

organizations, rural health clinics, Federally qualified health centers, community mental health centers, and end-stage renal disease facilities must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider's administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet Statement of Revenue and Expenses prepared by _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(v) A provider may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship or if the provider qualifies as a low or no Medicare utilization provider. The provider must submit a written request for delay or waiver with necessary supporting documentation to its intermediary no later than 30 days after the end of its cost reporting period. The intermediary reviews the request and forwards it, with a recommendation for approval or denial, to CMS central office within 30 days of receipt of the request. CMS central office either approves or denies the request and notifies the intermediary within 60 days of receipt of the request.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 21, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 24, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–21441 Filed 8–21–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Centers for Disease Control and Prevention

42 CFR Part 493

[CMS–2226–CN]

RIN 0938–AK24

Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Correction

AGENCY: Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on January 24, 2003, entitled “Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications.” This document is a supplement to the January 24, 2003 final rule.

EFFECTIVE DATE: September 22, 2003.

FOR FURTHER INFORMATION CONTACT:

Rhonda S. Whalen (CDC), (770) 488–8155.

Judith A. Yost (CMS), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 03–1230 of January 24, 2003 (68 FR 3640), there were several technical errors that are identified and corrected in the “Correction of Errors” section below. The corrections described below are effective September 22, 2003.

Specifically, this document corrects errors of omission, clarifies ambiguities, and corrects erroneous references and typographical errors. We would ordinarily publish these changes in a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. This notice and comment rulemaking procedure can be waived, however, if an agency finds good cause to do so (that is, notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest) and it incorporates a statement of the finding and its reasons therefore in the final rule. We find good cause to waive notice and comment procedures for the

corrections contained in this final rule for the reasons set forth in section III of this notice.

II. Correction of Errors

A. Preamble Corrections

■ In the final rule published on January 24, 2003 (68 FR 3640), make the following corrections:

■ On page 3641, in column three, in line seven from the bottom of the page, “Establish” is corrected to read “establish”.

■ On page 3642, in column two, in the first paragraph carried over from column one, in lines 13 and 14, the words “the National Registry for Clinical Chemistry” are corrected to read “the National Registry of Certified Chemists (formerly known as the National Registry in Clinical Chemistry)”.

■ On page 3643, in column two of the Table, in lines 18, 21, and 24, “systems” is corrected to read “system”.

■ On page 3648, in column three of the Table, in line 14, “§§ 493.1274(e)(1)(i) through (e)(1)(v), and (e)(2)” is corrected to read “§§ 493.1274(e)(1)(i) through (e)(1)(iii), and (e)(2)”.

■ On page 3650, in column two of the Table, in lines 2, 4, 5, 7, 9, 10, 12, 13, 14, 15, 16, 17, 19, 20, 22, 23, 24, 25, 28, 32, 38, 40, 42, 44, 45, 46, 47, 48, and 50 (twice), add the word “quality” before “assessment”.

■ On page 3650, in column three of the Table, in line 18, “§§ 493.1230; 493.1236(a)(1); 493.1239(a) and (b)” is corrected to read “§§ 493.1230; 493.1236(a); 493.1239(a) and (b)”.

■ On page 3671, in column two, in the first paragraph of the response, “the American Board of Medical Immunology” is corrected to read “the American Board of Medical Laboratory Immunology.”

■ On page 3671, in column two, in the first paragraph of the response, “the National Registry for Clinical Chemistry” is corrected to read “the National Registry of Certified Chemists (formerly known as the National Registry in Clinical Chemistry)”.

■ On page 3673, in column three, in the first paragraph of the response, in line 16, “quality systems include” is corrected to read “a quality system includes”.

■ On page 3674, in column two, in Subpart A—General Provisions (Definitions), in the first bullet point under that heading, add the words “nonwaived test” and “waived test” in alphabetical order.

■ On page 3674, in column two, in Subpart A—General Provisions (Definitions), add, above the third bullet, a new bullet with the words “We revised

§ 493.19(e)(1) by removing the reference to the former Subpart P.”

■ On page 3675, in column one, in the first paragraph carried over from the preceding page, “Systems” is corrected to read “System”.

■ On page 3675, in column two, in the section heading and in bullets number one and three, remove the “s” from the word “systems”.

■ On page 3694, in column two, in the last paragraph, and on page 3696, in column one, in the last paragraph of the page, “(Eisenberg, 1998)” is corrected to read “(Isenberg, 1998)”.

■ On page 3701, in column three, in the “References” section, “Eisenberg, Henry D., Ed.” is corrected to read “Isenberg, Henry D., Ed.” and is placed in alphabetical order.

B. Omitted Regulatory Text

The January 24, 2003 final rule (68 FR 3640) utilized a couple of terms that have never been formally defined in the CLIA regulations. We believe that any ambiguities about “nonwaived test” and “waived test” would be resolved by defining them at § 493.2.

The definition of “waived test” need not be subject to notice and comment rulemaking as the definition merely cites to the statutory criteria for waiver as specified in section 353(d)(3) of the Public Health Service Act (PHS). “Non-waived tests” is likewise defined in terms of the statutory criteria for waiver. As notice and comment rulemaking is unnecessary, we are adding these definitions to § 493.2.

In addition, we explained in the January 24, 2003 final rule that we were renaming, reorganizing, and consolidating similar requirements into one section, deleting duplicate requirements, and rewording numerous requirements to maintain and/or clarify their original intent, making the revised regulations easier to read and understand. As part of this effort, we removed “subpart P”, but neglected to remove references to subpart P in §§ 493.19(e)(1), 493.20(c), 493.25(d), 493.47(c)(2), and 493.1359(b)(2). As section “P” no longer exists, it is unnecessary to seek comments on these deletions as no purpose or interests would be served if they were maintained. As such, these references to subpart “P” are deleted by this final rule.

C. Regulatory Text Corrections

■ In FR Doc. 03–1230 of January 24, 2003 (65 FR 3640):

PART 493—LABORATORY REQUIREMENTS

■ 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)).

■ In § 493.2, the following definitions are added in alphabetical order to read as follows:

§ 493.2 Definitions.

* * * * *

Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

* * * * *

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

■ In § 493.19, paragraph (e)(1) is revised to read as follows:

§ 493.19 Provider-performed microscopy procedures.

* * * * *

(e) * * *

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

* * * * *

■ In § 493.20, paragraph (c) is revised to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

* * * * *

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

■ In § 493.25, paragraph (d) is revised to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

■ In § 493.47, paragraph (c)(2) is revised to read as follows:

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

* * * * *

(c) * * *

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

* * * * *

Table of Contents for Subparts J and K of Part 493 [Corrected]

■ On page 3703 in column one, in the heading of the Table of Contents for Subpart K, the word “Systems” is corrected to read “System”.

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, line 18, “§ 493.1125” is corrected to read “§ 493.1225”.

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, General Laboratory Systems, in line 15, add the word “quality” before “assessment.”

■ On page 3703, in column one, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Preanalytic Systems, in line 5, add the word “quality” before “assessment.”

■ On page 3703, in column two, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Analytic Systems, in line 22, “§ 493.1189” is corrected to read “§ 493.1289” and the word “quality” is added before “assessment.”

■ On page 3703, in column two, in the Table of Contents for Subpart K—Quality System for Nonwaived Testing, Postanalytic Systems, in line three, add the word “quality” before “assessment.”

§ 493.1105 [Corrected]

■ On page 3704, in column one, in paragraph (a)(3), in line four, “all analytic systems” is corrected to read “records documenting all analytic systems”.

■ On page 3704, in column one, in paragraph (a)(3)(ii), in line four, “CFR 606.160(b)(3)(ii), (b)(3)(v), and (d)” is corrected to read “CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d)”.

■ On page 3704, in column one, in paragraph (a)(5), in line one, the heading is corrected to read “*Quality system assessment records.*”

■ On page 3704, in column one, in paragraph (a)(6)(i), in lines two and three, “21 CFR 606.160(b)(3)(ii), (b)(3)(iv), and (d)” is corrected to read “21 CFR 606.160(d).”

■ On page 3704, in column one, in paragraph (b), in line five, “maintained” is corrected to read “retained”.

Subpart K—[Corrected]

■ On page 3704, in column one, in the section heading for Subpart K, the word “Systems” is corrected to read “System”.

§ 493.1200 [Corrected]

■ On page 3704, in column one, in paragraph (a), in line five, “quality systems” is corrected to read “a quality system”.

■ On page 3704, in column two, in paragraph (b), in line one, remove the words “Each of”, and capitalize the letter “T” in the word “The”.

■ On page 3704, in column two, in paragraph (b), in line two, “an assessment” is corrected to read “a quality assessment”.

■ On page 3704, in column two, in paragraph (c), in line two, the word “systems” is corrected to read “system”.

§ 493.1208 [Corrected]

■ On page 3704, in column three, in line two, “§§ 93.1281” is corrected to read “§§ 493.1281”.

§ 493.1234 [Corrected]

■ On page 3705, in column two, in line six, “individual” is corrected to read “person”.

§ 493.1239 [Corrected]

■ On page 3705, in column two, in the section heading, add the word “quality” before “assessment.”

■ On page 3705, in column three, in paragraph (a), in line three, “system requirements” is corrected to read “systems requirements”.

■ On page 3705, in column three, in paragraph (b), lines one and seven, add the word “quality” before “assessment”.

■ On page 3705, in column three, in paragraph (c), in line two, add the word “quality” before “assessment”.

§ 493.1249 [Corrected]

■ On page 3706, in column one, in the heading of § 493.1249 add the word “quality” before “assessment.”

■ On page 3706, in columns one and two, in paragraph (b), in lines one and seven, add the word “quality” before “assessment”.

■ On page 3706, in column two, in paragraph (c), in line two, add the word “quality” before “assessment”.

§ 493.1251 [Corrected]

■ On page 3706, in column two, in paragraph (b)(11), in line two, “results or panic or alert values” is corrected to read “results, or panic or alert values”.

■ On page 3706, in column three, in paragraph (b)(13), in lines five and six, “reporting imminent life threatening results, or panic, or alert values” is

corrected to read “reporting imminently life-threatening results, or panic or alert values”.

§ 493.1253 [Corrected]

■ On page 3707, in column one, in paragraph (b)(2), in lines eight through ten, remove the words “Gram stain, or potassium hydroxide preparations”.

§ 493.1256 [Corrected]

■ On page 3707, in column three, in paragraph (a), in line four, the word “analytical” is corrected to read “analytic”.

■ On page 3708, in column two, in paragraph (e)(1), in line four, add the phrase “(except those specifically referenced in § 493.1261(a)(3))” before the word “and”.

§ 493.1271 [Corrected]

■ On page 3709, in column three, in paragraph (f), in line one, the heading “Documentation.” is added.

§ 493.1273 [Corrected]

On page 3709, in column three, in paragraph (a), in line one, the phrase “As specified in § 493.1256(e)(3),” is added at the beginning of the first sentence, and the word “Fluorescent” is corrected to be lower-case.

§ 493.1274 [Corrected]

■ On page 3710, in column three, in paragraph (d)(2)(iii), in line one, “Nongynecologic slide preparation” is corrected to read “Nongynecologic slide preparations”.

■ On page 3711, in column two, in paragraph (h), in line one, the heading “Documentation.” is added.

§ 493.1276 [Corrected]

■ On page 3711, in column two, in paragraph (d), in line five, “System of Cytogenetic Nomenclature” is corrected to read “System for Human Cytogenetic Nomenclature”.

§ 493.1278 [Corrected]

■ On page 3712, in column two, in paragraph (g), in line one, the heading “Documentation.” is added.

§ 493.1289 [Corrected]

■ On page 3713, in the heading of § 493.1289, add the word “quality” before “assessment”.

■ On page 3713, in column one, in paragraph (b), in lines one and seven, add the word “quality” before “assessment”.

■ On page 3713, in column one, in paragraph (c), in line two, add the word “quality” before “assessment.”

§ 493.1291 [Corrected]

■ On page 3713, in column one, in paragraph (a), in line one, add the word “an” before the word “adequate”.

■ On page 3713, in column one, in paragraph (a), in line two, “systems” is corrected to read “system(s)”.

■ On page 3713, in column two, in paragraph (c)(1), in line three, “or an unique” is corrected to read “or a unique”.

■ On page 3713, in column two, in paragraph (g), in line six, “imminent” is corrected to read “imminently”.

§ 493.1299 [Corrected]

■ On page 3713, add the word “quality” before “assessment”: in the section heading; in column three, in paragraph (b), in lines one and seven; and in column three, in paragraph (c), in line two.

§ 493.1359 [Amended]

■ In § 493.1359, paragraph (b)(2) is revised to read as follows:

* * * * *

(b) * * *

(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

III. Waiver of Proposed Rulemaking

We ordinarily publish these changes in a notice of proposed rulemaking in the **Federal Register** and invite public comment before final changes are adopted. However, we can waive this notice and comment rulemaking if we find good cause to do so (that is, notice and comment procedure is impracticable, unnecessary, or contrary to the public interest) and the agency incorporates a statement of the finding and the reasons therefore in the final rule that is published.

In this case, we believe that it is unnecessary to undertake notice and comment rulemaking procedures because the changes this notice adopts have no substantive effect. Specifically, in this notice, the two definitions that have been adopted merely refer the reader back to the statutory criteria for waiver. The correction and/or update of names of entities and persons does not alter to whom the regulations are referring. The citations that have been removed were to non-existent regulatory cites. The addition of the word “quality” throughout the regulations merely provides clarification as to what the regulated entity is ultimately assessing without altering the means to be used for such assessments or the parties that must conduct those assessments. The relocation of one requirement from under one heading to

another did not alter what was required of whom. Also, the grammatical and capitalization changes that have been made had no effect on the meaning of the provisions that contain them. As the substance of the regulatory text itself governs regulated entities, the substantive alteration of the preamble to make it conform to the regulatory text had no substantive effect.

As these changes do not have any substantive effect, we believe that no benefit would come of submitting these changes to public comment. We therefore find that it is "unnecessary" to submit these changes to notice and comment rulemaking as that term is used in section 553(b)(B) of the Administrative Procedure Act. Thus, we find good cause to waive notice and comment rulemaking procedures.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 18, 2003.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 03–21549 Filed 8–21–03; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[PP Docket No. 00–67; FCC 00–342]

Compatibility Between Cable Systems and Consumer Electronics Equipment

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Commission adopted new rules on the labeling of digital television receivers and other consumer electronics receiving devices. Certain rules contained new and modified

information collection requirements and were published in the **Federal Register** on October 27, 2000. This document announces the effective date of these published rules.

DATES: The amendments to §§ 15.3, 15.19 and 15.18 published at 65 FR 64388, October 27, 2000, became effective on May 1, 2001.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Brooks, Office of Engineering and Technology, Policy and Rules Division, (202) 418–2454.

SUPPLEMENTARY INFORMATION: On May 1, 2001, the Office of Management and Budget (OMB) approved the information collection requirements contained in Sections 15.3; 15.19; and 15.118 pursuant to OMB Control No. 3060–0959. Accordingly, the information collection requirements contained in these rules became effective on May 1, 2001.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–21506 Filed 8–21–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03–2350; MB Docket No. 03–25, RM–10637]

Radio Broadcasting Services; Basin City and Othello, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Wheeler Broadcasting, Inc., substitutes Channel 248C2 for Channel 248C3 at Othello, Washington, reallots Channel 248C2 to Basin City, Washington, and modifies Station KLZN's license accordingly. Channel 248C2 can be allotted to Basin City, Washington, in compliance with the Commission's minimum distance separation requirements with a site

restriction of 7.2 km (4.5 miles) north of Basin City. The coordinates for Channel 248C2 at Basin City, Washington, are 46–39–26 North Latitude and 119–10–23 West Longitude.

DATES: Effective September 29, 2003.

FOR FURTHER INFORMATION CONTACT:

Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 03–25, adopted July 23, 2003, and released July 24, 2003. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail qualexint@aol.com.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Washington, is amended by adding Basin City, Channel 248C2, and by removing Othello, Channel 248C3.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 03–21505 Filed 8–21–03; 8:45 am]

BILLING CODE 6712–01–P