

We believe that healthcare providers consider a number of factors when selecting a testing provider, including:

- service capability and quality;
- accuracy, timeliness and consistency in reporting test results;
- pricing;
- patient insurance coverage;
- number and type of tests performed by the provider;
- number, convenience and geographic coverage of patient service centers;
- reputation in the medical community;
- healthcare information technology solutions;
- qualifications; and
- ability to develop new and useful tests.

We believe that we are an effective competitor in each of these areas. We also believe that the differentiation we are creating through our focus on a superior patient experience, Six Sigma quality, unparalleled access and distribution, the most comprehensive test menu and innovative test and information technology offerings provide us with a competitive advantage and enables us to compete on more than price alone.

We believe that large commercial clinical laboratories may be able to increase their share of the overall clinical testing market due to their large service networks and lower cost structures. These advantages should enable larger clinical laboratories to more effectively serve large customers and members of large healthcare plans. In addition, we believe that consolidation in the clinical testing industry will continue. However, a significant portion of clinical testing is likely to continue to be performed by hospitals, which generally have affiliations with community physicians that refer testing to us. As a result of these affiliations, we compete against hospital-affiliated laboratories primarily on the basis of service capability and quality as well as other non-pricing factors. Our failure to provide service superior to hospital-affiliated laboratories and other laboratories could have a material adverse effect on our net revenues and profitability. In addition, recent market activity, including actions by payers to exclude large national clinical laboratories from contracts, may enhance the relative competitive position of regional laboratories.

The diagnostic testing industry is faced with changing technology and new product introductions. Advances in technology may lead to the development of more cost-effective tests that can be performed outside of a commercial clinical laboratory such as (1) point-of-care tests that can be performed by physicians in their offices; (2) complex tests that can be performed by hospitals in their own laboratories; and (3) home testing that can be carried out without requiring the services of clinical laboratories. Development of such technology and its use by our customers and patients would reduce the demand for our laboratory testing services and negatively impact our net revenues. However, as a result of our point-of-care test strategy, we believe that we are well positioned to service this market for physicians and hospitals. We also believe that our overall point-of-care test strategy will strengthen our relationship with our customers by enabling us to offer more solutions that improve their effectiveness and the care of their patients by enabling faster diagnosis and treatment.

The diagnostic product market is highly competitive. We have many competitors, some of which have much more extensive experience in this market and some of which have greater resources than our Company. We compete in this area by attempting to find and exploit unique differentiated products, including products that take advantage of our healthcare information technology solutions. There is no guarantee that we will be able to compete successfully in this market.

**Employees.** At December 31, 2007, we employed approximately 43,500 people. This total excludes employees of the joint ventures where we do not have a majority interest. We have no collective bargaining agreements with any unions covering any employees in the United States, and we believe that our overall relations with our employees are good.

## **BILLING AND REIMBURSEMENT**

**Billing.** We generally bill for clinical testing services on a fee-for-service basis under one of two fee schedules. These fees are generally subject to negotiation with or discounted to non-governmental payers. The fee schedules are:

- “Client” fees charged to physicians, hospitals, and institutions for which a clinical laboratory performs testing services on a wholesale basis and which are billed on a monthly basis.
- “Patient” fees charged to individual patients and third-party payers, like Medicare and Medicaid.

Billing for clinical testing services is very complicated, so we have compliance policies and procedures that increase our billing costs. Patients, insurance companies, Medicare, Medicaid, physicians, hospitals and employer groups all have different billing requirements. Billing arrangements require us to bill various payers. We incur additional costs as a result of our participation in Medicare and Medicaid programs because clinical laboratory testing and anatomic pathology services are subject to complex, stringent and frequently ambiguous federal and state laws and regulations, including those relating to billing and reimbursement. These regulatory requirements increase costs related to: (1) the complexity of our billing processes; (2) training and education of our employees and customers; (3) compliance and legal costs; and (4) costs related to, among other factors, medical necessity denials and advance beneficiary notices. Changes in laws and regulations could further complicate our billing and increase our billing expense. CMS establishes procedures and continuously evaluates and implements changes to the reimbursement process. Other factors that complicate billing include:

- differences between our fee schedules and the reimbursement rates of the payers;
- disparity in coverage and information requirements among various payers;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- state laws that dictate who and when we must bill for services;
- billings to payers with whom we do not have contracts; and
- disputes with payers as to which party is responsible for payment.

In 2007, our bad debt expense was 4.5% of our net revenues. We believe that most of our bad debt expense is primarily the result of missing or incorrect billing information on requisitions received from healthcare providers and the failure of patients to pay the portion of the receivable that is their responsibility, rather than credit related issues. In general, we perform the requested tests and report test results regardless of whether the billing information is incorrect or missing. We subsequently attempt to contact the healthcare provider or patient to obtain any missing information and to rectify incorrect billing information. Missing or incorrect information on requisitions complicates and slows down the billing process, creates backlogs of unbilled requisitions and generally increases the aging of accounts receivable and bad debt expense. The increased use of electronic ordering reduces the incidence of missing or incorrect information.

**Billing Compliance.** As an integral part of our billing compliance program, we investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements. Any Medicare or Medicaid overpayments resulting from non-compliance are reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments, reimbursed the overpayments and taken appropriate corrective action.

Penalties for violations of laws relating to billing federal healthcare programs and for violations of federal and state fraud and abuse laws include: (1) exclusion from participation in Medicare/Medicaid programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business. Civil monetary penalties for a wide range of violations are not more than \$10,000 per violation plus three times the amount claimed and, in the case of kickback violations, not more than \$50,000 per violation plus up to three times the amount of remuneration involved. A parallel civil remedy under the federal False Claims Act provides for damages not more than \$11,000 per violation plus up to three times the amount claimed.

**Government Reimbursements.** The healthcare industry has experienced significant changes in reimbursement practices during the past several years. Government payers, such as Medicare and Medicaid, have taken steps and may continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical test services. With regard to the clinical test services performed on behalf of Medicare beneficiaries, we must bill the Medicare program directly and must accept the carrier’s fee schedule amount as payment in full. In addition, state Medicaid programs are prohibited from paying more (and in most instances, pay significantly less) than Medicare. Currently, Medicare does not require the beneficiary to pay a co-payment for clinical laboratory testing. Certain Medicaid programs require Medicaid recipients to pay co-payment amounts for clinical laboratory testing. Medicare patients generally are required to make co-payments for anatomic pathology services.

Federal law contains a Medicare fee schedule payment methodology for clinical testing services performed for patients covered under Part B of the Medicare program, and a national ceiling on the amount that carriers

could pay under their local Medicare fee schedules. Federal law also contains a Medicare fee schedule payment methodology for pathology and other physician services performed for patients covered under Part B of the Medicare program. These laws are periodically adjusted, but an adjustment to the national fee schedule for clinical testing services based on the consumer price index cannot occur before January 1, 2009. In December 2007, Congress changed the national physician fee schedule, replacing the scheduled 10% cut to the physician fee reimbursement rate with a 0.5% increase through June 30, 2008 and maintaining through June 30, 2008 the ability of independent clinical laboratories to bill Medicare directly for the technical component of certain pathology services provided to hospitals. We expect that Congress will take up the issue of the fee schedules again in 2008, and we cannot predict whether they will change. If Medicare fee schedules are reduced, or if independent clinical laboratories are prohibited from billing Medicare directly for the technical component of pathology services provided to hospitals, it could have a material adverse effect on our business.

Average Medicare reimbursement is not materially different than our overall average reimbursement rate from other third party fee for service payers. Despite the added cost and complexity of participating in the Medicare and Medicaid programs, we continue to participate in such programs because we believe that our other business may depend, in part, on continued participation in these programs, since certain customers may want a single laboratory capable of performing all of their clinical testing services, regardless of who pays for such services.

We are generally permitted to bill Medicare beneficiaries directly for statutorily excluded clinical testing services. An advance beneficiary notice (“ABN”) is a notice signed by the beneficiary which documents the patient’s informed decision to personally assume financial liability for clinical tests which are likely to be denied and not reimbursed by Medicare because they are deemed to be not medically necessary (these tests include limited coverage tests for which the ordering physician did not provide an appropriate diagnosis code and certain tests ordered on a patient at a frequency greater than covered by Medicare). If a Medicare beneficiary signs an ABN, we are also generally permitted to bill the beneficiary for clinical tests that Medicare does not cover due to “medical necessity” limitations. We do not have any direct contact with most of these patients and, in such cases, cannot control the proper use of the ABN by the physician or the physician’s office staff, who must obtain the ABN on our behalf. If the ABN is not timely provided to the beneficiary or is not completed properly, we may end up performing tests that we cannot subsequently bill to the patient if payment is denied by Medicare due to coverage limitations. CMS is currently considering potential changes to rules regarding ABN’s that may effectively increase the number of tests that we cannot subsequently bill to the patient.

Clinical laboratories that bill Medicare or Medicaid could be excluded from participation in any federal healthcare programs if it is determined that they have submitted bills or requests from payment for items or services substantially in excess of the laboratory’s usual charges for such items or services without good cause. The Department of Health and Human Services Office of Inspector General has periodically proposed to define the terms “substantially in excess” and “usual charges,” but has not done so.

CMS is permitted to adjust statutorily prescribed fees for clinical test services if the standard rules by which those payments are calculated will result in fees that are “grossly excessive.” CMS rules set forth a process and factors for establishing a “realistic and equitable” payment amount for clinical test services under Medicare Part B (and services paid under a prospective payment system) if existing payment amounts are determined to be inherently unreasonable; payment amounts may be considered unreasonable if they are either grossly excessive or deficient. Under CMS rules, if CMS or a carrier determines that an overall payment adjustment of less than 15% is needed to produce a realistic and equitable payment amount, then the payment amount is not considered “grossly excessive or deficient.” However, if a determination is made that a payment adjustment of 15% or more is justified, CMS could provide an adjustment of less than 15%, but not more than 15%, in any given year. Fees payable by Medicare could be reduced prospectively as a result of the application of these rules.

Historically, most Medicare and Medicaid beneficiaries were covered under the traditional Medicare and Medicaid programs directly administered by the federal government. Over the last several years, the federal government has sponsored programs to expand private health insurance options for Medicare beneficiaries and has encouraged such beneficiaries to switch from the traditional programs to the private programs, called “Medicare Advantage” programs. There has been rapid growth of health insurance plans offering Medicare Advantage programs and of beneficiary enrollment in these plans. In recent years, in an effort to control costs, states also have increasingly mandated that Medicaid beneficiaries enroll in private managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid beneficiaries to private health insurance options.

**Reduced Utilization of Clinical Testing.** Government payers, such as Medicare and Medicaid, have taken steps and may continue to take steps to control the utilization and delivery of healthcare services, including

clinical test services. Medicare carriers have adopted policies under which they do not pay for many commonly ordered clinical tests unless the ordering physician has provided an appropriate diagnosis code supporting the medical necessity of the test. Physicians are required by law to provide diagnostic information when they order clinical tests for Medicare and Medicaid patients.

**Medicare Administrative Contractors.** Historically, many different local intermediaries administered Medicare Part A and many different local carriers administered Medicare Part B (which covers services provided by independent clinical laboratories). Carriers often had inconsistent policies on matters such as: (1) test coverage; (2) automated chemistry panels; (3) diagnosis coding; (4) claims documentation; and (5) fee schedules (subject to the national fee schedule limitations). Inconsistent carrier rules and policies increase the complexity of the billing process for clinical laboratories. Federal law requires Medicare contracting reform. All historic intermediaries and carriers are being replaced, using a competitive bidding process, with Medicare Administrative Contractors who will handle both Part A and Part B. Approximately one half of the Medicare Administrative Contractors have been selected. It is expected that the revised system, when completed, will reduce the administrative complexity of billing for services provided to Medicare beneficiaries.

**Competitive Bidding.** CMS is required to conduct a demonstration project to determine whether competitive bidding can be used to provide clinical testing services for Medicare beneficiaries at fees below current Medicare payment rates while maintaining quality and access to care. CMS will conduct two separate demonstrations in isolated markets. The first will be conducted in the Metropolitan Statistical Area composed of the San Diego-Carlsbad-San Marcos, California area beginning in 2008. Under a plan announced by CMS in December 2007, bids were due February 15, 2008, winners will be selected in April 2008 and the pilot will begin July 1, 2008. CMS has not yet identified the site of the second competitive bidding demonstration project.

The industry remains concerned about the general lack of responsiveness by CMS to industry concerns and questions regarding the demonstration project and continues discussing with members of Congress and Committee staffs industry concerns regarding quality, patient access and CMS' flawed implementation of the demonstration project. We believe that clinical testing services are not commodities and that the quality of services and access to those services could be adversely impacted by implementation of competitive bidding. In an effort to delay or stop the demonstration project, the Company, other industry participants and several professional societies are supporting a complaint filed in the United States District Court for the Southern District of California in January 2008 on behalf of three local laboratories.

President Bush recently proposed a fiscal 2009 federal budget that includes savings of approximately \$2.4 billion over five years by establishing competitive bidding for clinical laboratory services provided to Medicare beneficiaries. If competitive bidding were implemented on a regional or national basis for clinical testing, it could materially adversely affect the clinical testing industry and us.

## REGULATION

The Company's business is subject to or impacted by extensive and frequently changing laws and regulations, including inspections and audits by governmental agencies, in the United States (including at both the federal and state levels) and the other jurisdictions in which the Company engages in business. We also must comply with other laws and regulations, including in the United States and in the other jurisdictions in which we engage in business, that apply to conducting business generally (e.g., the U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions). Set forth below are highlights of the key regulatory schemes applicable to the Company's business.

**CLIA and State Clinical Laboratory Licensing Regulations.** All of our laboratories and, where applicable, patient service centers are licensed and accredited by the appropriate federal and state agencies. The Clinical Laboratories Improvement Amendments of 1988 ("CLIA") regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely. The cost of compliance with CLIA makes it cost prohibitive for many physicians to operate clinical laboratories in their offices. However, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care test equipment to physicians and by selling to both physicians and patients test kits approved by the FDA for home use. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes.

CLIA does not preempt state laws that are more stringent than federal law. State laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. State laws also may