In this issue

Olea named executive director of Laboratory Accreditation program
Revised note aligns with CLIA, HIPAA changes; laboratories have until October 6 to comply
New: Waived testing requirements for critical access hospitals effective January 1, 2015
UnitedHealthcare recognizes Joint Commission laboratory accreditation in Florida
Standards Q&A: Documents needed for survey and Lab Central Connect requirements
Champions Oncology benefits from domestic, international reputation of Joint Commission
New: Standards BoosterPak on waived testing standards for all accreditation programs
Applications available for API laboratory student scholarships
CDC releases Ebola guidance on specimen collection for health care workers
New on the Web
See you there!

People

Olea named executive director of Laboratory Accreditation program
Stacy C. Olea, M.B.A., MT(ASCP), FACHE, has been appointed executive director of the Laboratory Accreditation program. Previously, Olea served as the laboratory field director and interim ambulatory field director at The Joint Commission since 2011.

How does your background and experience help in your job as executive director? I've worked at a variety of organizations, from critical access hospitals to large systems and freestanding laboratories, and I've also managed areas outside the laboratory, such as diagnostic imaging, sleep centers, and a plastic surgery center. These experiences have taught me that you need to take the time to really listen to what people are saying, you need to be creative in devising solutions, and that there is more than one way to do things right.

When should laboratorians contact you? I am always willing to explain The Joint Commission’s Laboratory Accreditation program and how it compares with other accreditors. If a lab has questions and they don’t know who to contact, they can start with me. If they are looking for a speaker, I can give presentations on Joint Commission accreditation and on issues such as competency, personnel qualifications and responsibilities, top noncompliance issues, and proficiency testing. I would also love to hear from labs about what we can do to help them.

What would you like laboratorians to know about The Joint Commission that they probably don’t know? They should know that The Joint Commission wants to inspire them to excel in providing safe and effective care of the highest quality and value. Accreditation is not just about the survey; we are in a partnership and we can help labs throughout the two-year cycle.

Olea can be reached at 630-792-5214 or solea@jointcommission.org.
Revised note aligns with CLIA, HIPAA changes; laboratories have until October 6 to comply
The Department of Health and Human Services (HHS) modified the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to give patients, or a person designated by the patient, a means of direct access to the patient’s completed laboratory test reports. As a result, The Joint Commission has revised Information Management standard IM.02.01.03, element of performance (EP) 5, Note 2, for laboratories: Test results are released only to authorized persons, the individual person(s) responsible for using the test results, and/or the laboratory that initially requested the test. The change (to “persons responsible”) is in the CLIA regulations at 42 CFR §493.1291(f) and is published in the spring 2014 E-dition® as well as the 2014 Update 1 to the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB). Joint Commission accredited laboratories have 240 days from CMS’ publication of the final rule (or until October 6, 2014) to comply with the revised CAMLAB requirement and survey process. For more information, see the June 11 issue of Joint Commission Online, the HHS news release or the CLIA memorandum.

New: Waived testing requirements for critical access hospitals effective January 1, 2015
New waived testing requirements that address policies, staff competency, quality control and documentation of test results will be effective January 1, 2015, for critical access hospitals. Because critical access hospitals offer many of the same services as small and rural hospitals, The Joint Commission determined that they should comply with the same standards to ensure patient safety and quality of care. The waived testing requirements will be included in the new Waived Testing (WT) chapter in the Comprehensive Accreditation Manual for Critical Access Hospitals that will appear in the fall 2014 E-dition® update as well as 2014 Update 2.

UnitedHealthcare recognizes Joint Commission laboratory accreditation in Florida
Effective October 1, 2014, Joint Commission accredited laboratories will be recognized as meeting UnitedHealthcare’s requirements for complex pathology tests. The requirements are published in the UnitedHealthcare Laboratory Benefit Management Program Administrative Protocol.

Documents needed for survey and Lab Central Connect requirements
Q. What information and documentation does my laboratory need to have ready for the survey? Do we need to update any information in Lab Central Connect?

A. There are a number of documents your laboratory should have ready for the survey. These include:
   • Name of key contact person who can assist in planning tracer selections
   • Clinical Laboratory Improvement Amendment (CLIA) certificates, specialties and subspecialties, state licenses, and personnel license or certification, if required by the state or organization policy
   • An organizational chart and map of the facility (include all CLIA required roles)
   • Ability to retrieve testing records for patients who have had laboratory tests or other services for the past 24 months (four months if an initial survey)
   • Performance improvement data for the past 24 months (four months if an initial survey)
   • Proficiency data by CLIA number for the past 24 months
   • Results of periodic laboratory environment inspections from the safety committee or safety officer
   • Manifests for the disposal of hazardous waste for the past 24 months (four months if an initial survey)
   • A list of tests performed (test menu) and instruments used including all ancillary and point of care sites
   • Employee personnel files
   • Validations for all tests and instruments added since your last survey
In addition, your lab is required to upload certain information into Lab Central Connect, a customized portal for Joint Commission accredited laboratories, including:

- Personnel: Laboratory director, technical supervisor (high complexity only), general supervisor (high complexity only), technical consultant (moderate complexity only), clinical consultant (both high and moderate)
- Test systems: List of all tests performed along with their specialty and level of complexity.
- Cytology workload and annual statistics: Upload your cytology workload (gynecological and non-gynecological for all primary screeners) and your lab’s annual cytology statistics.
- Indicate whether your laboratory accepts referral testing. This assists The Joint Commission in identifying the applicable state regulations for your laboratory.

For more information, see:

- 2014 Survey Activity Guide
- Preparing for Your Survey: How to get started, tips to prepare and resources available
- Joint Commission Lab Central Connect Important Information Checklist
- Lab Central Connect Frequently Asked Questions
- Lab Central Connect Helpful Hints

**Organization spotlight**

**Champions Oncology benefits from domestic, international reputation of Joint Commission**

Keren Paz, Ph.D., chief scientist, Personalized Oncology Solutions at Champions Oncology, Inc., Hackensack, New Jersey, discusses the benefits of Joint Commission laboratory accreditation.

Champions Oncology, which has a freestanding Joint Commission accredited laboratory, provides Personalized Oncology Solutions (POS) to oncologists by generating personalized TumorGraft models and performing drug sensitivity testing to assist in tailoring patient treatment.

**Why did your laboratory choose Joint Commission accreditation?**

Champions Oncology is always looking for ways to improve service, increase the proficiency of tests, and the competency of technicians. Guidance from The Joint Commission helped us meet those goals.

**How has Joint Commission accreditation assisted you in improving the services you provide?**

Suggestions provided during the on-site visit made our sample tracking and reports easier to handle. In addition, the support provided by The Joint Commission’s central office and the regulatory guidance have been very useful for our organization.

**What are the key benefits of Joint Commission accreditation?** Joint Commission accreditation is very prestigious. Together with federal recognition and recognition from different state departments of health (e.g., Maryland, New York and California), it adds to the reputation of Champions when dealing with government organizations in the U.S., as well as in other countries.

**Resources**

**New: Standards BoosterPak on waived testing standards for all accreditation programs**

A new Standards BoosterPak™ on waived testing is now available on The Joint Commission Connect™ extranet. Waived testing is the most common regulated testing performed by caregivers at the patient bedside or point of care. By law, waived tests should have insignificant risk of erroneous results, however, these tests are not completely error proof, and some can result in serious patient harm if performed incorrectly. The BoosterPak, applicable to all accredited organizations in which waived testing is
performed, provides regulatory requirements, implementation expectations, strategies for compliance, and links to additional resources.

**Applications available for API laboratory student scholarships**

Applications are available for the American Proficiency Institute (API) Scholarship Program. In its seventh year, the API program will award five scholarships totaling $10,000 to medical laboratory science students in 2014. Interested students should complete the application and submit it to their program director for a statement of support and signature. Program directors must submit the completed applications to API by November 17, 2014. The Joint Commission collaborates with API and the American Society for Clinical Pathology (ASCP) as part of Lab Advantage, a collaborative effort of three nationally known programs in the areas of accreditation, education and proficiency testing. The goal of the Lab Advantage program is to help labs of any size receive critical services in an efficient, value-added program that is customized to fit their organization’s specific needs.

**CDC releases Ebola guidance on specimen collection for health care workers**

The Centers for Disease Control and Prevention (CDC) has released Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease (EVD). Potentially infectious diagnostic specimens are routinely handled and tested in U.S. laboratories in a safe manner by following these standard safety precautions. Visit the CDC website for the latest information on EVD.

**New on the Web**

- Seeking Laboratory Accreditation
- Resources for Accredited Laboratory Customers
- Laboratory Services Standards Information
- Laboratory Proficiency Testing
- From Joint Commission Resources (JCR): Order by visiting the JCR Store or calling 877-223-6866:
    - Accredited price, $149. List price, $186.

**See you there!**

Stacy C. Olea, M.B.A., MT(ASCP), FACHE, executive director, Laboratory Accreditation, The Joint Commission, will present a three-hour workshop at The Blood Center meetings on October 7 in the Clarion Hotel in Covington, Louisiana, and October 8 at the Four Points Sheraton in Metairie, Louisiana. “The Joint Commission Laboratory Accreditation Program and Our Most Challenging Standards” will:

- Describe The Joint Commission laboratory accreditation process
- Provide tips on preparing for a Joint Commission laboratory survey
- Explain how to do mock tracers
- List The Joint Commission’s most challenging standards
- Identify ways to bring a lab into compliance with the most challenging standards

The workshops are $25. To register go to The Blood Center website.