TRUMP ADMINISTRATION RELEASES BLUEPRINT TO SUPPORT DEVELOPMENT OF STATE TESTING PLANS

President Trump released his <u>Blueprint for Testing Plans and Rapid Response Programs</u>, intended to supplement his administration's *Opening up America Again* Guidelines and support States in establishing robust testing plans.

Overall, the plan briefly outlines how the federal government plans to support state and local governments, and partner with private entities, to support a nationwide testing strategy. It emphasizes the need to targetedly test asymptomatic patients and employ contact tracing measures. The administration also highlights upcoming efforts, including supporting the development of additional, novel testing technologies and preparing for the concurrence of the upcoming flu season.

Of note, Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Patty Murray (D-WA) released a <u>statement</u> in response to the Blueprint. She stated the plan does "nothing new" and does not include "numeric goals" or a "timeframe" for implementation. She also criticized the administration "[shirking] obviously federal responsibilities by assigning them solely to states instead."

Last, the Paycheck Protection Program and Health Care Enhancement Act (full summary here) requires HHS to submit its own national COVID-19 testing strategy to Congress (due 30 days after enactment). The administration's plan released yesterday does not appear to satisfy the criteria and detail required by statute to constitute a plan:

- Assist states, localities, territories, and tribes in understanding COVID-19 testing for both active
 infection and prior exposure, including hospital-based testing, high-complexity laboratory testing,
 point-of-care testing, mobile-testing units, testing for employers and other settings, and other tests
 as necessary;
- Include estimates of testing production that account for new and emerging technologies, as well as guidelines for testing;
- Address how the HHS Secretary will increase domestic testing capacity, including testing supplies;
- Address disparities; and
- Outline federal resources that are available to support testing plans of each state, locality, territory, and tribe.

Details on the President's Blueprint follow.

The document begins first by establishing **the roles and responsibilities** for stakeholders involved in executing the plan. Stakeholders include the federal government, states, localities, tribal governments, and the private sector and professional associations.

• <u>Federal Government</u> – Among the responsibilities listed, the federal government is charged with publishing guidelines for testing plans; providing strategic direction; expedite regulatory authorizations for tests and testing equipment; and, providing technical assistance on the best available technologies.

- <u>State, Local, and Tribal Governments</u> The Blueprint charges these entities with developing local testing plans and response programs; maximizing the use of all available testing platforms and venues; determining solutions to current barriers; and, monitoring the results of such programs.
- <u>Private Sectors & Professional Associations</u> These entities are responsible for developing new testing technologies; seeking emergency use authorizations (EUAs) for emerging technologies; accelerating production of key solutions; sharing data; and, partnering with local governments to enhance testing strategies.

Following this, the Blueprint then establishes the **Core Principles** and **Core Elements** of the President's envisioned testing plan.

- Core Principles The Blueprint reaffirms the President's ethic that testing programs will be "federally supported, State managed, and locally executed." Briefly, the guidelines emphasize that all symptomatic patients should be tested in a timely fashion. It also calls for sentinel monitoring at "critical locations" (e.g., congregate living settings) to detect asymptomatic patients that test positive. Testing strategies should supplement sentinel monitoring with contact tracing. Of final note, the Blueprint calls for focused testing capacity increases at hot spots, the use of new technologies (e.g., antigen and POC nucleic acid tests), assessing the number of those previously infected, and using data to drive adaptations to testing plans.
- Core Elements The Blueprint includes three elements that it deems central to a testing plan.
 - o **Robust Diagnostic Testing Plans:** The Blueprint calls for comprehensive testing strategies that leverage all platforms and venues that can address localized and widespread outbreaks. Plans should also focus on vulnerable and high-risk populations, including senior citizens and the health care workforce. The Blueprint then outlines actions the administration has taken to support states in devising testing strategies.
 - Expanding the number of testing platforms: The administration highlights the 70 EUAs issued for new diagnostic and serological tests.
 - Increasing testing and laboratory supplies: Here, the administration points to its invoking of the Defense Production Act to increase production capacity of necessary supplies.
 - *Unlocking full laboratory capacity*: The administration states it has inventoried all testing platforms that exist in each state and has had discussions with laboratory directors to better understand current testing barriers.
 - *Enhancing sample collection*: The administration details how it has partnered with experts to improve sample collection, specifically stating that tests today are less invasive and can be self-administered.
 - O **Timely Monitoring Systems:** The administration recommends states use nationwide clinical monitoring systems such as the ILI Net and NSSP. It recommends states do so through the duration of the summer and beyond. The guidance also emphasizes the importance of identifying asymptomatic cases, and recommends states partner with the Centers for Disease Control and Prevent (CDC) for doing so. The administration says again that it will provide technical assistance to states to ensure they maximize laboratory capacity.

• Rapid Response Programs: Here, the administration again highlights the importance of contact tracing programs, and screening anyone who has come into contact with an individual who has tested positive for COVID-19. The administration offers technical assistance on this front as well.

Following these core elements, the administration then outlines its envisioned path forward and steps it will take to support a national testing strategy. It first points to the use of antibody testing and that it continues to explore ways to improve the accuracy and reliability of these tests. The **Appendix** on p. 9 depicts how the use of two antibody tests instead of only one improves the predictive value of a testing program. In addition, the administration states it is also investigating the development of antigen tests, as well as using genome sequencing for COVID-19 detection. Last, the administration notes its plans for updating testing algorithms and protocols in light of the upcoming flu season and other diseases that may occur concurrently.