

Organization of the CLIA

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CLIA = 42 CFR 493

- Code of Federal Regulations (CFR)
- Title 42 – Public Health
- Part 493 – Laboratory Requirements
- Subparts (13)
 - A, B, C, D, E, F, H, I, J, K, M, Q, R
- Section – Each Subpart has a series of sections.

42 CFR 493 Sections

- Each Section is segregated into paragraphs
- Paragraphs are subdivided as follows-
 - (a), (b), (c)
 - (1), (2), (3)
 - (i), (ii), (iii)

Read Together

- Title Section Paragraph Subparagraph
- 42CFR 493. 1405 (a)(1)(i)

Subparts and Descriptions

- Subpart A
 - General Provisions –
 - §493.1- .493.25
 - Definitions, Test Complexity
- Subpart D –
 - Certificate of Accreditation –
 - §493.55 – 493.63
 - Description, requirements for obtaining a certificate o accreditation
- Subpart E –
 - Accreditation by Private, Nonprofit Accreditation Organizations
 - §493.551 - 493.575
 - requirements for obtaining deemed status
- Subpart F –
 - General Administration
 - §493.602 – 493.649
 - CLIA fees

Subparts and Descriptions

- Subpart H
 - Participation in PT
 - PT Requirements by Specialty
 - §493.801 – 493.865
- Subpart I
 - Requirements for PT Providers
 - §493.901 – 493.959
 - PT frequency and acceptability
- Subpart J
 - Facility management
 - §493.1101 – 493.1105
 - Retention requirements
- Subpart K
 - Quality Systems
 - §493.1200 – 493.1299
 - Path of work flow

Subparts and Descriptions

- Subpart M
 - Personnel Requirements
 - §493.1351 - .493.1495
 - Responsibilities
- Subpart Q
 - Inspections
 - §493.1771 – 493.1780
 - Conducting a CLIA assessment
- Subpart R
 - Enforcement procedures
 - §493.1800 – 493.1850
 - Bad stuff