DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Ref: S&C-09-35 EXPIRED

DATE: December 4, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Clinical Laboratory Improvement Amendments (CLIA) --Impact of A/H1N1 Swine Flu on CLIA Operations

Memo Information:
Memo expiration date: **2025-12-04**
Original release date: **2009-05-06**

Memorandum Summary

- **Delay of Public Health Laboratory (PHL) Surveys:** The Centers for Medicare & Medicaid Services (CMS) has agreed to delay routine surveys of State PHLs temporarily, unless there is immediate jeopardy to patient health and safety, until May 15, 2009, at which time we will re-assess this determination.
- **Suspended Influenza Proficiency Testing (PT) for One Event:** CMS has notified the PT Programs with viral antigen modules which contain testing for influenza A that these should be suspended until May 15, at which time this decision will be re-assessed. Laboratories subject to PT for viral flu testing have discretion regarding their participation for this event.
- **Guidance from Centers for Disease Control and Prevention (CDC) for Swine Flu Testing, Specimen Collection, and Processing:** Information regarding this testing can be found at the following link: http://cdc.gov/h1n1flu/specimencollection.htm. Clinicians and laboratories should monitor this site regularly for additional information and updates on testing protocols, etc.
- **Food and Drug Administration (FDA) Information on Emergency Use Authorized (EUA) Swine Flu Test:** Information regarding the CDC-developed presumptive test utilized by PHLs and the FDA-cleared test for swine flu can be found on the FDA Web site at: http://www.FDA.gov/oc/opacom/hottopics/H1N1Flu/

Survey Delays

Significant workload increases with a short turnaround in State PHLs due to the A/H1N1 (swine flu) have lead the Association of Public Health Laboratories (APHL) to appeal to CMS to temporarily delay routine biennial surveys of the 77 laboratories involved in this testing while the bolus of this work is completed. CMS agreed to delay these surveys until May 15, 2009, at which time we will re-evaluate. We will re-assess this delay until the immense workload incurred by these laboratories due to the A/H1N1 swine flu outbreak has diminished to a manageable size.

However, if there is immediate jeopardy to patient health and safety, then the survey should proceed timely with a minimum of disruption to the laboratory in the areas where the flu testing is occurring.

Proficiency Testing (PT) Deferral

CMS is also responding to the concerns about a diminishing supply of test kits for influenza A screening for patients. Toward that end, we are suspending a PT event for PT programs that include challenges for influenza A viral testing and discretion for laboratories that are subject to PT for these tests. The language provided to the PT Programs is included here for your information and if you should receive any inquiries.

> "CMS is allowing certain regulatory activities related to the recent influenza A (H1N1) virus outbreak to be suspended. These suspensions will be allowed through May 15, 2009.
>
> The Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, in keeping with our agency's direction, will not impose certain requirements for the next testing event for viral antigen modules that include the need to test for influenza A. The regulatory requirements for any modules scheduled to be shipped after the May 15 date will be addressed prior to that date.
>
> For your participants this means each laboratory may decide whether to test the PT samples for the next event or reserve their influenza A test kits for any unexpected increase in patient testing.
>
> *If a participant decides not to test the PT samples and/or leaves the results blank, please use reason code #8, "Excused Participation" and assign a score of 100% when submitting PT data to the CMS PT monitoring system."*

Helpful Web sites

Lastly, Web sites for CDC and FDA regarding sample collection and testing protocols and more specific test information are provided in this memo summary and they should be routinely checked for updates by States, regions, and laboratory professionals.

We appreciate your cooperation and assistance during this public health situation and encourage you to follow the HHS Guidance for Employees to ensure your health and safety and that of your family, peers and the laboratories we oversee until this circumstance has concluded.

Contact:

For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

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