our behavioral health stakeholders we began rapid dissemination of guidance and support. First SAMHSA promoted the existing Technical Assistance publication Disaster Planning Handbook for Behavioral Health Treatment Programs, which included continuity of clinical care instructions during a pandemic. In March 2020, SAMHSA published guidance for the management and triage for both community and inpatient state psychiatric settings. Recognizing that the isolation may also increase risk in vulnerable populations, SAMHSA issued guidance for the management of alcohol and benzodiazepine withdrawal at crisis locations and considerations for those affected by intimate partner violence. In the spirit of maintaining connections to recovery, SAMHSA posted online virtual recovery services. For those with opioid use disorder SAMHSA worked closely with State Opioid Treatment Authorities to authorize extended take home medications which are currently still in effect. For the safety of providers and patients, in concert with the DEA, SAMHSA has waived the in-person physical exam for those receiving buprenorphine while also permitting the use of telehealth for established patients with OUD. These provisions balanced patient and community safety. Additionally SAMHSA has provided guidance to first responders administering naloxone for the reversal of opioid overdose during the pandemic with an emphasis on safe practices and options while keeping patient care paramount. Our Technology Transfer Centers have been working tirelessly to provide technical assistance and training during the pandemic. Most importantly, as we realized that many providers were not poised or prepared to implement telemedicine,

SAMHSA's technical assistance efforts have been mobilized for telehealth training among mental health providers. In addition, SAMHSA has continuously offered updated technical assistance and guidance to providers of mental/substance use disorder prevention, treatment, and recovery services to ensure the best and most accurate strategies are known and used in communities across the country.

SAMHSA received $425 million in supplemental funding to address the mental health and substance use disorder effects of COVID -19. To date, SAMHSA has awarded $424,244,671 in Emergency Grants to Address Mental and Substance Use Disorders During COVID-19 (Emergency Response COVID-19); Certified Community Behavioral Health Clinics (CCBHC COVID) Expansion Grants; Tribal Behavioral Health (TBH COVID) supplements to meet the increased mental and substance use disorders of tribes during the COVID-19 pandemic; Suicide Prevention Lifeline Crisis Center Follow-Up (CCF-COVID) Expansion Grants; Suicide Lifeline/Disaster Distress Helpline (SPH COVID) supplement to support the Lifeline's use of text messaging and expand access to the Lifeline services across the nation in response to current and anticipated need during the national COVID-19 pandemic; and the COVID-19 Emergency Response for Suicide Prevention (COVID-19 ERSP) Grants.

SAMHSA has been working with other federal partners (CDC, FEMA, and ASPR) to coordinate efforts. SAMHSA participates in regular meetings concerning vulnerable populations disproportionately affected by COVID-19. SAMHSA is also a key partner in the behavioral health resiliency workgroup in response to the pandemic. SAMHSA has worked with the DEA to allow flexibilities in prescribing buprenorphine and amplified the Office of Civil Rights' Notice of Enforcement Discretion in waving penalties for potential confidentiality issues when using telehealth technology during this crisis. SAMHSA has also participated in webinars with CMS and ONDCP in disseminating information about our emergency grants and flexibilities during the COVID-19 pandemic.

CDC is providing technical assistance to a mental health and resilience initiative called *How Right Now*, led by NORC at the University of Chicago and funded by CDC Foundation, which is expected to launch in August 2020. This partnership-based communication initiative will focus on addressing people's mental health challenges by increasing individual coping skills through information, support and resources in English and Spanish.

b. The Heroes Act included $3 billion for SAMHSA to increase mental health services, substance use disorder treatment, and outreach to communities during this challenging time. What additional resources do you believe are necessary to help with the Administration's response efforts for individuals experiencing mental health impacts of this pandemic?

Response:

SAMHSA has concerns regarding the increased need for mental and substance use disorder services during the time of the pandemic. Research clearly demonstrates that individuals, even with short quarantine/lockdown periods experience mental health symptoms which are potentially lifelong. The stressors of social isolation, unemployment, fear, and anxiety may lead to stress disorders, depression and potentially suicidality. This coupled with a mental and substance use disorder treatment system which is struggling under a social distancing/telehealth rubric is a potential set up for another major national health crisis.

SAMHSA has learned through stakeholder efforts and surveying that the majority of treatment providers are operating on a very small amount of back up operating revenue—less than 90 days in some cases. This struggling delivery system faces challenges in addressing the known increase in service need. Pre-pandemic, we lost 180,000 lives to drug and alcohol-related deaths and suicide. We only expect this figure to increase with current conditions.

SAMHSA's current operating budget to address the behavioral health needs of the 330 million Americans across the nation is less than $6 billion.

c. Another area of concern and interest has been the mental health impact of this pandemic on our frontline health workers. What does the Administration know now about the short- and long-term effects of the coronavirus pandemic on our Nation's frontline health workers and would the Administration support further research in this area?

Response:
SAMHSA recognizes the impacts to front-line workers are enormous. Research has demonstrated, in previous similar (although less severe situations) healthcare workers experience stress, trauma and also stigma. Often, with contagious infection, individuals are reluctant to interact with frontline worker for fear of contracting the infection.

The effects of these situations may be long-lasting for some, and the risk of suicide needs to be monitored. For this reason, SAMHSA specifically required that all Emergency COVID Response grants (funded through the CARES Act) addressed specifically the behavioral health needs of frontline workers.

Given what we know about trauma, stress, fear, burnout, it does not appear that more research is needed; however, SAMHSA recommends considering more targeted resources specifically for treatment services for this population.

The Honorable Tony Cárdenas (D-CA)

1. According to the opinion of experts at the Centers for Disease Control and Prevention/U.S. Department of Health and Human Services (CDC/HHS) and CDC/HHS data, as of June 23,

2020, what diagnostic testing capacity is required for federal, state, and local public health agencies for the detection of COVID-19 in Americans?

Response:
Subsequent to the date of the hearing, in August 2020, the Federal Government is providing each state the materials required to test at least 2 percent of their population each month. Many states are testing above the 2 percent baseline.

2. On what date did the CDC/HHS get notified that COVID-19 was anticipated to affect American citizens in the United States?

   Response: HHS was monitoring the developing situation around the world from the earliest stages.

   a. What was the first estimated quantity of tests and test kits that the United States would need for the detection of COVID-19? What was the first estimated quantity of Personal Protective Equipment (PPE) – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – that the United States would need?

   b. Subsequent to the initial estimates of tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – needed, when was the next adjustment to that estimate? How often did the CDC/HHS update these estimates and projected needs? What were the estimates per week from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

   c. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – did the CDC/HHS have available per day from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

   d. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – did the CDC/HHS distribute to each state, territory, and tribe per day from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

   e. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – were requested by each state, territory, and tribe per day from the first anticipated date of COVID-19 affecting American citizens in the United States through June 23, 2020?

   Response (a-e):
   Since the beginning of COVID-19, HHS and the Federal Government have constantly assessed the evolving situation as it presented itself and the required materials and equipment needed to meet the demand. Through the various actions taken by the Federal Government, the United States is in a fundamentally different and improved position to

meet the needs of the country as the pandemic response continues. State requests for materials were prioritized through the FEMA process and data informed decision making. Further information requests can be referred to the HHS Office of the Assistant Secretary for Preparedness and Response or to FEMA.

The Honorable Cathy McMorris Rodgers (R-WA)

1. I read news reports last week about dexamethasone, a low-dose steroid treatment that showed some promising results in helping critically ill COVID-19 patients on ventilators. The UK has added 200K courses to its stockpile. In addition, I have seen studies regarding Giapreza, a Food and Drug Administration (FDA) approved treatment for septic shock. My understanding is about 50% of severe COVID-19 cases develop septic shock and this treatment showed almost a 30% benefit for patients on mechanical ventilation.

    a. Does HHS plan to incorporate potential treatments like these into the Strategic National Stockpile?

    b. And if not, how is the agency ensuring hospitals have all the tools necessary to fight this epidemic?

Response (a and b):
Requirements for the Strategic National Stockpile (SNS) are established through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates federal efforts to enhance chemical, biological, radiological, and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA). As new threats emerge, the PHEMCE reviews relevant information (threat assessments, available resources, etc.) and will issue a determination if procurement is needed to enhance overall preparedness capabilities.

The Honorable Adam Kinzinger (R-IL)

1. Many on this committee are deeply concerned about – and have pushed for – stronger World Health Organization (WHO) accountability: not only accountability for what the WHO knew and when about the COVID-response, but also accountability to broader U.S. interests, concerns and priorities related to public health. While the WHO can play a critical role in an effective, global pandemic response, the organization – and its leadership – clearly must take steps to rebuild trust through significant reform. The United States has long played a critical role at the WHO pushing for these reforms, speaking up for U.S. interests, and pushing back on harmful initiatives that would undermine U.S. health and economic leadership. The Administration's July 7 letter to U.N. Secretary-General Antonio Guterres giving one year's notice for withdrawal from the WHO sends a clear signal that the United States will not stand

for an organization that is unwilling to reform, and provides important leverage to push for both answers about how the WHO has handled the pandemic and how it will change to address current criticisms. Yet the follow-up steps are not quite clear – and many have questions about how the U.S. will use the one-year window to press for the reforms that we all agree are needed. I am concerned that these necessary reforms will not happen without the United States leading the charge for change, while leaning in and working with other likeminded countries that share these concerns.

a. What reforms does the United States need to the WHO to make to address global criticisms and rebuild trust?

b. How has the United States presented its priorities to the WHO leadership, and how have they responded?

c. What is the Administration's plan during the withdrawal period to press for those reforms? How can it work with like-minded countries?

Response:
As the Representative of the United States on the Executive Board of the World Health Organization (WHO), I am engaged in ensuring meaningful reform will be brought to the organization. It is essential that the WHO be held to its commitment to transparency, accountability, and continuous improvement while also promoting health and ensuring that the world is prepared for any potential health challenges.

The Honorable Gus M. Bilirakis (R-FL)

1. As we continue to progress, we know there will come a time for the public health emergency declaration associated with COVID-19 to end and with it the waiver authorities associated with response.

a. Can you describe what metrics will factor into HHS's decision to end the emergency declaration?

b. With concerns around a potential 2nd wave co-occurring in the fall with the flu season, does the Agency envision making this decision prior to entering the upcoming flu season?

c. Does HHS envision these waiver authorities expiring immediately or taking more of a glide path?

d. Are there any specific waivers HHS currently envisions keeping?

e. Will HHS be engaging provider stakeholders on this and, if so, how and when does the Agency envision that occurring?

Response (a-e):
All relevant data and metrics will be considered and weighed before a decision is made in ending the Public Health Emergency (PHE). All pertinent information is constantly being

examined to inform the continued efforts of the Federal Government's response to COVID-19. In regards to a potential second wave, HHS is continually monitoring the evolving COVID-19 situation and this constant vigilance will inform all decisions now and into the future. The flexibilities and waiver authorities granted by the PHE that have been implemented are being constantly evaluated in order to provide the correct data to determine if extending them is in the best interest of the response or the health of the American People. HHS always considers the valuable input from a multitude of stakeholders or data points to inform decision making and will continue to do so when considering all options in regards to the PHE.

2. Today's lean manufacturing supply chains often operate "just in time" instead of "just in case" to reduce costs and maximize efficiency; however, this is a duel edge that can present challenges in the midst of a pandemic response – as we saw with personal protective equipment. How can we balance resiliency with value?

Response:
HHS, together with our federal partners, is constantly evaluating ways to invest, promote, and incentivize resiliency in the personal protective equipment (PPE) manufacturing process in the United States; this includes various Defense Production Act investments and actions taken during the response to the COVID-19 pandemic and through other mechanisms. The COVID-19 pandemic revealed vulnerabilities in the global medical supply chain that required HHS to reassess, replenish and restructure the SNS to better protect the health and safety of all Americans. As part of this effort, HHS is working to build a 90- day capacity of the most critical supplies for the COVID-19 response needs of the U.S. healthcare system.

3. Did COVID-19 illuminate barriers to care? If so, what are those barriers? Does the Agency have the necessary authority to address these barriers and, if not, what can Congress do to address?

Response:
Many persons with opioid use disorder have historically faced barriers in access to substance use disorder treatment, in part due to laws requiring initial prescriptions of medications for opioid use disorder to be issued only after an in-person examination by a clinician. Currently, only 5 percent of physicians have completed the Federal waiver allowing them to prescribe buprenorphine, one of the primary medications for treating opioid use disorder, and more than half of rural counties in the U.S. do not have a waivered buprenorphine provider. The emergency exemptions for in-person prescribing of buprenorphine and expanded use of telemedicine have created new opportunities to link persons with opioid use disorder to care during the pandemic, and it will be important to explore opportunities to continue those exemptions and use of telemedicine for substance use disorder treatment after the state of emergency.

COVID-19 strained many of the systems in our Nation and illuminated the challenges faced by the most vulnerable in the United States. HHS is constantly engaged in addressing the disparities and inequities the most vulnerable face in order to promote health across the Nation. HHS is leveraging the offices and resources at its disposal to overcome these

challenges. Furthermore, the COVID-19 pandemic has changed how health care is delivered in the United States and has affected the operations of healthcare facilities. Effects may include increases in patients seeking care for respiratory illness that could be COVID-19, deferring and delaying non-COVID-19 care, disruptions in supply chains, fluctuations in facilities' occupancy, absenteeism among staff because of illness or caregiving responsibilities, and increases in mental health concerns. Currently, no FDA-approved medications to treat COVID-19 or vaccines to prevent it are available.

Healthcare facilities need to provide care for all patients in the safest way possible for patients and healthcare personnel (HCP) and at the appropriate level, whether patients need home-based care, outpatient care, urgent care, emergency room care, inpatient care, or intensive care.

4. Were states and localities properly set up to order and receive shipments from the Strategic National Stockpile – if not, how did that impact the effectiveness of their response?

Response:
In the event state and local supplies are depleted and commercial supplies are unavailable, states may request federal assistance from HHS. This includes requests for SNS assets such as personal protective equipment (PPE). During the COVID-19 response, in March 2020, HHS was utilizing a pro-rata allocation of PPE from the SNS. With limited amounts of PPE in the SNS, the pro-rata allocation ensured that all States received some product (and considerations were made for those States experiencing significant outbreaks).

When FEMA was designated to lead the coordination of the Federal Government's COVID-19 response, requests for SNS assets from states, tribes, and territories were routed through the FEMA regions to the National Response Coordination Center to be reviewed and adjudicated.

Once assistance was approved, the HHS Secretary, or the Assistant Secretary for Preparedness and Response (ASPR) under the HHS Secretary's authority, directed the SNS to deploy supplies. The state was then responsible for distributing the supplies to areas in need based on established distribution plans.

States, tribes, and territories continue to work through HHS and FEMA to submit resource requests.

5. Moving forward, how can essential workers and industries (groceries, meat processing, delivery, etc.) be better reflected disaster planning? Are there best practices states and their localities should be aware of?

Response:
The Centers for Disease Control and Prevention has issued guidance documents that provide essential workers and industries information on how to address COVID-19. Other guidance and technical assistance have been given to various states, localities and industries on how to prepare and address their needs and the needs of their workforce during this time. Websites are available that provide information to workers and industries to address COVID-19

including general information for the workplace:(https://www.cdc.gov/niosh/emres/2019_ncov_default.html) and resources for specific industries and occupations: (https://www.cdc.gov/niosh/emres/2019_ncov_byindustry.html), including food production and services.

6. Under the Inpatient Prospective Payment system, the diagnosis related group (or DRG) is based on the average resources used to treat an inpatient patient from admission to discharge. However, given the novel nature of COVID-19, I'm aware of reports from providers that it's hard to understand the full scope of costs associated with treating these patients and the DRG has the potential to create a cost conflict for hospitals to provide certain treatments for patients – especially impactful to small, rural areas. Is HHS aware of this issue and (if so) what is the Agency considering – has the Agency considered excluding COVID-19 treatments from the DRG bundle?

Response:
The Centers for Medicare & Medicaid Services (CMS) issued an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. CMS announced on April 14, 2020, that it was implementing section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which requires a 20 percent temporary adjustment to Inpatient Prospective Payment System (IPPS) hospital payments for treatment of an individual diagnosed with COVID-19. The IPPS also provides for Medicare payments to hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs, as outlier payments. In addition, during the COVID-19 public health emergency, Medicare will pay the diagnosis-related group payment and any outlier costs to hospitals for a patient who needs to be isolated or quarantined in a private room and cannot yet be discharged from the hospital, such as because skilled nursing facilities (SNFs) are not accepting patients.

Additionally, CMS approved a blanket waiver that includes the expanded ability for hospitals to offer long-term care services ("swing-beds") for patients who do not require acute care but meet the SNF level of care criteria as set forth at 42 CFR 409.31. Care furnished to these beneficiaries can be paid under the SNF prospective payment system.

Through the Hospitals Without Walls initiative, CMS has ensured that hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or hospitals can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.

CMS will continue to consider ways in which we can provide flexibilities to providers during the COVID-19 public health emergency, and we are currently reviewing ways in which we can provide additional payment to hospitals to address their needs during the COVID-19 public health emergency.

7. After a COVID-19 vaccine is developed, the conversation shifts to coverage. Are these conversations already occurring – if not, when would you expect those payer conversations to occur?

   Response:
   The Administration is committed to providing free or low-cost COVID-19 countermeasures to the American people as fast as possible. .

8. Are there any underreported successes in the Administration's COVID-19 response that you would like to discuss?

   Response: Not at this time.

The Honorable Earl L. "Buddy" Carter (R-GA)

1. My understanding is that there are a number of drugs currently in shortage or at-risk of being in shortage. In some cases, the ingredients that go into making these drugs are manufactured exclusively overseas which presents national security concerns. I also read that some of the products in the National Stockpile needed to be discarded because they had passed their expiration date.

   a. What do you think about using the existing commercial distribution network here in the U.S. to manage and replenish a supply of pharmaceutical products identified by the government as being at high risk of market disruption?

   b. Wouldn't a government-private sector arrangement to ensure we have a stockpile of needed medicines available enable us to address the ongoing shortage concerns and more urgently, ensure we are prepared for future unforeseen health care outbreaks?

   c. How can we develop a longer-term solution to this problem so we are ready for the evolution of the current crisis and for critical patient needs for these products in the future?

Response:
We note that the questions above were also asked of the FDA Commissioner Dr. Hahn in the questions for the record (QFRs) for the June 23, 2020 hearing. The FDA is the appropriate agency to provide a response to these questions. We defer to Dr. Hahn's responses.

The Honorable Jeff Duncan (R-SC)

1. Regarding PPE shortages, I'd like to note how amazing it's been to see several local companies just in my district coming forward offering to alter their manufacturing operations to provide PPE to businesses and individuals in need during COVID-19.

   a. Does HHS know if the U.S. manufacturing base for PPE is usually enough to meet the needs of our country, outside of a pandemic situation?

Response:
Prior to the COVID-19 pandemic, no law required medical device manufacturers to notify FDA when they became aware of a circumstance that could lead to a device shortage. We appreciate the device shortages authority Congress provided to FDA in the CARES Act, which applies during or in advance of a declared public health emergency. However, at this time, FDA does not have authority for routine oversight of device shortages.

b. If it's not, are there steps that could be taken by the Administration or Congress to encourage additional domestic production of PPE?

Response:
The HHS Assistant Secretary for Preparedness and Response is working in collaboration with DoD partners to expand the domestic production of PPE products and the key production ingredients required to make those products, through the investment of CARES Act funding in American businesses to meet critical PPE needs today and moving forward. For several of these product lines, increased production capacity and good contracting work early in the pandemic have resulted in significant increases in PPE supplies in the SNS. As requests for PPE are received by FEMA and HHS, these products available in the SNS may be deployed to meet urgent requirements or address spot shortages until productions and commercial supplies can catch up.

2. Following the release of the Administration's testing blueprint, I know several private companies and universities, including Clemson University in my district, came forward with new widespread diagnostic testing proposals. It's really been a whole-of-America approach here. Can you speak to the overall progress our Nation has made on COVID-19 testing, including the many widespread diagnostic testing proposals that private industry folks have released?

Response:
Since March 12, we have increased our daily testing over 32,000 percent. As of August, we had completed over 65 million tests. Through the efforts of the Federal Government to galvanize the testing infrastructure in the United States, we are able to conduct testing at unprecedented levels. Testing enables clinical decision-making, it heralds impending outbreaks, it informs resource allocation, and it assists in minimizing economic and social disruption. However, we cannot test our way out of this, or any other, pandemic. Testing does not replace personal responsibility. It does not substitute for avoiding crowded indoor spaces, or washing hands, or wearing a mask. The progress we have made in testing is important and allows our nation to provide the right test, at the right time, to the right people with timely and actionable results. HHS will continue to work with our public and private partners to ensure testing is available as needed across the country.

Subsequent to the date of the hearing, on August 27, 2020, the Administration announced that a $750 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 Ag Card point-of-care tests. HHS will distribute approximately 100 million tests to states and territories through the end of December 2020, distributed by proportion of their population. Governors will determine the best use of tests for their states; suggested deployment includes use cases for which a low-cost, rapid, easily administered test is uniquely able to fill state needs, such as opening of K-through-12 schools through testing

of teachers, staff, and students, protecting first responders, supporting critical infrastructure, enhancing higher education programs, and other priorities the governors deem fit.

On October 13, HHS in collaboration with the Department of Defense (DOD) awarded a $481 million Other Transaction Agreement to Cue Health, Inc. to expand U.S. production capacity for a cartridge-based point-of-care COVID-19 molecular test that produces results in about 20 minutes. It is FDA-authorized for use in anyone suspected of having COVID-19 by their healthcare provider, whether asymptomatic or symptomatic. This investment will allow Cue to expand its industrial base and increase domestic production to 100,000 COVID-19 test kits per day, enabling this technology to be deployed throughout our testing ecosystem to benefit all Americans. Cue fills an important niche in the testing ecosystem between rapid point-of-care antigen tests and sophisticated laboratory-based PCR tests.

The Administration will continue to execute to achieve all testing objectives as we move together into the future.