
D8100

Subpart Q--Inspection

§493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in §493.1773 and the specific requirements for its certificate type, as specified in §§493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§493.1773 and 493.1780, when applicable.

D8101

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.

Interpretive Guidelines §493.1773(a)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- *Explain your authority to conduct the survey and the consequences of failure to permit a survey;*
- *If necessary, consult with your supervisor or the RO; and*
- *For failure to permit entry into or on inspection of the laboratory, use D8101.*

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures and the Adverse Action Procedures in the SOM.

Conduct complaint surveys on an unannounced basis. All other surveys should be announced. See the policy for announcing surveys in the SOM.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible; accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

D8103

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA

certificate and CLIA-exempt laboratories.

(b) General requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

Interpretive Guidelines §493.1773(b)-(c)

The regulations do not require a laboratory to maintain records on-site. During the survey, the laboratory must be able to retrieve copies of all records and necessary information upon request. Determine what constitutes a reasonable timeframe based on the information requested.

- (b)(1) Test samples, including proficiency testing samples, or perform procedures.**
- (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.**
- (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).**
- (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:**
 - (b)(4)(i) Specimen procurement and processing areas.**
 - (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports.**
 - (b)(4)(iii) Testing and reporting areas.**
- (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.**
- (c) Accessible records and data.** A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.
- (d) Requirement to provide information and data.** A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

D8105

§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

Interpretive Guidelines §493.1773(e)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- *Explain your authority to conduct the reinspection and the consequences of failure to permit a survey;*
- *If necessary, consult with your supervisor or the RO; and*
- *For failure to permit entry into or on inspection of the laboratory, use D8101.*

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures and the Adverse Action Procedures in the SOM.

Conduct complaint surveys on an unannounced basis. All other surveys should be announced. See the policy for announcing surveys in the SOM.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

(f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

Interpretive Guidelines §493.1773(f)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- *Explain your authority to conduct the inspection and the consequences of failure to permit a survey;*
- *If necessary, consult with your supervisor or the RO; and*
- *For failure to permit entry into or on inspection of the laboratory, use D8101.*

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures and the Adverse Action Procedures in the SOM.

Conduct complaint surveys on an unannounced basis. All other surveys should be announced. See the policy for announcing surveys in the SOM.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

(g) Failure to permit an inspection or reinspection. Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

Interpretive Guidelines §493.1773(g)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- *Explain your authority to conduct the survey and the consequences of failure to permit a survey;*
- *If necessary, consult with your supervisor or the RO; and*
- *For failure to permit entry into or on inspection of the laboratory, use D8101.*

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures and the Adverse Action Procedures in the SOM.

Conduct complaint surveys on an unannounced basis. All other surveys should be announced. See the policy for announcing surveys in the SOM.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

§493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

Interpretive Guidelines §493.1775(a)

To cite deficiencies related to an inspection of a laboratory holding a certificate of waiver or a certificate of provider performed microscopy procedures, use D8100, D8101 and D8103, as appropriate.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

Interpretive Guidelines §493.1775(b)

In any laboratory holding a CLIA certificate, tests listed on the waived list are not subject to routine surveys. A survey for waived tests may be conducted only when authorized by the RO in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

- (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.**
- (b)(2) Evaluate a complaint from the public.**
- (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.**

Interpretive Guidelines §493.1775(b)(3)

When a laboratory has failed to obtain a registration certificate before performing and reporting patient results for non-waived testing, notify the RO of a possible action by the Office of the Inspector General (OIG) if the laboratory does not obtain the appropriate certificate or cease the non-waived testing.

- (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.**
- (c) The laboratory must comply with the basic inspection requirements of §493.1773.**

§493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) Initial inspection.

Interpretive Guidelines §493.1777(a)

If for any reason a facility denies entry to or does not permit you to conduct a survey, take the following steps:

- *Explain your authority to conduct the survey and the consequences of failure to permit a survey;*
- *If necessary, consult with your supervisor or the RO; and*
- *For failure to permit entry into or an inspection of the laboratory, use D8101.*

If the laboratory continues to refuse a survey refer to Subpart R – Enforcement Procedures and the Adverse Action procedures beginning at §493.6300 of the SOM.

(a)(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.

(a)(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) Subsequent inspections.

(b)(1) CMS or a CMS agent may conduct subsequent inspections on a biennial basis or with such other frequency as CMS determines to be necessary to ensure compliance with the requirements of this part.

(b)(2) CMS bases the nature of subsequent inspections on the laboratory's compliance history.

Interpretive Guidelines §493.1777(b)

In any laboratory holding a CLIA certificate, tests listed on the waived list are not subject to routine surveys. A survey for waived tests may be conducted only when authorized by the RO in one of the following instances:

- *To collect information on waived tests;*
- *To determine whether the laboratory is testing beyond its certificate;*
- *If a complaint is alleged; or*
- *You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.*

When authorized to perform a survey of waived tests, in addition to the requirements in

this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

(c) Provider-performed microscopy procedures. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) Compliance with basic inspection requirements. The laboratory must comply with the basic inspection requirements of Sec. 493.1773.

D8401

§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) Validation inspection. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

Interpretive Guidelines §493.1780

Validation surveys of accredited laboratories will be conducted by the State survey agencies. Refer to special procedures for accredited laboratories in the SOM. The RO is responsible for conducting validations of CLIA-exempt laboratories.

(b) Complaint inspection. CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

Interpretive Guidelines §493.1780(b)

In any laboratory holding a CLIA certificate, tests listed on the waived list are not subject to routine surveys. A survey for waived tests may be conducted only when authorized by the RO in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as

much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(c)(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.

(c)(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.