focus on proficiency testing, process audits, statistical process control and personnel training for all of our laboratories and patient service centers. We continue to implement our Six Sigma and standardization initiatives to help achieve our goal of becoming recognized as the undisputed quality leader in the healthcare services industry. Our Nichols Institute facility in San Juan Capistrano was the first clinical laboratory in North America to achieve ISO certification. Two of our clinical trials laboratories, our diagnostic kits facility and two of our routine laboratories are also ISO certified. These certifications are international standards for quality management systems.

Internal Proficiency Testing, Quality Control and Audits. Quality control samples are processed in parallel with the analysis of patient specimens. The results of tests on quality control samples are monitored to identify trends, biases or imprecision in our analytical processes. We also perform internal process audits as part of our comprehensive Quality Assurance program.

External Proficiency Testing and Accreditation. All of our laboratories participate in various external quality surveillance programs. They include, but are not limited to, proficiency testing programs administered by the College of American Pathologists, or CAP, as well as some state agencies.

CAP is an independent, non-governmental organization of board certified pathologists. CAP is approved by CMS to inspect clinical laboratories to determine compliance with the standards required by the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CAP offers an accreditation program to which laboratories may voluntarily subscribe. All of our major regional laboratories are accredited by CAP. Accreditation includes on-site inspections and participation in the CAP (or equivalent) proficiency testing program. "CAP whistle blower" hotline posters, which are used to escalate unresolved quality and laboratory safety concerns to CAP, are posted in all of our CAP accredited laboratories.

Regulation of Clinical Laboratory Operations

The clinical laboratory industry is subject to significant federal and state regulation, including inspections and audits by governmental agencies. Governmental authorities may impose fines or criminal penalties or take other actions to enforce laws and regulations, including revoking a clinical laboratory's federal certification, which is required to operate a clinical laboratory operation. Changes in regulations may (i) increase our operating costs including, but not limited to, those costs associated with performing clinical laboratory tests, and administrative requirements related to billing or (ii) decrease the amount of reimbursement related to testing services performed.

CLIA and State Regulation. All of our laboratories and (where applicable) patient service centers are licensed and accredited by the appropriate federal and state agencies. CLIA regulates virtually all clinical laboratories by requiring they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA does not preempt state laws that are more stringent than federal law. For example, state laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. 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 laboratory 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.

Drug Testing. The Substance Abuse and Mental Health Services Administration, or SAMHSA, regulates drug testing for public sector employees and employees of certain federally regulated businesses. SAMHSA has established detailed performance and quality standards that laboratories must meet to perform drug testing on these employees. All laboratories that perform such testing must be certified as meeting SAMHSA standards. All of our laboratories that perform such testing are certified as meeting SAMHSA standards.

Controlled Substances. The federal Drug Enforcement Administration, or DEA, regulates access to controlled substances used to perform drugs of abuse testing. To obtain access to controlled substances, laboratories must be licensed by the DEA. All of our laboratories that use controlled substances are licensed by the DEA.

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