Issue Brief

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CMS Issues Proposed Rule Addressing CLIA Fees; Histo-compatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule regarding the ***Clinical Laboratory Improvement Act*** of 1988(CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.

A copy of the 138-page document is available at: https://public-inspection.federalregister.gov/2022-15300.pdf. The proposal is scheduled for publication on July 26. A 30-day comment period is provided.

CLIA requires the Secretary to impose two separate types of fees: "certificate fees" and "additional fees." Certificate fees are imposed for the issuance and renewal of certificates and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of non-accredited laboratories and for the cost of evaluating accredited laboratories to determine overall if an accreditation organization's standards and inspection process are equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines relevant, which may include the total test volume and
scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

COMMENT

Another rule without a table of contents. We are adding selected page numbers (in red).

This proposed rule increases certain CLIA Fee requirements and will affect approximately 265,335 clinical laboratories, resulting in some budget implications.

CMS says that: (Page 103)

1. CLIA Fees

"Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees."

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4712 Country Club Drive
Jefferson City, Mo. 65109

P.O. Box 60
Jefferson City, Mo. 65102

573/893-3700
www.mhanet.com

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MISSOURI HOSPITAL ASSOCIATION

2. Histocompatibility, Personnel, Alternative Sanctions

"CMS estimates that the cost to laboratories, accrediting organizations, and exempt states to comply with the changes proposed would range between $11,421,708 and $16,983,208 in 2020 dollars for the first year and between $629,200 and $1,635,545 in subsequent years. Although the proposed changes will increase laboratory costs, implementation of these changes, if finalized, streamline and simplify regulations, add flexibility in laboratory hiring practices, ensure that the laboratory director (LD) is on-site at least twice per year, and align histocompatibility testing with current methods and practices. These changes will also allow alternative sanctions to be imposed on CoW laboratories."

Proposed Changes to Histocompatibility Requirements (Page 36)

Below are some of the changes CMS is proposing;

- At § 493.1278(a)(1), CMS is proposing to amend the requirement by changing "an audible alarms system" to "a continuous monitoring and alert system."
- At § 493.1278(a)(2), CMS is proposing to modify the requirement by expanding the regulatory language to include that the laboratory must establish and follow written policies and procedures for the storage and retention of patient specimens based on the specific type of specimen because the type and duration of specimen storage are equally important as ease of retrieval.
- At § 493.1278(a)(3), CMS is proposing to delete the labeling requirement for in-house prepared typing sera reagent requirement.
- At § 493.1278(a)(4), CMS is proposing to remove the examples (that is, antibodies, antibody-coated particles, or complement) to clarify that these technologies, as well as current and future technologies, are allowed for the isolation of lymphocytes or lymphocyte subsets.
- At § 493.1278(b)(5)(i) through (iv), CMS is proposing to delete the requirements for preparation of cells or cellular extracts, selecting typing reagents, ensuring that reagents used for typing are adequate, and assignment of Human leukocyte antigen (HLA) antigens as they are already addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, and 493.1252, and therefore, are duplicative.
- At § 493.1278(c), CMS is proposing to delete the requirement for control procedures and materials regarding disease related studies because this is addressed by the general requirements for all test systems under §§ 493.1256(d) and 493.1451(b)(4), and therefore, is duplicative.
- At § 493.1278(d)(1) through (3) and (5) through (7), CMS is proposing to delete requirements for antibody screening laboratory procedures as they are addressed by the general requirements for all test systems under §§ 493.1445(e)(1) and (e)(3)(i), 493.1251, 493.1252, and 493.1256, and therefore, are duplicative.

Proposed Changes to Personnel Requirements

1. ***Definitions (§ 493.2)*** (Page 42)
   - At § 493.2, CMS is proposing to amend the definition of midlevel practitioner by adding a nurse anesthetist and clinical nurse specialist to the definition.
   - At § 493.2, CMS is proposing to add a definition for "Continuing

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education (CE) credit hours" to state that it means either continuing medical education (CME) or continuing education (CE) units.

- At § 493.2, CMS is proposing to add a definition for "doctoral degree" to state that it means an earned post-baccalaureate degree with at least 3 years of graduate-level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology.
- At § 493.2, CMS is proposing to add a definition for "Laboratory training or experience" to state that it means that the training or experience must be obtained in a facility that meets the definition of a laboratory under § 493.2 and is not excepted from CLIA under § 493.3(b).

2. PPM laboratory director responsibilities (§ 493.1359) (Page 51)

- At § 493.1359, CMS is proposing to clarify the competency assessment (CA) requirements for Provider Performed Microscopy (PPM) laboratories in the Standard for PPM laboratory director (LD) responsibilities, as this testing is moderate complexity per § 493.19(b)(2) and subject to CA.

3. Laboratory director qualifications (§ 493.1405) (Page 53)

- At §§ 493.1405(b)(1)(ii), 493.1411(b)(1)(ii), 493.1443(b)(1)(ii), and 493.1449, CMS is proposing to remove "or possess qualifications that are equivalent to those required for such certification."
- At §§ 493.1405(b)(2)(ii)(C) and 493.1443(b)(2)(i), CMS is proposing to remove the residency provision.
- At § 493.1405(b)(3), CMS is proposing to revise paragraph (b)(3)(ii) to include an educational option that includes a qualification algorithm for an individual that does not have an earned doctoral degree in a chemical, biological, or clinical laboratory science or medical technology.

4. Laboratory director qualifications on or before February 28, 1992 (§ 493.1406) (Page 63)

- At § 493.1406, CMS is proposing to remove the grandfather provision as they had to have been met by February 28, 1992.

5. Laboratory director responsibilities (§ 493.1407) (Page 63)

- At §§ 493.1407(c) and 493.1445(c), CMS is proposing to revise the requirements so that the LD must be on-site at the laboratory at least once every 6 months, with at least a 4-month interval between the two on-site visits. However, laboratory directors may elect to be on-site more frequently.

6. Technical consultant qualifications (§ 493.1411) (Page 66)

- CMS is proposing to amend § 493.1411(b)(1)(ii) by removing "or possess qualifications that are equivalent to those required for such certification."

7. Testing personnel qualifications (§ 493.1423) (Page 68)

8. Laboratory director qualifications (§ 493.1443) (Page 69)

9. Laboratory director responsibilities (§ 493.1445) (Page 71)

10. Technical supervisor qualifications (§ 493.1449) (Page 71)

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Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

11. General supervisor qualifications (§ 493.1461) (Page 72)

12. General supervisor qualifications on or before February 28, 1992 (§ 493.1462) (Page 72)

13. General supervisor responsibilities (§ 493.1463) (Page 72)

14. Cytotechnologist qualifications (§ 493.1483) (Page 73)

- At §§ 493.1483(b)(2) and 493.1489(b)(2)(ii)(B)(1), CMS is proposing to replace "CAHEA" with CAAHEP (Commission on Accreditation of Allied Health Education Programs) and to remove, "or other organization approved by HHS."

15. Testing personnel qualifications (§ 493.1489) (Page 73)

16. Technologist qualifications on or before February 28, 1992 (§ 493.1491) (Page 74)

17. Proposed removal of earned degree in physical science as an educational requirement (Page 74)

- At §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489, CMS is proposing to remove "physical science" and add a new educational requirement for the ability to qualify based on semester hours.

18. Clinical Laboratory Science and Medical Technology (Page 75)

- At §§ 493.1405(b)(3) and (b)(5)(i), 493.1411(b)(4) and (6), 493.1443(b)(3)(i), and 493.1449(c)(3)(i), (c)(5)(i), (d)(3)(i), (d)(5)(i), (h)(2)(i), and (i)(2)(i), CMS is proposing to remove any text referring to "medical technology" degrees and replace such text with references to degrees in "clinical laboratory science and medical technology" so that the latter phrase appears consistently throughout subpart M.

FINAL COMMENT

We have not added a number of specific changes to several section heads above. Many of the changes being proposed are technical in nature. Those impacted by these items need to review the proposal itself.