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A NATIONAL COVID-19 SURVEILLANCE SYSTEM: ACHIEVING CONTAINMENT

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This Duke-Margolis resource on COVID-19 response policies is intended to inform and help guide policy makers addressing the evolving COVID-19 pandemic in the United States and around the globe, and will be updated as the pandemic and response capabilities change over time.

It contains recommendations for a U.S. Federal response as well as steps and resources for stakeholders across the health care ecosystem. We will add further resources to address a range of related, critical policy challenges.

We thank our many collaborators, co-authors, and reviewers who have contributed significant expertise and guidance on these rapidly evolving issues. Please reach out to us with additional suggestions for resources and effective policies at <u>dukemargolis@duke.edu</u> - we welcome your input.

This report describes the features and capabilities of a national surveillance system to mitigate the current COVID-19 pandemic wave and to limit and suppress future outbreaks. Developing these capabilities in each state and region will enable the U.S. to move beyond extreme and disruptive physical isolation measures. The proposed COVID-19 surveillance system builds on existing models and principles of public health surveillance, but recognizes that the transmissibility and virulence of COVID-19 require a much more substantial capacity for rapid detection and public health response.

Timely and efficient implementation of such a surveillance system will require ongoing coordination between health care providers and state and local public health authorities, with Federal support coordinated through the Centers for Disease Control and Prevention (CDC) to achieve effective implementation throughout the country as soon as possible, and certainly in time for the Fall, when COVID-19 may become a seasonal threat.

Brief summaries of specific recommendations for government agencies and officials at both the <u>Federal</u> and <u>State</u> levels can be found at the end of this report.

A National COVID-19 Surveillance System: Achieving Containment

Executive Summary

The immediate priorities of our national efforts to address the COVID-19 epidemic are appropriately aimed at suppressing chains of transmission through community-wide measures like stay-in-place orders and at surging hospital capacity to expand our ability to care for the rising number of sick patients.

At the same time that we confront the current crisis, we must plan for the future by putting in place tools to enhance our ability to conduct effective surveillance, containment, and case management. As incidence of COVID-19 declines, case-based interventions will again become an option. Building those capabilities now will enable us to move beyond the extreme and disruptive physical isolation measures in place across the United States.

Every region of the country should aim for the following outbreak surveillance and response capabilities:

- 1) Test and Trace Infrastructure: Capacity for Widespread Diagnostic Testing and Data Sharing to Enable Rapid Case-Based Interventions
 - a) The capacity to conduct <u>rapid diagnostic testing</u> for everyone with COVID-19 symptoms and those with exposures or at higher risk of contracting or transmitting the virus (health care workers, those in congregate settings), with a robust sentinel surveillance system that routinely monitors for infection among samples of the population to enable early identification of small outbreaks, particularly in vulnerable populations;
 - b) Routine, straightforward, and secure electronic data sharing to support surveillance;
- 2) Syndromic Surveillance: Integration of Test and Trace into an Enhanced National Syndromic Surveillance System
 - a) Surveillance based on syndromic indicators of spikes and falls in potential COVID-19 related symptoms, building on existing public health syndromic surveillance capabilities
 - b) Timely and transparent reporting of COVID-19 outbreaks and testing and response capacity at the local level
- 3) Serologic Testing: Capacity to Conduct Widespread Serologic Testing to Identify Reliable Markers of Immunity
 - a) The development of regional measures of community exposure and immunity
 - *b)* The use and integration of accurate serologic testing of individuals for effective surveillance and containment
- 4) Rapid Response: Capacity for Isolation, Contact Tracing, and Quarantine
 - a) The capacity to isolate new cases and trace, test, and quarantine contacts rapidly
 - b) The capacity to treat new COVID-19 cases effectively, at home or in a hospital

The surveillance expansion effort described here should be coordinated by the Centers for Disease Control and Prevention (CDC) in collaboration with state and local public health authorities. The effort should leverage Federal funding and oversight through COVID-19 grants

to states. Support for health care providers should be coordinated with the Centers for Medicare and Medicaid Services (CMS) and private payers, with support tied to high quality reporting on testing. With goals and resources provided by the Federal government, the operational details of implementation should be left to state and local authorities, because the best approach to augment existing surveillance capabilities is likely to vary based on the local context.

The following sections describe the steps needed to develop capabilities in every state and region, as well as the Federal government's role in providing the national infrastructure and support to accelerate progress. Summary recommendations for Federal and State governments at the end of the report describe potential benchmarks for the development of the surveillance capabilities, in conjunction with <u>progress toward reopening</u> from the current surge phase of the epidemic, through the recovery and broad immunity phases.

Capability #1 – Test and Trace Infrastructure: Capacity for Widespread Diagnostic Testing and Data Sharing to Enable Rapid Case-Based Interventions

Robust COVID-19 case detection, contact tracing, and isolation measures provide a foundation to maintain outbreak suppression while gradually lifting community restrictions. These public health activities are often coordinated and supported federally but conducted principally at the state and local levels. Not one of the 50 U.S. states currently has surveillance capabilities sufficient to enable case-based interventions at the necessary scale. While these capacities are being scaled up in some places around the country, getting them to a level adequate to mitigate the risk of future outbreaks and epidemics will require a substantial expansion of our public health infrastructure and case-based management capabilities. With Federal support, surveillance mechanisms can be increased or implemented and better integrated with testing by providers.

A reasonable first approach is to support rapid pilot program in some regions of the country that are already supporting existing surveillance capabilities. For example, Massachusetts recently announced <u>a new program</u> to hire and train 1,000 people to support contact tracing. Successful early models and best practices would provide the basis for CDC's guidance to expand these capabilities throughout the country.

Public health workers engaged in this expanded surveillance system will need to be supported by technological tools that help increase the efficiency and ease of contact tracing- such as enhanced directories, multichannel messaging applications, real-time translation services, symptom reporting and isolation monitoring.

While this surveillance system is critical now for containing and mitigating the COVID-19 epidemic, the capacities developed for this response would also provide a stronger foundation for detecting and responding to future outbreaks.

COVID-19 Diagnostic Testing Capacity

Unlike many other viral respiratory infections where test results may guide treatment but are generally not linked to public health actions, positive COVID-19 test results should be linked to patient isolation and contact tracing. The estimate of a <u>national capacity of at least 750,000</u> tests per week to allow for isolation and contact tracing is intended to serve as a capacity guide once there is sufficient diagnostic testing to manage the current epidemic. This estimate may be revised as additional details and evidence become available, and more capacity may be needed to help contain outbreaks that are part of the current epidemic.

The ultimate goal for diagnostic testing should be that all patients with COVID-19 symptoms seeking outpatient or hospital care receive a reliable diagnostic test. The current "gold standard" of testing is a polymerase chain reaction (PCR) laboratory test. Timely PCR testing or validated and reliable point-of-care (POC) testing should be widely available in the outpatient setting. In addition to those with symptoms, other priority groups, including health care workers and workers in essential roles, and close contacts of confirmed cases, should also be prioritized for testing. For example, health care workers in nursing homes and long-term care facilities could be tested before each shift in order to prevent outbreaks in those settings.

Testing in sentinel surveillance programs, e.g., in select populations or in settings where people congregate with high risk of transmission, should be considered once sufficient local outpatient diagnostic capacity is established. Having in place strong background surveillance on representative and at-risk samples of the population (and to capture asymptomatic and mildly symptomatic spread that might otherwise go undetected) is potentially important to identify outbreaks before they grow out of control. Sentinel surveillance will be a critical tool for identifying asymptomatic or mildly symptomatic spread that may evade symptom-based surveillance but that could be an early indicator of – or prelude to – larger outbreaks.

In order to test at that scale, states will need to expand testing capacity, including through validated POC testing. These systems should enable test results to be returned in minutes or hours rather than days. The technology for addressing these needs is advancing. Other innovations that will greatly expand the ease and use of testing are validated, self-administered tests that reduce the need for infection prevention resources like personal protective equipment. These tests may potentially be used effectively for at-home sample collection, e.g. from symptomatic contacts identified through contact tracing. Under this approach, patients would be able to administer a swab themselves, if linked to a reliable method for transport to a lab for analysis. As we have noted previously, the Federal government can take steps to accelerate progress innovation in the quality and convenience of testing, for example through CMS payment policies for diagnostic testing, and coverage guidance for new diagnostic tests.

Medicare, Medicaid, and private payer payment reforms for providers that are implemented as part of COVID-19 response and recovery should be linked to effective participation in the surveillance and response system. For example, payments might be increased for providers who share timely test result data from tests that meet Federal standards, and for those who track

COVID-19 risk and exposure in their patient populations electronically. CMS could also provide coverage and payment guidance for laboratory test developers that offer additional payment for test platforms that demonstrate effective electronic data sharing and that report additional high quality and interoperable data (e.g., symptoms and date of onset), or that provide additional payment when new tests approved by FDA for emergency use demonstrate their ability to meet or exceed performance standards for sensitivity, specificity, and timeliness in practice. Surveillance grants could also be used to position testing tools in Federally-sponsored community health clinics and other priority community settings that states determine are critical to achieving surveillance goals.

Federal COVID-19 grant payments and provider payments should encourage rapid progress in the validation of emerging testing options and adaptation to continuing improvements in testing capacity that make appropriate screening accessible to patients. For example, payments for new laboratory tests should be linked to the developer's participation in validation studies across a range of practice settings, and tests that do not meet minimum standards for sensitivity, specificity, and reliability in practice should not be reimbursed. CMS should also explore mechanisms for adjusting test payments over time based on performance in practice, to encourage manufacturers to improve tests and providers to use the most effective and efficient platforms.

Electronic Data Sharing to Support Test and Trace

In collaboration with states and the private sector, CDC, CMS and the Office of the National Coordinator for Health Information Technology (ONC) should encourage the adoption and widespread use of electronic standards and reporting to enable rapid electronic reporting of COVID-19 related laboratory test results from health care providers, laboratories, or other testing sources using existing automated electronic reporting infrastructures. This process can be enabled by designating COVID-19 as reportable to state and local health officials, and as a nationally notifiable condition that must be reported to the CDC. These reports would be used to trigger public health interventions like isolation, contact tracing, and quarantine, which are needed to prevent further spread of SARS-CoV-2.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act requires any laboratory that performs tests to detect SARS-CoV-2 to report the results (both positive and negative) to the HHS Secretary during the period of public health emergency. To support effective understanding of the course of the outbreak, the data collected should include presence of symptoms, date of symptom onset, and test platform (to help assess new testing platforms that have limited evidence on test sensitivity and specificity), in addition to usual laboratory result data fields such as patient demographics, geographic location, and test result. This should be enabled through an "Ask on Order Entry" (AOE) input requirement at the time of test ordering, and implemented by commercial laboratories in collaboration with the Council of State and Territorial Epidemiologists.

Health care providers should also have standard, straightforward processes for sharing data on clinical cases with public health officials. ONC has developed electronic standards and use cases

for transmitting data to enable rapid case reporting as part of the Meaningful Use of certified EHR technologies. Such electronic standards are compatible with existing electronic record systems. These approaches build on recent ONC and CMS interoperability requirements. They should be adapted here. However, progress to date in expanding this electronic case reporting through the Initial Case Report (eICR) Project has been slow and is well below the level needed for reliable and timely surveillance. Linking data sharing to provider payment will accelerate progress. Intensive pilots in some regions and states will also help to develop approaches that can be adopted to implement these capabilities nationwide. Other steps to encourage electronic participation by providers include developing resources to share best practices on appropriate attribution to public health jurisdictions, tools for data mapping and completeness, hospital onboarding processes, and further targeted initiatives to support participation in jurisdictions that are falling behind. The goal of these efforts should be to automate such data sharing as tests are ordered, reported, and billed in electronic record systems, with minimal additional effort required by providers. <u>CSTE</u> has outlined some challenges and recommendations in this area that should be prioritized going forward.

These data should also be used in public health studies to improve evidence on the sensitivity and specificity of particular diagnostic tests and testing methods, and the role of testing in predicting risk of transmission, case severity, immunity, and other clinical outcomes. The case reports should be automatically compiled into a database to enable epidemiologists and other researchers to continually learn about, and monitor changes in, the distribution and determinants of COVID-19, as we describe in more detail below.

Capability #2 – An Enhanced National COVID-19 Syndromic Surveillance System that Supports Effective "Test and Trace"

Integration of Test and Trace into a National COVID-19 Syndromic Surveillance System

Over the past decade, a national infrastructure has been established for the real-time monitoring of a sample of emergency department visits for different syndromes of public health interest, including for influenza-like illness (ILI). Early experiences from New York, California and Washington suggest that these systems can provide leading indicators of COVID-19 trends. Over the past decade, the <u>National Syndromic Surveillance Program</u> has expanded to include data flows from over 70% of US hospitals, data mappings, analytic methods for outbreak detection, state and local onboarding, access, and user controls, audit, security, and privacy protections.

As we implement comprehensive testing and tracing, this data collection and analysis infrastructure should be enhanced to provide additional support for COVID-19 decision making. Among the information that should be prioritized are measures that can provide early signals of community outbreaks indicating the need for more aggressive suppression, as well as potential declines in emergency or urgent care visits and admissions following successful efforts at mitigation. This is especially important for states that have not yet established widespread, timely diagnostic testing of all potential COVID-19 cases. An enhanced syndromic surveillance

system could also support monitoring of people with milder symptoms through ongoing symptom surveys. Syndromic surveillance can help states prioritize where to assure widespread testing capacity first, getting the testing capacity to where it's most needed, and to correlate test results with impacts on health care utilization. Indeed, some states are already building out their existing surveillance systems to begin to support rapid testing, tracing, and tracking of COVID-19 transmission.

To support these enhancements, the COVID-19 surveillance system would benefit from timely access to other sources of electronic data, including electronic feeds on admissions, discharges, and transfers (ADT). Building on efforts already underway, a CDC-led collaboration with state and local public health authorities could provide guidance and technical support for expanding these systems for more comprehensive monitoring of COVID-19 related signals. This expanded monitoring would include creation of more specific "groupers" (e.g. that include symptoms such as anosmia and exclude other diagnosed viral infections), looking for a characteristic age distribution of COVID-19 increases, correlating with clinical observations, and extending to surveillance of hospital admissions and ICU transfers.

After we contain and defeat the current pandemic, this enhanced COVID-19 syndromic surveillance system should provide a foundation for an effective, long-term capacity to detect and respond rapidly to potential future outbreaks. Such a modern surveillance system should have the capacity to integrate timely electronic data from a broad range of sources – including public health surveillance, health care, and the community – and should be linked to ongoing. systematic testing using advanced multiplex molecular assays and rapid response capabilities in every state. This aligns with the CDC's vision for a modernized public health surveillance system, which should be fully funded and supported.

Timely and Transparent Reporting of COVID-19 Outbreaks, Testing, and Response

In collaboration with the CDC, states should use these integrated capabilities for COVID-19 surveillance, incorporating testing results, to produce daily summaries by metro area or region of COVID-19 related case trends, as well as the comprehensiveness of testing and response activities based on testing results. This will not only provide needed transparency about local outbreaks, but also about areas where further progress on effective testing is needed, as suggested in the President's March 26th letter to governors.

Capability #3 – Serologic Testing: Widespread and Effective Testing for COVID-19 Exposure and Immunity

Regional Measures of Community Exposure and Immunity

At the population level, a rigorous large-scale community serosurvey is urgently required to understand the true extent of COVID-19 infections, with important implications for calibrating

epidemic models. For example, serosurveys are needed to accurately assess the infection fatality risk, and for understanding to what extent children are susceptible to infection.

Serologic testing is not an effective method to serve as a primary diagnostic tool for current infection. Instead, it is useful for understanding patterns of past exposure to SARS-CoV-2 and the background rate of immunity in different populations and geographies. This data is important for informing public health decision making. For example, if there in an outbreak in a county that is largely susceptible, it might prompt more aggressive measures at containment and mitigation than a comparable outbreak where serology testing identifies a higher rate of overall immunity.

CDC is <u>conducting initial serologic testing</u> in samples from hotspots, and additional serologic testing is also expected for health care workers and other special populations. Innovative approaches to assess COVID-19 antibodies to determine immunity with greater reliability and speed are in development and coming into use in the U.S. and across the globe. These tools include fingerstick point of care tests and more quantitative ELISA methods like those currently used in research applications.

Federal guidance, informed by Federally supported research, should describe the testing strategies needed for to develop an accurate understanding of regional population exposure and immunity, and its association with characteristics of the population and the regional response. Preliminary population-level estimates could be derived from blood samples already collected as part of routine health care. These estimates could be augmented by additional serologic testing of sample populations, to obtain more accurate and refined measures of regional immunity.

<u>Use and Integration of Serologic Testing of Individuals for Effective Surveillance and</u> <u>Containment</u>

Looking ahead, reliable serologic evidence of immunity at the individual level will also have important implications for the conditions under which individuals return to work, and their ability to work in settings at high risk for coronavirus transmission, particularly certain health care settings. However, there are still uncertainties about the characteristics of immunity, including durability and completeness of protection. These questions will need to be settled before serostatus could be considered for individual decision making. Coverage and payment policies like those described in the previous section for validating new POC and self-administered tests can accelerate the development of needed evidence on sensitivity and reliability of new serologic tests in practice.

As these issues are addressed, and as serologic testing capacity expands and the performance of these tests improves, federal and state governments will need to establish criteria for valid tests to determine immunity and priorities for testing, and for appropriate mechanisms to incorporate data from individual testing into measures of regional population immunity and risk of spread. The electronic reporting capabilities and supports described in the previous section can also be applied to encourage the appropriate use of increasingly effective and

convenient serologic tests. Approaches to serologic testing, and the use of this information, need to be done with adherence to all appropriate expectations governing patient privacy and with careful attention paid to the ethical complexities of using serostatus in this way.

The results of work-related testing and immunity certification could also have implications for surveillance and response strategies. **State and national surveillance strategies should be updated to guide health care providers and businesses in making determinations about immunity based on serology test results.** At this stage of the epidemic, and through the recovery stage, serologic testing is a complement not a substitute for widespread diagnostic testing.

Capability #4 – Rapid Response Capacity: Contact Tracing, Rapid Testing, Quarantine, and Isolation

Capacity to Isolate New Cases and Trace, Test, and Quarantine Contacts Rapidly

The state and local public health workforce will need to be substantially strengthened to be able to generate, manage and respond to the data from all three surveillance systems listed above. This is particularly urgent for the capacity to conduct aggressive case identification and contact tracing.

Ideally, when a new case of COVID-19 is identified, local public health officials will assure that the affected individual is isolated, and that their close contacts are identified and asked to quarantine. However, existing local public health capacity for such response activities is very limited, and many jurisdictions have abandoned contact tracing in favor of community-level mitigation measures. To enable a return to case-based interventions as incidence declines, these capacities need to be expanded. Improved capacity will be most effective if coordinated with health care providers, health systems, and health plans and supported by timely electronic data sharing. Cell phone-based apps recording proximity events between individuals are unlikely to have adequate discriminating ability or adoption to achieve public health utility, while introducing serious privacy, security, and logistical concerns. Instead, timely contact tracing can be achieved through strengthened public health case investigation augmented by technology and community-level collaborations.

Public health authorities must be able to rapidly obtain additional demographic and clinical information on laboratory-reported cases. Today, Federal, state and local public health authorities are all trying to query individual hospitals, hospital systems, electronic health record vendors and health information exchanges. The Coronavirus task force has <u>set up a mechanism</u> for regular hospital reporting of test results at the Federal level. **To improve data collection and reduce burden, the CDC and the Association of State and Territorial Health Officials (ASTHO), in collaboration with ONC and the Office of Civil Rights, should establish a common platform for facilitating automated queries to hospitals on behalf of Federal, state, and local public health.** The <u>two national information trusted exchange networks</u> that currently capture the vast majority of U.S. hospitals should participate in this common platform. The initiative should also aim to improve sharing of clinical summaries with public health authorities and provide public

health agencies with tools for parsing clinical documents to extract and download useful information for case investigations, including ongoing monitoring of hospitalization status, ICU transfer, and discharge or death. OCR recently released an <u>enforcement discretion action</u> to address these issues.

The regional surveillance system should develop a sufficient level of local contact tracing and management capacity within the public health system to address expected contact tracing needs, based on the potential burden of further outbreaks. Growing this capacity will require training and technical and financial support. The CDC-led surveillance system funding should support augmenting this public health capacity in state and regional authorities, with accountability for demonstrating that the capacity is being developed effectively but with flexibility in how states do so. That funding should encourage efficient and sustainable approaches, including coordination and collaboration with health care providers and health plans, and should identify best practices and track state performance (e.g., share of reported cases with contacts traced and quarantined within 48 hours) using surveillance and outbreak data.

Home isolation of cases and quarantine of their close contacts should be encouraged. However, some individuals may prefer to engage in isolation or quarantine outside of the home, due to risk of exposure to other individuals (e.g. a high-risk older adult), or an unsafe or inadequate home environment. State and local health departments should, with the help of Federal funding, make available adequate local facilities for isolation and quarantine of individuals who voluntarily choose to use them. CDC should support sharing best practices for implementing, sustaining, and using such facilities effectively, based on models being implemented around the country.

The CDC-led collaboration should take steps to engage health care organizations in achieving case isolation, contact tracing and quarantine. Health care organizations, especially those with good electronic data capabilities and the ability to engage their patients longitudinally, are well positioned to assist in testing and in the management of their patients with positive tests. For example, some primary care groups and health systems are using case managers, telemedicine services, and digital apps supported by electronic algorithms and dashboards to manage their populations and are continuing to improve these capabilities. Health plans (including Humana, United Healthcare, and Blue Cross Blue Shield of North Carolina) are also implementing similar supports for their patients who test positive.

Capacity to Treat New COVID-19 Cases Effectively, at Home or in Local Isolation to the Extent Possible

The CDC-led collaboration, working with CMS, private payers, and providers, should support the identification of approaches, best practices, and supporting tools to expand effective COVID-19 case management models. The goal of these models should be to maximize the capacity to treat patients at home (or in local isolation facilities) through the course of their infection and recovery, to avoid burdens and potential contagion risks in health care facilities.

The care models should take advantage of enhanced funding by CMS and private payers for telemedicine services and for the use of alternative sites of service.

In addition, CMS and CDC should explore mechanisms to support these best practices through linkages to additional provider payments as part of the COVID-19 response. For example, CMS could support the development of a case-based alterative payment model that supports case management to achieve better outcomes (e.g., whether positive cases are self-managed, require home- or community-based support, or hospitalization), based on the same data shared by providers who participate in the COVID-19 surveillance network. State and local health departments should be encouraged to coordinate such activities with willing health care providers.

These response capabilities are critical for containing COVID-19. However, the steps to support more effective public health response capacity, and its linkage to enhanced COVID-19 case management capabilities in collaboration with health care providers, is aligned with major priority of <u>public</u> and <u>private</u> health care payment reform initiatives to enhance population health. As a result, the COVID-19 response program will strengthen the ability of public health systems and health care providers to assess population risks and detect future outbreaks early, as part of their efforts to improve population health.

Applied Research and Development for Better COVID-19 Surveillance and Response Methods

Our current understanding of how to contain COVID-19 effectively is limited in many critical areas, including the role of asymptomatic and minimally symptomatic individuals in transmission, the impact of more refined physical distancing measures, the ability to predict and influence case severity, and the role of children in transmission. A CDC-led effort, in collaboration with the private and academic sectors, should prioritize these urgent questions, and provide financial support and data for researchers and analysts to address them. This initiative could build on existing public and private collaborations, as well as privately-announced prizes and grants to address key questions in effective surveillance. Research could be based on anonymized large-scale testing data linked to clinical data, to support better predictive models of the association of test results with infection outcomes and immunity Such analyses could produce better surveillance and response strategies, and also more meaningful metrics to describe surveillance capacity and risk of spread at the regional level. This would enable more effective surveillance policies, increasing confidence that reductions in physical distancing measures in will not result in significant or unmanageable increases in cases.

Going forward, a range of other electronic data systems could also contribute to more sophisticated and effective disease surveillance capabilities. In collaboration with FDA, CMS supports an <u>influenza monitoring program</u> that helps identify emerging influenza hot spots based on insurance claims for related services (with COVID-19 now a reported diagnosis in claims). Private insurers and other health data aggregators also have considerable analytic capacity that is being directed to support outbreak detection and response. CDC should support efforts to

mobilize and integrate insights developed through these systems into the COVID-19 surveillance system.

Conclusion

Building on the nation's intense efforts to address COVID-19 epidemic, we will succeed in our current efforts to break the epidemic spread of the virus. But equally critical to our success in moving forward from the current intensive isolation steps is the need to work now to make sure we can contain future outbreaks. There is no time to lose. We need to implement the tools and policies to conduct more effective surveillance, containment, and case management for the future. Building these capabilities now will accelerate our ability to assure the public's safety – the foundation for a sustainable and secure approach to reopening our communities.

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Federal Support and Monitoring to Establish Secure National Surveillance

The ability of States to implement these steps will depend on **financial and technical support from the Federal government**, coordinated through CDC. Key steps for CDC include:

- Enable CDC to provide COVID-19 surveillance grants to states to implement the surveillance system. The surveillance grants should give states flexibility in how they achieve the needed capabilities. The CDC should provide guidance, technical assistance, and information on best practices, and should track state performance in achieving the surveillance capabilities.
- In collaboration with ASPR, FEMA, and other relevant agencies, CDC should help assure that all states have adequate access to tests and associated materials required for testing. There should be active monitoring of local testing capacity and federal agencies should assure the adequacy of diagnostic supplies in states.
- In collaboration with FDA, NIH, and CMS, CDC should support evaluations of diagnostic test performance and reliability in "real-world" settings, including reliability assessments across multiple laboratories and impact on containing outbreaks. These data should support continuing updates on the reliability and performance of each test for virus detection, leading to convenient, timely, and accurate testing. Similar data collection and testing will be needed to assure that serology tests for individual immunity are accurate and reliable.
- CDC should establish national standards for tracking new cases and outbreak containment, to enable ongoing national monitoring and public reporting of the status of local outbreaks. CDC should support daily reporting on local outbreaks, and the accuracy and completeness of testing at the local level.
- CDC should report on state surveillance performance, identifying gaps and taking effective steps to support states in addressing the gaps.
- In collaboration with NIH, AHRQ, FDA, and CMS, CDC should support public-private research and development collaborations to identify more efficient and effective surveillance strategies.

Because health care providers and health systems will have an integral role in implementing effective surveillance, changes to **payment and coverage policies are critical for effective surveillance**:

 CMS should develop clear guidance and policies for coverage and payment for innovative tests, and aim to clarify any coverage and payment issues with manufacturers ahead of marketing. CMS policies for existing PCR lab-based tests have been clear and straightforward, but diagnostic tests with new capabilities (e.g., selfadministration and potentially home testing) may raise additional issues about appropriate reimbursement for the new features, and about demonstrating their reliability in practice. More significant issues about validity and reliability exist for new serologic tests intended to assess immunity from prior COVID-19 exposure. Coverage and payment may need to be linked to the ability of test manufacturers to support

timely data sharing and to support the development additional evidence on the value of the test in practice. Patients should have no copays for appropriate testing, as reflected in COVID-19 legislation, though CMS payment policies should discourage inappropriate testing especially if test supplies are limited.

- CMS payments to providers and laboratories to support recovery and response to COVID-19 should be linked to timely, automated reporting of key data on tests and their results to state surveillance systems and the CDC's national surveillance network.
 Providers and laboratories should have strong incentives to adopt standard electronic approaches for timely reporting.
- CMS should develop payment mechanisms as part of test reimbursement for providers who participate in COVID-19 case management and contact tracing, using standard electronic systems.
- CMS should collaborate with private payers and state Medicaid programs to encourage aligned policies across all payers, to support the capabilities and timely data sharing needed for effective surveillance.

CMS and the Office of the National Coordinator for Health Information Technology (ONC) should collaborate with electronic medical record companies, laboratory associations, and health care providers to enable rapid, widespread implementation of electronic reporting to support the national surveillance system. This includes development of "use cases" that can be adopted by a diverse range of health care providers, laboratories, and state public health systems, technical assistance and other resources to assist with implementation, and programs to encourage the development and adoption of apps, electronic record dashboards, and other electronic tools to facilitate the surveillance system.

State-Led COVID-19 Public Health Surveillance Systems

In collaboration with health care providers and communities, States should implement the following surveillance capabilities:

- 1) Test and Trace: Rapid case detection to enable case-based containment
 - Rapid testing of individuals with symptoms of COVID-19 and those who have had exposure to COVID-19, and testing of those at high risk of contracting or transmitting the virus
 - Sentinel surveillance in each region to detect small outbreaks and asymptomatic spread
 - Collection and reporting of individual-level case data, including symptoms and risk factors
- 2) Syndromic Surveillance: Integration of Track and Trace into an enhanced national syndromic surveillance system for COVID-19
 - Integration of new Test and Trace with enhanced surveillance of potential COVID-19 symptoms and outbreaks, building on existing public health surveillance capabilities
 - Timely and transparent reporting at the local level of COVID-19 outbreaks, and of testing and response capacity
- 3) Serologic Testing: Conduct of testing for exposure and markers of immunity
 - Tracking of exposure and immunity in each region of the state, through testing representative blood samples
 - Use of reliable and appropriate testing for assessment of immune status in individuals as that technology becomes available
- 4) Rapid Response Capacity: Case Isolation and Contact Tracing, Rapid Testing, and Quarantine
 - Expanded public health workforce capable of tracing close contacts, equipped with digital tools and resources to enable a rapid response to new cases
 - Coordination with health care providers to isolate and treat new cases, either at home or in local facilities for individuals who choose not to isolate at home
 - Effective quarantine of contacts, either at home or in local facilities for individuals who choose not to isolate at home

States should build on their existing public health and surveillance systems to establish these capabilities, aiming for rapid, electronically-based tracking of performance in all of these dimensions. States should begin piloting efforts now, with plans to scale up to statewide implementation, using CDC guidance, recommendations on best practices, and technological tools. Health care providers, academic medical centers, regional laboratories, community organizations, and businesses can support these capabilities. Test data and tracking and tracing data should be shared with the CDC's national COVID-19 surveillance system. States should have timely, standard mechanisms for reporting any anticipated shortages of required materials for testing or other complications in surveillance to the CDC's national surveillance support capabilities for assistance.



States should collaborate with health care organizations for support and implementation assistance to enable effective, appropriate testing, case identification, isolation and treatment. Health care providers should receive timely payment for appropriate testing, and for participation in COVID-19 surveillance through timely reporting of test results and assistance with case management and contact tracing and testing.