



**June 25, 2021**

TO: Oregon Clinical Laboratory

FROM: Stephanie Ringsage, Manager 503-693-4126  
Laboratory Compliance/ CMS CLIA State Agency

RE: **Announced/Unannounced CMS CLIA Surveys**

It has come to our attention that there are questions about the CMS CLIA survey process. Be advised this document provides in brief the survey process for Announced/Unannounced CMS CLIA Surveys. The CLIA Oregon State Agency (SA) makes determinations of compliance with CLIA requirements based on survey findings. Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced surveys, but it is generally CMS's policy to use announced surveys. For clarification, there are two types of surveys:

- **Unannounced Surveys**
  - Complaint or revisit surveys must be conducted on an unannounced basis.
  - For either an initial CLIA survey or recertification CLIA survey, an unannounced survey may be performed after one appointment is cancelled by the laboratory.
- **Announced**
  - For announced surveys, we allow up to two weeks' notice.
  - Laboratory will be called to set up an agreed mutually acceptable date and time
    - Written letter of confirmation of the agreed date and time will be sent via mail or emailed
    - Letter to include the required documents to be readily available for surveyor review, to reduce survey time and unnecessary disruption to staff and patients. **Please read completely upon receipt of Presurvey Letter.**

The survey protocol will be the same whether this is an announced or unannounced survey. The following process must be in place prior to allowing a surveyor access to your laboratory or facility.

Upon arrival, surveyors are to present the following:

- Appropriate identification -
  - Oregon State photo ID or Federal photo ID
  - Oregon State business card or Federal business card
- Letter with Authority to Review, Use or Disclose Individually Identifiable Health Information as a Health Oversight Agency- this letter serves as Authorization to review PHI.
- Surveyor to Request pertinent staff members to join in the entrance interview to inform the facility's administrator, director or supervisor of the purpose of the survey, if this is an initial survey, a recertification survey, validation survey or a Complaint and explain the survey process for that type of survey.

**If the visitor fails to provide the appropriate verification you may call Stephanie Ringsage at 503-693-4126 to confirm the**

- ✓ **identity of individual representing as a CMS Federal and or SA Surveyor and the**
- ✓ **purpose of the site visit.**

**It is highly recommended you implement the established security procedures for your facility if the identity of the individual and the purpose of the visit is not confirmed.**