fee-for-service claim transactions and our electronic fee-for-service remittance transactions. In September 2005, as part of HIPAA Administrative Simplification, HHS published a Notice of Proposed Rulemaking on Standards for Electronic Health Care Claims Attachments. We are commenting on this proposal through ACLA, our industry trade association, and final rule publication from HHS is not anticipated prior to mid-2006. Upon final rule publication, the implementation period for electronic health care claim attachments is anticipated to be two years at a minimum.

The HIPAA transaction standards are complex and subject to differences in interpretation by payers. For instance, some payers may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. We are working closely with our payers to establish acceptable protocols for claims submissions and with our industry trade association and an industry coalition to present issues and problems as they arise to the appropriate regulators and standards setting organizations.

**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 additional 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 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 some or all of a clinical laboratory's 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. In addition, the 2005 Physician Fee Schedule rule proposed to lower Medicare's payment rates for flow cytometry services in 2005. Quest Diagnostics believed that CMS failed to properly value these services and commented on this proposed change through ACLA. Pathology services are reimbursed by Medicare according to a Physician Fee Schedule based on a resource-based relative value scale, or RBRVS, that is periodically updated by CMS. On

November 21, 2005, CMS published its Final Physician Fee Schedule Rule (effective January 1, 2006) but did not implement any changes to the Practice Expense values in the new fee schedule, leaving the lower reimbursement for flow cytometry in place for 2006. In addition, the formula used for RBRVS calls for a 4.4% reduction in the 2006 payment level for physicians services, including anatomic pathology services payable to clinical laboratories. In February 2006, Congress eliminated the 4.4% reduction in the 2006 Physician Fee Schedule, keeping the reimbursement for physician services (including anatomic pathology services billed by clinical laboratories) unchanged from 2005. Approximately 1% of our net revenues are derived from pathology services reimbursed by Medicare based on RBRVS.

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 from participation in the Medicare program, including clinical laboratories, 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 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 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 allowed amount for clinical laboratory tests and would be required to bill Medicare beneficiaries for the 20% balance of the Medicare allowed amount. The co-payment provision was dropped from the bill as passed (known as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003). We cannot provide any assurances to investors that Congress would not seek to re-impose a copayment 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. 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 patients directly for some statutorily excluded clinical laboratory services. If a patient signs an advance beneficiary notice, or ABN, we are also generally permitted to bill patients 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. Although HHS has finalized a number of uniform test coverage/diagnosis coding policies, it has not taken any final action to replace the local carriers with five regional carriers.

**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 that mandated that the laboratory's "home" carrier maintain and apply the clinical laboratory fee schedule applicable to the carrier region where the 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 carriers to issue Medicare provider numbers to the billing laboratory. 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 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 has not made any final decisions on the RTI draft design, but was required to submit its initial report on the competitive bidding proposal by December 31, 2005. CMS' status report is currently in the clearance process at CMS and has not yet been submitted to Congress. The President's 2007 Budget Proposal presented in January 2006 included cost savings from competitive bidding for clinical laboratory services. The budget proposal did not contain substantive details. ACLA, the trade association for the clinical laboratory industry, issued a press release commenting negatively on the budget proposal. Quest Diagnostics and ACLA will monitor the design and implementation phase of the competitive bidding pilot and the Congressional reaction to the 2007 budget proposal. The diagnostic testing industry is concerned that the competitive bidding demonstrations or nation-wide expansion of competitive bidding will not take into account all of the factors involved in the timely delivery of high quality clinical laboratory testing to a broad range of clients in diverse geographic settings.

In December 2004, the State of Florida issued an Invitation to Negotiate (ITN) seeking competitive bids for the provision of clinical laboratory tests on a capitated-basis for some Medicaid recipients and on a reduced fee-for-service basis for other Medicaid recipients. The ITN contemplates that the Florida Medicaid Agency (AHCA) will negotiate with the three highest-scoring bidders for an exclusive statewide contract of at least three years plus a potential renewal period. ACLA, the industry trade association for clinical laboratories, filed two petitions with AHCA challenging the ITN on public policy and legal grounds. In addition, Quest Diagnostics and another large laboratory independently filed bid protests with AHCA. On February 18, 2005, AHCA announced, without further explanation, that it was withdrawing the ITN. AHCA has not yet reissued its ITN. 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 have personally, or through a family member, 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.

**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. 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 billing practices. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs and additional liabilities from third party claims. In addition, certain federal and state statues, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government or private payers 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 18% of our net revenues during 2005.

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. These lawsuits include class action and individual claims by patients arising out of the Company's billing policies. In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount.