''Sunflower'' by revising the expiration date ''12/30/00'' to read ''12/31/02''.

§ 180.508 [Amended]

9. In § 180.508, in the table to paragraph (b) amend the entry for ''Canola'' by revising the expiration date ''7/15/01'' to read ''12/31/03''.

FR Doc. 00–33292 Filed 12–27–00; 1:00 pm

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration Centers for Disease Control and Prevention

42 CFR Part 493

[HCFA–2024–FC2]

RIN 0938–AI94

Medicare, Medicaid, and CLIA Programs; Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA

AGENCY: Centers for Disease Control and Prevention (CDC) and Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule extends certain effective dates for clinical laboratory requirements in regulations published on February 28, 1992, that implemented provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule extends the phase-in date of the quality control requirements applicable to moderate and high complexity tests and extends the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

These effective dates are extended to allow the Department to revise quality control requirements and establish the qualification requirements necessary for individuals with doctoral degrees to serve as directors of laboratories performing high complexity testing. These effective date extensions do not reduce the current requirements for quality test performance.

DATES: *Effective Date:* December 29, 2000.

Comment Date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 27, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following addresses:

Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2024–FC2, P.O. Box 8018, Baltimore, MD 21244–8018; and

Centers for Disease Control and Prevention, Department of Health and Human Services, Attention: HCFA–2024–FC2, 4770 Buford Hwy., N.E., MS F11, Atlanta, Georgia 30341–3724.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–8018.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2024–FC2. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890). For information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen (CDC), (770) 488–8155, Cecelia Hinkel (HCFA), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

Availability of Copies, and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–7800 (or toll free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

On February 28, 1992, we published in the **Federal Register** (57 FR 7002) final regulations with an opportunity for public comment. These regulations set forth the requirements for laboratories that are subject to CLIA. These regulations established uniform requirements for all laboratories regardless of location, size, or type of testing performed. In developing the regulations, we included requirements that would ensure the quality of laboratory services and be in the best interest of the public health. We recognized that a rule of this scope required time for laboratories to understand and implement the new requirements. Therefore, certain requirements were phased-in and given prospective effective dates. We also planned to address the comments we received on the February 28, 1992 rule and make modifications, if necessary, in the subsequent final rule.

On December 6, 1994, May 12, 1997, and October 14, 1998, we published in the **Federal Register** (59 FR 62606, 62 FR 25855, and 63 FR 55031, respectively) final rules with opportunity for comment. These rules extended the phase-in of the quality control requirements applicable to moderate and high complexity tests and the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing. These changes were made due to the resource constraints

that had prevented the Department of Health and Human Services from establishing a review process for manufacturers' test system quality control instructions for CLIA compliance and the inability of many laboratory directors to complete certification requirements within the time period originally specified.

II. Revisions to the Regulations

The date extensions provided by the October 14, 1998 rule have proven to be inadequate for the reasons set forth below. In addition, based on our evaluation of comments submitted in response to the May 12, 1997 rule, advice from the Clinical Laboratory Improvement Advisory Committee (CLIAC) concerning the quality control requirements appropriate to ensure quality testing, and the qualification requirements for laboratory directors, we have found it necessary to make the following revisions to our regulations:

- We are extending from December 31, 2000, to December 31, 2002, the current phase-in quality control requirements for moderate and high complexity tests. The phase-in quality control requirements for unmodified, moderate complexity tests cleared by the Food and Drug Administration (FDA) (through 510(k) or premarket approval processes, unrelated to CLIA) are less stringent than the requirements applicable to high complexity and other moderate complexity tests.
- We are extending from December 31, 2000, to December 31, 2002, the date for laboratories to meet certain CLIA quality control requirements by following manufacturers' FDA CLIA-cleared test system instructions.
- We are extending from December 31, 2000, to December 31, 2002, the date by which individuals with doctoral degrees must obtain board certification to qualify as directors of laboratories that perform high complexity tests.

These revisions are discussed in more detail below.

A. Quality Control Requirements

42 CFR 493.1202 contains the quality control requirements applicable to moderate and high complexity tests and allows a laboratory that performs tests of moderate complexity, using test systems cleared by the FDA through the section 510(k) or premarket approval processes, until December 31, 2000, to comply with the quality control provisions of part 493, subpart K, by meeting less stringent quality control requirements, as long as the laboratory has not modified the instrument, kit, or test system's procedure.

Section 493.1203, effective beginning December 31, 2000, establishes a mechanism for laboratories using commercial, unmodified tests to fulfill certain quality control requirements by following manufacturers' test system instructions that have been reviewed and determined by the FDA to meet applicable CLIA quality control requirements. Implementation of this review process, however, depended upon the availability of sufficient additional resources necessary to meet the projected workload. These resources were not available due to financial and other constraints of the program.

Following the publication of some of the previous extensions, we received comments that the current quality control requirements are not appropriate for some test methodologies, and that a comprehensive quality control regulation should be developed to address current quality control needs. A final rule addressing quality control issues raised by these commenters is close to completion; however, it will not be published by December 31, 2000. Commenters also raised issues that stressed the need to ensure that the quality control requirements are practical and flexible enough to accommodate different testing sites and test systems that range from current methodologies to new and emerging technologies, in order to not impede access. We must also, as the commenters suggest, base the requirements on technical considerations as well as their impact on patient care.

To assist us in determining the types of quality control requirements necessary to monitor laboratory test performance, we also considered advice provided by the CLIAC, as well as information obtained from a public meeting held in September 1996 for manufacturers and others to make presentations on quality control.

Due to the complexity of the issues that must be addressed, we are extending the December 31, 2000 sunset date for quality control standards in § 493.1202 to December 31, 2002, and extending the effective date for § 493.1203 from December 31, 2000 to December 31, 2002, to allow laboratories to continue to meet current regulations until we make further determinations regarding quality control issues. We are extending the effective date for these sections to ensure that we have sufficient time to develop final rules concerning quality control that address new technology, including point-of-care testing, molecular methods and advances in testing in the specialties and subspecialties. Subsequent to the publication of the final regulations and prior to the actual implementation of the revised requirements, we must develop new surveyor guidelines, design new survey forms, reprogram the CLIA data system, conduct surveyor training, and inform and educate the laboratory community, State programs with CLIA-exempt laboratories and HCFA-approved accreditation organizations. Time must be allocated for HCFA-approved State licensure programs and HCFA-approved accreditation organizations to review their requirements and determine whether they must make changes to maintain their overall equivalency with the CLIA requirements. State programs with CLIA-exempt laboratories may need to make changes to their State laws and implementing regulations. Accreditation organizations may also need time to revise policies and requirements and have them approved by their organizations for adoption. An implementation period will provide States and accreditation organizations the time needed to make changes to their program requirements and for their subsequent review by CDC and HCFA. Failure to provide sufficient time for education and implementation could cause confusion and interfere with laboratories' continued compliance with CLIA requirements and jeopardize the continued equivalency of State programs with CLIA-exempt laboratories and accreditation organizations.

B. Laboratory Director Qualifications

Section 493.1443(b)(3) provides that a director of a laboratory performing high complexity testing, who has an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, must be certified by a board recognized by the Department as of December 31, 2000. The phase-in was designed to allow the Department adequate time to review requests for approval of certification programs and to ensure that a laboratory director with a doctoral degree had sufficient time to successfully complete the requirements for board certification.

As stated previously in the preamble to the December 1994 final rule, a number of comments to the February 1992 final rule suggested that board certification not be a mandatory requirement for currently employed individuals. In addition, CLIAC suggested the development of alternative provisions to qualify currently employed individuals with a doctoral degree on the basis of laboratory training or experience, in lieu of requiring board certification.

We are extending the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing to December 31, 2002. This extension will allow time for review of the qualifications required for laboratory director to determine whether modifications should be made for inclusion in the final rule being developed.

In summary, we are extending the phase-in period in § 493.1443(b)(3) from December 31, 2000, to December 31, 2002.

III. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The revisions in this final rule are essential, because if the dates for quality control requirements are not extended, many laboratories performing moderate complexity testing will be faced unnecessarily with meeting more stringent and burdensome quality control requirements at a time when we are actively working to revise these same quality control requirements. While this activity is nearly complete, the issues we are addressing are many and complex, particularly in light of changing technologies. Since we will be revising the quality control requirements in the reasonably near future, to impose more stringent requirements now is unreasonable, unnecessary, and confusing. With respect to the personnel standards addressed in this rule, if the date is not extended, those individuals currently qualified as laboratory directors under the phase-in requirements based on their doctoral degree and laboratory training and work experience would no longer qualify to serve as directors of laboratories performing high complexity testing. Since we are contemplating revisions that would allow individuals with a doctoral degree to qualify under alternative provisions that would recognize their laboratory training and experience, we would not want to disenfranchise these currently employed directors at this time. Extending the dates governing laboratory director qualifications will provide the opportunity for individuals with a doctoral degree who have laboratory training and experience, but do not have board certification to continue to qualify as laboratory directors of high complexity testing while we consider appropriate revisions to the CLIA regulations.

Accordingly, we believe that it is impracticable, unnecessary, and not in the public interest to engage in proposed rulemaking and believe there is good cause for not doing so and are therefore issuing this final rule with a 60-day comment period. To do otherwise would create confusion among laboratories in understanding the requirements they must meet with respect to quality control and laboratory director qualifications. It could also impose unnecessary burdens on laboratories and hardships on persons affected by these requirements. Because current regulations will expire on December 31, 2000, additional urgency has been placed on the implementation of this rule. We, therefore, believe there is good cause to waive a delay in the effective date of this rule. To do otherwise would create unnecessary confusion among laboratories in understanding the requirements they must meet with respect to quality control and laboratory director qualifications. It could also impose unnecessary burdens on laboratories and hardships on individuals affected by these requirements.

IV. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all laboratories are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Extending the phase-in periods will continue the quality control and personnel requirements in effect prior to December 31, 2000, allow adequate time for addressing all concerns with respect to revising quality control requirements, and not change costs, savings, burden, or opportunities to manufacturers, laboratories, individuals performing tests, or patients undergoing the tests.

For these reasons, we have determined, and the Secretary certifies, that this regulation does not result in a significant impact on a substantial number of small entities and does not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in annual expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. The final rule has no consequential effect on State, local, or tribal governments. We believe the private sector costs of this rule fall below these thresholds, as well.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

List of Subjects in 42 CFR Part 493

Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV, part 493 is amended 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), and 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)).

§ 493.1202 [Amended]

2. In § 493.1202, in the section heading, remove ''December 31, 2000'' and add in its place ''December 31, 2002''.

§ 493.1203 [Amended]

3. In § 493.1203, in the section heading, remove ''December 31, 2000'' and add in its place ''December 31, 2002''.

§ 493.1443 [Amended]

4. Section 493.1443 is amended as set forth below:

a. In § 493.1443(b)(3)(ii) introductory text, remove ''December 31, 2000,'' and add in its place ''December 31, 2002,''.

b. In § 493.1443(b)(3)(ii)(C), remove ''December 31, 2000,'' and add in its place ''December 31, 2002,''.

(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: November 20, 2000.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention.

Dated: November 28, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

Dated: December 18, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–33288 Filed 12–26–00; 1:13 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN 0991–AB08

Technical Corrections to the Standards for Privacy of Individually Identifiable Health Information Published December 28, 2000

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, DHHS.

ACTION: Technical corrections to final rule.

SUMMARY: These technical corrections address changes that inadvertently were excluded from the preamble of the Standards for Privacy of Individually Identifiable Health Information published December 28, 2000.

DATES: The effective date of these changes is February 26, 2001, the same as the effective date of the Standards for Privacy of Individually Identifiable Health Information published December 28, 2000.

FOR FURTHER INFORMATION CONTACT: Kimberly Coleman, 1–866–OCR–PRIV (1–866–627–7748) or TTY 1–866–788–4989.

Technical Corrections

Correction 1: In the section-by-section description of the rule provisions, under the description of section 164.510(a)—Use and Disclosure for Facility Directories, paragraphs seven and eight beginning ''We believe that allowing clergy . . .,'' and ''More specifically, . . .,'' are deleted and replaced with the following:

We believe that allowing clergy access to patient information pursuant to this section does not violate the Establishment Clause because the exemption from the final rule's authorization requirement for disclosure to clergy of the specified protected health information is a permissible religious accommodation. The purpose and effect of this provision is to alleviate significant governmental interference with the exercise of religion, and we anticipate that the exemption would rarely, if ever, impose any significant burdens on patients or other individuals.

Without this exemption, covered entities would have to obtain authorizations before disclosing the limited protected health information to clergy, thereby making is more difficult than it commonly has been for clergy to provide services to patients. Accordingly, the clergy exemption permitting limited disclosure of protected health information in the circumstances noted above is ''rationally related to the legitimate purpose of alleviating significant governmental interference with the ability of religious organizations to define and carry out their religious missions.'' *Corporation of the Presiding Bishop of Jesus Christ of Latter-Day Saints* v. *Amos*, 483 U.S. 327, 339 (1987). Moreover, in certain cases the clergy exemption might also alleviate significant governmental interference with patients' religious exercise that the final rule's authorization requirement otherwise would impose—for example, by eliminating delay that might inhibit the ability of a patient to obtain sacraments provided during last rights.

Correction 2: In the section-by-section discussion of comments, under the discussion of section 164.534—EFFECTIVE DATE AND COMPLIANCE DATE, the last sentence of the second paragraph should be replaced with the following language. Although the regulation is effective as of 60 days from publication in the **Federal Register**, section 1175 of HIPAA makes clear that no covered entity shall be required to comply with any standard or implementation specification for 24 months (or 36 months for small health plans). We will not enforce the regulation prior to those dates, and the regulation's provisions will not preempt or otherwise alter state or other law prior to those dates. A covered entity may, or course, voluntarily implement policies that would comply with the regulation prior to those dates, but the regulation itself will neither compel disclosure nor provide a basis to refuse disclosure. We intend, therefore, for all of the provisions of the rule to come into force in 24 months (or 36 months for small health plans).

Dated: December 27, 2000.

LaVerne Burton,

Executive Secretary.

[FR Doc. 00–33444 Filed 12–27–00; 1:33 pm]

BILLING CODE 4150–04–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 980414095-8240-02; I.D. 121800D]

Fisheries of the Northeastern United States; Dealer Reporting Requirements

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of termination of the deferral of Interactive Voice Response (IVR) System reporting requirements for Atlantic cod and haddock purchases.

SUMMARY: NMFS announces that it is terminating the current deferral of IVR reporting requirements of Atlantic cod and haddock beginning January 28, 2001. One of the management measures for Atlantic cod includes two conditional 1-month closures in the Gulf of Maine (GOM) when the trigger of 1.67 million lbs (759 mt) is reached. One management measure for haddock is an adjustment to the daily landing limit as specified in Framework 33 to the Northeast Multispecies Fishery Management Plan (FMP) to provide the industry with the opportunity to harvest