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 facilitate the creation of healthcare information interoperability standards and a national healthcare network, including adopting standard clinical code sets and standards for healthcare information 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 and codes 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 and clinical coding systems. On August 8, 2006, the Office of the Inspector General, or 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 permitting various entities to provide e-prescribing items and services and electronic health records (EHR) items and services. Under the final rules, certain donors (but not laboratories) may provide e-prescribing items and services to referral sources at no charge, and a broader range of donors (including laboratories) may provide a broader range of HCIT items and services in return for a payment of fifteen percent (15%) of the donor's cost and compliance with other conditions.

We and ACLA, our trade association, continue to monitor standards development, proposed legislation and the rulemaking process. Through representatives on various industry work groups and governmental advisory bodies, 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 the Department of Health and Human Services ("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. 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.