Economics of Testing During a Public Health Emergency:
Lessons learned from two years of COVID-19

Selection of members of the 2021 Economic Affairs Committee of the Association for Molecular Pathology:

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I. INTRODUCTION

The emergence of COVID-19 as a pandemic in the United States in early 2020 brought unprecedented challenges to the nation with particular strain for health care systems and the economy. Laboratories played an essential early and subsequent ongoing role in the pandemic response, providing visibility into the emergence, spread, and eventual molecular evolution of the virus. At the onset of the pandemic, U.S. laboratories rapidly developed diagnostic tests capable of effectively detecting the causative virus, SARS-CoV-2. However, laboratories just as quickly faced a myriad of challenges including in the supply chain for essential reagents, regulatory requirements, and the availability of qualified personnel to perform the testing. Operational challenges directly impacted and were in turn impacted by uncertain and confusing economic policies, especially during the early months of the pandemic. Despite diagnostic testing being one of the few health measures available to inform behavior and mitigate the impact of the pandemic, laboratories were hampered by uncertain or ineffective action to address economic issues. Policy measures addressing coverage, pricing and funding for clinical laboratory testing were slow to appear, lacked appropriate input, or generally failed to provide the assurance of economic stability needed for laboratories to bring forward solutions with confidence in avoiding financial ruin. Laboratories needed greater clarity on the financial picture along with investment in all stages of development and delivery to support their role in protecting Americans' health during the public health emergency.

An effective response to the pandemic required all parties in health care and public health, including laboratories, manufacturers, policymakers, and insurers, to be nimble and adapt to a quickly changing landscape. This was particularly important at the outset. However, traditional U.S. reimbursement policies and processes, including those for molecular diagnostic procedures, are intricate and typically require significant amounts of time to evolve during which stakeholders deliberate over key policies before they are finalized.[1] During a public health emergency, changes must be made to coding, coverage, and pricing processes for tests and must be considered in the context of the overall financial impact to both the providers of testing and those

[1] Sireci AN, Patel JL, Joseph L, Hiemenz MC, Rosca OC, Caughron SK, Thibault-Sennett SA, Burke TL, Aisner DL. Molecular Pathology Economics 101: An Overview of Molecular Diagnostics Coding, Coverage, and Reimbursement: A Report of the Association for Molecular Pathology. J Mol Diagn. 2020 Aug;22(8):975-993. doi: 10.1016/j.jmoldx.2020.05.008. Epub 2020 Jun 3. PMID: 32504675; PMCID: PMC7267794.

who pay for it. While careful consideration is needed, the traditional time-consuming methods are challenged to meet the needs for an effective pandemic response where rapid, even daily, adjustments may be needed.

Throughout the first two years of the COVID-19 pandemic, the Association for Molecular Pathology (AMP) has made the utmost effort to meet the education, clinical practice, and advocacy needs of its members developing and performing SARS-CoV-2 testing. In this white paper, we reflect on the first two years of the COVID-19 pandemic and the unique economic challenges faced by laboratories, particularly at the onset. We dissect policies on coding, coverage, and pricing enacted to respond to the COVID-19 pandemic for SARS-CoV-2 molecular diagnostic tests and provide recommendations for how the challenges laboratories faced can be prevented or at least mitigated in the future. During reflection, we developed one overarching recommendation that we believe will serve laboratories and patients more effectively as the COVID-19 pandemic continues into its third year and for possible future pandemics: **The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) should engage laboratory stakeholders early and across the spectrum of care delivery environments before laboratory policies are implemented. This recommendation will ensure that reactionary policies do not have unintended and negative consequences for laboratories and impede their ability to respond effectively.**

II. CODING

At the onset of the COVID-19 public health emergency, both CMS and the American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel moved relatively quickly, outside of the regular CPT editorial panel timeline, to develop codes for SARS-CoV-2 diagnostic tests. A full list of codes and dates on which they became active are listed in Table 1. This section and paper focus only on codes for SARS-CoV-2 diagnostic RT-PCR testing. Additionally, AMA CPT Editorial Panel approved Category 1 codes for antigen and antibody SARS-CoV-2 tests as well as numerous Proprietary Laboratory Analysis (PLA) codes but those are not discussed here.[2]

Later in 2020, the AMA CPT Editorial Panel began to consider additional coding needs for COVID-19. On October 7, 2020, they approved two multiplex codes, 87636 and 87637. These codes are for multi-virus panel tests that can detect both COVID-19 and other viruses, like the flu. Before the creation of these two codes, providers would normally use CPT code 87631 (infectious agent detection by nucleic acid; 3-5 targets) to report a test panel that detects the flu and RSV infections, but the coverage provision within the Families First Coronavirus Response Act created the need for providers to distinguish these other viruses from COVID-19 in order for those tests to be covered by insurers.[3]

Unfortunately, in an effort to act quickly, the creation of multiple codes for SARS-CoV-2 detection using molecular techniques sent unclear information to laboratories on appropriate coding. As shown in Table 1, from the middle of February 2020 to the middle of March 2020, two HCPCS codes (U0001 and U0002) and one CPT code (87635) were created. While each had some distinct criteria within the descriptor (e.g., U0001 required use of the CDC assay), the codes were largely for the same service. The decision of which codes to use depended on the payor and their ability process claims with new codes. Compounding the issue, in April 2020, two more HCPCS codes (U0003 and U0004) were created, which provided codes for services using "high throughput

[2] CPT® Category I and Proprietary Laboratory Analyses (PLA) Codes for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) Updated February 21, 2022. Accessed March 21, 2022. https://www.ama-assn.org/system/files/coronavirus-long-descriptors.pdf

[3] The Families First Coronavirus Response Act of 2020 div F s 6001. Accessed March 4, 2022. https://www.congress.gov/116/bills/hr6201/BILLS-116hr6201enr.pdf

technologies" for either the CDC or non-CDC assays. CMS defined high throughput technology broadly as one that employs automated processing of more than two hundred specimens a day.

Table 1: SARS-CoV-2 Molecular Diagnostic Test Codes

DATE	CODE	DESCRIPTOR
February 13, 2020[4]	HCPCS Code U0001	CDC 2019 novel coronavirus (2019-ncov) real-time RT-PCR diagnostic panel
March 5, 2020[5]	HCPCS Code U0002	2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-CDC
March 13, 2020[6]	CPT Code 87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), amplified probe technique
April 14, 2020[7]	HCPCS CodeU0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R.
	HCPCS Code U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R.
October 6, 2020[2]	CPT Code 87636	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
	CPT Code 87637	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
October 15, 2020[8]	HCPCS Code U0005	Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), amplified probe technique, cdc or non-cdc, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either hcpcs code u0003 or u0004) as described by cms-2020-01-r2
February 21, 2022[2]	CPT Code 87913	Infectious agent genotype analysis by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(coronavirus disease [COVID-19]), mutation identification in targeted region(s)

[4] Public Health News Alert: CMS Develops New Code for Coronavirus Lab Test. Updated February 13, 2020. Accessed March 21, 2022. https://www.cms.gov/newsroom/press-releases/public-health-news-alert-cms-develops-new-code-coronavirus-lab-test

[5] CMS Develops Additional Code for Coronavirus Lab Tests. Updated March 5, 2020. Accessed March 21, 2022. https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests

[6] https://www.ama-assn.org/system/files/coronavirus-long-descriptors.pdf

[7] Centers for Medicare & Medicaid Services. CMS Ruling 2020-1-R. April 14, 2020. Accessed March 21, 2022. https://www.cms.gov/files/document/cms-2020-01-r.pdf

[8] Centers for Medicare & Medicaid Services. CMS Ruling 2020-1-R2. January 1, 2021. Accessed March 21, 2022 https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf

The COVID-19 pandemic, and the emergence of multiple variants of concern throughout 2021, has underscored that public health crises evolve quickly and are unpredictable. Up until this point, COVID-19 diagnostic tests have simply looked for the presence or absence of the virus, however there emerged a clinical need to detect specific viral variants that had impacts for patients, such as the Omicron variant and the reduced efficacy of monoclonal antibody therapy. In February of 2022, the AMA CPT Editorial Panel approved CPT code 87913, which will code for tests that detect variants of SARS-CoV-2 in targeted regions. Additionally, as the world enters the third year of the COVID-19 pandemic it is possible that the virus will change so substantially that it will escape the detection of our current testing mechanisms. As we look to the future of this current public health crisis, it is likely that new codes will need to be created to reflect clinical and public health needs. For this reason, it is imperative that policies are considered now to improve the coding response and prepare for future developments.

AMP offers three recommendations with respect to coding. **First, AMP encourages CMS to coordinate early and broadly with the laboratory community, the AMA CPT® Editorial Panel, and other stakeholders regarding diagnostic coding.** Engagement with relevant stakeholders allows essential partners in the pandemic response to offer guidance and feedback on critical coding decisions that impact their ability to effectively respond. **Second, AMP urges CMS to work closely with stakeholders to develop a process for providing clear, up-to-date coding guidance relevant to the pandemic.** Clear communication from CMS avoids unnecessary confusion that creates delays, especially for partners weighing their ability to engage in responding to demand for services**. Third, to prepare for future needs AMP encourages CMS to develop a process for rapidly developing interim codes and coding guidance using input from relevant stakeholders.** Rapid availability of interim codes, while imperfect, would serve an essential role and could remain in place until the AMA CPT® Editorial Panel develops permanent codes and guidance. AMP believes adopting these measures would mitigate laboratories' confusion about proper coding of tests.

III. PRICING

Background on the CMS Pricing Process

Each year, CMS adds new laboratory test codes to the Clinical Laboratory Fee Schedule (CLFS) and corresponding prices are developed through a public comment process. Specifically, CMS holds an annual CLFS public meeting around June each year to gather stakeholder feedback on new or revised HCPCS codes being considered for Medicare payment in the next calendar year. At the meeting, stakeholders have the opportunity to present comments and recommendations both on the methodology used and payment amount for the services. Following the public meeting, the Advisory Panel on Clinical Diagnostic Laboratory Tests provides recommendations for the basis of payment to either crosswalk or gapfill each new laboratory test. When a code is crosswalked the payment rate is made by comparison to an existing code. When a code is gapfilled, each Medicare Administrative Contractor (MAC) independently establishes a payment amount, submits those values to CMS, and a rate is set based on the median of rates submitted by the MACs for each code. The agency typically releases its preliminary pricing determinations in the early fall and then finalizes them later in the year after a public comment period. When a new laboratory test is crosswalked, the payment amount is established for the next calendar year; however, payment for a new test that will be priced via gapfill is not established until the following year since gapfill is a yearlong process. This pricing system is not designed to develop prices quickly, which forced CMS to use other methods to set prices for COVID-19 diagnostic tests during the early months of the COVID-19 pandemic.

Setting Prices During a Pandemic

As discussed in the previous section, CMS and the AMA CPT® Editorial Panel worked relatively quickly to develop new codes for SARS-CoV-2 testing. However, once the codes were established CMS determined that local MACs would be responsible for developing the price for the newly created codes (HCPCS codes U0001 and U0002 and CPT codes 87635, 87636, and 87637) in their respective jurisdictions until Medicare established national payment rates.[9] This pricing process lacked transparency. By delegating pricing to the MACs, CMS did not provide for public comment, or appear to take the actual costs of performing these tests into account. Even during a public health emergency, the pricing process should be transparent and allow for stakeholder comment. A full list of the pricing for the SARS-CoV-2 diagnostic codes is provided in Table 2. **For the duration of the current pandemic and in the future, CMS should prioritize working with stakeholders to gain reliable data on the real-world costs of running a test during an emergency situation, which will improve pricing accuracy from the outset. Additionally, CMS should rely on laboratories from all sectors to set prices to ensure reimbursement is reflective of the costs of performing these tests in all settings, including in smaller laboratories.** All laboratory stakeholder costs should be considered, as individual laboratories have different needs, and some may require more resources to provide testing for their patient population**.**

As discussed previously, the routine annual pricing process does not align with the need to price tests quickly during a pandemic. In 2020, during the annual pricing process for the calendar year (CY) 2021 CLFS, AMP and other stakeholders recommended CMS price CPT code 87635 at $100 reflecting the resources required to develop and furnish COVID-19 diagnostic testing quickly in a resource-strapped, emergency environment. However, CMS ultimately determined this code should be gapfilled, an exercise that takes over a year to complete. This decision, made against the advice of the stakeholder community, further delayed the determination of a national price during the pandemic. In a developing public health emergency, it is possible that the gapfill process would not even be complete before the public health emergency has concluded! It is not feasible to wait for the annual pricing process to establish payment amounts for new laboratory tests when laboratories require clear information quickly to respond to a pandemic.

CMS must ensure that the pricing for tests is completed in a timely fashion yet with opportunity for stakeholder input from across the spectrum of different partner laboratories. During the COVID-19 pandemic, laboratories saw substantially higher costs due to supply chain constraints and personnel shortages. Further, any laboratory investment in offering COVID-19 testing faced an uncertain future with unknown demand and the potential for additional costs due to evolving regulatory and clinical need. **CMS must ensure that pricing takes into account the uncertainties, increased costs, and resources needed to develop and implement testing during a pandemic.**

Table 2: Pricing of SARS-CoV-2 Diagnostic Codes

Code	Initial Price	Current Price	Method of Initial Pricing Setting	Preliminary Gapfill Rate
HCPCS Code U0001	$35.92	$35.92	Contractor Priced	$35.92
HCPCS Code U0002	$51.31	$51.31	Contractor Priced	$51.31
CPT Code 87635	$51.31	$51.31	Contractor Priced	$51.31
HCPCS Code U0003	$100	$75	CMS Ruling 2020-1-R	$75.00
HCPCS Code U0004	$100	$75	CMS Ruling 2020-1-R	$75.00
CPT Code 87636	$142.63	$142.63	Contractor Priced	Code not gapfilled
CPT Code 87637	$142.63	$142.63	Contractor Priced	Code not gapfilled
HCPCS Code U0005	**	$25	CMS Rule 2020-1-R2	Code not gapfilled
CPT Code 87913	TBD***	TBD	Contractor Priced	TBD

*** HCPCS code U0005 was established in CMS Ruling 2020-1-R2 as an add-on payment to be billed in addition to HCPCS codes U0003 and U0004*

****CPT Code 87913 is currently undergoing contractor pricing.*

Pricing Based on Turnaround Time

In April 2020, CMS began paying $100 for COVID-19 tests that utilize high throughput technologies as outlined in the first Administrator's Ruling[7]. These tests were identified by HCPCS codes U0003 and U0004. CMS defines high throughput as a technology that "uses a platform that employs automated processing of more than two hundred specimens a day." Examples of high throughput technology were stated to include but are not limited to the following: Roche cobas 6800 System, Roche cobas 8800 System, Abbott m2000 System, Hologic Panther Fusion System, GeneXpert Infinity System, and NeuMoDx 288 Molecular. In October 2020, CMS reversed course in the second Administrator's ruling[8] and announced that beginning in CY 2021 payment would be reduced to $75 for COVID-19 tests using these technologies (HCPCS codes U0003 and U0004) and provided an add-on payment of $25 if the laboratory completed the test in two calendar days or less from specimen collection.

According to results from a survey of laboratories conducted by AMP in August 2020, laboratories reported establishing as many as five different testing methods to provide results in a timely manner – all at their own expense.[10] Laboratories also reported that they were continuing to face severe and ever-changing challenges with COVID-19 testing supplies and reporting burdens.

Laboratories quickly adapted their testing practices and have continued to do so, in order to respond to the evolving COVID-19 pandemic. Table 3 shows which resources surveyed laboratories reported needing to implement and maintain COVID-19 testing during the pandemic.

AMP's survey results also showed that the COVID-19 pandemic has affected other testing performed in laboratories and that there are costs for COVID testing not related to the technology or turnaround time. Specifically, members have previously and continue to report staffing shortages, supply chain issues, and an inability to obtain resources, instruments, and technology, resulting in delays or interruptions for other testing.[16] (The recommendations developed from the AMP COVID-19 survey can be found in the Appendix and include detailed recommendations regarding increased transparency and coordination of the diagnostic testing supply chain, result reporting, and regulatory requirements during a PHE, among many other topics.)

Economic uncertainty for laboratories is a barrier to offering or providing timely results to patients, and laboratories may make the decision not to enter the testing field if they do not know that reimbursement will cover their expenses. At the outset of a public health emergency, there needs to be an understanding that there will be unanticipated, increased costs for laboratories other than the materials and resources required to perform the test, including the cost of new machines and staffing. It was a leap of faith for laboratories to set up COVID-19 testing when they did not know how these services would be reimbursed, particularly given the financial challenges they were already facing. In a pandemic-response situation, it is critical that CMS recognize that there will be uncertainty that cannot be foreseen and should have reimbursement policies that are flexible enough to respond to a rapidly changing situation.

[10] Association for Molecular Pathology SARS-CoV-2 Molecular Testing; Summary of August SARS-Co-V-2 Molecular Testing Survey. The Association for Molecular Pathology. Updated October 8, 2020. Accessed March 21, 2022. https://www.amp.org/AMP/assets/File/advocacy/Survey_Report_August_2020_AMP_SARSCoV2_FINAL.pdf?pass=14 (Page 28)

Table 3: August 2020 AMP survey results on what laboratories needed to maintain testing

Resource	**Percent of Surveyed Laboratories**
Sample extraction/processing platforms	27%
Testing platforms	45%
General laboratory reagents (e.g., buffers)	25%
Commercially-available testing kits	61%
Reagents for LDPs (e.g., RNA extraction kits, buffers)	17%
Reagents required for commercially-available testing kits (e.g., buffers not included in kits)	25%
Specimen collection materials	45%
Technologists with appropriate training	49%
Training from manufacturers	7%
Platform-specific laboratory consumables (e.g., pipette tips, Eppendorf tubes)	52%
General laboratory consumables (e.g., pipette tips, Eppendorf tubes)	46%
Personal protective equipment (PPE)	30%
Laboratory testing shifts	28%
Administrative support staff – for regulatory needs	16%
Administrative support staff – for compliance needs	10%
Administrative support staff – for legal needs	3%
Administrative support staff – for IT needs	24%

Table 3: Table 3 shows data from 105 respondents and includes respondents from all laboratory types including academic medical center laboratories, community hospital or health system laboratories, commercial reference laboratories, and public health laboratories.

While CMS Rulings have the benefit of being clear statements of policy, the agency determined pricing for tests based on test methodology and turnaround time, which created a novel and disruptive market for equipment, supplies, and tests. Yet neither test methodology nor turnaround time accounted for the actual variables affecting the true costs of running COVID testing. **As the COVID-19 pandemic continues to evolve, as well as in future pandemics, AMP urges CMS to ensure that reimbursement for testing aligns with the unique needs and costs associated with offering and maintaining testing and supplies under the uncertainty created by a public health emergency.** AMP discourages the use of novel factors, e.g., the testing platform or whether it is considered high throughput, when setting pricing. **Additionally, elements outside of the control of laboratories, such as turnaround time, should not be used as a consideration for payment or pricing.** There are many rural and underserved areas of the country where specimens cannot be transported quickly enough to be turned around in two days from the time of specimen collection. The policy as articulated by CMS unfortunately penalizes laboratories serving those areas, many of which are already underserved areas and populations.

IV. COVERAGE

During the early months of the COVID-19 pandemic, coverage requirements from Medicare and commercial payers for diagnostic testing were unclear. This created uncertainty for laboratories about whether they would even be paid for any testing they performed. Subsequently, delays in coverage decisions, lack of coverage for testing performed using any available platform, and a lack of communication from policymakers about tests being covered without a co-pay generated confusion and contributed to the uncertainty faced by laboratories and the healthcare facilities they served. Meanwhile, laboratories continued to try to meet patient care demands with whatever resources they could find. Over time two issues emerged as substantial coverage problems for laboratories. First, coverage decisions did not reflect real-world testing availability and capabilities, causing laboratories to be denied payment for testing that was their only option due to supply chain constraints. Second, the need to move quickly to meet unprecedented demand for testing coupled with a lack of timely and clear communication from payers about coverage requirements left laboratories vulnerable to denial for payment due to bureaucratic or technical issues in meeting coverage requirements. These two issues put added economic strain on laboratories already taxed to meet the demands of patient care.

Types of Tests Covered

Congress moved quickly to respond to the pandemic and passed the Families First Coronavirus Response Act (P.L. 116-127) [11] on March 18, 2020. Section 6001 of this legislation included provisions meant to ensure coverage of COVID-19 testing. Specifically, the legislation promised free testing for patients for all FDA-approved tests. This provision created a large coverage gap as there are categories of laboratory tests that are offered to patients that would not meet this description, and this language was inconsistent with existing regulatory requirements for laboratory developed testing procedures (LDPs). Section 3201 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136)[12], which passed later in the month on March 27, ultimately included language to fill this coverage gap by allowing the following tests to be covered for COVID-19 testing:

[11] Families First Coronavirus Response Act of 2020. Accessed March 12, 2022. https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf [12] The Coronavirus Aid, Relief, and Economic Security Act of 2020. Accessed March 21, 2022. https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf
[12] The Coronavirus Aid, Relief, and Economic Security Act of 2020. Accessed March 21, 2022. https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf

(1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19, and the administration of such a test, that—

> (B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb– 3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe.

Moving forward, policymakers must ensure emergency coverage policies are not more restrictive than the coverage standards in place during non-emergency situations.

Coverage of Respiratory Viral Panels

Coverage of respiratory viral panels (RVPs) was severely limited at the onset of the COVID-19 pandemic. Local coverage determinations for these panels in place prior to the start of the public health emergency restricted coverage to CPT code 87631 for only 3-5 pathogens and only in patients who are immunocompromised. During the public health emergency, panel tests have proven critical for ruling other viral respiratory conditions in or out when testing for COVID-19 and helping to guide immediate appropriate treatment. Additionally, these panels provide important clinical information, preserve personal protective equipment (PPE), and allow for rapid triage to assign appropriate levels of care and minimize disease transmission to patients, healthcare personnel, and others, while reducing adverse impacts on emergency departments and hospital bed capacity. As panel tests have proved crucial to helping the healthcare system manage patient testing, laboratories have absorbed the costs of running these tests due to lack of coverage. AMP and other stakeholders urged CMS to provide immediate national coverage for these tests during the public health emergency[13].

Even prior to the current public health emergency, the laboratory industry has been moving towards panel testing and in a constrained fiscal environment, panel testing may be the best way to test for a single pathogen. Unfortunately, CMS did not allow for downcoding of panel testing for COVID-19, so if a laboratory performed a panel test that included COVID-19 in their list of targets, the laboratory could not simply code for a COVID-19 test, even if the panel test was the only testing platform they could access due to supply chain issues.

In the face of high demand for testing and a myriad of external pressures on laboratories to respond quickly during a pandemic, CMS must ensure that Medicare local coverage policies support the full range of tests available to appropriately diagnose and guide treatment, and do not contribute to significant burden on laboratories. CMS must account for the real-world availability of tests, testing platforms, and supplies that can be utilized when determining coverage policies.

Ordering Requirements

In the April 28, 2020 Interim Final Rule with comment period (IFC),[14] CMS removed the ordering requirements for a number of diagnostic laboratory tests, which allowed tests to be covered when ordered by any healthcare

[13] Association for Molecular Pathology. Sign on Letter to Administrator Verma Regarding National Coverage for Multiplex Polymerase Chain Reaction Respiratory Viral Panel Tests. April 28, 2020. Accessed March 21, 2022. https://www.amp.org/AMP/assets/File/advocacy/FINAL_Sign-On%20Letter%20to%20CMS_Coverage%20for%20RVP%20Tests_042820.pdf?pass=98

[14] Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

professional authorized to do so under state law. This IFC greatly improved access to testing for patients during the public health emergency.

When testing is critical to responding to a public health emergency, as during the COVID-19 pandemic, CMS should act early to waive burdensome ordering requirements as a way to expand access to testing. As good practice, CMS also should avoid routinely making ordering requirements overly prescriptive, as these barriers only add to the burden on health care professionals during a pandemic.

Need for Additional Guidance from HHS

The move to cover SARS-CoV-2 testing for all Americans without a co-pay quickly expanded access to crucial testing services, however logistically it created confusion and administrative burdens for laboratories. Section 6001 of the Families First Coronavirus Response Act (P.L. 116-127) [3] and Section 3201 of the CARES Act (P.L. 116-136)[15] established that SARS-CoV-2 testing would be covered by insurers without a co-pay for the duration of the public health emergency. CMS implemented these provisions in the November 2020 IFC and through FAQs Part 42 and 43. However, there was no specific guidance provided to clinical laboratories regarding how they should be billing for tests performed for individual patients whose insurance refused to cover the testing or for patients without health insurance. While testing was "free" to individuals, it was often unclear whether insurance or the government would cover testing and how laboratories' fees would be covered. Additionally, there was confusion about coverage and payment for asymptomatic and pre-symptomatic testing, which was critical from a public health perspective to respond to COVID-19. As Medicare does not typically cover screening tests except under specific circumstances, laboratories had confusion over coverage, and ultimately, reimbursement for this critical group of patients.

When considering how to prepare for future pandemics, HHS and CMS should develop a process to provide clear, coordinated guidance on coverage policy for populations outside of existing policy, e.g., the asymptomatic, pre-symptomatic, and symptomatic individuals during the COVID-19 pandemic. Further, any change in policy, such as removing the requirement of a co-pay, should be accompanied by clear, coordinated guidance on how established processes for billing and coverage are impacted. Strong consideration should be given to relaxing the typical requirements for coverage so that laboratories can be confident they will be reimbursed for any testing performed.

While laboratories need clear guidance on coverage during a pandemic, HHS should also provide clear guidance to private payers about the coverage requirements. Although private payers were required to cover COVID-19 diagnostic tests, AMP members reported that private payers' interactions were often unclear on numerous points regarding coverage and payment for these tests. For example, one payer did not believe that any payment was owed to a laboratory running the CDC COVID-19 assay, since the laboratory was provided the reagents free-of-cost. Additionally, early in the pandemic there was confusion if COVID-19 tests performed on asymptomatic individuals with private insurance would be covered. **To ensure coverage of, and payment for, necessary diagnostic tests in this pandemic and future pandemics, HHS must provide clear guidance to laboratories and private payers on coverage requirements and minimum payment amounts for these crucial tests.**

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and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. Centers for Medicare and Medicaid Services. CMS-5531-IFC. April 26, 2020. Accessed March 21, 2022. https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf

[15] The Coronavirus Aid, Relief, and Economic Security Act of 2020 Families First Coronavirus Response Act of 2020. Section 3201. P.L. 116-136. Accessed March 21, 2022https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf

V. Additional Policy Considerations

Besides coding, coverage, and pricing, a number of other economic-related issues arose during the pandemic that influenced laboratories' abilities to meet the testing needs of their communities. Below we discuss two of these issues at a high level.

Viral Genomic Sequencing

As the pandemic progressed, virus variants continued to emerge. It became clear that sequencing is required to understand how a virus spreads and mutates across the country. Yet, a year into the pandemic the U.S. lacked a nationwide system for genomic sequencing of SARS-CoV-2 to assess and track new variants[16]. The American Rescue Plan Act (P.L. 117-2),[17] which was enacted on March 11, 2021, one year into the pandemic, included financial support to academic institutions that develop partnerships with their local public health departments or large commercial laboratories that service a sizeable portion of the country for this work. In an ideal viral pandemic response, sequencing of clinical patient samples will occur at the onset of the public health emergency to provide insight on the scope of the spread and track the evolution of the virus throughout the community and country. The clinical laboratory network within the U.S. is diverse and each type of laboratory plays a slightly different but very complementary role in a pandemic response. **In order to ensure that a wide range of clinical samples across the country are sequenced for public health surveillance, AMP encourages the development of federal guidance and funding that is accessible to *all* clinical laboratory types for these activities.** This will provide additional certainty to laboratories as they are forced to make economic decisions quickly to respond to the growing public health needs of their patient community during this type of public health emergency. In addition to the American Rescue Plan, efforts continue in Congress to build up America's sequencing efforts as well as other aspects of pandemic preparedness[18]. AMP supports these ongoing efforts and is working to provide key input on behalf of the membership[19].

Burden of Reporting Requirements

As the federal response to the COVID-19 pandemic evolved, clinical laboratories were required to report data on their test results to a number of different agencies. While this information was necessary to inform the federal response, it created a large financial and operational burden on laboratories who were already facing staffing issues. Laboratories who had not previously been required to report this type of information needed to transform their practices by increasing staff and developing an appropriate reporting process. Even for laboratories who were already experienced in reporting infectious disease results, the evolving reporting requirements proved challenging for them to adapt their procedures. **In preparation for the next pandemic and to better assist laboratories during this pandemic, the federal government, in consultation with clinical and public health laboratories, should ensure that federal funding streams and resources exist and are available to support laboratory reporting at the outset of any future pandemic.**

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[16] Zimmer C. U.S. Is Blind to Contagious New Virus Variant, Scientists Warn. New York Times. January 6, 2021. https://www.nytimes.com/2021/01/06/health/coronavirus-variant-tracking.html

[17] https://www.congress.gov/117/bills/hr1319/BILLS-117hr1319enr.pdf

[18] Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act Draft. S. 3799. Updated March 7, 2022. Accessed March 21, 2022. https://www.congress.gov/117/bills/s3799/BILLS-117s3799is.xml

[19] Association for Molecular Pathology Letter to HELP Chair Murray and Ranking Member Burr on PREVENT Pandemics Act. Updated February 4, 2022. Accessed March 21, 2022. https://www.amp.org/AMP/assets/File/advocacy/AMP%20Comments%20on%20draft%20PREVENT%20Pandemics%20Act-FINAL-2-4-2022.pdf?pass=10

VI. Conclusion

This white paper has explored the lessons learned from the first two years of the COVID-19 pandemic based on the financial experience of the clinical laboratories who responded to help the country. As detailed, laboratories responding to the need for diagnostic testing faced financial uncertainties arising from challenges in coding, pricing, and coverage during the pandemic. The experience of the laboratory community revealed structural problems that constrained the healthcare system, especially for laboratories serving rural or underserved populations, preventing an ideal response to the pandemic. Thoughtful reflection on those problems can help inform the nation's preparation for the testing needs of future public health emergencies. To improve the country's response to the continuing COVID-19 pandemic and all future pandemics, it is critical that policymakers establish policies and certainty around reimbursement for testing services and other pandemic-specific economic considerations for laboratories. Policymakers should engage with all stakeholders to have transparency on these decisions moving forward. Additionally, the experience of clinical laboratories during the COVID-19 pandemic cannot be viewed in isolation from the pricing and coverage issues that laboratories face in general. Successful mitigation of pandemic-related health inequalities and rapid access to testing also depends on a robust and healthy clinical laboratory system prior to any public health emergency. It is AMP's hope that that the considerations and recommendations made in this white paper can help guide the preparedness for future pandemics and thereby improve our nation's response and the wellbeing of all our patients.

A summary of the recommendations outlined in this paper follows:

<u>Priority 1. Coding</u>

- 1.1 Coordination - AMP encourages CMS to coordinate early and broadly with the laboratory community, the AMA CPT® Editorial Panel, and other stakeholders regarding diagnostic coding. This would allow these key stakeholders to provide guidance and feedback on coding decisions.
- 1.2. Coding guidance - AMP urges CMS to work closely with stakeholders to develop a process for providing clear, up-to-date coding guidance relevant to the pandemic.
- 1.3. Interim codes and coding guidance – AMP encourages CMS to develop a process for rapidly developing interim codes and coding guidance using input from relevant stakeholders.

<u>Priority 2. Pricing</u>

- 2.1. Pricing accuracy - In the future, CMS should work with stakeholders to gain reliable data on the real-world costs of running a test during an emergency situation, which will improve pricing accuracy from the outset.
- 2.2. Consideration of all laboratory stakeholders - CMS should rely on laboratories from all sectors to set prices to ensure reimbursement is reflective of the costs of performing these tests in all settings, including in smaller laboratories. All laboratory stakeholder costs should be considered, as individual laboratories have different needs and some may require more resources to provide testing for their patient community.
- 2.3. Ensuring adequate reimbursement - In the future, CMS must ensure that the price of tests align with the resources required to develop and facilitate them as well as other costs associated with supply chain issues. CMS must ensure that the pricing for tests is completed in a timely fashion yet with opportunity for stakeholder input from across the spectrum of different partner laboratories.
- 2.4. Pricing considerations during a public health emergency - In future pandemics, CMS must ensure that reimbursement for testing aligns with the unique needs and costs associated with offering and maintaining testing and supplies under the uncertainty created by a public health emergency.

Additionally, elements outside the control of laboratories, such as turnaround time, should not be used as a consideration for payment or pricing.

Priority 3. Coverage

- 3.1. Align emergency coverage policies with non-emergency policies - Moving forward, policymakers must ensure emergency coverage policies are not more restrictive than the coverage standards in place during non-emergency situations.
- 3.2. Determining coverage policies - In the face of high demand for testing and a myriad of external pressures on laboratories to respond quickly during a pandemic, CMS must ensure that Medicare local coverage policies support the full range of tests available to appropriately diagnose and guide treatment, and do not contribute to significant burden on laboratories.
- 3.3. Remove burdensome ordering requirements - When testing is critical to responding to a public health emergency, as during the COVID-19 pandemic, CMS should act early to waive burdensome ordering requirements as a way to expand access to testing. As good practice, CMS also should avoid routinely making ordering requirements overly prescriptive, as these barriers only add to the burden on health care professionals during a pandemic.
- 3.4. Need for transparent guidance for laboratories - HHS and CMS should develop a process to provide clear, coordinated guidance on coverage policy for populations outside of existing policy, e.g., the asymptomatic, pre-symptomatic, and symptomatic individuals during the COVID-19 pandemic. Further, any change in policy, such as removing the requirement of a co-pay, should be accompanied by clear, coordinated guidance on how established processes for billing and coverage are impacted. Strong consideration should be given to relaxing the typical requirements for coverage so that laboratories can be confident they will be reimbursed for any testing performed.
- 3.5. Clarity for private payers – HHS must provide clear guidance to laboratories and private payers on coverage requirements and minimum payment amounts for necessary diagnostic tests during a public health emergency.

Priority 4. Genomic Sequencing

- 4.1. Need for federal guidance and resources - In order to ensure that a wide-range of clinical samples across the country are sequenced for public health surveillance, AMP encourages the development of federal guidance and funding that is accessible to *all* clinical laboratory types for these activities.

Priority 5. Reporting Requirements.

- 5.1. Plan for laboratory reporting - In preparation for the next pandemic, AMP suggests that the federal government, in consultation with clinical and public health laboratories, should ensure that federal funding streams and resources exist and are available to support laboratory reporting at the outset of any future pandemic.

About AMP

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostic industry.

APPENDIX:

Recommendations from AMP's August 2020 SARS-CoV-2 Molecular Testing Survey[20]

RECOMMENDATION	IMPORTANCE & POTENTIAL SOLUTIONS
Reassess type and location of SARS-CoV-2 testing services needed	In order to provide acute care, safely reopen businesses and reinvigorate the economy, there should be a reassessment of what type of testing is needed and where. Each one of the situations below could require a different method of testing (*e.g.,* molecular test or serology test) with a different necessary turnaround time: • Symptomatic, recovering, and asymptomatic patients • Acutely presenting patients (*e.g.*, ED, trauma surgery) • Scheduled surgical and labor & delivery patients • Contact tracing for facility outbreaks • "Back to work" clearance testing
Reprioritize supply allocations based on clinical testing needs, which could change over time	Depending upon the prevalence of SARS-CoV-2 in a community, there may be a shift in testing methodology and related supply needs over time. The need for testing supplies designed for acute care, surveillance, high-throughput, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations. Ideally these monitoring systems would be proactively established, rapidly activated following novel pathogen identification, and maintained throughout the course of response.
Increase transparency, communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government)	There is a need for laboratories to understand in real-time the resource availability and reagent and supply quantities, to include: • Ongoing communication regarding shipment and delivery date • Manufacturer's anticipated delays and types of delays (*e.g.*, production, allocation) • Governmental allocation strategies
Real-time coordination amongst laboratories to leverage moments of excess capacity	Based on data regarding testing capacity and demand, there may be an opportunity to coordinate regionally to ensure that any excess test capacity is leveraged to ensure samples get processed as quickly as possible (*e.g.,* a dashboard consisting of laboratories, manufacturers, and government representatives would allow real-time supply chain understanding and help to prevent communication and resource bottlenecks)

[20] Association for Molecular Pathology SARS-CoV-2 Molecular Testing; Summary of August SARS-Co-V-2 Molecular Testing Survey. The Association for Molecular Pathology. Updated October 8, 2020. Accessed March 21, 2022. https://www.amp.org/AMP/assets/File/advocacy/Survey_Report_August_2020_AMP_SARSCoV2_FINAL.pdf?pass=14

Standardize agency reporting format and processes for reportable infectious diseases during a pandemic	Complying with multiple agency reporting requirements with variable formats has been burdensome to the clinical laboratories. To improve future responses, the public health laboratory community, clinical laboratories, and CDC should collaborate to: • Define minimal required data elements for supporting public health contact tracing • Establish standardized reporting format that Electronic Health Records (EHR) / Laboratory Information Systems (LIS) vendors could adopt • Establish a standardized and centralized reporting agency / process that minimizes delays in return of results and eliminates need for laboratories to duplicate reporting to multiple agencies • Provide logistical support for laboratories to provide reportable infectious disease data electronically

Additional data from the August survey has resulted in the following two new recommendations:

RECOMMENDATION	**IMPORTANCE & POTENTIAL SOLUTIONS**
Ensure that regulatory requirements for clinical laboratories are not duplicative or burdensome, especially during a pandemic	The declaration of the public health emergency effective January 27, 2020 required that all tests for SARS-CoV-2, regardless of whether they are boxed-and-shipped testing kits or laboratory developed testing procedures (LDPs), obtain emergency use authorization (EUA) from the FDA prior to being deployed for patient use, which restricted labs from developing LDPs. Despite FDA policy changes to loosen EUA regulations, laboratories still struggle with the FDA EUA process. • Maintaining the Centers for Medicare & Medicaid Services (CMS) via the Clinical Laboratory Improvement Amendments (CLIA) program as the regulatory agency responsible for oversight of LDPs ensures that the US can rapidly develop and deploy the testing needed during a public health emergency.
Support the clinical laboratory workforce as essential to providing an effective medical and public health pandemic response	• Promote improved and ongoing collaboration and communication between the public health and clinical laboratories and relevant state and Federal agencies to better understand challenges and more effectively leverage capacities and capabilities. • Ensure financial infrastructure to support laboratory staff needs during a public health emergency (e.g., hazard pay programs) • Support providing career pathways, training, and ongoing education to ensure adequate and effective workforce is available to respond to future pandemics.