Laboratory result reporting to caregivers falls under important regulatory and accreditation requirements. These requirements are intended to assure documentation of the source of the information, any supplemental information necessary for interpretation, and the circumstances that may affect the validity of the result. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) address the communication of laboratory data and place the responsibility on the laboratory director for ensuring that all required information be reported. The requirements can be readily satisfied if the data are directly reported by an in-house laboratory information system with pathologist oversight; however, when a distributed system involving an external electronic health record (EHR) is involved, ensuring that these requirements are met becomes a challenge.

### CLIA REGULATIONS FOR REPORTING

Specifically, under 42 CFR §493.1407 (e) (moderate complexity) and 42 CFR §493.1445 subparagraph (e)(8) (high complexity), all pertinent laboratory information required for interpretation must be provided in the test results report. Whether necessary for interpretation or not, the regulation also requires that the results report indicates the following:

1. Positive patient identification
2. Name and address of the performing laboratory
3. Test report date
4. Test performed
5. Specimen source, when appropriate
6. The test result and, as applicable, the units of measure-ment or interpretation, or both
7. When necessary, information on the condition and disposition of compromised specimens.

In addition, the performing laboratory must make “pertinent ‘reference intervals’ or ‘normal values’” available to the test orderer and the user of the results, if the two are different. The requirement, in this case, does not explicitly state that this latter information must be reported along with the result, but rather that the caregiver must have access to these values. However, under the Centers for Medicare and Medicaid Services’ interpretive guidelines for inspection of CLIA laboratories (State Operations Manual Appendix C), the state inspector is given the following probe question: “If the laboratory does not print normal ranges on the test report, how does the laboratory notify the client that reported results are abnormal for the patient due to their particular sex and/or age?”

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**Accreditation and Regulatory Implications**—Castellani et al

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- The Clinical Laboratory Improvement Amendments of 1988 include strict regulations for reporting content, and it falls on the named director to ensure that this content is available to the caregiver. With the electronic health record serving as the conduit to the end user of the laboratory data, the laboratory generally, and the director specifically, must verify accurate transmission of these content components. An understanding of regulatory and accreditation requirements is essential both to allow the proper discharge of these mandated responsibilities and to enforce the role and authority that the pathologist must have to ensure that these requirements are satisfied by the reporting system. The regulatory requirements will be discussed in the context of the Clinical Laboratory Improvement Amendments of 1988 standards; however, interpretation and expansion on these regulations exist both in Clinical Laboratory Improvement Amendments of 1988 inspection guidelines from the Centers for Medicare and Medicaid Services and in accreditation program requirements. This regulatory expectation both places the laboratory director in a position of risk and provides leverage to ensure meaningful and accurate communication of laboratory information.

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problematic if the laboratory director has little or no input on
the laboratory director beyond reporting systems under direct
control. Interfaced electronic reporting systems must display
the above information to the caregivers, and the laboratory
director must ensure compliance, even when the interfaced
software is owned and controlled by the caregivers.

Specifically, the CLIA regulations require that the laboratory
have "systems(s) in place to ensure test results and other
patient-specific data are accurately and reliably sent from
the point of data entry (whether interfaced or entered
manually) to final report destination, in a timely manner.
This includes . . . [r]esults and patient-specific data elec-
tronically reported to network or interfaced systems." 5

Direct laboratory reporting through the LIS has historically
allowed the laboratory director to oversee the format and
content of the information. With the advent of widespread adoption of EHR systems by caregivers, the
laboratory now has diminished control over the display of
these test results in the EHR systems. This significantly
affects both interpretation and display of specimen condi-
tion issues, abnormal value documentation, and data from
reference laboratories, which are often included as com-
ments or flags. Because the EHR becomes the default
reporting system for the clinician, clinical interpretation and
patient safety may be significantly affected if the display of
these supplemental pieces of information is under limited or
no control of the laboratory. Regardless of the degree of
control the laboratory can exercise over the display of its
data in the EHR, under CLIA, the laboratory director still
has responsibility for "ensur[ing] that transmitted reports
are legible and the information received at the final
destination was the same data sent by the laboratory"
(SOM D5801 §493.1291(a)). For send-out laboratory
results, CLIA requires that the referring laboratory not revise
results or information directly related to the interpretation of results.6

In the CLIA Interpretive Guidelines for state inspectors,
laboratory data received from outside sources, whether
manually entered into the LIS or electronically transmitted,
must be periodically verified for accuracy and timely reporting
(SOM D5801). For accreditation purposes, this requirement has been expanded to include a biennial review of the format
and completeness of all laboratory data. This review includes
flags, comments, and footnotes, all of which must be
transmitted correctly by the LIS to the EHR, where this
information must be displayed appropriately to allow for
correct, meaningful interpretation of the data. It is also
important, for documentation purposes, to have corrected
reports archived in the reporting system of record so that
diagnostic decision making associated with earlier reports can be
correlated. In the interpretive guideline for §493.1291(k)(2),
"[c]orrected reports, either hard copy or electronic, must
clearly indicate both the corrected result(s) and the fact that
the report is a corrected report" (SOM D5821 as modified by
Ref: S&C-10-12-CLIA). Meeting these requirements can be
problematic if the laboratory director has little or no input on
the ability of the EHR solutions to handle the data and is not
consulted on the display of laboratory results.

REPORTING THROUGH THE EHR

Most EHRs have limited capabilities to display results,8
and input from the laboratory is essential to ensure that the
design of the EHR display facilitates appropriate communi-
cation of both the primary data as well as their associated
information as required by law. Further, under the Health
Information Technology initiative of the Accountable Care
Act, modifications of CLIA7 have been implemented for
meaningful use (vide infra). This was done through changes in
the interpretive guidelines in the SOM, including
§493.1291(a), which states that “[r]egardless of the means
used to transmit laboratory results, routine checks should be
conducted to verify that transmissions are being accurately
and reliably conveyed to the final report destination. For
CLIA purposes, the final report destination for test results is
considered to be the authorized person or their designated
agent . . . ” (SOM D5801 as modified by Ref: S&C-10-12-
CLIA).7 The accreditation requirement from the College of
American Pathologists Laboratory Accreditation Program
establishes guidelines for these routine checks, which are not
further defined in the regulation.

In the context of data transmission to a hospital-based
EHR, the laboratory director (or a designee) must have
access to the hospital’s EHR or, at minimum, copies of
reports displayed in the EHR to compare against the original
data. This routine check requirement is made more difficult
when the laboratory data are transmitted to external EHR
systems, as obtaining the necessary documentation for
verification requires the assistance of the receiving client.
There currently is no requirement that a client receiving the
transmission assist with the verification, and the client may
feel that the effort to provide the necessary data represents
either a technical or financial burden without seeing any
obvious value in return. Getting client support for meeting
this requirement is especially problematic for reference
laboratories, but any laboratory serving outreach and
providing electronic data transfer may be challenged by
client unwillingness to assist with these routine checks. The
laboratory has the option of terminating its arrangements
with uncooperative clients; however, such a client will
merely transfer its business to a laboratory test provider that
will not require verification of data transmission. In the
absence of mandated coordinated approaches to laboratory
test validation procedures for EHRs, the laboratory is limited
to deciding what level of risk it is willing to accept with
clients who are unwilling to assist with verification of
accurate and reliable data transmission.

COMMINGLED DATA FROM MULTIPLE SOURCES
IN THE EHR

Further complicating the relationship between the labo-
ry director and the EHR is the need to display results
collated from different sources in a single EHR. Although
the laboratory usually serves as the conduit for send-out test
results that it refers, clinical services often wish to
incorporate (commingle) outside test data and possibly
even the results of at-home or point-of-care testing into the
patient record, which typically duplicates testing done by or
through the laboratory. Often, the desire is to display these
outside data in association with results produced by the
laboratory itself. This may be heightened by the recent
interoperability initiatives to create and use health information exchanges, where patient medical information is brought together to facilitate ongoing care. Commingling such data superficially appearing to be the same often does not take into account the differences between 2 laboratories’ test results or, in particular, differing interpretations in problematic cases. Often, the data display in EHRs will not provide clear differentiation of the origin of the result, and, even more troubling, the clinician typically is not aware of the differences that can arise when a sample or specimen is tested by 2 different methods or interpreted by 2 different pathologists (consider the high degree of variability between different methods for tumor markers or endocrine tests). The laboratory director may have no regulation-specified role in ensuring that commingled results are clinically consistent or that in-house laboratory results are separated from outside data entered by clinical services; however, if the EHR lacks the functionality to allow direct entry of test results, the laboratory may be asked to enter these “outside” results into the LIS so that they can be subsequently entered electronically into the EHR. In this situation, the laboratory director must be involved in the process; if the laboratory is accredited by the College of American Pathologists the laboratory director is required to review such situations (College of American Pathologists Laboratory General Checklist GEN.41077). Ideally, this review should occur in the design phase of implementing commingling data, rather than modifying the display of such data; the laboratory director would have much less impact on the completeness and display of these data if specific elements (such as laboratory source or source-specific reference range) are not required as elements when these outside data are entered into the patient’s EHR record.

RESULT REPORTING DIRECTLY TO PATIENTS

Pressure from both patients and federal legislation is pushing health care organizations and providers to furnish patients with access to electronic portals, allowing patients to actively participate in their own care. For the laboratory, this means that patients may wish to review their diagnostic test results and track results over time, or even enter the results from home testing such as blood glucose monitoring. This functionality does not exist in all EHRs, although many vendors have developed separate patient portals, and there are many patient portal products not directly associated with EHR development. Health care legislation is pushing toward more secure messaging capabilities between providers and patients, including the ability of patients to view all laboratory results electronically, and this presents a problem for laboratories in many states. A recent revision of CLIA in keeping with the Health Information Technology initiative of the Accountable Care Act initiative allows direct release of laboratory results to properly identified patients if allowed by state law. This modifies the original restriction of reporting results only to authorized persons and to individuals responsible for using test results. Thirty states permit results release only to licensed providers, either those who order the test or those who are authorized by the ordering provider to receive results, whereas 26 states and US territories have no definition of an authorized provider; these are identified as being impacted by this final rule. In contrast, 7 states allow provider-approved release to patients whereas 9 states define patients as persons authorized to directly receive results without requiring permission from the ordering provider (see Table 3 in CLIA Program and HIPAA Privacy Rule). This final rule, jointly issued by the Centers for Medicare and Medicaid Services, the Office of the National Coordinator, and the Office for Civil Rights, is intended to allow release of information directly to a properly identified patient from laboratories covered under the federal Health Insurance Portability and Accountability Act of 1996. Under the rule, the laboratory is responsible for providing the patient (or the patient’s “personal representative”) with completed test results within 30 days of the request. Patient portals are allowable if these give the patient access to all laboratory data and if the patient accepts the information in this format; however, the intent of the rule is to provide “an additional avenue for an individual to obtain test reports directly from laboratories.” The laboratory and the laboratory director have the responsibility to ensure that the report being provided contains the full completed result records, as this rule does not allow any test result exclusions from a patient’s request. The only flexibility allowed is the abovementioned 30-day delay in providing the report so that the ordering physician may have an opportunity to discuss this information with the patient. The patient also has the right to request that this information be provided in a specific format and, if this can be produced, to receive the report in that format. The commentary response in the rule gives only vague guidance as to the limits to which the laboratory must comply with the patient’s format request, but the laboratory is expected to reach an agreement with the patient if the report can be provided only in an alternate format.

MEANINGFUL USE AND THE FUTURE

Meaningful use, as described by the Centers for Medicare and Medicaid Services, includes the incorporation of laboratory data into the EHR, optionally as part of stage 1, but as a requirement in stage 2 of implementation. Aside from the CLIA requirements that must be met when reporting any data produced by the laboratory (as described in the Health Information Technology initiative of the Accountable Care Act revisions of the Medicare State Operations Manual), a significant concern is ensuring that the information is displayed in a way that allows for appropriate correlation, particularly in systems that receive laboratory data from multiple sources. The College of American Pathologists GEN.41077 checklist requirement for entry of outside data in the patient record requires that the laboratory director be aware of instances where multiple laboratory data sources are being commingled in the EHR patient record. Ideally, the laboratory director should ensure that the quality of the outside laboratory has been evaluated, that such data are displayed in the EHR with clear delineation of the source of each piece of laboratory data, and that issues such as methodologic differences in units of measurement and reference range will not cause confusion when clinicians interpret commingled data. However, this requirement is focused on a laboratory-hospital environment; it would be very difficult for the laboratory to dictate display requirements to outreach clients with independent EHR systems. Unfortunately, the issues with result integration are no less significant for these clients. Unless addressed by regulation, the laboratory may find itself unable to do more than ensure the accurate transmission of
its data to a recipient system, whereupon it loses all control of its use, interpretation, and integration.

CONCLUSION: IMPACT ON THE LABORATORY DIRECTOR

The CLIA and accreditation requirements identify the laboratory director as having ultimate responsibility for the quality and utility of the result reporting process. Anecdotally, issues with EHR laboratory reporting are not frequently cited in the College of American Pathologists’ Laboratory Accreditation Program, but this may represent a lower level of awareness and scrutiny of these requirements during inspections. With current federal initiatives intended to promote the electronic transfer and availability of laboratory data, familiarity with the technical and operational issues necessary to meet these goals is required, as the level of scrutiny is likely to rise. This is especially significant when primary reporting occurs through the EHR, because the CLIA regulations hold the laboratory director responsible for the completeness of the data in that system. Failure to comply with these regulatory requirements for laboratory result reporting, especially if deemed to place the patient at risk, commonly leads to a citation against the laboratory director for failure to fulfill the required duties described above. Although this appears to only put the laboratory director at risk for sanctions, including the inability to participate in the Medicare and Medicaid programs as a provider for 2 years, monetary penalties can also be levied against the health care institution per day of noncompliance.14 The risk to the patient and the penalties that this can incur should be used by the laboratory director to leverage authority over the display of laboratory results in the EHR to go along with the responsibility that the director position is given in the CLIA regulations. Equally important is the responsibility that the pathologist has to keep abreast of changes in these requirements: Centers for Medicare and Medicaid Services guidance transmittals, especially through the SOM, change CLIA more rapidly than the actual enforcement can be formally altered. As the landscape for electronically based patient care evolves, and as regulatory and accrediting agencies focus on overseeing these changes, pathologists and the laboratory must take ownership and must have the authority for ensuring that the information that is seen by the caregiver is correct, meaningful, and accurate.

References
2. Medicare and Medicaid Programs; Laboratory Requirements; Quality System for Nonwaived Testing; Postanalytic Systems; Standard: Test report, 42 CFR §493.1291 (c) (2010).