

the Clinical Laboratory Improvement Amendments of 1988—the example of pediatric office-based cholesterol screening.” *Pediatrics* 96, 2 (1995), pp. 230–234.

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List of Subjects in 42 FR Part 493

Grant programs—health, Health facilities, Incorporation by Reference, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV part 493 as set forth below:

PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), and the sentence following 1395x(s)(11) through 1395x(s)(16)).

Subpart A—General Provisions

2. In § 493.2, the introductory text is republished, and the following definitions are added in alphabetical order to read as follows:

§ 493.2 Definitions

As used in this part, unless the context indicates otherwise—

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Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system’s calibration throughout the reportable range for patient test results.

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FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use. Unless otherwise stated,

this includes test systems exempt from FDA premarket clearance or approval.

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Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

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Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

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§ 493.3 [Amended]

3. Amend § 493.3, as follows:

a. In paragraph (b)(3), remove the words “National Institutes on Drug Abuse (NIDA)” and add, in their place, the words “Substance Abuse and Mental Health Services Administration (SAMHSA)”.

b. In paragraph (b)(3), remove the word “NIDA” and add, in its place, the word “SAMHSA”.

§ 493.20 [Amended]

3a. Amend § 493.20, as follows:

a. In paragraph (b), remove the reference to “subpart P”.

b. In paragraph (b), remove the cross reference to “§ 493.1777” and add, in its place “§§ 493.1773 and 493.1777”.

c. In paragraph (c), remove the cross reference to “§§ 493.15(e) and 493.1775” and add, in its place, “§§ 493.15(e), 493.1773, and 493.1775”.

§ 493.25 [Amended]

4. Amend § 493.25 as follows:

a. In paragraph (b), remove the reference to “subpart P”.

b. In paragraph (c), remove the reference to “subpart P”.

c. In paragraph (c), remove “§ 493.1777” and add, in its place, “§§ 493.1773 and 493.1777”.

d. In paragraph (d), remove the reference to “subpart P”.

e. In paragraph (d), remove the cross reference to “§§ 493.15(e) and 493.1775” and add, in its place, “§§ 493.15(e), 493.1773, and 493.1775”.

Subpart C—Registration Certificate, Certificate for Provider-Performed Microscopy Procedures, and Certificate of Compliance

§ 493.43 [Amended]

6. In § 493.43(a), remove the words “tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests,” and add, in their place, the words “nonwaived testing”.

§ 493.45 [Amended]

7. In § 493.45(c)(3), remove the reference to “subpart P”.

§ 493.47 [Amended]

8. Amend § 493.47 as follows:

a. In paragraph (c)(2), remove the reference to “subpart P”.

b. In paragraph (c)(3), remove the cross reference to “§ 493.1776” and add, in its place, “§§ 493.1773 and 493.1775”.

§ 493.49 [Amended]

9. In § 493.49(a)(3), remove the reference to “subpart P”.

Subpart F—General Administration

§ 493.643 [Amended]

10. In § 493.643(c)(3)(ix), add the word “Clinical” before the word “Cytogenetics”.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

11. Revise the heading of Subpart H to read as set forth above.

§ 493.801 [Amended]

12. In § 493.801(a)(2)(ii), remove the cross reference to “§ 493.1709” and add, in its place, “§ 493.1236(c)(1)”.

§ 493.803 [Amended]

13. In § 493.803(a), remove the words “tests of moderate complexity (including the subcategory) and/or high complexity” and add, in their place, the words “nonwaived testing”.

§ 493.807 [Amended]

14. Revise the heading of § 493.807 to read as follows:

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

15. Revise the heading of subpart I to read as set forth above.

§§ 493.911, 493.913, 493.915, 493.917, 493.919, 493.923, 493.927, 493.931, 493.933, 493.937, and 493.941 [Amended]

16. In §§ 493.911(c)(1), 493.913(c)(1), 493.915(c)(1), 493.917(c)(1), 493.919(c)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), and 493.941(c)(1), remove “90 percent” and add, in its place, “80 percent” wherever it appears.

§ 493.945 [Amended]

17. In § 493.945(a)(1), remove “§ 493.1257” and add, in its place,