any providers are permitted to be donors of e-prescribing or EHR items or services, then all providers should be entitled to the same protections afforded by the proposed safe harbor and self-referral prohibition exceptions.

We and ACLA, our trade association, are monitoring standards development, proposed legislation and rulemaking proceedings and we are providing relevant information to policy makers to ensure that issues important to medical laboratories are reflected in any interoperability standards, HCIT legislation and proposed regulations.

Privacy and Security of Health Information; Standard Transactions

Pursuant to HIPAA, the Secretary of HHS has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged. Three principal regulations have been issued in final form: privacy regulations, security regulations and standards for electronic transactions.

The HIPAA privacy regulations, which fully came into effect in April 2003, establish comprehensive federal standards with respect to the uses and disclosures of protected health information by health plans, healthcare providers and healthcare clearinghouses. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payment for our services and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information; and
- administrative, technical and physical safeguards required of entities that use or receive protected health information.

We have implemented practices to meet the requirements of the HIPAA privacy regulations. The HIPAA privacy regulations establish a "floor" and do not supersede state laws that are more stringent. Therefore, we are required to comply with both federal privacy standards and varying state privacy laws. In addition, for healthcare data transfers relating to citizens of other countries, we need to comply with the laws of other countries. The federal privacy regulations restrict our ability to use or disclose patient-identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the final privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

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. HHS issued guidance on July 24, 2003 stating that it would not penalize a covered entity for post-implementation date transactions that are not fully compliant with the transactions standards, if the covered entity could demonstrate its good faith efforts to comply with the standards. However, beginning October 1, 2005, CMS no longer processes incoming non-HIPAA compliant electronic Medicare claims.

Many of our payers were not ready to implement the transaction standards by the October 2003 compliance deadline or were not ready to test or trouble-shoot claims submissions. Since that time, significant progress has been made in implementing the transaction standards with our payers. As of December 31, 2005, we are substantially complete with the conversion to the required standard format for our electronic

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