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Understanding and evaluating deal considerations in the diagnostic and medical laboratory sector

An update for private equity investors

Investments in diagnostic and medical laboratories require careful consideration. This issue explores certain strategic, financial, and tax issues that private equity investors should take into account when evaluating investments.

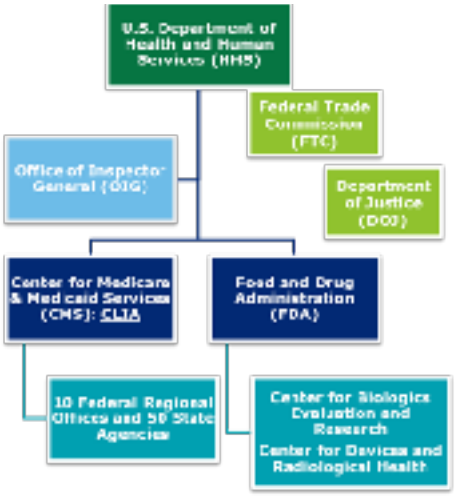
Financial and operational considerations

Regulation and compliance— Diagnostic and medical laboratories operate in a highly regulated industry. The US Department of Health and Human Services is the overarching federal agency, while the Office of Inspector General (OIG) initiates and conducts investigations on behalf of the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA).

CMS regulates laboratory testing through the Clinical Laboratory Improvement Amendments, which covers more than 250,000 laboratories and ensures quality testing. The FDA enforces medical device regulation, including in vitro diagnostic products.

The Federal Trade Commission investigates false or misleading advertising within the industry, while the

Department of Justice prosecutes criminal behavior. The table below illustrates the hierarchy governing the industry.



The OIG published Compliance Program Guidance for Clinical Laboratories that identifies many of the compliance risks for laboratories.

One risk is around overutilization (an unnecessary test is ordered). Both overutilization and underutilization (a necessary test is not ordered) can lead to negative consequences for laboratories, providers, and patients. While underutilization may result in a delayed diagnosis or misdiagnosis for a patient, overutilization results in excess costs and potential penalties.

Even if physicians order certain laboratory tests, laboratories can take actions to curb overutilization by implementing steps to help ensure tests ordered by physicians are medically necessary. Further, laboratories can help prevent overutilization by refraining from providing custom laboratory test profiles to physicians, which often result in physicians ordering excess tests.

Another risk is around the Stark Law and anti-kickback statutes. Training and oversight of sales personnel is important to prevent violations, including practices related to providing inappropriate inducements to physicians in exchange for their business.

Investors should consider the regulatory and compliance practices in place at laboratories, as noncompliance might expose companies to regulatory fines and lower-than-anticipated revenues.

Gross-to-net revenue recognition— The type of test (for example, clinical or anatomical pathology) and provider setting (for example, inpatient, outpatient, or ambulatory care) can influence the payment method for laboratory services, which can range from prospective payment systems, where rates are based on the patient's diagnosis, to capitated payments and discounted fee-for-service arrangements. The spectrum of payment methods results in differences between gross amounts charged by laboratories and contractual rates agreed upon by payer. As a result, significant judgment is involved in determining future expected cash collections and the value of accounts receivable.

Investors may wish to perform an analysis to assess whether historical accounts receivable estimates have been realized through subsequent cash collections and whether historical trends indicate current accounts receivable may be collectible. The ultimate realizability of collections can have a significant impact on historical or projected earnings.

Reimbursement—Laboratory services have increased with the prevalence of preventative care, in part attributable to the aging population, which has increased testing for conditions including diabetes, congestive heart failure, and arthritis. Reimbursement for laboratory services depends on the medical necessity of tests and proper submission of claims. However, the payer may scrutinize the medical necessity of tests in certain areas that typically have high volumes of testing, such as toxicology testing for rehab patients.

Despite increasing volumes, laboratories face pricing pressures from multiple factors:

- *Managed care organizations (MCOs)—*As patients seek to reduce out-of-pocket spending, they turn to MCOs to control costs through contracts with clinical laboratories. While MCOs may contract with some laboratories and negotiate fees charged, other laboratories contract with providers or use capitated payments.
- *Health care reform—*The Protecting Access to Medicare Act of 2014 required clinical laboratories to report private payer rates and volumes to Medicare in 2017. This process will repeat every three years. Using this data, CMS revised the Medicare Clinical Laboratory Fee Schedule (CLFS) rates for 2018 based on the weighted median private payer rates. The preliminary private payer rate-based CLFS payment amounts are estimated to have an impact on Medicare Part B, including the Part B premium effects, of about -$670 million for calendar year 2018, or a reduction of approximately 10 percent in the amount Medicare pays annually for lab tests.
- *Increasing accessibility—*With hospitals and other practices implementing point-of-care testing to increase patient access, demand has declined for some tests traditionally performed at laboratories, lowering revenue.

Ongoing health care reform and the focus by patients to reduce out-of-pocket costs will result in continued pricing pressure for laboratory reimbursement.

Partnerships and affiliations— Laboratories are increasingly attempting to provide testing services for large hospitals or other providers through partnerships or joint ventures. By securing contracts with providers that lack in-house testing, laboratories are able to boost revenue while limiting external competition. This may be a source of concentrated growth for financial investors or a barrier to entry that should be evaluated.

Laboratories also strategically look to partnerships with contract research organizations (CROs) for clinical trials, as CROs rely on laboratories to collaborate

and improve efficiency throughout the clinical trial process. These partnerships offer access to complex testing while balancing budget restrictions, geographical challenges, and timely delivery. Working with laboratories enables CROs to streamline and integrate the clinical trial processes and identification of clinical trial candidates.

Economies of scale—Because many laboratories operate on a business model with high fixed costs, consolidation of multiple laboratories under one platform may offer benefits such as economies of scale. Equipment purchases can be shared across larger organizations, and variable costs such as supplies can often be secured at a discount for larger operations. In addition, larger operators may be able to expand their overall business by offering a wider selection of services to customers.

Expanded service offerings and economies of scale may allow laboratories to improve profitability, making acquisitions of new laboratories and consolidation with current portfolio companies an attractive option for investors.

Bundled supply contracts—Laboratories often bundle supply contracts with equipment leases (for example, flow cytometers). Investors should evaluate such instances separately, as embedded leases should be identified and accounted for separately under the new leases standard, Accounting Standards Update 2016-02 – Leases (Topic 842). The new guidance requires lessees to recognize right-of-use assets and lease liabilities for nearly all leases, including embedded leases. Under previous guidance, a lease was not recorded on the balance sheet if classified as an operating lease. However, under the new standard, a lessee will recognize depreciation and interest associated with the leased assets and liabilities reported on the balance sheet, resulting in an EBITDA impact that investors should consider in valuation models.

Tax considerations

Sales and use tax—Sales and use tax laws are constantly evolving, with state and local jurisdictions generally expanding the types of products and services that they consider taxable. As a result, laboratories must closely monitor these changing laws in the state and local jurisdictions in which they operate, as well as the jurisdictions in which their customers operate. Depending upon the jurisdiction in which a laboratory or the laboratory's customers operate, services rendered and materials provided in the course of rendering those services may be subject to sales and use tax. Adding further complication, certain jurisdictions may include exemptions and may not tax laboratory and diagnostic services that are specifically provided to customers that are exempt from tax; however, in such cases, a laboratory may be required to maintain a tax-exempt exemption certificate issued by its tax-exempt customers. Investors should assess a laboratory's sales and use tax processes and compliance to identify whether there are gaps that may result in potential exposure.

Revenue recognition—As mentioned above, the spectrum of payment methods may result in differences between gross amounts charged by laboratories and contractual rates agreed upon by payer. Contractual allowances and bad-debt reserves that are based simply on estimates may not be currently deductible for tax purposes. As such, due diligence efforts should evaluate whether laboratories may have unrecognized book-to-tax differences attributable to revenue recognition that could result in pre-closing cash tax exposures.

State income and gross receipt taxes—While most laboratories rely on hospital networks to collect and ship lab specimens for analysis, some laboratories manage customer (that is, hospital-owned) laboratories and provide their own employees at the facility to perform laboratory work. Depending on the activities performed and the amount of time spent in any particular jurisdiction, a laboratory may establish state income tax nexus in the state where the hospital/customer is located. Establishing state income tax nexus could give rise to additional state and local income tax filing and payment obligations. Further, certain states (for example, Ohio, Nevada, and Washington) levy a gross receipts tax. An investor should assess a laboratory's state tax footprint to determine the extent to which the laboratory may have additional state income tax filing/payment obligations.

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