

Intellectual Property Rights. We own significant intellectual property, including patents, patent applications, technology, trade secrets, know-how, copyrights and trademarks in the United States and other countries. From time to time, we also license U.S. and non-U.S. patents, patent applications, technology, trade secrets, know-how, copyrights or trademarks owned by others. In the aggregate, these intellectual property assets and licenses are of material importance to our business. We believe, however, that no single patent, technology, trademark, intellectual property asset or license is material to our business as a whole.

Our approach is to manage our intellectual property assets to safeguard them and to maximize their value to our enterprise. We generally actively defend our intellectual property assets and pursue protection of our products, processes and other intellectual property where possible.

Our success in remaining a leading innovator in the diagnostic testing industry by continuing to introduce new tests, technology and services will depend, in part, on our ability to license new and improved technologies on favorable terms. Other companies or individuals, including our competitors, may obtain patents or other property rights on tests or processes that we may be performing, particularly in such emerging areas as gene-based testing and other specialty testing, that could prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.

Employees. At December 31, 2008, we employed approximately 42,800 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, and 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, and there are several other factors that complicate billing (e.g., disparity in coverage and information requirements among various payers; incomplete or inaccurate billing information provided by ordering physicians). 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. 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.

In 2008, 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 and Advance Beneficiary Notices (ABNs) 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. Deteriorating economic conditions may adversely impact our bad debt expense. In general, we perform the requested tests and report test results regardless of whether the billing information is correct or complete. 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 may be assessed on a per violation basis. A parallel civil remedy under the federal False Claims Act provides for damages on a per violation basis, plus damages of 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 can be expected to 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. Effective January 1, 2009, the national fee schedule for clinical testing services was increased 4.5%. 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. Effective January 1, 2009, the national fee schedule for physician fees was increased 1.1%. If Medicare fee schedules are reduced, or if independent clinical laboratories are prohibited from billing Medicare directly for certain services, such as the technical component of pathology services provided to hospitals, it could have a material adverse effect on our business.

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 has issued manual changes requiring ABNs to include a specific price estimate for tests covered by ABNs. As a result, incorrectly completed forms could increase, resulting in more invalid ABNs and more tests that we cannot 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 without good cause they have submitted bills or requests for payment for items or services substantially in excess of the laboratory's usual charges for such items or services. 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 finalized definitions of these terms.

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). They often had inconsistent policies, increasing the complexity of the billing process for clinical laboratories. They are being replaced with contractors who will handle both Part A and Part B. It is expected that the revised system will reduce the administrative complexity of billing for services provided to Medicare beneficiaries.

REGULATION

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

CLIA and State Clinical Laboratory Licensing Regulations. All of our laboratories and, where applicable, patient service centers are licensed and accredited as required by the appropriate federal and state agencies. 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 require detailed review of our scientific validations and technical procedures for each test before approval for use or marketing of services.

Fraud and Abuse Rules. Federal anti-kickback laws and regulations prohibit making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or certain other federal or state healthcare programs. The penalties for violation of these laws and regulations may include monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws.

In addition, federal anti-self-referral laws and the laws of some states generally prohibit Medicare and Medicaid payments for clinical tests referred by physicians who have a personal investment in, or a compensation arrangement with, the testing laboratory. Some states have similar anti-self-referral and other laws that are not limited to Medicare and Medicaid referrals and could also affect investment and compensation arrangements with physicians.

Drug Testing. The Substance Abuse and Mental Health Services Administration (“SAMHSA”) regulates drug testing for public sector employees and employees of certain federally regulated businesses. All laboratories that perform such testing must be certified as meeting SAMHSA’s detailed performance and quality standards. All of our laboratories that perform such testing are so certified.