The final HIPAA security regulations, which establish requirements for safeguarding electronic patient information, were published on February 20, 2003 and became effective on April 21, 2003, although healthcare providers had until April 20, 2005 to comply. We have implemented policies and standards to reasonably and appropriately comply with the requirements of the regulations.

The final HIPAA regulations for electronic transactions, which we refer to as the transaction standards, establish uniform standards for electronic transactions and code sets, including the electronic transactions and code sets used for billing claims, remittance advices, enrollment and eligibility. We have completed conversion to the required standard format for our electronic fee-for-service claim transactions and our electronic fee-for-service remittance transactions.

In addition to having completed conversion to the required standard format for our electronic claim and remittance transactions, we are actively in the process of completing systems planning for compliance with HIPAA regulations on adoption of national provider identifiers ("NPI"). The NPI regulations require health care providers to adopt new, unique identifiers for reporting on claims transactions after May 23, 2007. The new identifiers will replace existing identifiers, such as provider numbers historically assigned by Medicare to laboratories and unique physician identification numbers ("UPIN") assigned by CMS to Medicare participating physicians, on claims that require provider identifiers. We have obtained NPIs for all of our laboratory facilities and we have updated our billing systems so that we can report our NPIs to Medicare, Medicaid and other commercial health plans. We have also updated our billing systems so that we can report the NPIs of referring physicians for our claims that require referring physician NPI information after May 23, 2007, such as claims submitted to the Medicare program. We are in the process of obtaining NPI information from our physician clients, and expect that the process will continue up to and beyond May 23, 2007. As of February 23, 2007, CMS reports that approximately 60% of physicians have obtained NPIs. There is industry concern with the number of physicians and other health providers who have not yet obtained NPIs, and various groups have requested that CMS consider adopting a contingency period of one year or more for compliance with NPI regulations. While CMS has adopted similar contingency periods for electronic claim and remittance transactions in the past, there is no indication yet that they will do the same for NPI. We will continue efforts to obtain available referring physician NPIs, and expect that most of the available NPIs will be obtained prior to May 23, 2007.

Regulation of Reimbursement for Clinical Laboratory Services

Overview. The healthcare industry has experienced significant changes in reimbursement practices during the past several years. Government payers, such as Medicare (which principally serves patients 65 years and older) and Medicaid (which principally serves indigent patients), as well as private payers and large employers, have taken steps and may continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical laboratory services. If we cannot offset future reductions in the payments we receive for our services by reducing costs, increasing test volume and/or introducing new procedures, it could have a material adverse impact on our net revenues and profitability.

While the total cost to comply with Medicare administrative claims requirements is disproportionate to our cost to bill other payers, average Medicare reimbursement rates are not materially different than our overall average reimbursement rate from all payers, making this business generally less profitable. 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 laboratory testing services, regardless of who pays for such services.

Billing and reimbursement for clinical laboratory testing is subject to significant and complex federal and state regulation. Penalties for violations of laws relating to billing federal healthcare programs and for violations of federal 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.

Reduced Reimbursements. In 1984, Congress established a Medicare fee schedule payment methodology for clinical laboratory services performed for patients covered under Part B of the Medicare program. Congress then imposed a national ceiling on the amount that carriers could pay under their local Medicare fee schedules.

Since then, Congress has periodically reduced the national ceilings. The Medicare national fee schedule limitations were reduced in 1996 to 76% of the 1984 national median of the local fee schedules and in 1998 to 74% of the 1984 national median. The national ceiling applies to tests for which limitation amounts were established before January 1, 2001. For more recent tests (tests for which a limitation amount is first established on or after January 1, 2001), the limitation amount is set at 100% of the median of all the local fee schedules established for that test in accordance with the Social Security Act. The MMA eliminated for five years (beginning January 1, 2004) the provision for annual increases to the Medicare national fee schedule based on the consumer price index. Thus, by law an adjustment to the national fee schedule for clinical laboratory services based on the consumer price index cannot occur before January 1, 2009. However, the MMA added coverage for certain cardiovascular screening tests and diabetes screening tests, subject to certain frequency limitations. The MMA evaluates new diagnostic tests for coverage as they are introduced.

With regard to the clinical laboratory 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. Major clinical laboratories, including Quest Diagnostics, typically use two fee schedules for tests billed on a fee-for-service basis:

- "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. These fees are generally subject to negotiation or discount.
- "Patient" fees charged to individual patients and third-party payers, like Medicare and Medicaid. These fees generally require separate bills for each requisition.

The fee schedule amounts established by Medicare are typically substantially lower than patient fees otherwise charged by us, but are sometimes higher than our fees actually charged to certain clients. During 1992, the OIG of the HHS issued final regulations that prohibited charging Medicare fees substantially in excess of a provider's usual charges. The laboratory industry believes that the term "usual charges" specifically applies to amounts charged to similarly-situated third-party payers and to patients and that client fees should not be included in "usual charges". The OIG, however, declined to provide any guidance concerning interpretation of these rules, including whether or not discounts to non-governmental clients and payers or the dual-fee structure might be inconsistent with these rules.

A proposed rule released in September 1997 would have authorized the OIG to exclude providers, including clinical laboratories, from participation in the Medicare program that charge Medicare and other programs fees that are "substantially in excess of . . . usual charges . . . to any of [their] customers, clients or patients". This proposal was withdrawn by the OIG in 1998. In November 1999, the OIG issued an advisory opinion which indicated that a clinical laboratory offering discounts on client bills may violate the "usual charges" regulation if the "charge to Medicare substantially exceeds the amount the laboratory most frequently charges or has contractually agreed to accept from non-Federal payers". The OIG subsequently issued a letter clarifying that the usual charges regulation is not a blanket prohibition on discounts to private pay customers.

In September 2003, the OIG published a Notice of Proposed Rulemaking that would amend the OIG's exclusion regulations addressing excessive claims. Under the proposed exclusion rule, the OIG would have the authority to exclude a provider for submitting claims to Medicare that contain charges that are substantially in excess of the provider's usual charges. The proposal would define "usual charges" as the average payment from non-government entities, on a test by test basis, excluding capitated payments; and would define "substantially in excess" to be an amount that is more than 20% greater than the usual charge. We believe that the proposed rule is unnecessary for the clinical laboratory industry because Congress has already established fee schedules for the services that the rule proposes to regulate. We also believe that the proposed rule is unworkable and overly burdensome. Through our industry trade association, we filed comments opposing the proposed rule and we are working with our trade association and a coalition of other healthcare providers who also oppose this proposed regulation as drafted. If this regulation is adopted as proposed, it could potentially reduce the amounts we bill and collect from Medicare and other federal payers, affect the fees we charge to other payers, or subject the Company to penalties for non-compliance, and could also be costly for us to administer.

The 1997 Balanced Budget Act permits CMS to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are "grossly excessive". In December 2002, CMS issued an interim final rule setting forth a process and factors for establishing a "realistic and equitable" payment amount for all Medicare Part B services (except physician services and services paid under a prospective payment system) when the existing payment amounts are determined to be inherently unreasonable. Payment amounts may be considered unreasonable because they are either grossly excessive or deficient. In December 2005, CMS

published the final rule clarifying that 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. We cannot provide any assurances to investors that fees payable by Medicare could not be reduced as a result of the application of this rule or that the government might not assert claims for reimbursement by purporting to retroactively apply this rule or the OIG interpretation concerning "usual charges."

Currently, Medicare does not require the beneficiary to pay a co-payment for clinical laboratory testing. When co-payments were last in effect before adoption of the clinical laboratory services fee schedules in 1984, clinical laboratories received from Medicare carriers only 80% of the Medicare allowed amount and were required to bill Medicare beneficiaries for the unpaid balance of the Medicare allowed amount. If re-enacted, a co-payment requirement could adversely affect the revenues of the clinical laboratory industry, including us, by exposing the testing laboratory to the credit of individuals and by increasing the number of bills. In addition, a laboratory could be subject to potential fraud and abuse violations if adequate procedures to bill and collect the co-payments are not established and followed. The Medicare reform bill approved by the United States Senate in June 2003 included a co-payment provision, under which clinical laboratories would receive from Medicare carriers only 80% of the Medicare clinical laboratory fee schedule amount for clinical laboratory tests and would be required to bill Medicare beneficiaries for the 20% balance. The co-payment provision was dropped from the bill as passed (known as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) ("MMA"). We cannot provide any assurances to investors that Congress would not seek to re-impose a co-payment requirement payable by Medicare beneficiaries for clinical laboratory services. Certain Medicaid programs already require Medicaid recipients to pay co-payment amounts for clinical laboratory testing.

Reduced Utilization of Clinical Laboratory Testing. In recent years, CMS has taken several steps to reduce utilization of clinical laboratory testing paid by Medicare and Medicaid. Since 1995, 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. However, CMS has not prescribed any penalty for physicians who fail to provide this diagnostic information to laboratories. Moreover, regulations adopted in accordance with HIPAA require submission of diagnosis codes as part of the standard claims transaction.

We are generally permitted to bill Medicare beneficiaries directly for statutorily excluded clinical laboratory services. If a Medicare beneficiary signs an advance beneficiary notice, or ABN, we are also generally permitted to bill the beneficiary for clinical laboratory tests that Medicare does not cover due to "medical necessity" limitations (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). An ABN is a notice signed by the beneficiary which documents the patient's informed decision to personally assume financial liability for laboratory tests which are likely to be denied and not reimbursed by Medicare because they are deemed to be not medically necessary. 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. 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 they are not reimbursable by Medicare due to coverage limitations.

Inconsistent Practices. Currently, many different local carriers administer Medicare. They have 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 have increased the complexity of the billing process for clinical laboratories. As part of the 1997 Balanced Budget Act, HHS was required to adopt uniform policies on the above matters by January 1, 1999, and to replace the current local carriers with no more than five regional carriers. Additionally, the MMA required that CMS consolidate the administration of Part A and Part B benefits under the same contractor, titled the Medicare Administrative Contractor (MAC). Currently, different contractors administer Part A and Part B benefits for the same geographic area. On July 31, 2006, CMS announced that they had awarded the first of 15 MAC contracts to Noridian Administrative Services. Noridian will serve as the first contractor to process and pay both Part A and Part B claims for Medicare beneficiaries in Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming. The remaining contracts will be awarded by 2011 in order to meet the requirements of the MMA.

Carrier Jurisdiction Changes for Lab-to-Lab Referrals. On October 31, 2003, CMS announced its intention to change the manner in which Medicare contractors currently process claims for lab-to-lab referrals of

clinical laboratory tests. While laboratories are, under certain criteria, permitted to directly bill Medicare for clinical laboratory tests they refer to other laboratories, they must be reimbursed at the correct fee schedule amount based on the Medicare fee schedule in effect in the Medicare carrier region in which the test was actually performed. Historically, laboratories needed to enroll with and file claims to multiple carriers in order to bill for such out-of-area test referrals, to ensure receipt of the appropriate payment amount. This has proven to be an administratively difficult process, with many obstacles to obtaining accurate claims payment, including applying the correct fee schedule. On July 1, 2004, CMS implemented a change mandating that the laboratory's "home" carrier maintain and apply the clinical laboratory fee schedule applicable to the carrier region where the referred test was performed. This streamlined process allows a laboratory to file all of its clinical laboratory claims to its "home" carrier.

CMS also has announced a parallel change with regard to purchased diagnostic interpretations (pathology services). A previously announced change in Medicare carrier jurisdiction rules required laboratories to bill the carrier where a purchased diagnostic interpretation service was performed. This would have required multiple carriers to issue Medicare provider numbers to a laboratory billing for purchased diagnostic interpretation services performed by others. In October 2004, CMS posted a "change notice" permitting laboratories to temporarily bill their local carriers for purchased diagnostic tests or interpretations regardless of the location where the interpretive service was furnished. The final change notice was issued on October 29, 2004, effective April 1, 2005. The final notice requires carriers to implement a new edit to check for duplicate claims for referred clinical diagnostic laboratory and purchased diagnostic services submitted by physicians/suppliers to more than one carrier.

Competitive Bidding. The MMA requires CMS to conduct two demonstration projects of competitive bidding for clinical laboratory tests. CMS awarded the clinical laboratory competitive bidding demonstration design and implementation contract to RTI International, Research Triangle Park, North Carolina, and its subcontractor, Palmetto GBA. Palmetto is a Part B carrier and previously conducted for CMS a competitive bidding demonstration for Durable Medical Equipment (DME). In August 2005, RTI presented its draft design at a public meeting. The RTI proposal incorporated several ACLA recommendations, including having bidders bid on the full range of tests paid under the laboratory fee schedule, utilizing a fee-for-service basis for bidding, and allowing bidders to subcontract. CMS was required to submit its initial report on the competitive bidding proposal by December 31, 2005. In April 2006, CMS issued a brief status report endorsing the RTI draft design. CMS is holding to its plans to announce the competitive bidding demonstration areas and begin accepting bids from clinical laboratories by the second quarter of 2007. However, the Office of Management and Budget (OMB), which has approved the bidding form, has not yet approved CMS's design for the competitive bidding program or the two sites for the pilots. Since a number of necessary steps must occur after OMB approval, at this time it is uncertain when an actual demonstration could begin. In addition, because the laboratory industry is concerned about the general lack of responsiveness by CMS to industry concerns about the bidding process, it is discussing industry concerns with members of Congress and Committee staffs. In addition, the President's 2008 budget proposes Medicare cost savings from competitive bidding for clinical laboratory services of $2.38 billion over five years, including $110 million in 2008. This estimate appears to presume that CMS would implement competitive bidding before completion of the Medicare competitive bidding demonstration. We believe that clinical laboratory services are not commodities like DME and the quality of services and access to those services could be adversely impacted by implementation of competitive bidding. If competitive bidding were implemented on a regional or national basis for clinical laboratory testing, it could materially adversely affect the clinical laboratory industry and us.

Future Legislation. Future changes in federal, state and local regulations (or in the interpretation of current regulations) affecting governmental reimbursement for clinical laboratory testing could adversely affect us. We cannot predict, however, whether and what type of legislative proposals will be enacted into law or what regulations will be adopted by regulatory authorities.

Fraud and Abuse Regulations. Medicare and Medicaid anti-kickback laws prohibit clinical laboratories from making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or other federal programs. As noted above, the penalties for violation of these laws may include criminal and civil fines and penalties and/or suspension or exclusion from participation in federal programs. Many of the anti-fraud statutes and regulations, including those relating to joint ventures and alliances, are vague or indefinite and have not been interpreted by the courts. We cannot predict if some of the fraud and abuse rules will be interpreted contrary to our practices.

In November 1999, the OIG issued an advisory opinion concluding that the industry practice of discounting client bills may constitute a kickback if the discounted price is below a laboratory's overall cost (including

overhead) and below the amounts reimbursed by Medicare. Advisory opinions are not binding but may be indicative of the position that prosecutors may take in enforcement actions. The OIG's opinion, if enforced, could result in fines and possible exclusion and could require us to eliminate offering discounts to clients below the rates reimbursed by Medicare. The OIG subsequently issued a letter clarifying that it did not intend to imply that discounts are a per se violation of the federal anti-kickback statute, but may merit further investigation depending on the facts and circumstances presented.

In addition, since 1992, a federal anti-"self-referral" law, commonly known as the "Stark" law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the testing laboratory. Since January 1995, these restrictions have also applied to Medicaid-covered services. Many 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. We cannot predict if some of the state laws will be interpreted contrary to our practices.

In April 2003, the OIG issued a Special Advisory Bulletin addressing what it described as "questionable contractual arrangements" in contractual joint ventures. The OIG Bulletin focused on arrangements where a healthcare provider, or Owner, expands into a related healthcare business by contracting with a healthcare provider, or Manager, that already is engaged in that line of business for the Manager to provide related healthcare items or services to the patients of the Owner in return for a share of the profits of the new line of business. While we believe that the Bulletin is directed at "sham" arrangements intended to induce referrals, we cannot predict whether the OIG might choose to investigate all contractual joint ventures, including our joint ventures with various hospitals or hospital systems.

In August 2006, the OIG published a final rule providing safe harbors to the federal anti-kickback statute and CMS published a final rule providing exceptions to the Stark self-referral prohibition law with respect to e-prescribing items and services and electronic health records (EHR) items and services. See "Healthcare Information Technology."

Government Investigations and Related Claims

We are subject to extensive and frequently changing federal, state and local laws and regulations. We believe that, based on our experience with government settlements and public announcements by various government officials, the federal government continues to strengthen its position on healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse. While we seek to conduct our business in compliance with all applicable laws, many of the regulations applicable to us, including those relating to billing and reimbursement of tests and those relating to relationships with physicians and hospitals, are vague or indefinite and have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our pricing and/or billing practices. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third party claims, all of which could have a material adverse effect on our business. Certain federal and state statues, regulations and other laws, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

During the mid-1990s, Quest Diagnostics and SBCL settled significant government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. The federal or state governments may bring additional claims based on new theories as to our practices that we believe to be in compliance with law. The federal government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 17% of our net revenues during 2006.

We understand that there may be pending qui tam claims brought by former employees or other "whistle blowers" as to which we have not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability. We are also aware of certain pending lawsuits related to billing practices filed under the qui tam provisions of the civil False Claims Act and other federal and state statutes, regulations and/or other laws. These lawsuits include class action and individual claims by patients arising out of the