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LEGISLATIVE AND REGULATORY STEPS FOR A NATIONAL COVID-19 TESTING STRATEGY



Legislative and Regulatory Steps for a National COVID-19 Testing Strategy

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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 dukemargolis@duke.edu - we welcome your input.

Executive Summary

To curb the spread of disease and open the economy, the U.S. must implement a national strategy to increase testing of both symptomatic and asymptomatic people while ensuring timely test results. For people with COVID-19 symptoms and people in close contact with known cases, highly accurate laboratory diagnostic tests ("PCR" tests) are required, with results turned around in 24-48 hours to allow effective contact tracing. Better support is also needed for people who face difficulties in isolating if they test positive. For people without symptoms, we also need broad availability of more rapid but sometimes less accurate screening tests (involving a number of test platforms including pooled PCR, "antigen" tests, and other point-of-care tests) to detect outbreaks sooner and give people more confidence in their workplaces and schools. This is particularly important for high-risk populations such as nursing homes, essential workplaces, and hard-hit communities that currently have limited resources for testing. Financial support for test recipients is needed because screening tests are generally not covered by insurance. Guidance from regulators and public health authorities will also be required on how to use these tests effectively. These tools are needed to control transmission and facilitate safer reopening of schools and workplaces.



Solution: A National Strategy for Effective Testing and Containment

Congress would direct \$75 billion in funding to allow rapid, accurate, less costly, and more effective testing, contact tracing, isolation, and containment.

- Developing Smarter Testing: Fund an additional \$300 million in research and development to accelerate and expand access to rapid, accurate point-of-care testing and easy sample collection. Provide additional review resources to the Food and Drug Administration (FDA) to speed authorization pathways for rapid turn-around screening tests for asymptomatic individuals, and to improve data and assessments on test performance in real-world conditions. Support a regulatory pathway to open up unused capacity to run laboratory "PCR"-based pooled screening tests at academic and research labs.
- Increasing Testing Capacity: Provide \$45 billion to create a robust national testing capacity, including Federal provision of screening test platforms and grants to states and local governments to secure testing access for at-risk populations, including public schools and colleges, nursing homes, essential workers, and others at elevated risk. Provide Federal guidance on effective screening protocols for high-risk and vulnerable populations and on contracting models to support effective and inexpensive screening.
- Widening the Supply Chain: Direct the Department of Health and Human Services (HHS) to address critical testing supply chain shortages and report on progress, with \$6 billion to fund advance purchase contracts or support use of the Defense Production Act (DPA) for testing equipment, infrastructure, and related supplies.
- Tracing and Isolating: Provide \$24 billion to support state and local governments to implement additional contact tracing, provide local isolation for those who cannot do so at home, and support infected workers who lose pay in isolation, similar to support for jury duty service.
- Reporting: Standardize and publish key information on testing and community risk by state and region stratified by age, sex, race and ethnicity, so that local epidemic response decisions (e.g., testing, contact tracing closures) can respond effectively to shifts in the pandemic.
- **Communicating:** Implement a cohesive public communications strategy at the Federal level to keep all Americans informed about testing opportunities, turn-around times for results, contact tracing, and support for preventing spread.



Introduction

Testing for COVID-19 infections is the cornerstone of successful disease suppression and harm mitigation. The Centers for Disease Control and Prevention (CDC) and other public health authorities have endorsed use of reliable diagnostic tests for people with symptoms and close contacts of infected individuals. Rapid testing of such individuals enables appropriate isolation and contact tracing, which are well-established core public health strategies to break infection chains and contain outbreaks.

In addition, testing in asymptomatic and pre-symptomatic¹ people has emerged as a critical strategy for controlling COVID-19, because 30%-60% of people with COVID-19 are infectious but asymptomatic. As a result, a growing number of tests are being performed on at-risk asymptomatic populations, such as residents of nursing homes, essential workers, patients scheduled for elective procedures, students and faculty, and workers.

Reflecting the importance of increased testing capacity for people with symptoms and for screening asymptomatic individuals, recent reports have recommended substantial testing increases in the United States. A recent report from the Rockefeller Foundation recommends at least 30 million per week, with potential benefits from even larger-scale testing as we improve our national testing strategy. Other researchers estimate 10 million or more tests per day could be needed.

Testing in the United States is currently falling far short of these goals, as access to laboratory testing for COVID-19 demonstrates. Because of the spread of COVID-19 around the country, increased use of tests to try to avoid outbreaks while reopening, and continued shortages of critical testing supplies, the demand for lab tests is far outstripping supply even as lab testing continues to increase. Many individuals who should get quick access to diagnostic tests and timely results aren't able to get them. Large commercial labs report that the entire testing process from sample collection to communicating the results to patients has recently exceeded a week in many circumstances. Shortages of needed pipettes or reagents, limited access to approved testing swabs, and delays in obtaining or replacing testing equipment have also constrained testing during the pandemic surge. And despite the importance of screening tests for COVID-19 containment, there is no consistent or reliable guidance on how and when to appropriately use screening tests for people who are asymptomatic, nor is there low-cost access to appropriate screening tests to catch these "silent infections" before they spread.

The country needs a national testing strategy to start testing smarter, and the resources and policies to implement it rapidly. That begins by matching the right test for the right purpose. Highly accurate diagnostic tests (often "PCR" laboratory tests but also high-performing antigen tests) need to be rapidly available for people with symptoms of COVID-19 or close contacts of

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¹ Asymptomatic people will never show symptoms but are still infectious. Pre-symptomatic people are individuals that will show symptoms eventually, but do not currently. There is evidence that pre-symptomatic patients are infectious for several days before symptoms eventually appear. For the rest of this paper, we will refer to both categories as "asymptomatic".



people that have been diagnosed, with quick return of results to enable contacts to be traced. However, our national capacity for such diagnostic tests is far below what is needed if it is used for both definitively confirming diagnoses *and* for supporting large-scale screening tests. Moreover, laboratory-based PCR tests generally require a day or two to provide results even when the system is not backlogged.

Providing much greater availability of fast turnaround **screening tests**, even if they are somewhat less accurate than definitive diagnostic tests, would alleviate the backlog of diagnostic tests and enable much faster results in minutes to hours. Screening tests should be used for people without symptoms or a specific reason to believe they had been exposed to COVID-19 to detect outbreaks sooner and give people more confidence about returning to workplaces and schools — especially in high-risk settings like nursing homes, essential workplaces, and hard-hit communities that have limited resources to support testing.

Finally, there is a need for population-based **surveillance testing**, which involves research to inform and update workplace, community, or regional policies but is not used to make decisions about whether particular individuals need to take actions like isolation.

Strategic use of these three types of tests as we work to make them more available will allow the country to contain the outbreak more effectively as we wait for a vaccine. Congress has already taken important steps to improve access to effective testing. The CARES Act eliminated cost-sharing requirements for diagnostic tests ordered by clinicians for insured individuals, and guaranteed that Medicaid will act as a payer of last resort for uninsured individuals who receive a diagnostic test. Congress is also funding the National Institutes of Health (NIH) to implement the Rapid Acceleration of Diagnostics (RADx) initiative to make available more tests that are fast, inexpensive, and reliable enough for widespread use, supported by \$1.5 billion in appropriations from the Paycheck Protection Program and Health Care Enhancement Act. This includes support for advancing new testing platforms into emergency use in the next several months. NIH announced on July 31 that they had already awarded contracts as part of this program to an initial seven platforms to increase test types and availability as early as September. The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have also taken many steps to create timely and reliable regulatory pathways for needed innovations in diagnostic tests.

While these are welcome developments, there remains a great deal of uncertainty around which populations should get screening tests and how that type of testing should be performed, as well as important regulatory and financial challenges around how large-scale screening tests can be implemented. The <u>CARES ACT does not provide any financial support or coverage requirements</u> for screening tests for safer return to work or helping to contain outbreaks in high-risk settings. As a result, despite growing awareness of the need for larger scale screening, states, local governments, and public schools and colleges have limited resources to implement effective screening strategies. And without clear funding or screening protocols, test manufacturers are not getting a clear signal for investing in much larger testing capacity for the months ahead. Finally, there are limited resources available to address other key issues related to testing:



mitigating critical supply chain shortages for testing supplies, providing adequate contact tracing, and helping individuals adhere to isolation requirements if they test positive but face loss of wages or have no easy ability to isolate in their homes.

The following policy and funding solutions would address the current crisis in U.S. testing by:

- promoting the development of more accurate and timely tests for screening and diagnosis,
- increasing effective screening and diagnostic testing especially in at-risk vulnerable populations,
- creating much more clarity about the level of testing that manufacturers and laboratories should invest to make available,
- addressing supply chain issues,
- supporting contact tracing and isolation for those who have difficulty doing so successfully,
- and providing needed public information and engagement.

Together, these steps would enable a national testing strategy to contain the pandemic.

Developing Smarter Testing

Screening tests are critical for containment and public confidence. But there are only a handful of rapid COVID-19 tests, including "point of care" (POC) tests, currently authorized for use in the U.S. While the manufacturers of those tests continue to add capacity, the country will need far more tests that are rapid, easy to use, and sufficiently reliable to effectively screen at-risk populations. Providing \$300 million would augment the RADx program, which is advancing the development and production of rapid, accurate, and inexpensive tests, to bring to market more innovative products explicitly designed to support large-scale testing that are faster, cheaper, and easier to use. The funding should prioritize technology to facilitate the reporting of results and electronic data sharing of demographic information, to facilitate follow-up actions and public health reporting where appropriate. RADx should also provide funding for evaluations of test performance and testing protocols as these new rapid tests reach the market.

Additional funding of \$100 million would enable the FDA's Center for Devices and Radiological Health (CDRH) to support additional review staff to address the current backlog of Emergency Use Authorization (EUA) applications. The funding would also support the development of needed regulatory guidance and templates for rapid POC or "at home" screening tests, particularly those that are labeled to be used as part of frequent, routine screening protocols, not as individual tests ordered by a health-care professional. FDA has already provided some guidance on testing and screening of asymptomatic individuals. However, this guidance is in the context of one-time tests rather than within protocols that call for frequent repeated screenings. FDA should update its current guidance to allow for more flexibility for test use in asymptomatic screening, to support use in screening protocols that are being developed for repeat testing to reduce infection spread.



In general, screening tests have been designed to be sensitive (few false negative results) but less specific (potential for more false positives) than more costly, definitive diagnostic tests. In the COVID-19 screening context, where the goal is diminishing spread among people without symptoms, rapid tests with lower sensitivity but high specificity also have potentially important uses: if inexpensive and easy to administer, even if sensitivity is well under the current FDA expectations of 90% or higher, they can significantly reduce transmission when they are used frequently with fast action based on results. Regulatory guidance, labeling, and instructions for users should reflect that these tests are intended for screening protocols to diminish infection transmission, but would miss cases if used as a basis for diagnosis. These instructions will be particularly important for home or site-based testing that is not done under the supervision of a health care professional, but is intended solely for screening purposes.

A screening regulatory pathway would support intended uses in which tests are to be used on a population of asymptomatic people who don't have particular reasons to suspect that they have been exposed to or infected with COVID-19.²

The regulatory pathway should recognize that such a test is not intended to identify all asymptomatic infected individuals, particularly those with low levels of the virus who may be less infectious or post-infectious anyway, but is intended for population screening to reduce transmission at the population level. That is, when used with sufficient frequency in many people, the test can identify outbreaks and enable interventions to reduce spread more quickly than no use of screening tests or limited use of laboratory tests with greater delays. The screening test could be paired with follow-up confirmatory testing; in such cases, FDA labeling requirements should reflect that positive results from these tests would be presented as "presumptive" and not definitive in the absence of a confirmatory diagnostic test.

In low prevalence areas, pooled PCR testing can also be an effective way to screen for outbreaks in at-risk populations. If supply shortages and regulatory barriers for pooled PCR testing can be addressed, many academic and research laboratories could add substantial capacity for screening through pooled testing. CMS has clarified that laboratory testing for population surveillance research is not subject to the requirements of the Clinical Laboratory Improvements Amendments (CLIA) that apply to clinical laboratories. However, there is no such exception nor yet a straightforward regulatory path for use of such "research use only" lab testing as part of a screening protocol for an at-risk population like students or workers, in which those who screen positive will be informed so they can isolate until they receive a confirmatory diagnostic test.

Congressional guidance could encourage CMS to create an umbrella temporary waiver that allows research facilities that meet certain requirements to screen asymptomatic patients during the public health emergency. Positive screening results would be considered "presumptive positive" and the patients referred for confirmatory testing using a CLIA-approved lab or FDA-approved point-of-care diagnostic test. The waiver would include minimum

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² People with symptoms of COVID-19 or have been identified as being in close contact with the individual with COVID-19 should always seek out a highly accurate diagnostic test rather than relying on a screening test.



requirements for quality including laboratory oversight by a medical director. As an alternative to the umbrella waiver, CMS could clarify that the research laboratory could return positive results for ethical or public health reasons. A mechanism for timely reporting of actionable results to public health agencies should accompany the use of the waiver. Because results are simply "presumptive" and "presumed positive" patients are referred to confirmatory testing, reporting requirements should be centered on identifying new outbreaks quickly rather than individual case reporting.

Additional resources allocated for FDA would also support steps to enable data sharing and analysis of anonymized real-world data on test performance in different settings. This would augment performance data provided by test manufacturers for emergency use authorization and create a stronger evidence base for optimal use of the tests in screening and diagnosis protocols.

Increasing Testing Capacity

Alongside support for the development of rapid and reliable tests, additional Federal guidance and financial support are needed to make available much more effective screening test capacity along with diagnostic testing to contain outbreaks. In the absence of guidance from CDC that specifies when and how screening tests should be used to prevent or suppress outbreaks, the Rockefeller Foundation is supporting the development of testing protocols in high-priority settings including nursing homes, schools, and higher-risk communities. Other organizations are developing and implementing testing protocols, such as Testing for America's collaborations to support Historically Black Colleges and Universities. To use available testing capacity effectively, and to provide a more certain outlook about the continued level of use of screening tests, the CDC should provide guidance to advance public-private collaborations to enhance these testing protocols.

Federal action is also needed to assure the adequate availability of screening tests. While some businesses are paying for the use of screening tests, the <u>CARES ACT does not provide any direct financial support or coverage requirements</u> for screening tests. Consequently, many at-risk populations need financial support to implement screening effectively. These at-risk populations include residents of nursing homes and assisted living facilities as well as essential workers, and account for a disproportionate share of COVID-19 hospitalizations and deaths. Those at highest risk are predominantly low-income, minority, and immigrant populations in communities that have higher burden of COVID-19 infection. Many Tribal nations have been particularly hard-hit. At-risk populations also include students and staff at public K12 and colleges, which similarly have limited resources to invest in effective testing strategies. We estimate that at least \$45 billion in Federal support is needed to provide adequate testing in these populations, primarily for screening tests but also to provide convenient and timely access to diagnostic tests (details are provided in the <u>Appendix</u>).

Such support would be provided through Federal procurement contracts for testing capacity and through grants to states, localities, and Tribal governments with guidance to enable them to



enter into purchasing arrangements for test capacity. Appropriate uses of additional testing funds would include:

- Advance purchase contracts, under which HHS and states would commit to large-scale, longer-term purchase of testing platforms that meet performance criteria for reliability, speed, materials availability and cost per test.
- Population-based payment contracts, where states, local governments, school districts, or other public entities would contract with a testing provider to deliver an expected volume of tests over a period of time to meet a testing protocol (for example, one million tests over 3 months for screening tests for a school district). Such contracts might be implemented directly by the public entities, or undertaken through insurers or other companies and organizations that have begun to provide testing solutions in businesses and other settings. In contrast to paying on a per-test basis using a set fee per test, this approach encourages advance planning and competition and innovation to improve screening for at-risk populations, including the adoption of tests that are better and less costly as they become available.

Congressional action to provide substantial funding for screening tests, coupled with the development of clear guidance and protocols and guidance on screening tests and contracts for at-risk populations, would provide substantial additional clarity to test manufacturers and clinical laboratories about the magnitude of future demand. This market signal will increase their investments in testing platforms and boost manufacturing of critical components and consumables to meet the far higher testing capacity needed to contain the pandemic. As a result, existing test manufacturers as well as those developing new tests through RADx and other incentives will not only develop the tests but also the capacity needed to make the tests sufficiently available as quickly as possible. The combination of support for development and advanced purchasing contracts has led to greater investments by manufacturers of vaccines and some therapeutics as part of Project WARP SPEED, but similar methods have not yet been applied to address the testing shortfall.

Widening the Supply Chain

Testing shortages and backlogs will continue to occur unless all supplies and the collection infrastructure needed for testing are scaled up alongside the increased availability of test platforms and certainty about payment for tests. Today, even as substantial scale-up is needed, labs are reporting shortages of <u>critical chemical reagents</u>, and other testing supplies such as <u>pipettes and testing trays</u>. While point-of-care tests used for screening often have simpler materials requirements, such as lateral flow tests on paper, massive supply increases are also needed for test collection materials such as swabs for nasal collection or vials for saliva collection. Supply availability is a complex problem with a global supply chain.

Providing a clearer market signal about the long-term need and availability of funding to support testing will encourage some additional private investment in the supply chain. To augment this, Congress should provide \$6 billion to resolve critical current and anticipated



supply chain shortages. Building on the requirements for device shortage reporting and current activities to assess supply chain status, <u>researchers from John Hopkins</u> have suggested the Department of Health and Human Services (HHS) should provide to Congress and make publicly available an ongoing end-to-end inventory of the entire testing supply chain for all major types of tests, focusing on current and projected shortages and choke points. This report should be publicly available and regularly updated, including action plans to resolve identified capacity constraints. The additional funding to secure the supply chain would facilitate HHS entering into advance purchase contracts to alleviate shortages of critical materials, with an emphasis on reliable domestic production and supply. HHS has taken analogous steps to increase critical supplies in pharmaceuticals and medical devices. If these steps are insufficient, funding could also be used to provide compensation under the Defense Production Act to prioritize the manufacture or procurement of key elements that constrain the expansion of fast, timely, and needed testing.

Tracing and Isolating

Contact tracing is the key public health intervention that can break infection chains. Contact tracing begins with the return of a positive test. Contact tracing workers or systems contact the person that has tested positive for COVID-19 and interview them to collect the names and contact information of individuals who had been in close contact with the infected individual. Outreach is made to the close contacts to arrange for quarantine and often diagnostic testing. While awaiting testing and the results, these close contacts are potentially infectious so they should be quarantined from the broader community. Manual contact tracing can potentially be supplemented by additional voluntary tools like phone or wearable-based methods that use technology to monitor contacts. This approach has been adopted in some work and academic environments, but concerns bear to achieve "critical mass" for participation in voluntary programs have limited broader use.

Effective diagnostic testing, contact tracing, and isolation remains challenging to implement in the United States, and will remain so without further action even if testing capacity limits and delays are addressed. Currently there are approximately 37,000 contact tracers nationwide, but experts from John Hopkins University estimate that 100,000 contact tracers are needed. Even after a contact is identified, isolation is a challenge as many people cannot safely isolate at home, or are afraid to be asked to isolate because they would not be able to work, and do not work for an employer that provides sick leave during their isolation.

Appropriations totaling approximately \$24 billion would address these critical gaps. Direct grants to states and local governments of \$4 billion would support the hiring of more contact tracers. The additional \$20 billion would be used to support more effective isolation. Of this \$20 billion, Congress would first appropriate \$4 billion in grants to states and local governments to rent currently unoccupied hotel rooms to function as an isolation space for individuals who cannot safely isolate in their homes. Second, Congress would put into place a \$16 billion program that would work like jury duty, paying workers a modest amount while they isolate (for example, \$50 per worker per day to replace lost income). These steps will enhance the current test, trace,



and isolate program and <u>enable effective tracing and isolation</u> to suppress community-wide viral spread.

Reporting

Timely identification of the size and scope of local community spread and transmission is critical for local decision making. Key indicators including positivity rate (the percentage of tests that come back positive), test turnaround times, testing rate, new case rates and hospitalization rates in local areas could help guide the effective deployment of diagnostic and screening test capacity. However, not all states report such data in a timely manner, or provide information at the local community level. Congress would direct HHS to develop a model reporting strategy and provide support for implementing it. HHS would issue publicly available reports regularly, including both current information and updates on gaps and how they are being addressed. HHS would provide timely data access to public health agencies and experts to support planning and response. These reports should be stratified by age, gender, race/ethnicity and be collected at the state, and preferably county, level. Resolve to Save Lives has recommended that any reporting contain fifteen metrics including the following which are immediately relevant to testing-tracing-isolation actions:

- 7-day trends on new lab confirmed and probable cases
- 7-day trends on diagnostic PCR turnaround time
- Time from specimen collection to isolation of cases
- Per capita testing rates by type of test
- Percentage of cases that can be traced to a previously identified case.

Communicating

Finally, public trust is critical for any public health intervention to work. A successful test, trace, and isolate campaign requires public buy-in and cooperation as information needs to be accurately and rapidly shared with public health workers employed by the government or local service providers. Misinformation is widespread. Public communication should constantly engage and educate individuals about common forms of misinformation. Trusted experts will need to provide accurate and clear information on a regular cadence. This information campaign should regularly and consistently promote best public health practices that encourage social distancing, mask wearing, and other measures that will slow community spread, along with practical information on appropriate testing and how to get it. In collaboration with other Federal agencies and private-sector partners, the CDC should engage in a widespread, enduring, and comprehensive messaging campaign based on these principles. It could be similar in technique and execution to major CDC public health campaigns against tobacco and for increased physical activity, using up-to-date media techniques and insights from behavioral economics and other relevant research. Effective and consistent messaging will facilitate public engagement in the critical challenges of a successful public health response to a pandemic where the actions of all Americans matter.



Conclusion

Timely Congressional action would enable a successful national testing strategy to address the ongoing COVID-19 pandemic. Smart testing, effective tracing, and support for isolation of potentially infectious individuals implemented can enable all Americans to participate in a more successful re-opening and path forward in the COVID-19 pandemic.

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Appendix - Additional Federal Support for Access to Effective Testing

We estimate that at least \$45 billion in Federal support is needed to provide adequate testing support in at-risk populations that do not currently have the resources to access needed testing. This support is primarily for screening tests, but also can support convenient and timely access to diagnostic tests in underserved areas.

HHS is already providing screening test platforms for some nursing homes but not most at-risk residents in congregate living facilities. Nursing homes, assisted living, and hospice settings house approximately 3.6 million residents and employ over 1.3 million workers. Other at-risk settings that have limited resources to implement testing include public K-12 schools, with over 50 million students and 5 million adult employees. Appropriate screening and timely access to appropriate diagnostic testing should also be provided for other essential public employees like first responders and public transit workers, as well as high-risk congregate settings such as shelters and communities where there is a high risk of further outbreaks due to high density living arrangements. In addition, prisons and jails house over 1.46 million individuals and employ over 400,000 workers. Altogether, this amounts to over 70 million individuals. (Many other people may need or want tests, but they are less likely to need Federal financial support to obtain them and the public health indications for testing are less compelling.)

Most of these 70 million individuals are not in high-risk settings and do not need screening tests. At least initially, screening protocols will likely recommend that only highest-risk populations should be tested - those in settings where community prevalence of COVID-19 is high and working from home is not possible, or there are other known risk factors for significant, costly outbreaks that cannot be mitigated through means other than testing. We estimate that approximately 20% or 14 million people on average will be in high-risk settings that need regular testing. The specific populations that need testing will shift, as new outbreaks grow and others are suppressed.

We estimate that adequate screening tests will require an average of two tests per week, which is in line with recommended testing protocols in high-risk settings (some recommend more frequent testing, which will be easier as tests become simpler to use and cheaper). Our model assumes that Federal funding will be provided to assure adequate testing for 18 months. The time frame must be sufficient to encourage investment in sufficient screening test capacity. In addition, it is likely that there will be significant viral activity for some time, even after a vaccine becomes available, so that screening tests will still be needed to resume more normal activities. If a higher rate of testing turns out to be needed because of more frequent outbreaks, the funding would end up needing earlier renewal. We estimate an average cost of \$20 per test over this time frame. This is significantly lower than current prices for collecting samples and performing screening tests. But we expect prices to fall as new tests reach the market and supply increases, especially if HHS and states enter into large-scale advance purchase contracts.