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Valuation of Clinical Laboratories: Technology & Reimbursement

As discussed in the first installment of this three part series on the valuation of clinical laboratories, services provided by these labs rely on common diagnostic laboratory tests and disease-specific diagnostics to diagnose medical conditions. Medical advancements and technological innovation have brought new tests and equipment, as well as new techniques, which have allowed greater efficiency and automation. Clinical lab technology is expected to play a crucial role in the delivery of future healthcare services, especially given that healthcare reimbursement for clinical lab services (as discussed below) does not rise and fall to meet supply and demand.[1]

The U.S. government is the largest payor of medical costs, through Medicare and Medicaid, and has a strong influence on laboratory reimbursement. In 2021, Medicare and Medicaid accounted for an estimated $900.8 billion and $734 billion in healthcare spending, respectively.[2] The prevalence of these public payors in the healthcare marketplace often results in their acting as a price setter, and being used as a benchmark for private reimbursement rates.[3]

Medicare Part B provides coverage for clinical lab services that are "medically reasonable and necessary… [and must be] ordered by a physician or a qualified nonphysician practitioner."[4] Notably, during the COVID-19 public health emergency, these requirements have been relaxed so that additional healthcare professionals can order diagnostic tests; this is likely to be rescinded at the end of the public health emergency (PHE).[5] Most clinical lab services are paid under the Clinical Lab Fee Schedule (CLFS), although some services that require physician input (e.g., surgical pathology) are paid under the Medicare Physician Fee Schedule (MPFS).[6] There are over 1,600 Healthcare Common Procedure Coding System (HCPCS) codes that are reimbursed under the CLFS.[7]

Effective 2018, the Protecting Access to Medicare Act (PAMA) required CLFS payment rates to be "based on the weighted median of private payer rates."[8] This weighted median for each HCPCS code is calculated annually by CMS and has been slowly phased in to ensure payment rates are not significantly reduced. Between 2022 and 2024, payment rates for any service cannot be reduced more than 15% from year to year.[9] Notably, unlike most Medicare payment systems, CLFS rates do not vary geographically and are not updated annually based on inflation; there is one CLFS payment rate for all facilities, and most payment rates are in effect for at least three years at a time.[10]

Because COVID-19 tests did not exist before the pandemic, the reimbursement rates for these tests had to be determined by CMS outside of the annual CLFS update. Currently, CMS reimburses clinical labs $100 per COVID-19 test (when ordered by a physician or other healthcare practitioner) if the test is turned around within two calendar days; however, if a laboratory takes longer than two days, CMS only reimburses $75 per test.[11] Notably, the regulations dictating this reimbursement is only effective for the term of the PHE.[12] Once the PHE expires, it is unclear whether CMS will continue reimbursing for COVID-19 tests and, if so, whether the reimbursement amount will remain the same.

An important driver in the changing marketplace of clinical labs has been automation. There are stages to automation within a laboratory, which occur in three parts.[13] The first stage, the pre-analytic stage, begins with test ordering through computer systems to help assist in turnaround times of results. For hospital settings, cylinder tube delivery systems may be utilized to receive samples, and for independent labs, couriers are utilized. Specimens are then collected and analyzed by laboratory staff to ensure the minimum specific amount and appropriate tubing is used. Specimens are often labelled with barcodes to further automate the diagnostic process, and processes like specimen handling or preparation can even be automated. While some clinical lab tests are manually evaluated, most are performed using technically advanced instrumentation. There is still potential for additional automation, particularly in preanalytic processes (e.g., specimen collection, labeling, transfer, and preparation).[14]

The second stage, the analytic stage, begins with automation. Over the past few years, there have been major technological advancements in laboratory medicine's analytic phases, which have significantly improved clinical lab diagnostics and monitoring.[15] For example, laboratory automation has proliferated in recent years, by way of devices such as the Robot Chemist, which automated historically manual analytical steps.[16] Development in the area of automation has allowed for "improved efficiency, higher throughput, larger assay menus, and reduced errors."[17]

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The third and final stage begins with the use of computer programs to deliver results and can be expected to reduce costs that are incurred through fax and phone usage. Laboratory staff can assist providers in further evaluating results of tests; however, this final step allows for the care of patients to revert back in to the hands of a provider. Other parts of this stage can include the routine maintenance of equipment within the laboratory.[18]

Additionally, the concurrent development of artificial intelligence (AI) "may pave the way for an era of precision and personalized medicine, adding significant value to the critical role of the laboratory within healthcare provision."[19] AI is utilized in medical labs through identifying health problems by lab samples from patients and comparing it to other results in a database. Additionally, pathologists have begun to use it to reduce the possibility of medical errors.[20] While AI is currently used in only a minority of clinical labs, those who do utilize AI largely believe it to be valuable or extremely valuable, and apply it in disease diagnosis, patient risk profile review, preempting rapid response solutions, and transmittal of laboratory results.[21]

While technological advancements may increase patient access to testing, these advancements may also pose a competitive threat to clinical labs going forward.[22] For example, point-of-care testing, such as at-home COVID-19 tests, can be completed without the input of a clinical lab.[23] Nevertheless, such advancements may ameliorate the workforce shortage in clinical labs. For example, the Abbott ID NOW COVID-19 assay, has equipped hospitals, physician offices, and urgent care clinics all over the nation to detect positive COVID-19 results in five minutes or less. This device, which was approved under the Food and Drug Administration's (FDA) Emergency Use Authorization, can use nasal, throat, and nasopharyngeal swabs.[24] The company has also manufactured devices that address other illnesses such as strep, respiratory viruses, and both types of influenza, allowing quick on-site turnarounds for testing without the input of a clinical lab.

Considering the trends discussed in this series, clinical labs may face some additional challenges in the coming years. As noted in the first installment in this series, the growth in the Baby Boomer population, a significant portion of whom have one or more chronic conditions, may create significant demand that greatly benefit clinical labs. However, a clinical lab's ability to meet this demand may be tempered by the shortage of pathologists and other laboratory professionals. While ensuring their workforce does not dwindle during periods of high demand, clinical labs will also need to adhere to federal and state law to avoid regulatory scrutiny, as discussed in the next installment of this series. Additionally, as discussed in this installment, clinical labs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to automate some manual work in order to thwart any workforce shortage.

The last installment in this three-part series will discuss the regulatory environment in which clinical labs operate.

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