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New Recommendations Chart a Path Forward for Respiratory Infection Testing after End of PHE

Plan Includes Engaging the Public, Ensuring Affordable Access to OTC Testing, and

Reducing Testing Costs

Washington, DC—The end of the COVID-19 Public Health Emergency (PHE) on May 11, 2023 will impact Americans' free access to tests and diminish people's ability to access early testing and prevent infectious disease spread, note authors of a new Duke-Margolis and COVID Collaborative report, "Testing for Respiratory Infections: Beyond the COVID-19 Public Health Emergency." The authors issue a set of recommendations to embed low-cost testing for those that need it most into national health policy and payment strategies to ensure that these diagnostic tools are accessible to the public long-term.

"Recent progress in diagnostic testing for respiratory viruses has created powerful and effective tools to help people protect themselves and their loved ones while living their lives, but we are not yet on a course to take advantage of these advances," said **Mark McClellan**, director of the Duke-Margolis Center for Health Policy. "There are some clear steps that the Federal government, including Medicare and Medicaid, as well as health care organizations can take outside of any public health emergency to make access and use of testing easier and routine—and prevent hospitalizations and deaths."

The report sets out policy steps to support practical information, availability, affordability, and equitable access to innovative and convenient tests for respiratory infections to empower Americans and protect the most vulnerable, by supporting them in making better informed decisions in their daily lives to protect themselves and their loved ones and take action to get treated if needed. The recommended approaches avoid substantial restrictions, extraordinary measures, or large new government appropriations.

"Testing empowers Americans to safeguard their own health and those around them. The goal is to create a stable market and availability of testing over the long term so that people can respond when they have respiratory symptoms," said **John Bridgeland**, Co-Founder and CEO of the COVID Collaborative. "Key to ensuring public engagement and support of testing post-PHE starts with clear, straightforward communication on testing recommendations, and ensuring clinicians and community and public health workers have access to the supporting evidence for those recommendations. This guidance should include concise, practical information that can be used by community leaders to inform the public and answer questions about when to test and how to act on the results."

The nation needs a strategy in place, ideally before the end of the public health emergency, to leverage testing to support people in their ability to make personal choices in terms of protecting themselves, and those most vulnerable in the communities, from respiratory viruses, the authors note. Further, this plan should aim to avoid the health and access inequities made evident through the COVID-19 pandemic. Continued public funding for accessible over-the-counter (OTC) testing is important for

individuals who would not otherwise have easy access to COVID-19 tests. For example, offering uninsured Americans (approximately 30 million people) six free tests per year, purchased in bulk by the federal government and distributed through the mail, could likely be accomplished for under \$6 per test delivered.

"After the PHE, many people will be faced with paying for COVID-19 tests for the first time," said **Gary Edson**, President of COVID Collaborative. "This will decrease willingness to test, even for people at high risk, and will result in continued reductions in manufacturing, leaving the United States once again without enough tests to face any new surges."

The report addresses these and other key issues, including payment, summarized in the chart below:

Engaging the Public and Promoting Uptake

Clear, updated guidance should be made available to the general public, health care providers, and other trusted authorities, with the acknowledgement that recommendations will evolve with the COVID-19 threat and new evidence on testing.

Updated guidance is also needed on when to use emerging multiplex testing⁴.

Accurate information should be available from a range of trusted sources. Health providers, public health agencies, employers, community leaders, and businesses can help promote straightforward messages to ensure that individuals are aware of whether they are at elevated risk of hospitalization or death from COVID-19 or other infections, and the importance of testing and early treatment.

The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and provider associations like the American Medical Association (AMA) and others should work together to ensure that guidance on testing recommendations for clinicians and community and public health workers is clear and up-to-date, with the supporting research to justify those recommendations.

Ensuring Access and Reducing Costs for OTC Testing

Reducing Prices Through Reliable Supply

OTC tests should be the first-line testing response, and therefore, must be free or very affordable (\$3-\$5 per test), especially for those at higher risk or with limited means.

Federal and state governments, as well as health plans and health systems supplying OTC tests to patients at elevated risk, should enter purchase agreements with select OTC test manufacturers to improve access for such individuals. The purchasing power and greater test purchase leads to lower prices per test, greater use among the high-risk, and more predictable demand for capacity investment and supply maintenance.

Insurance Coverage

OTC tests are substantially less costly and more readily available than laboratory tests. The Centers for Medicare and Medicaid Services (CMS) should establish a new demonstration program for OTC test access as the PHE ends, to evaluate whether Medicare and Medicaid coverage of OTC tests using advance bulk purchases can achieve better outcomes and lower costs than only coverage of professionally administered testing. This coverage should prioritize allowing patients to access tests easily, through options like mail-order and pick-up at the pharmacy counter.

Private insurers should implement strategies to assure timely and efficient testing, including mechanisms to procure and use low-cost OTC tests effectively, at least for their higher-risk members who will benefit from timely treatment.

The federal government should implement OTC test purchase contracts for uninsured individuals.

Incentives for Health Plans and Health Systems

CMS should implement accountability measures and financial incentives related to testing and treatment for common, high-burden respiratory infections like COVID-19, to encourage Medicare and Medicaid health plans and health systems to assure timely access and evidence-based use of OTC tests for their higher-risk patients. States and employers should adopt similar accountability measures and incentives for their health plans and providers.

Ensuring Access and Reducing Costs for Lab-Based and POC Testing

Lab-based and POC tests should be accessible and affordable, especially for those unable to test themselves, unlikely to test serially, at higher risk, or already experiencing significant symptoms.

Public Payers

Because a large proportion of Medicare and Medicaid beneficiaries are at elevated risk from COVID-19, CMS should clarify that laboratory tests (and OTC tests prescribed by a clinician) continue to have no co-pays in Medicare, Medicare Advantage, and Medicaid. This clarification should also include no co-pay for prescribing and sample collection.

Commercial Payers

The US Department of Health and Human Services (HHS) should take steps based on the COVID-19 experience to encourage efficient and adequate networks of test providers, leading to lower prices with sufficient access.

Commercial insurers should have incentives to maintain access to no-cost COVID-19 testing, especially for high-risk individuals and families, with reasonable in-network restrictions.

The United States Preventive Services Task Force (USPSTF) should evaluate whether COVID-19 or other respiratory infection testing has achieved an "A" or "B" rating, for high-risk individuals and for all other individuals, requiring coverage from most insurers without cost-sharing (in network) under the Affordable Care Act.

States can enact legislation to require private coverage of in-network tests without cost-sharing under state-regulated non-ERISA health plans, at least for higher-risk individuals.

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About Duke-Margolis

The mission of the Robert J. Margolis, MD, Center for Health Policy at Duke University is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. For more information, visit healthpolicy.duke.edu and follow us on Twitter @DukeMargolis.

About COVID Collaborative

The COVID Collaborative is a national bipartisan assembly of experts, leaders and institutions in health, education and the economy, and associations representing the diversity of the country, united to turn the tide on the pandemic by supporting global, federal, state, and local COVID-19 response efforts. COVID Collaborative includes former FDA commissioners, CDC directors, and U.S. surgeon generals; former U.S. secretaries of Education, Defense, Homeland Security, and Health and Human Services; leading public health experts and institutions that span the country; leading business groups and CEOs; major global philanthropies; and associations representing those on the frontlines of public health and education. For more information, visit: www.covidcollaborative.us.