STATE OF NEW YORK
DEPARTMENT OF HEALTH

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September 27, 2010

Dear Laboratory Owner/Operator:

Between 2011 and 2015, it is predicted that nationally 350,000 or more physicians will implement **electronic health record systems** (EHRs) for use in their daily practices. The rapid and widespread adoption of EHRs by both hospitals and physician practices is unprecedented, and creates several **challenges for clinical laboratories**. First, health care purveyors (e.g., medical practitioners such as physicians), will be likely to ask laboratories to pay for (donate) or contribute to the cost of the interface to client EHRs, Regional Health Information Organizations (RHIOs), or other qualified health information exchange entity as determined by the Department of Health. Second, practitioners may also ask laboratories to donate or cost-share up to 85% of the cost of new EHRs. Third, it will be critical for laboratories to employ adequate information technology staff to update laboratory information systems (LISs) and interface client EHRs, RHIOs, or other qualified entity with the laboratory's LIS.

The federal and New York State (NYS) governments are involved in a variety of efforts to encourage the use of health information technology. These initiatives include federal incentive payments and, in NYS, health information technology grants for interoperable EHR technology, as authorized by NYS's Healthcare Efficiency and Affordability Law (HEAL-NY). The Department's Office of Health Technology Transformation (OHITT) is actively involved in a variety of efforts to encourage the use of health information technology. Primary in this effort is the development of a Statewide Health Information Network for New York (SHIN-NY). This network will enable widespread interoperability among disparate systems, including LISs.

The Department has also become aware of **abusive business practices.** Specifically that clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner. This arrangement may influence the practitioner's choice of laboratory, rather than his or her relying on quality, timely access to results or the specific needs of patients. As such, these arrangements have the potential to adversely impact competition, reduce quality of services, and risk potential overutilization of health care services, resulting in unnecessary increased overall health care costs.

As you may know, the federal anti-kickback rule includes a *safe harbor* and the federal "Stark" law contains an exception under which a clinical laboratory may pay up to 85% of the cost of EHR technology, software and training, for a practitioner or group practice, if specific requirements are met. NYS rules do not allow cost sharing; therefore, **provision of EHR, software and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in NYS**. The preamble to the federal EHR regulations, published in the Federal Register on August 8, 2006, makes it clear that the 85:15 EHR-related federal payment allowance does not preempt State laws and/or regulations.

Laboratories should closely review the contents of this letter, as it reflects the Department's position on cost-sharing and providing EHR technology, at less than fair market value (FMV), by a laboratory to practitioners. Under existing NYS law, cost-sharing or donation of EHR software, information technology, and training services would be a violation of both NYS's laboratory business practices and physician self-referral prohibitions (Sections 587 and Title II-D of Article 2 the Public Health Law, respectively):

- The laboratory business practice regulations prohibit the provision by a laboratory to a health care purveyor (e.g., a medical practitioner), at less than fair market value, of any computers, including hardware, hard drives, monitors or software, unless the items are solely and exclusively used for, and are solely and exclusively dedicated to, enabling the physician to participate in specifically defined laboratory-related activities (See 10 NYCRR § 34-2.9). Accordingly, the donation to physicians of any computer system or functionality that exceeds laboratory-related interactions is prohibited.

- Under the health care practitioner referrals statute and regulations, a physician may not refer specimens to a laboratory in which the physician has a financial relationship, such as a compensation arrangement (See 10 NYCRR Subpart 34-1). Nonmonetary remuneration in the form of EHR hardware, software, information technology or training services by a laboratory to a referring physician would create a compensation arrangement under NYS law, and any referrals by the physician to the laboratory would be prohibited.

Therefore, clinical laboratories operating in NYS may not donate EHRs to physicians. However, they may provide limited types of software and hardware that facilitate test ordering and the transfer and storage of laboratory-generated data. For example, laboratories may:

1. Interface their LIS to the client's existing EHR to enable seamless laboratory test ordering and laboratory test reporting, and facilitate other laboratory-related functions (see bullet #2 below), and may assume, as a cost of doing business, the cost of such a limited interface;

2. Provide to a practitioner computer hardware, software, and information technology training and supplies that are restricted to laboratory-related functions that enable the practitioner to (i) order tests from the laboratory, including access to a directory of services (i.e., specimen type, collection container and test information); (ii) receive, access, print and store test results received from the laboratory, including store cumulative results for individual patients; (iii) transmit data necessary for the laboratory to prepare requisitions and generate bills, invoices or claims for reimbursement; and (iv) transfer laboratory data received from the laboratory to any computer system maintained by the practitioner;

3. Provide computer hardware and software as noted above that also contains functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals; and

4. Provide to a RHIO or HIE computer equipment and supplies, information technology, and software in accordance with the requirements in bullet #2 above. Laboratories may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's costs of participation unless in accordance with the requirements in bullet #2 above. Nothing in this bullet requires a laboratory to provide such EHR components to a RHIO or HIE for its participants.

Additionally, laboratories operating in NYS *must* retrieve all computer equipment placed with the health services purveyor and related unused supplies referenced in bullet #2 above, and discontinue paying for an interface upon termination of a laboratory services agreement with a practitioner, or arrange for a one-time purchase at FMV that transfers ownership of hardware and software to the practitioner. Laboratories have an obligation to remind practitioners that NYS rules prohibit their solicitation or receipt of consideration, in exchange for referring a person (i.e., a specimen) for laboratory services, even if the transaction is for other legitimate business purposes. In fact, under Education Law § 6530(18), it is professional misconduct for physicians to receive consideration for a referral; and under Social Services Law § 366-d and 18 NYCRR § 515.2(b)(5) it is illegal for a Medicaid provider to give or receive consideration for the referral of Medicaid services.

The majority of newly-installed EHRs feature the latest generation information technology with the capability to support HIPAA 5010 and ICD-10. Many laboratories continue to use LIS products that were purchased and installed many years ago, and may need to upgrade or switch their LIS to a version that is HIPAA 5010 and ICD-10 capable. This is likely to be an overlooked challenge created by mass adoption of EHRs. The Department asks for your commitment in meeting this challenge.

Our common goal -- interoperability and universal connectivity of EHRs -- cannot be realized when systems are deployed without consideration of their capability to function seamlessly with other systems. In this regard, please be reminded that any software or services must comply with the Statewide Policy Guidance and align with the federal regulations on meaningful use and certified EHR technology. Additional information may be accessed at http://www.nyehealth.org/index.php/resources/nys-policies.

As you know, the accurate diagnosis and treatment relies on laboratories for efficient and timely patient health information data exchange. Thank you for your continued cooperation in adapting your laboratories to the ever-changing health care environment.

Sincerely,

Rachel Block
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Technology Transformation

Betty Kusel
Director, Regulatory Affairs
Deputy Director, Division of
Laboratory Quality Certification
Wadsworth Center