

WHITE PAPER

Actionable Policy Insights to Cut the Red Tape in the Face of COVID-19

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Introduction

This report is an extension of the op-ed [*To Fight the Coronavirus, Cut the Red Tape*](#), that was published in The New York Times on March 24, 2020 by Sendhil Mullainathan and Richard H. Thaler.

The research team reviewed the public submissions from the www.pauseregulations.com website in which individuals who were closely impacted by regulations provided ideas for what policies might be changed during the time of COVID-19. The purpose of this report is to present the research findings and recommendations for three specific changes to regulations which may prove to support the efforts of the medical workers and healthcare industry to bring down barriers and foster innovation in the fight against this virus.

Because of the COVID-19 pandemic, we have seen a shortage of healthcare providers. Governors in crisis areas are making pleas for more medical staff to come and assist and are looking for options to provide healthcare services to everyone in need. As our research shows, there are roadblocks which prevent retired physicians, physician assistants and international medical graduates from easily supporting the “all hands on deck” effort in the ER and ICU, where they are most needed. And in every state, medical facilities continue to see an influx of individuals needing healthcare, both COVID-19 and non-virus related. Capacity and social distancing while receiving treatment remains an issue and restrictions around non-physical sites in which medical care can be accessed is being challenged. The COVID-19 pandemic is also creating a frenzy around testing. Regulations currently hinder research labs that are able to demonstrate their fitness in conducting diagnostic checks to either help expand testing efforts or validate approved COVID-19 tests.

In this brief, we propose ways to help the healthcare industry expand and increase access to medical services during a state of emergency by reducing their regulatory burdens.

Increase Physician Supply

As the world faces the unprecedented pandemic of the COVID-19, physicians, nurses and other medical practitioners have been as overworked as ever before, while hospitals are facing understaffing and shortages of personnel. According to the Association of American Medical Colleges (AAMC), there is a shortage of 29,000 to 42,900 doctors in the U.S. as of 2020¹, which is a key factor in explaining the failure to treat all the infected individuals in a timely manner. In the face of this catastrophic pandemic, now more than ever we need to increase the amount of medical practitioners that can help combat the ever-increasing COVID-19 cases. In light of this fact, we recommend tapping into the following three sources of medical expertise: retired physicians, physician assistants (PAs) and International Medical Graduates (IMGs).

Retired Physicians: Currently, the procedures for reinstating retired physicians in the U.S. vary greatly by state. Due to the state-federal regulatory dichotomy in this matter, there are no centralized regulations to reinstate retired doctors, and the complexity levels and procedures vary greatly by state. Further, in order to practice medicine in a different state, physicians must first obtain a state license, either through the traditional licensing process or through the newly implemented Interstate Medical Licensure Compact (IMLC) to obtain an expedited license for any of the 27 participating states.

As shown in the COVID-19 reinstatement guidelines published by the Federation of State Medical Boards

¹<https://www.medpagetoday.com/infectiousdisease/covid19/85661>

(FSMB)², certain states—such as Illinois, Michigan and New Jersey—have expedited reinstatement procedures, while others such as Georgia and North Dakota do not have unique public health emergency expedited licensing procedures in place. This asymmetrical approach to reinstating licensed physicians in different states is hindering the battle against COVID-19; as such, a centralized regulatory solution needs to be adopted as soon as possible so that all states can have as many retired physicians as needed.

PAs Scope of Work: Similarly, the scope of work for PAs is not determined by a centralized entity, but rather by the state level licensing boards. Under our current pandemic, there are countless PAs that cannot exercise their full capabilities due to limitations in their scope of work. For instance, PAs in Virginia working under a Supervising Physician (SP) with a specialty (such as a general surgeon, dermatologist or OBGYN) can only work in their SP’s field³. Many PAs have experience working under different specialties throughout their careers and could provide crucial help in the hospitals, but currently are not allowed to perform duties in the ER or ICU, despite potentially having the capabilities and knowledge to do so.

Moreover, as explained in the article by the Wisconsin Academy of Physician Assistants⁴, the state medical boards tend to defer the decision process of individual medical practices to determine the scope of work that each PA can undertake. The issue with this approach is that because of the high level of fragmentation in determining the scope of work of PAs, a fast and efficient widespread call to action is virtually impossible.

International Medical Graduates: Beyond the domestically trained physicians, PAs and nurses, another key source for obtaining qualified medical professionals is from IMGs, who are either currently in the U.S. or are looking to move here from abroad and unable to practice. A vast amount of doctors

trained abroad have large potential to save numerous lives, however, with the current hold on J-1 visas put in place by the State Department⁵, the nearly 4,200 recently graduated IMGs that have been trained abroad will not be able to come to the U.S. to do their residencies and help fight the spread of COVID-19. Furthermore, doctors who have obtained their licenses and certifications internationally have an incredibly difficult time obtaining a license to practice in the U.S., due to the different licensing requirements in each state as well as the overarching requirements of completing the licensure examinations and providing vast documentation on their credentials⁶. As a result, even for IMGs that are physically present in the U.S., there are tremendous barriers to practicing medicine alongside American medical professionals.

In light of the shortages of physicians mentioned above, it is imperative to consider the main regulatory obstacles that prevent them from strengthening the U.S. workforce to increase the amount of medical practitioners combatting COVID-19. As the current pandemic stands, we are not in a position to turn away the help of qualified medical professionals. In the following section, we provide an actionable plan to fortify the medical capacity of the United States by increasing the medical practitioners on the frontlines of the battle against COVID-19.

Relevant Governing Bodies

Retired Physicians: In order to lower the barriers to the reinstatement of retired physicians, it is crucial to work closely with the FSMB and the U.S. Department of Health and Human Services (HHS) in order to ease restrictions on reinstatement procedures outlined in the Social Security Act. The FSMB oversees the reinstatement, evaluation and licensing for physicians across 70 medical boards in U.S. states and territories. The President of the FSMB, Humayun Chaudhry, is a strong advocate of the “Maintenance of Licensure” (MOL) and “Maintenance of Certification” (MOC)

²<https://www.fsmb.org/siteassets/advocacy/pdf/states-expediting-licensure-for-inactive-retired-licensees-in-response-to-covid19.pdf>

³<https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/state-law-physician-assistant-scope-practice.pdf>

⁴<https://www.wapa.org/page/Scope>

⁵<https://www.statnews.com/2020/03/23/as-coronavirus-spreads-thousands-of-foreign-doctors-could-be-blocked-from-u-s-entry-group-warns/>

⁶<https://www.ama-assn.org/education/international-medical-education/licensure-information-international-medical-graduates>

requirements⁷, which require professional development and learning hours for all doctors seeking reinstatement⁸. Despite being the law of the land, the MOL and MOC requirements are deeply unpopular among the medical community because they are costly and time consuming; as such, in the following section we will recommend waiving MOL and MOC requirements for all physicians pending their maintenance requirements completion. The FSMB is deeply fragmented⁹ due to the individual responsibilities and self-determination of each state; therefore, reaching an overarching solution to reinstate doctors would have to require substantial institutional change. Although it is important to work with state medical boards, so that a top-down solution does not interfere with their independence in establishing reinstatement requirements, in the face of a national public health emergency it is crucial to have a centralized approach to ease the reinstatement process for the entire U.S. As such, in the following section we will also recommend a potential easing of section 1128(b)(4) of the Social Security Act¹⁰ to facilitate a more swift reinstatement process across the entire U.S..

Physician Assistants: The key entities that regulate the scope of work of PAs are the state-level boards of physician assistants. As outlined in the American Academy of PA Scope of Practice document¹¹, the scope of practice of PAs is determined by “education and experience; state law; policies of employers and facilities, and the needs of the patients”¹². Therefore, the scope of work for PAs is anything but uniform across the entire U.S.. As such, it is necessary to have a centralized approach that can apply to all states in order to expand the scope of work that PAs can do during the a declaration of public health emergency like COVID-19. Similarly to the issue of reinstating retired physicians, the fragmentation of the rules and protocols make this problem significantly more difficult to approach.

International Medical Graduates: In terms of IMGs, there are two key entities that we must work with: the Educational Commission for Foreign Medical Graduates (ECFMG), which is under the U.S. Department of Health and Human Services (HHS) and the U.S. Citizenship and Immigration Services (USCIS). On one hand, the ECFMG determines the requirements for licensing IMGs, which include obtaining ECFMG certification (consisting of clinical knowledge and passing a clinical skills exams), passing the Test of English as a Foreign Language (TOEFL) exam, applying for and completing one to three years of residency, passing the U.S. Medical Licensing Exams and finally applying to a state medical board to obtain a license.

On the other hand, the USCIS determines the eligibility for IMGs to enter the U.S. using a J-1 visa. This visa requires doctors to have a contract with an approved healthcare facility and to receive a “no-objection” letter from their home government¹³. Ideally, the USCIS could expedite the processing of J-1 visas in order to streamline the process and bring more IMGs to assist in understaffed hospitals, so as to ease the shortage of physicians experienced by the U.S..

Recommendations for Increasing Physician Supply

1. Reduce the fragmentation of the state-level responses to:

- a. Reinstatement of retired physicians*
- b. PAs scope of work*

As a result of the state-level rules and decision making regarding reinstatement of retired doctors and determining the scope of work of PAs, it is necessary to find a centralized approach to the problem. In the interest of time and efficiency, we recommend one of the three approaches:

⁷https://journals.lww.com/academicmedicine/FullText/2012/08000/Continuing_Medical_Education_and_Maintenance_of.5.aspx

⁸<http://www.acehp.org/d/do/88>

⁹<https://aspe.hhs.gov/basic-report/state-discipline-physicians-assessing-state-medical-boards-through-case-studies>

¹⁰https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm&sa=D&ust=1591712151214000&usg=AFQjCNFUrhd_MgF3COZ1ZuaZfiT9ezcYxg

¹¹https://www.aapa.org/wp-content/uploads/2017/01/Issue-brief_Scope-of-Practice_0117-1.pdf

¹²<https://www.votervoice.net/mobile/PSPA/Campaigns/68591/Respond>

¹³<https://www.immi-usa.com/j1-visa-waiver/j1-visa-waiver-for-physicians/>

a. Work directly with the President of the FSMB and the Secretary of HHS to create a standardized retired physician reinstatement pipeline for all states to follow.

i. Specifically, section 1128(b)(4) of the Social Security Act states that an individual may apply for early reinstatement if they have obtained “(1) a different health care license in the same state or (2) any health care license in a different state”¹⁴, which could be eased to incorporate cross border reinstatement.

ii. Further, we recommend that the FSMB should waive the MOL and MOC requirements for the duration of the declared public health emergency or until all U.S. states have moved past their State of Emergency proclamations.

iii. Despite not having the procedures in place to issue an overarching solution for a quick reinstatement for retired physicians, there are individual states that could serve as models of how to implement this solution. For instance, on March 23, Governor Pritzker of Illinois issued a “call to action” for retired doctors and nurses to help with the barrage of patients flooding the hospitals across the state, by allowing them to practice with expired licenses temporarily until September 30, 2020. Other states could follow the example of Illinois and allow retired medical professionals to practice with an expired license, at least until the individual states overcome their state of emergency.

b. Work directly with the Secretary of HHS to create a temporary expansion of the scope of work for PAs, such as removing the requirement for direct supervision so that they can provide hospital management and other clinical duties.

i. It is important to note that once the COVID-19 emergency measures are no longer necessary, the temporary expansion of scope can be rescinded (or expire) and PAs would

return to their main duties of assisting physicians within their specialty.

c. If recommendations 1a and 1b are not feasible, we recommend working with the President of the United States to pass an Executive Order to streamline the reinstatement process for retired physicians and expand the scope of work and responsibilities for PAs during the declared public health emergency.

To avoid having significant pushback from current doctors in the workforce who are concerned about their profits and duties being split with the aforementioned groups, we recommend setting a specific timeframe for the items in Recommendation 1. For instance, we could set the timeframe for the reinstatement and PA expansion to coincide with the state of emergency declarations for each state, where each state can opt to expand the timeframes based on their public health needs. For instance, certain states with lower amounts of cases could set the time frame until a COVID-19 vaccine is widely available, while other states in more critical conditions, such as New York or New Jersey, could opt to expand the timeframe in order to ameliorate the understaffing in their hospitals. This flexible time frame could provide individual states with a sense of self determination while also allocating medical practitioners more effectively across the country. However, there can also be an option to renew the reinstatement and PA expansion conditional on the status of the pandemic or an option for medical professionals to opt-out after the call to action period.

2. Leverage existing legislative efforts to increase the likelihood of bringing more IMGs to the U.S. and accelerate the current licensing process.

We recommend using economic resources and political efforts towards supporting current legislation to increase the amount of IMGs in the U.S.. Currently, Democratic Congress members Debbie Mucarsel-Powell (D-FL) and Tony Cárdenas (CA-29) introduced legislation H.R. 6432¹⁵ to remove legal barriers for doctors trained abroad

¹⁴https://www.ssa.gov/OP_Home/ssact/title11/1128.htm

¹⁵<https://www.congress.gov/bills/116th-congress/house-bill/6432?s=1&r=11>

to practice medicine in the U.S. to help with the COVID-19 pandemic¹⁶. In practice, this would mean easing restrictions from USCIS (such as expanding the J-1 visa acceptances) and the HHS (by expediting the licensing requirements for IMGs). Further, due to the extensive requirements to be licensed as a doctor by the ECFMG, it is crucial to emphasize the temporary nature of the license to practice in the U.S..

Moreover, it is pivotal to accelerate the aforementioned licensing requirements for IMGs. The expedited licensing could consist of 1) waiving the residency requirement for IMGs who have completed residencies abroad, 2) condensing the medical licensing exams into one comprehensive exam, 3) issuing temporary ECFMG certifications upon completion of a condensed clinical skills and knowledge exam.

Similarly to the previous recommendations, the licenses for IMGs could be approved for a time period determined by each individual state, based on their public health needs.

Although this could have significant pushback from immigration hardliners, we believe that by partnering with the efforts by the American Medical Association (AMA) we could help this legislation pass. The AMA staunchly supports increasing the pool of doctors available to help with the current crisis¹⁷ and they have a strong voice in Congress, as evidenced by the \$20.9 million spent on lobbying in Congress during 2019¹⁸.

Given the severe medical staff shortages facing the U.S. healthcare system, it is imperative to act quickly and efficiently to enact these recommendations. We are not asking for a landmark reform to modify these regulations permanently, but rather limited-time solutions to lessen the impact of the COVID-19 pandemic. The longer we have capable retired physicians, PAs and IMGs sitting idly on the sidelines due to bureaucratic barriers, the more

drawn out and inefficient our response will be. We are not recommending anything in the spirit of ideology or partisan politics, instead, we are providing a pragmatic approach to boost our response efforts before it is too late.

Increase Access to Telehealth

The COVID-19 pandemic has created a challenge for the current medical system in treating an influx of patients both emergent and non-emergent, which has prompted the need for telehealth with its unique advantages over the conventional practice of medicine. More and more, there are individuals in the U.S. are seeking out alternative care so that they do not have to leave their homes. Telehealth reduces the spread of COVID-19 by decreasing the potential patients traveling to and entering medical centers. Telehealth can also help care providers treat more patients at lower costs. With optimal setup, the digitized medical environment on a telehealth platform automates many costly processes and saves resources. Telehealth provides increased accessibility to patients who are constrained by disabilities, geographical locations, and legal barriers. Although the Pew Research Center's statistics reveal that there are inequalities on access to home broadband services¹⁹, the U.S. network infrastructure that facilitates adoption of telehealth has significantly increased during the past decade. This following will display the need and demand for streamlining the current laws and regulations for telehealth so that access to non-emergent medical care curing a public health emergency like COVID-19 can be accessed without going to a hospital.

Telehealth Regulations

The birth of modern telehealth can be attributed to the University of Nebraska where it first transmitted real-time neurological examinations through video in 1959²⁰. The expansion of network infrastructure afterwards further broadened practice of telehealth,

¹⁶<https://mucarsel-powell.house.gov/news/documentsingle.aspx?DocumentID=462>

¹⁷<https://www.ama-assn.org/education/international-medical-education/ama-fighting-img-physicians-several-fronts-many-allies>

¹⁸<https://www.opensecrets.org/orgs/summary?all=2020&id=D000000068>

¹⁹Pew Research Center: <https://www.pewresearch.org/internet/fact-sheet/internet-broadband/>

²⁰Marilyn J. Field, *Telemedicine: A Guide to Assessing Telecommunications in Health Care*. Washington, D.C.: National Academy, 1996.

but its usage has been limited to special purposes or to substitutes for conventional medicine in its absence. Overall, practice of telehealth has been restricted due to laws and regulations that disincentivized medical personnel to practice telehealth. These regulations must be lifted to increase accessibility and availability of medical service during the COVID-19 pandemic.

There are myriads of laws and regulations that restrict practice of telehealth. Regulations on licensure that vary by each state qualify the types of medical services that can be delivered through telehealth. Regulations on reimbursement also limit the types of medical services that can be compensated through health insurance programs. The changes in the regulations on licensure and reimbursement need to be aligned with each other to make an effective change. For instance, lessening restrictions in licensure in certain states are not going to translate into expansion of the service unless the change in the compensation structure happens accordingly. The diversity of governing bodies with respective authorities dictating the requirements of licensure and the reimbursable types of medical services pose the biggest challenge in adopting telehealth as the alternative form of medicine. We propose that to achieve real change, these laws and regulations need to be considered one integrated unit.

Licensure: Physicians have to obtain licensure to practice telehealth. However, to obtain a licensure it requires, coursework, in-person interviews, up to six months of processing time depending on the state and it costs hundreds of dollars for fees. Forty-nine states require physicians practicing telehealth to obtain licenses pursuant to each state's laws and regulations. Some of these states require special purpose licenses for telehealth. The Federation of State Medical Boards (FSMB) have outlined the rules and regulations for telehealth in each state²¹. Currently, the majority of states have temporarily suspended these regulations in response to

COVID-19. As a result, it is now possible for physicians to practice telehealth without some constraints such as pre-existing provider-patient relationships. Also, many state governments allow out-of-state physicians to practice telehealth to patients residing in their states²². Despite these concerted efforts, the absence of uniformity in the regulations across states pose unique challenges in practicing telehealth. For instance, it is practically impossible for a physician to be informed about the legal restrictions regarding telehealth in each state depending on the residence of each patient.

Reimbursement: Many health insurers provide limited coverage of telehealth medical services. The degree to how much and what types of telehealth the health insurance companies will cover vary by the type of insurance²³. There are four primary health plans where the majority of Americans are covered: Medicare, Medicaid, Self-Insured Health Plans, and Fully-Insured Health Plans.

Medicare: Medicare has previously imposed many restrictions on its fee-for-service reimbursement related to what telehealth services were provided. It also regulates where telehealth services can be accessed. For instance, beneficiaries had to live in rural areas to receive telehealth or a patient's home did not qualify as an originating site to access telehealth visits. Currently, the Coronavirus Aid, Relief, and Economic Security (CARES)²⁴ Act has waived some of these restrictions and it is now possible for beneficiaries to access telehealth visits without geographical and telehealth platform restrictions. Despite some progress, restrictions on what types of telehealth medical services Medicare can reimburse continue to discourage the adoption of telehealth.

Medicaid: Each state has its own Medicaid policies and it is up to each state's capacity to implement more extensive coverage of telehealth. Although the federal government can promote telehealth coverage through funding or subsidies, the state

²¹Federation of State Medical Boards – Board Overview: https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf

²²Federation of State Medical Boards – U.S States and Territories Modifying Requirements for Telehealth in Response to COVID-19: <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>

²³Kaiser Family Foundation – Health Insurance Coverage of the Total Population: <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortMod-el=%7B%22collid%22:%22Location%22,%22sort%22:%22asc%22%7D>

²⁴<https://home.treasury.gov/policy-issues/cares>

governments dictate the rules for practice, coverage, and reimbursement of and for telehealth. The Center for Connected Health Policy outlines the reimbursement rules in each state²⁵. Currently, the majority of states are issuing emergency policies to increase the coverage of telehealth through Medicaid. Nevertheless, changes that vary across states make it difficult for both providers and patients to utilize telehealth as an alternative form of medicine.

Self-Insured & Fully-Insured Health Plans: Self-Insured plans are regulated by the federal government through the U.S. Department of Labor and thus can be easily modified in response to COVID-19. However, fully-insured health plans are subject to both federal and state regulations. Telehealth is not likely to be practiced by physicians in states that do not require payment parity because health care plans can exclude it from coverage of a medical services.

Recommendations to Increase Access to Telehealth

The major problem in the usage of telehealth lies in the fragmentation of governing bodies regulating telehealth and the failure to fully reflect the organic relationship between licensure and reimbursement regulations. Any unaligned set of policies impose unnecessary coordination costs that discourages both providers and patients from utilizing telehealth. Therefore, new policies should connect the governing bodies of licensure and reimbursement regulations to encourage the adoption of telehealth as a legitimate form of medicine.

1. Make a permanent federal licensure guideline for telehealth across states.

The wide variety of licensure guidelines across states make it difficult for both providers and beneficiaries to maintain a consistent medical relationship. It is necessary to make uniform licensure guidelines for telehealth across states in order to minimize unnecessary costs and to increase access.

- a. Establish the Federal Board of Medical Licensing, comprised of representatives from each state and enforce uniform licensure regulations across states.
- b. If 1a is not feasible, establish the West, Central, South, and East Board of Medical Licensing to enforce uniform regulations across contiguous states.
- c. If both 1a and 1b is not feasible, work with the FSMB to engineer a balanced solution that increases cooperation among states through signing long-term contracts between states.
- d. If 1a, 1b or 1c is not feasible, work with the President of the United States to pass an Executive Order to create federal licensing guidelines.

2. Make federal reimbursement regulations that require payment parity.

The difference in the types of telehealth covered in each insurance plan makes it difficult for both providers and beneficiaries to maintain a consistent medical relationship. It is essential to implement federal reimbursement regulations to stabilize the supply of telehealth medical service and to increase its accessibility. Furthermore, payment parity must be enforced to incentivize physicians to practice telehealth.

- a. Make federal guidelines on reimbursable types of telehealth medical services across Medicare and Medicaid.
- b. Designate and expand the portions of federal funding for Medicaid for enforcement of payment parity.
- c. Require state governments to make payment parity a necessary condition for Self-insured and Fully-insured Health Plans.

3. Establish a combined unit force that jointly supervises regulations for Licensure and Reimbursement.

The failure to understand the organic relationship between regulations of telehealth and regulations

²⁵Center for Connected Health Policy – State Telehealth Laws & Reimbursement Policies: <https://www.cchpca.org/sites/default/files/2019-10/50%20State%20Telehealth%20Laws%20and%20Reimbursement%20Policies%20Report%20Fall%202019%20FINAL.pdf>

of reimbursement causes inadvertent coordination costs. It is vital to make aligned changes in both the licensure and reimbursement regulations for effectiveness.

- a. Work with HHS to create a committee that supervises and promotes coordination between the two regulatory bodies.
- b. If (a) is not possible, enact legislation that requires any change in either Licensure and Reimbursement regulations be jointly approved by each regulatory body.

Access to medical services is an integral part of our society that must not be interrupted. Making access to telehealth more feasible for all can be one way to successfully cope with COVID-19. While other policy changes may be activated as a result of a public health emergency, it is our recommendation that these changes telehealth regulation be put into action as a result of COVID-19 and remain in effect for the foreseeable future.

Increase Testing Supply with Temporary Laboratory Certifications

As the COVID-19 outbreak intensifies, widespread testing continues to play a critical role in understanding the severity of the crisis and in mitigating and preventing the spread of the disease. This role is also important for reasons associated with reducing uncertainty, informing decisions made by policymakers, and restoring the economy. While the availability of tests across the U.S. has increased over time according to the Centers for Disease Control and Prevention (CDC)²⁶, there still exists an opportunity to expand the supply of testing. At the writing of this report, nearly 400,000 new tests were being conducted per day²⁷, however, a growing consensus to increase testing still remains²⁸.

Currently, there are a number of research and university laboratories in the U.S. that are unable to conduct COVID-19 diagnostic tests (to check for an active infection) or antibody tests (to check for any developed antibodies), despite having the knowledge, experience, and equipment to do so. A research team at Michigan State University's (MSU) Department of Translational Neuroscience was able to validate a diagnostic test to detect COVID-19 with greater sensitivity than standard tests²⁹. They were able to do so without using the same chemical reagents that have recently been in short supply. However, many academic research labs, such as MSU's, that may possess the capability to assist testing efforts are prohibited from doing so because they aren't certified by the Centers for Medicare and Medicaid Services (CMS).

Testing Regulations

CMS regulates all laboratory testing performed on humans through the federal Clinical Laboratory Improvement Amendments (CLIA) program³⁰, which was established by Congress in 1988 to ensure the accuracy and reliability of patient-specific test results. CLIA requires both the facility and staff to obtain a certain certificate and meet licensure requirements to perform tests on human specimens for the purposes of diagnosing or treating a disease. The certificate obtained generally corresponds to the type of tests performed, which are categorized as waived, moderate complexity, or high complexity. Almost all COVID-19 tests authorized through the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) authority have been considered moderate or high complexity³¹. To obtain a certificate to perform these more complex tests, the laboratory must meet CLIA requirements related to facility standards and quality system standards, including quality control and assessment, and be subject to inspections. The laboratory must also meet personnel

²⁶<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html>

²⁷<https://covidtracking.com/data/us-daily>

²⁸https://ethics.harvard.edu/files/center-for-ethics/files/white_paper_6_testing_millions_final.pdf

²⁹<https://msutoday.msu.edu/news/2020/msu-researchers-identify-new-covid-19-testing-process/>

³⁰<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index?redirect=clia/>

³¹<https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf>

requirements that differ for moderate and high complexity testing³². For moderate complexity testing, the laboratory must have a laboratory director, a clinical consultant, a technical consultant, and testing personnel. For high complexity testing, the laboratory must have all the personnel required for moderate complexity, except instead of a technical consultant, they must have a technical supervisor and a general supervisor. Depending on the role, these individuals must meet specific degree requirements, be licensed in the state, or have the requisite experience and or training.

There are research laboratories across the U.S. that are unable to obtain an immediate certificate because they might not meet each and every facility standard and personnel requirement. As such, this takes for granted the existing expertise research laboratories have in testing for forensic purposes or in testing human specimens without the inclusion of patient-specific results, all of which can be useful during the COVID-19 pandemic. While the CLIA requirements are important and necessary, they can serve as a barrier at a time when additional testing is needed. In the agency guidance outlined in the next section, CMS has taken steps to temporarily reduce some of these barriers, but further action is needed to streamline and expand testing efforts.

Recent CMS Guidance

On March 26, 2020, CMS released CLIA guidance³³ for the duration of the COVID-19 public health emergency to accelerate testing and clarify current regulations. Specifically, CMS utilized its enforcement discretion to adopt a policy that would allow laboratories within a hospital or University hospital campus that are located within contiguous buildings on the same campus and under common direction to hold a single certificate for all of the laboratory sites at that physical location or address. Generally, each separate laboratory must obtain its own CLIA certificate, but this flexibility, exercised by CMS, has helped to increase COVID-19 testing at universities. CMS has also made minor adjustments to expedite

its application review of CLIA certificates to allow for a laboratory to begin testing as soon as they have identified a qualified laboratory director and provided the required information.

Given that CMS has used its discretion during this pandemic to relax certain processes and regulations, there is precedent here for additional action related to the approval of a temporary CLIA certificate for moderate and high complexity testing. In the following section, we present actionable steps that can be taken during a public health emergency to draw on the existing experience laboratories have in conducting complex tests in analogous settings.

Recommendation for Increasing Testing Supply

1. Offer a temporary CLIA certificate for laboratories that meet minimum standards and personnel requirements.

There are currently five types of CLIA certificates, which correspond to the different types of testing and stages. One particular certificate, the Certificate of Registration (COR), permits laboratories applying for a Certificate of Compliance or a Certificate of Accreditation to conduct moderate and high complexity tests until the laboratory undergoes an on-site survey that deems it is in compliance with CLIA regulations. Given that the COR is only valid for no more than two years, we recommend that another temporary certificate be provided for the duration of public health emergencies, but with minimum standards and requirements. As such, we specifically suggest the following:

- a. Work with the Secretary of HHS and CMS to develop a temporary certificate for moderate and high complexity testing, both of which have a unique role in establishing requirements for certifications, as well as publishing CLIA rules and regulations.
- b. Work with research and university

³²https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11351

³³<https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>

laboratories, in addition to 1a, to determine the specific facility standards and personnel requirements that present immediate barriers and can be relaxed without reducing the quality of the testing process.

Furthermore, establish the minimum threshold for obtaining the temporary certificate as a result of the determination.

c. Allow laboratories that meet the minimum threshold to utilize the temporary certificate when there is a public health emergency declaration by the Secretary of HHS³⁴, such as the one declared for COVID-19 on January 31, 2020. Ensure that it is only used while the emergency and any subsequent renewals last.

Looking ahead, we recommend keeping the availability of this certificate and the associated flexibility contingent on the declaration of a public health emergency by the Secretary of HHS. By doing this, the U.S. will be able to help ramp up the supply of testing rapidly and be able to respond appropriately should there be a future public health emergency or pandemic.

³⁴<https://www.fda.gov/media/135659/download>

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