

Medical Waste, Hazardous Waste and Radioactive Materials. Clinical laboratories are also subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and radioactive materials. We generally use outside vendors to dispose of such waste.

FDA. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has claimed regulatory authority over laboratory-developed tests, but has exercised enforcement discretion in not regulating most laboratory-developed tests performed by high complexity CLIA-certified laboratories. In December 2000, the Department of Health and Human Services, or HHS, Secretary's Advisory Committee on Genetic Testing recommended that the FDA be the lead federal agency to regulate genetic testing. In late 2002, a new HHS Secretary's Advisory Committee on Genetics, Health and Society, or SACGHS, was appointed to replace the prior Advisory Committee. In June 2004, SACGHS announced that its priorities included Overview of the Oversight of Genetic Technologies. Ultimately, SACGHS decided that it would continue to monitor the progress of the federal agencies in the oversight of genetic technologies, but it did not believe that further action was warranted. In the meantime, the FDA is considering revising its regulations on analyte specific reagents, which are used in laboratory-developed tests, including laboratory-developed genetic testing. FDA interest in or actual regulation of laboratory-developed tests or increased regulation of the various medical devices used in laboratory-developed testing could lead to periodic inquiry letters from the FDA and increased costs and delays in introducing new tests, including genetic tests. Representatives of clinical laboratories (including Quest Diagnostics) and the American Clinical Laboratory Association (our industry trade association), or ACLA, have communicated industry concerns to representatives of the FDA regarding potential FDA regulation of genetic testing in general and issues with regard to the impact of potential increased oversight over analyte specific reagents. We expect those discussions to continue.

Occupational Safety. The federal Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating specifically to workplace safety for healthcare employers. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through sharps or needle stick injuries.

Specimen Transportation. Transportation of most clinical laboratory specimens and some laboratory supplies are considered hazardous materials subject to regulation by the Department of Transportation, the Public Health Service, the United States Postal Service and the International Air Transport Association.

Corporate Practice of Medicine. Many states, including some in which our principal laboratories are located, prohibit corporations from engaging in the practice of medicine. The corporate practice of medicine doctrine has been interpreted in certain states to prohibit corporations from employing licensed healthcare professionals to provide services on the corporation's behalf. The scope of the doctrine, and how it applies, varies from state to state. In certain states these restrictions affect our ability to directly provide anatomic pathology services and/or to provide clinical laboratory services directly to consumers.

Healthcare Information Technology

Clinical laboratories use information technology to obtain laboratory orders and to communicate results and provide other laboratory reporting. Innovations in healthcare information technology, or HCIT, have the potential to improve patient care, promote efficiency and reduce expense. Both at the federal and state levels, there are public and private efforts to bring together healthcare providers, information technology vendors, and other stakeholders to coordinate federal healthcare information standards and develop a national healthcare network, including adopting standard code sets and developing standards for electronic interoperability (standards for the exchange and use of electronic healthcare data).

We and MedPlus, our HCIT subsidiary, could be impacted by any national healthcare information network and the adoption of standards for HCIT interoperability, because of substantial existing investments in software and hardware and the potential for having to make substantial future investments to comply with new or different standards. On October 11, 2005, as required by the MMA, the Office of the Inspector General, or OIG, published a proposed safe harbor to the federal anti-kickback statute and CMS published proposed exceptions to the Stark self-referral prohibition law that would permit certain providers other than clinical laboratories to provide e-prescribing items and services to physicians for free. If these regulations are adopted as proposed, certain providers would be able to provide broader packages of HCIT items or services than clinical laboratories which could create incentives for some customers to choose such providers. We are commenting on the proposed rules through our industry trade association, ACLA, reflecting our position that if

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