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COVID-19 IMPACTS, CHALLENGES, AND RISKS FOR CLINICAL LABORATORIES: AN OVERVIEW

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As COVID-19 continues to financially disrupt healthcare organizations across the nation, clinical laboratories of all sizes have played a vital role ramping up to meet the increased demand for COVID-19 testing. The importance of the clinical laboratory industry response to the pandemic was highlighted by the inclusion of the CEOs of both LabCorp and Quest Diagnostics among the private sector leaders at President Trump's March 13th press conference. However, as demand for COVID-19 testing has increased, volume for non-COVID-19 testing may have declined as patients put off elective procedures and routine doctor visits. Clinical laboratory revenue has declined by more than $5 billion since March of 2020. Despite a decrease in overall test volumes, the clinical laboratory industry is operating under an unparalleled strain to meet an urgent demand for testing, stemming in part from operational shortfalls as well as significant financial investments such as IT software costs related to remote work expansions, research and development for testing capacity, capital investment for equipment compatible with COVID-19 testing and adequate supplies.

The situation for hospital based clinical laboratories is coupled with the added responsibilities of ongoing patient care within the same four walls. Although costly, reliable in-house COVID-19 testing can play an important role in caring for affected patients. Originally among many hospital systems in Florida relying on a small number of external labs to assist with COVID-19 testing, the Orlando Health Department of Pathology was able to develop its own test, which was transformative in "clinical decision making, logistical planning, and decisions about how to use [its] crucial supply of personal protective equipment."[1] The responsiveness of in-house testing affords decreased turnaround time for results, increasing quality of care and health outcomes. Nevertheless, not all in-house clinical laboratories have the access to the capital and expertise required to develop in-house testing, necessitating outsourcing to external laboratories or diagnostic companies. Resourcefulness will remain a key component of the pandemic response throughout the industry and especially from privately owned clinical laboratories, clinical laboratories in community and rural hospitals, and specialty laboratories.

REIMBURSEMENT

The federal government has stepped in to financially assist clinical laboratories as they respond to the pandemic. Under the CARES Act, Congress appropriated $100 billion to Medicare and Medicaid

[1] Orlando Health Laboratory expertise, experience, and dedication led to development of COVID-19 test for in-house use. - Orlando Health - One of Central Florida's Most Comprehensive Healthcare Networks. (2020). Retrieved May 07, 2020, from https://www.orlandohealth.com/content-hub/orlando-health-laboratory-expertise-experience-and-dedication-led-to-development

enrolled suppliers and providers that provide diagnosis, testing or care associated with COVID-19.[2] The CARES Act has also provided relief to clinical laboratories in the form of delaying planned reimbursement reductions in 2021. Furthermore, the annual reoccurring reductions to the Clinical Laboratory and the Medicare Fee Schedules have been suspended. Coverage has also been expanded for all COVID-19 tests that have been approved, cleared, or authorized by the FDA and/or states. Initially, CMS established reimbursement for COVID-19 testing as follows:[3]

- CDC tests, reimbursed at $35.92 per test.
  - HCPCS code U0001: CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.
- Non-CDC tests, reimbursed at $51.31 per test.
  - CPT code 87365: 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).
  - HCPCS code U0002: 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC.

With recognition that the capital required to sustain testing would probably not cover all costs of clinical laboratories, particularly in community and rural hospitals, CMS increased reimbursement to $100 per test for tests that use high throughput technology, based on the following HCPCS codes:[4]

- U0003: 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.
- 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.

REGULATORY RISK AND COMPLIANCE

Two of the key regulations governing clinical laboratories are the Anti-Kickback Statute (AKS) and the Elimination of Kickbacks in Recovery Act of 2018 (EKRA).

AKS

Regardless of the financial burden COVID-19 testing puts on clinical laboratories, increased testing capacity will be an integral part of the effort to reopen the nation. As the federal government distributes funds to providers in response to demand for COVID-19 testing, scrutiny over potential compliance concerns and risks are escalating. Among other areas, clinical laboratories providing COVID-19 testing must ensure that their marketing and compensation arrangements do not violate the AKS. The United States Department of Justice (DOJ) has been instructed to "prioritize the detection, investigation and prosecution of all criminal conduct related to the current pandemic."[5] In late March 2020, federal prosecutors filed criminal charges under the AKS against the head of a marketing firm in Georgia who allegedly received illegal kickbacks to refer patients for COVID-19 testing reimbursed by federal and private healthcare programs[6].

[2] Key Health Care Provisions of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). (2020). Retrieved May 07, 2020, from https://www.natlawreview.com/article/key-health-care-provisions-coronavirus-aid-relief-and-economic-security-act-cares
[3] https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf
[4] Press release CMS Increases Medicare Payment for High-Production Coronavirus Lab Tests. (2020). Retrieved May 07, 2020, from https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-high-production-coronavirus-lab-tests-0
[5] U.S. Attorney Downing Appoints Experienced Prosecutor as Coronavirus Fraud Coordinator. (2020, March 20). Retrieved May 07, 2020, from https://www.justice.gov/usao-wdok/pr/us-attorney-downing-appoints-experienced-prosecutor-coronovirus-fraud-coordinator
[6] Georgia Man Arrested for Orchestrating Scheme to Defraud Health Care Benefit Programs Related to COVID -19 and Genetic Cancer Testing. Retrieved May 11, 2020, from https://www.justice.gov/usao-nj/pr/georgia-man-arrested-orchestrating-scheme-defraud-health-care-benefit-programs-related

EKRA

Originally enacted to target the abuse arising from opioid epidemic, EKRA "criminalizes knowingly and willfully soliciting, receiving, paying or offering any remuneration, including kickbacks, bribes or rebates, to induce a referral for, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory covered by a public or private health care program, unless an exception applies."[7]

EKRA applies even if no federal dollars are involved. The EKRA safe harbor for payments to "bona fide" employees and independent contractors expressly provides that payments to such personnel may not "vary by (A) the number of individuals referred to a particular … laboratory; (B) the number of tests or procedures performed; or (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular … laboratory."[8]

As providers continue to fulfill testing demand, clinical laboratories and their referral sources must ensure that compensation arrangements do not violate EKRA. The DOJ has made it clear they are prioritizing prosecution of criminal conduct related to the pandemic and EKRA provides another weapon in that effort. Additional details on EKRA and related Fair Market Value (FMV) issues are contained in a prior FMVantage Point here.

Clinical laboratories will remain on the front-line of the COVID-19 response for some time. The myriad challenges faced by laboratories will impact many of their financial relationships. HealthCare Appraisers' experienced team remains abreast of the changes impacting clinical laboratories and stands ready to assist your organization with FMV guidance.

[7] First DOJ Enforcement under New Opioids Kickback Law Announced. (2020). Retrieved May 07, 2020, from https://www.natlawreview.com/article/first-doj-enforcement-under-new-opioids-kickback-law-announced

[8] 18 USC 220: Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories. Text contains those laws in effect on May 6, 2020