Cosmetic Act: July 21, 1993. The applicant claims July 15, 1993, as the date the new drug application (NDA) for DIFFERIN Topical Gel (NDA 20–380) was initially submitted. However, FDA records indicate that NDA 20–380 was submitted on July 21, 1993.

3. *The date the application was approved*: May 31, 1996. FDA has verified the applicant's claim that NDA 20–380 was approved on May 31, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 433 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 7, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 4, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 17, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–2871 Filed 2–4–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–137]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match 42 CFR 411.20–411.206; *Form No.:* HCFA–R–137; *Use:* Employers who are identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b). *Frequency:* Semi-annually *Affected Public:* Individuals or Households, Business or other for profit, Not for profit institutions, Farms, Federal Government and State, Local or Tribal Government; *Number of Respondents:* 596,241; *Total Annual Responses:* 596,241; *Total Annual Hours Requested:* 2,325,449.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 29, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–2764 Filed 2–4–97; 8:45 am]

BILLING CODE 4120–03–P

[HSQ–244–N]

CLIA Program; Clinical Laboratory Improvement Amendments of 1988—Denial of Exemption of Laboratories in the Commonwealth of Puerto Rico

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: The Public Health Service Act provides for the exemption of laboratories from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) if the State in which they are located has been determined to have requirements equal to or more stringent than those of CLIA. Under our regulations, HCFA's decision to approve or deny a requested exemption from CLIA requirements is published in the Federal Register. This notice announces that a request from the Commonwealth of Puerto Rico for exemption from CLIA requirements has been denied.

EFFECTIVE DATE: The denial of exemption from CLIA was effective on October 28, 1996.

FOR FURTHER INFORMATION CALL:

Lee Feehely, (410) 786–3401.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act, as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet the requirements established by the Department of Health and Human Services. Regulations implementing section 353 of the Public Health Service Act are contained in 42 CFR part 493, Laboratory Requirements. Subject to specified exceptions included in subpart D, laboratories must have a current and valid CLIA certificate to test human specimens. Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from CLIA requirements in a State that is

determined to have requirements that are equal to or more stringent than those of CLIA. The statute does not specifically require the promulgation of criteria for the exemption of laboratories in a State. The authority to determine whether a State qualifies for an exemption has been delegated by the Secretary to the Administrator of HCFA.

Part 493, subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program, implements section 353(p) of the Public Health Service Act. Section 493.513 provides that we may exempt from CLIA requirements, for a period not to exceed 6 years, State licensed or approved laboratories in a State if the State meets specified conditions.

When a request for exemption from CLIA is not granted, the State may request a reconsideration. Our policy on reconsiderations is set forth in our regulations in Part 488, subpart D—Reconsideration of Adverse Determinations-Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs. Sections 488.205 and 488.207 provide for the opportunity for an informal hearing and set out the informal hearing procedures. The hearing officer presents his findings within 30 days of the close of the hearing (§ 488.209). Section 488.211 provides that the hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision. The Administrator may accept, reject, or modify the hearing officer's decision. If the Administrator chooses to review the hearing officer's decision, the Administrator's decision becomes the final decision. Section 488.211 provides that we will publish, in the Federal Register, the final reconsideration determination.

On December 5, 1992, the Commonwealth of Puerto Rico, which is considered a State for CLIA purposes, requested exemption from the CLIA requirements. The Health Quality and Standards Bureau, HCFA, notified Puerto Rico on May 10, 1995 that its request was denied. On July 10, 1995, the Commonwealth requested a reconsideration. A reconsideration hearing was held on August 30, 1996. The hearing officer rendered his decision on September 27, 1996, affirming the denial of the request for exemption. The Administrator declined his right to review the hearing officer's decision. Thus, in accordance with § 488.211(a), the hearing officer's decision became the final reconsideration determination on October 28, 1996.

II. Notice of Denial of CLIA Exemption to Laboratories in the Commonwealth of Puerto Rico

Attached as an addendum to this notice is the hearing officer's decision on the Commonwealth of Puerto Rico's request for exemption from CLIA.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: January 27, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Addendum—Reconsideration of the Commonwealth of Puerto Rico's Application for Exemption From CLIA

Hearing Officer's Recommended Decision

I. Background

The Clinical Laboratories Improvement Amendments of 1988 (the ''CLIA'') requires that all laboratories must be certified in order to perform testing on human specimens. (Section 353 Public Health Service Act, 42 U.S.C. 263a). The Health Care Financing Administration (the ''HCFA'') using scientific and technical support, as needed, from the Centers for Disease Control (the ''CDC''), Public Health Service (the ''PHS''), administers the CLIA program for the Department of Health and Human Services. HCFA has promulgated regulations containing the requirements concerning the Medicare, Medicaid and CLIA programs in 42 CFR part 493.

The CLIA statute provides that ''[i]f a State enacts laws relating to matters covered by [CLIA] which provide for requirements equal to or more stringent than the requirements of [CLIA], the Secretary may exempt clinical laboratories in that State from compliance with [CLIA].'' 42 U.S.C. 263a(p)(2). This statutory authority is reflected in HCFA's regulations which provide that HCFA may exempt from CLIA program requirements all State-licensed or approved laboratories in a State [1] if the State meets the requirements of 42 C.F.R. 493.513(a). Section 493.513(a)(1) of the regulations, which mirrors 42 U.S.C. 263a(p)(2), explains that in order to be granted an exemption from CLIA, the State must have in effect laws that provide for requirements equal to or more stringent than condition-level requirements.[2] Section 493.513(a)(1).

On December 5, 1992, the Secretary of Health for the Commonwealth of Puerto Rico submitted an application for exemption from CLIA. On May 10, 1995, the Commonwealth was notified that its application for CLIA exemption was denied.[3] The basis for the denial was a determination by HCFA that several of Puerto Rico's personnel standards did not meet the respective CLIA condition level requirements and that the Commonwealth's laboratory licensure requirements, especially as applied to tests performed by physicians, were less stringent than CLIA requirements.

By letter dated July 10, 1995, and in accordance with § 488.201 of the regulations, the Commonwealth requested a reconsideration of the denial of its application for CLIA exemption. At the same time, Puerto Rico also requested permission to submit a proposal addressing HCFA's concerns and establishing equivalencies with applicable CLIA requirements. The revised proposal was sent by the Commonwealth on July 26, 1995. This proposal addressed Puerto Rico's laboratory environment and outlined proposed changes to regulations establishing educational standards for certain laboratory personnel. On October 24, 1995, the Hearing Officer then appointed by HCFA requested that the Commonwealth submit materials pertinent to its request for exemption and recommended that the Commonwealth submit a complete and current application for exemption.

On December 5, 1995, Puerto Rico submitted revised application materials, including an updated cross-walk of the Puerto Rico equivalents to the CLIA regulations together with complete addenda, to HCFA for review. On May 22, 1996, after having reviewed the revised application materials, HCFA again decided to deny the Commonwealth's application for exemption.[4] The Commonwealth was advised that the application failed to demonstrate the existence of CLIA-level laws and regulations in several key

[1] For purposes of CLIA, the term ''state'' includes each of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements. 42 CFR Section 493.2.

[2] Condition-level requirements are defined as any of the requirements identified as ''conditions'' in subparts G through Q of Part 493. 42 CFR Section 493.3.

[3] See May 10, 1995, letter to Dr. Carmen Feliciano de Melecio, Secretary of Health from Anthony J. Tirone, Director of the Office of Survey and Certification, Health Standards Quality Bureau.

[4] *See* May 22, 1996 letter to Dr. Feliciano from Anthony Tirone, hereinafter referred to as the ''denial'' or ''initial determination.''

areas including, but not limited to, those identified in the May 10, 1995 letter and in the areas of enforcement authority, proficiency testing and quality assurance.[5]

In accordance with 42 CFR § 488.201, *et seq.*, the Commonwealth requested a reconsideration of HCFA's denial of the application for CLIA-exemption. A hearing was scheduled for August 30, 1996 to review each of the grounds for denial identified by HCFA in making its initial determination. In an effort to facilitate a full understanding of the Commonwealth's position on each of those issues, the Commonwealth was asked to submit a Position Paper prior to the scheduled hearing date. The Position Paper was submitted and the hearing took place, as scheduled, on August 30, 1996 at HCFA's Headquarters in Baltimore, Maryland.

II. Issue

Whether the Commonwealth of Puerto Rico has submitted evidence in connection with its application for exemption from CLIA that, in accordance with 42 U.S.C. 263a(p)(2) and 42 CFR 493.513(a)(1), demonstrates that it has in effect laws that provide for requirements equal to or more stringent than condition-level CLIA requirements.

III. Discussion

In reaching its initial determination to deny the Commonwealth's application for exemption, HCFA identified several different grounds for denial in a summary referred to in and attached to the May 22, 1996 denial letter. In the following discussion, for each of the grounds for denial, I review the CLIA requirements, the cited deficiency, and the evidence of equivalency offered by Puerto Rico in its submissions, Position Paper and at the hearing. My finding of fact is provided at the end of each section.

A. Basis and Scope

Upon review of the initial application, HCFA determined that the Commonwealth failed to clarify whether testing performed in certain locations was subject to the Commonwealth's laboratory licensing regulations. Of particular concern was testing in physician's office laboratories, clinics, group practices, seropheresis centers, non-hospital transfusion services, blood and blood products processing centers, temporary testing sites, such as health fairs, and testing performed during patient examinations in a physician's office.

The CLIA regulations set forth the conditions that all laboratories must meet to be certified to perform testing on human specimens. 42 CFR 493.1. A laboratory is defined, in pertinent part, as ''a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.'' 42 CFR 493.2.

HCFA's assessment was that when compared with the CLIA regulations, the Commonwealth's laboratory regulations did not clearly show that all testing sites were regulated. The agency also viewed as problematic the issue of whether physician-operated laboratories were required to be licensed.

In its Position Paper, the Commonwealth explained that the statutory provisions regulating clinical laboratories are contained in Public Law 97 and Regulation 83. (Position Paper, pg. 21). Section 91 of Public Law 97 mandates the issuance of a license by the Secretary of Health prior to establishing and operating clinical analysis laboratories, plasmaphereses centers, seropheresis centers or blood banks. Similarly, Regulation 83, Chapter 2 states that ''(n)o entity, be it a natural or juridical person, may establish or operate a clinical analysis laboratory, an anatomical pathology laboratory, or a Blood Bank, a licensed (sic)[7] issued by the Department of Health is previously obtained.'' Thus, the Commonwealth's position is that any place where clinical analysis is performed must be licensed and is subject to the laboratory regulations. (Position Paper, pg. 23). It is their contention that this includes cases where clinical analysis is performed in temporary testing sites, such as physician's offices and at health fairs. *Id*.

During the proceedings, testimony was offered by witnesses called by the Commonwealth that all testing sites in Puerto Rico were regulated. (Position Paper, pp. 65, 69, 74, and 83). The key inquiry appears not to be who is performing the test but whether a clinical analysis test covered by Regulation 83 is being performed. *Id*. at 69. In cases where a physician elects to perform clinical analysis testing in his or her office, Regulation 83 requires that the physician comply with applicable licensing requirements. *Id*. at 70. In such instances, the physician must secure a special license in accordance with Regulation 83, Chapter 2, Article I, sec. 3(a). *Id*. at 80.

Based upon the foregoing, I believe that the Commonwealth has sustained its burden of demonstrating that all laboratories of the type covered by CLIA, including physician operated laboratories, must be licensed. Regulation 83 encompasses all locations where clinical analysis is performed and explicitly mandates that, as a prerequisite of performing such tests, a license must be obtained. While arguably the Commonwealth's regulations could be amended to explicitly include physician operated laboratories in the list of covered laboratories, the regulations currently are broad enough to include physician operated laboratories. Thus, I disagree with HCFA's initial determination that the Commonwealth's regulations defining the scope of coverage are not as broad as the CLIA regulations and find that the scope is in fact, equivalent.

B. Categories of Test by Complexity

HCFA determined in its initial review of the application that the Commonwealth needed to provide clarification and evidence on how

[5] The Commonwealth has asked, for purposes of rendering a decision on reconsideration, that the Hearing Officer disregard the May 22, 1996 letter. According to counsel for the Commonwealth, ''Puerto Rico finds this May 22 letter highly irregular'' since it was issued approximately a year after the May 1995, notice of denial and it identifies additional reasons underlying HCFA's decision to deny the application for exemption. (Position Paper, pg. 10). However, I note that by letter dated July 26, 1995, the Commonwealth submitted a ''new proposal'' to ''override the objections stated in * * * (the) May 10, 1995 (denial) letter.'' *See* July 26, 1995 letter to Anthony Tirone from Dr. Carmen A. Feliciano de Melecio. In that same letter, the Commonwealth offered to meet with HCFA to discuss the proposed new standards and included ''a copy of the final official documentation of the application for exemption.'' *Id*. at pg. 15. Thus, while I agree that it was unusual for HCFA to send two separate letters representing initial determinations, the record suggests that the second letter illustrates HCFA's attempts to accommodate the interests of the Commonwealth. HCFA could have elected to limit the Commonwealth's recourse to a reconsideration hearing after it sent the May 1995 letter. However, the agency allowed the Commonwealth a chance to buttress its application outside of the reconsideration process. Therefore, for purposes of this reconsideration determination, I will consider in its entirety the May 22, 1996 letter sent by HCFA to the Commonwealth.

[6] ''Clinical Analysis'' is defined broadly as ''any facility, place or location, where any sample obtained from a human being is handled and/or processed for the purpose of it being tested or analyzed by any biological, biophysical, microbiological, serological, immunological, chemical, hematological, immunohematological, cytogenetical or any other test of materials derived from the human body (sic) are performed with the purpose of providing information for the prevention, diagnostic (sic) and treatment of any disease, or deterioration, or for the health evaluation of human beings.'' Reg. 83, Chpt. 1, Art. III, sec. 1.

[7] Should likely read ''unless a license.''

provider-performed microscopy (PPM) procedures and waived tests were regulated. In its application, the Commonwealth indicated that all tests were treated as high complexity tests. However, the application was silent with regards to waived tests and PPM procedures.

HCFA categorizes laboratory tests as waived tests, tests of moderate complexity, including PPM procedures, or tests of high complexity. 42 CFR 493.5. The type of CLIA certificate issued is a function of what type of testing the laboratory performs. 42 CFR 493.5(c); § 493.3. The CLIA regulations at §§ 493.15 and 493.19 explain that waived tests include simple laboratory examinations that impose no reasonable risk to the patient if done properly while PPM procedures are moderately complex tests performed by certain health care practitioners.

In its Position Paper, the Commonwealth explained that regardless of complexity, all clinical analysis testing is regulated in the same way. (Position Paper, p. 24). Both waived tests and PPM procedures are included in the definition of clinical analysis testing and are subject to the requirements of Regulation 83. *Id*. In other words, rather than issuing different certificates for high-complexity, waived tests or PPM procedures, the Commonwealth regulates all clinical analysis tests in the same way. Similarly, during the hearing, witnesses for the Commonwealth reiterated that all tests in Puerto Rico were treated as high complexity and, thus, were subject to the standards applicable to high complexity tests. (Position Paper, p. 62, 81).

Based upon my review of the Commonwealth's regulations and an evaluation of the testimony given at the hearing, I reverse HCFA's finding with regard to waived tests and PPM procedures. I find that the Commonwealth's use of a single criterion for all tests, which is comparable to the CLIA requirement for high complexity tests, should be recognized as more stringent than the CLIA regulations.

C. General Requirements for Exemption

1. Retrospective Review of Cytology Smears. Section 493.513(a)(4) of the CLIA regulations states that a State seeking exemption from CLIA must ''(demonstrate) that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.'' One of the grounds for HCFA's initial denial of the application for exemption was that the Commonwealth failed to demonstrate an administrative structure and adequate resources to arrange for a retrospective review of cytology smears by appropriately trained individuals if necessary to investigate or enforce cytology requirements. The application and materials submitted together with the application were silent with regard to this issue.

In its Position Paper, the Commonwealth indicated that it would develop a cytology enforcement program to support the Laboratory Inspection Division. (Position Paper, p. 25) However, there was no indication in either the Position Paper or through testimony that there are current procedures for performing retrospective reviews of cytology smears or for the investigation and enforcement of cytology requirements.

Thus, I concur with HCFA's initial determination and find that the Commonwealth has not satisfied the requirements of § 493.513(a)(4) insofar as they concern retrospective reviews of cytology smears.

2. Enforcement Authority, Administrative Structure, and Resources. Section 493.513(c)(3) of the CLIA regulations states that an application for exemption must include ''(a) description of the State's enforcement authority, administrative structure and resources to enforce the State standards.'' When reviewing the application submitted by the Commonwealth, HCFA determined that Puerto Rico failed to submit adequate information necessary to evaluate its enforcement authority, administrative structure or resources for enforcement.

In its Position Paper, the Commonwealth asserted that the organizational charts found in addenda 18 and 19 of the application for exemption clearly set forth the information required by § 493.513(c)(3). (Position Paper, p. 25). Addendum 18 simply is an organizational chart for the Office of the Assistant Secretariat for Regulation and Accreditation of Health Facilities for the Department of Health. Addendum 19 merely represents the Fiscal Year 1994–1995 budget for the Laboratory Division for the Department of Health.

During the hearing, testimony was offered with regard to the enforcement authority that could be exercised by the Department of Health. Counsel for the Commonwealth explained that the ''Uniform Administrative Procedures Act'' (the ''UAPA'') empowered the Secretary to take immediate remedial action, *ex parte*, against laboratories where there is a (sic) indication of immediate and serious threats to public health and safety. (Position Paper, p. 91) According to the Commonwealth, section 2167 of the UAPA allows an agency to use emergency adjudicatory procedures in any situation in which there is imminent danger to the public health, safety and welfare. Section 2201 of the UAPA provides that any violations of laws administered by agencies shall be penalized by administrative fines not to exceed $5000 for each violation. With the exception of discussing the UAPA, which is a statute of general application, little additional information on the Commonwealth's enforcement authorities was provided at the hearing.

By contrast, subpart R of part 493 sets forth detailed requirements relating to the use of intermediate sanctions, and on the suspension, limitation or revocation of laboratory certifications. These requirements direct the correction of deficiencies within a certain time period, provide for alternative sanctions and set forth the penalties that may be assessed in the event a laboratory operates without a license.

Neither the application nor Position Paper submitted by the Commonwealth provided sufficient information to assess the scope and breadth of the Commonwealth's enforcement authority as compared to subpart R of part 493. Accordingly, I must concur with HCFA's initial determination and find that the Commonwealth failed to produce adequate evidence concerning the enforcement authority, administrative structure and resources available in its laboratory program to demonstrate that its requirements are equal to or more stringent than the CLIA requirements.

3. Cases Involving Immediate and Serious Jeopardy. Section 493.513(c)(5) of the regulations directs a State applying for exemption from the CLIA program to provide information concerning its procedures for responding to and investigating complaints against licensed or approved laboratories. In its initial determination, HCFA found that the Commonwealth did not explain how it would investigate complaints indicating possible immediate and serious jeopardy to public health.

In its Position Paper, the Commonwealth referenced Regulation 83, Chapter 10, Art. VI, Sec. 10 as the section identifying procedures for responding to and investigating such complaints. Also referenced was a Letter of Intent dated February 24, 1995 which represents that if an onsite investigation or inspection is required, appropriate personnel will visit the facility within 30 days of receiving the complaint. (Position Paper, p. 25).

I have considered the information submitted by the Commonwealth and reject the agency's determination in this regard. I note that § 493.513(c)(5) only requires a State to submit information on the State's procedures for responding to and investigating complaints against laboratories. This section of the regulation does not direct, in any way, the *manner* in which the State must respond to or investigate any such complaints.[8] In order to satisfy § 493.513(c)(5), the State need only include with its application for exemption this required information. Since the Commonwealth included a copy of Regulation 83 in its application, which at Chapter 10, Art. VI, Sec. 10 outlines its investigation and complaint procedures, I find that the plain requirements of 42 CFR 493.513(c)(5) were satisfied.

4. Documentation Requirement. Section 493.513(d) of the regulations directs that States applying for exemption submit supporting documentation on the ability to furnish HCFA with electronic data in ACSII compatible code and a statement acknowledging that it will notify HCFA through electronic data transmission of certain licensure and specialty change events. In the initial determination, HCFA found that Puerto Rico failed to submit documentation demonstrating the intent and ability to provide HCFA with this data.

In a Letter of Intent dated February 24, 1995, the Commonwealth assured HCFA that it would notify HCFA ''by electronic transmission of any laboratory having its license revoked, limited, withdrawn or suspended and/or of all enforcement actions of sanctions imposed and/or any changes in licensing or inspection requirement and/or any changes in specialties and/or subspecialities of laboratories'' within 30 days after such event. The Letter indicated that the Commonwealth would modify the ASPEN system, currently utilized by the Medicaid program, to satisfy this requirement. In its Position Paper, the Commonwealth assured HCFA that it is currently mechanizing operations and, once the process is completed, would be able to provide the necessary information via electronic transmission. (Position Paper, pg. 25–26).

The regulations at § 493.513(d) specifically require that at the time of application the State must demonstrate its ability to provide HCFA with electronic data in ASCII compatible code. However, the Commonwealth has not been able to document its current ability to satisfy this requirement. Hence, I concur with the initial determination of HCFA on this issue and find that the Commonwealth has failed to demonstrate an ability to furnish HCFA with electronic data in the appropriate code format.

D. Enrollment and Testing of Samples

Section 493.801 of the regulations requires that each laboratory must enroll in a proficiency testing program that meets the criteria of subpart I of part 493 and is approved by HHS. In its initial determination, HCFA found that the Commonwealth's proficiency program was not HHS-approved for direct antigen testing in bacteriology and that the regulations did not require all licensed laboratories to seek enrollment with another HHS-approved program if the Commonwealth lost its Federal approval.

The Commonwealth points out that Regulation 83, Chapter 6, Art. I, sec. 1(a) provides that each institution which processes clinical analysis tests must participate satisfactorily in a proficiency program established by the Department of Health. (Position Paper, p. 26). The regulation further provides that those programs must be accredited by HHS. *Id.* As explained by the Commonwealth in its Position Paper, in cases involving direct antigen testing, the laboratory must participate in an HHS-approved proficiency program. (Position Paper, p. 26)

Based upon the language of the regulations and the assurances provided in the Position Paper, I reverse the initial determination of HCFA on this matter and find that the Commonwealth has in effect laws equal to or more stringent than 42 CFR 493.801.

E. Referral of Specimens

Section 493.1111 of the CLIA regulations at subsection (b) states that referring laboratories may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. In its application, the Commonwealth cited as an equivalent regulation its Regulation 83, Chpt. 7, Art. IV, sec. 2(1), which states that the referring laboratory ''will deliver the original report sent by the testing laboratory directly to the physician or to the patient.''

In its initial determination, HCFA found that the Commonwealth's regulation raised concerns because it appeared to allow the testing report to be given to either the patient or to the physician, without assuring that a copy of the test results would be sent to the individual who initially requested the test.

The Position Paper submitted by the Commonwealth provided additional information regarding reporting test results. (Position Paper, pp. 26–27) First, other subsections of section 2 of Regulation 83, Art. IV, more fully explain how referred laboratory tests are handled and, at subsection (3), states that ''(t)he referring institution may permit each testing laboratory to sent (sic) the test result directly to the physician who initially requested the test.'' *Id.* Secondly, the Commonwealth cites section 1(a) of the same Article, which provides that ''(a)ll laboratory report (sic) must be sent promptly to the authorized physician who requested said test.'' (Position Paper, p. 27) Testimony also was given to clarify that all laboratory reports are sent to the physician ordering the test. (Position Paper, p. 109)

Thus, based upon the Commonwealth's current regulations, I reject the initial determination of HCFA and find that the Commonwealth has in effect laws which are equal to those set forth at 42 CFR 493.1111.

F. Quality Control Issues

1. Control Procedures. Section 493.1218(f)(1) of the regulations directs each laboratory, as part of its routine control procedures, to check each batch or shipment of reagents, discs, stains, antisera and identification systems when prepared or opened for positive and negative reactivity, as well as graded reactivity.

In both its application and its Position Paper, the Commonwealth cites to its comparable regulation, Regulation 83, Chapter 8, Article IV, sec. 1(a)(6). (Position Paper, p. 28). That section provides that each laboratory will ''(v)erify each lot and delivery of reagents, media (if applicable), disks, stains, antiserums, and identification systems when they are prepared or opened for positive or negative reactions.'' However, in its initial determination, HCFA noted that the Commonwealth's requirements fell short of the requirements of § 493.1218(f)(1) since they do not require laboratories to check for graded reactivity, if applicable.

Similarly, § 493.1218(f)(3) requires that laboratories check fluorescent stains for positive and negative

[8] While § 493.513(c)(5) does not dictate the manner of investigation and response to complaints that each State must show in an application for exemption, § 493.513(a)(1) requires a demonstration of the existence of laws at least comparable with CLIA condition-level requirements. Thus, a review of the State's process for investigating and responding to complaints must be done when considering how the State's enforcement laws compare with those set forth in subpart R of Part 493. See discussion at I. Subpart R—Enforcement, section 1, (pp. 32–34) of this Decision.

reactivity each time of use, unless otherwise specified in subpart K of part 493. The Commonwealth's regulations on this aspect of reagent and supply checks requires laboratories to check fluorescent stains for reactivity each time of use, unless otherwise indicated. Reg. 83, Chpt. VIII, Art. IV, sec. 1(a)(8).

In its Position Paper, the Commonwealth acknowledged that the current regulations do not require laboratories to check for graded reactivity or to check fluorescent stains for positive and negative reactivity each time of use. (Position Paper, p. 28) In order to resolve the lack of regulations equivalent to paragraphs (1) and (3) of § 493.1218(f), the Commonwealth has offered to amend its regulations. *Id.*

Notwithstanding the offer to amend the deficient regulations, since they currently do not include such requirements, I must concur with the initial determination made by HCFA. I find that the Commonwealth's regulations on control procedures are not equivalent to the corresponding CLIA requirements set forth at §§ 493.1218(f)(1) and 493.1218(f)(3).

2. Syphilis Serology. In order to meet the quality control requirements for syphilis serology, the current CLIA regulations at section 493.1239 state that a laboratory must comply with applicable requirements including, as relevant here, employing positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages. In the initial determination, the Commonwealth was advised that it needed to show evidence to assure HCFA that its regulations met this specific requirement. However, neither in its Position Paper, which set out in great detail SARAFS Quality Control Specific Requirements, nor in testimony offered at the hearing, was the Commonwealth able to identify a specific regulatory provision that indicated that it required laboratories to use positive and negative controls *in all phases* of the syphilis serology. (Position Paper, pp. 28–30; Testimony, pp. 106–107).

Hence, based upon the application, Position Paper and the testimony offered at the hearing, I must concur with the initial determination made by HCFA. I find that the Commonwealth has failed to demonstrate that it has regulations in place, comparable to 42 CFR 493.1239, which require laboratories to employ positive and negative controls that evaluate all phases of syphilis testing.

3. Urinalysis Testing. In order to meet the quality control requirements for urinalysis, § 493.1251 of the regulations states that the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. In its application, the Commonwealth indicated that it requires facilities to comply with all applicable general quality control and routine chemistry requirements as well as additional requirements for urinalysis. However, HCFA's initial review suggested that these requirements appeared to conflict.

The Position Paper submitted by the Commonwealth clarified the apparent inconsistency and explained that institutions must comply with general quality controls and routine chemistry requirements. (Position Paper, p. 30). In addition, certain positive controls and confirmatory tests must be run for urinalysis. *Id.* I believe that this explanation clears up the inconsistency noted by HCFA and, thus, I find that the Commonwealth has demonstrated the existence of regulatory requirements equal to those set forth at 42 CFR 493.1251.

G. Personnel Qualifications

At the outset, I must note that the issues relating to the personnel qualifications have been the most contentious. The Commonwealth, HCFA and CDC have spent a significant amount of time discussing the educational and training levels for key laboratory personnel. The Commonwealth has suggested in its Position Paper that Puerto Rico has distinct sociological and economic limitations that should militate in favor of establishing different educational qualifications for laboratory personnel. (Position Paper, pp. 1–9) However, as I counseled the Commonwealth in the hearing, the discretion granted to the Hearing Officer in CLIA reconsideration hearings is limited. *See* 42 CFR 488.201, *et seq.* Accordingly, my decision must be based on whether the Commonwealth can cite existing regulations or laws that represent criteria or standards equal to or more stringent than those required by CLIA. Sociopolitical, economic nor cultural differences may not be considered. It is also inappropriate for me to consider proposed laws that would amend the Commonwealth's laws.

The Commonwealth also argues that applying the CLIA standards strictly, especially as regards personnel qualifications, does not allow a consideration of whether the Commonwealth's laws demonstrate ''equivalency'' with CLIA. (Position Paper, p. 9) As used in the CLIA regulations, ''equivalency'' means that:

> An accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by HCFA, taken as a whole. It is acceptable for (a) * * * State laboratory program's requirements to be organized differently or otherwise to vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the * * * State requirements as a whole.

Thus, the term ''equivalency'' as defined in § 493.2 of the regulations requires a consideration of the *entirety* of the State's program and a consideration of whether the same protections provided by CLIA would be provided under that State's program. Accordingly, it would be inappropriate to use ''equivalency'' as a tool to measure whether or not a *particular* standard or requirement is present in a State's program when compared with CLIA. Instead, it is necessary to evaluate the totality of the State's program consonant with the scope and intent of CLIA.

That said, I will now address the specific personnel requirements at issue in the Commonwealth's application.

1. Laboratory Director. The regulations at § 493.1443 set forth the qualifications for laboratory directors. The laboratory director must be qualified to manage and direct the laboratory personnel, to perform certain tests and be eligible to be an operator of a laboratory within the requirements of subpart R. Subsection (b) of § 493.1443 specifies the educational criteria necessary for laboratory directors and states, in pertinent part, that the laboratory director must (1) be a licensed doctor of medicine or osteopathy and certified in anatomic or clinical pathology, or both; (2) be a licensed doctor of medicine, osteopathy, or podiatric medicine and have either at least one year of laboratory training during medical residency or two years experience directing or supervising high complexity testing; or, (3) hold an earned doctoral degree in chemical, physical, biological or clinical laboratory science and be certified by specified licensing organizations. Section 493.1443. Provision is made in the regulations for ''grandfathering'' in laboratory directors who qualified and served as such on or before February 28, 1992.

The Commonwealth's current regulations do not establish educational criteria for laboratory directors that are at all comparable to those set forth in § 493.1443. HCFA was advised in

correspondence, and testimony was offered in the hearing, that the Commonwealth would be willing to amend its existing regulations to establish new qualifications equivalent to CLIA. However, as of the date of the hearing, such action has not been taken by the Commonwealth.

Consequently, I must concur with the initial determination reached by HCFA. I find that the personnel requirements for laboratory directors in the Commonwealth of Puerto Rico are not equal to or more stringent than those set forth in section § 493.1443.

2. Technical Supervisor. Section 493.1447 mandates that laboratories performing high complexity testing must have a technical supervisor who meets the qualification requirements of § 493.1449 and who provides technical supervision in accordance with § 493.1451. Section 493.1449 requires that laboratories employ one or more persons qualified by education and either training or experience to provide technical supervision for each of specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. In § 493.1449 the education and experience qualifications differ based upon the types of procedures and tests that the laboratory performs.

The Commonwealth was notified by HCFA in May 1995, that the standards set forth in its existing regulations for laboratory supervisors, when compared with those required by CLIA for the various types of laboratory testing, were insufficient. More specifically, HCFA explained that

> For most specialties, CLIA requires individuals with a bachelor's degree to have 4 years training/experience in the specialty with, if applicable, a minimum of 6 months experience in a subspecialty. Although Puerto Rico requires an individual with a bachelor's degree to have 5 years experience, two of which should be supervisory, there is no requirement for the experience to be in the specialty/subspecialty. In addition, CLIA requires a technical supervisor of histocompatibility or clinical cytogenetics to have at minimum a doctoral degree and 4 years of specific training or experience, or both. PR [sic] allows an individual with a bachelor's degree in medical technology and specialized training * * * to serve as a technical supervisor in these specialties.

The Commonwealth never disputed HCFA's characterization of the apparent differences in qualifications for technical supervisors. Instead, the Commonwealth asserted that ''the nature of the practice of laboratory testing in Puerto Rico is very different from that on the mainland'' [9] and offered to change its regulations on technical supervisor qualifications ''in order to upgrade this particular personnel standard to the C.L.I.A. standard'' contingent of the approval of Puerto Rico's request for exemption. (Position Paper, p. 16 and Feliciano letter).

However, as discussed at the outset, the requirements for exemption from CLIA are clear. In order to be granted an exemption, the State must demonstrate the current existence of laws that represent standards equal to or more stringent than CLIA condition level requirements. An offer to change existing regulations at sometime in the future to meet the ''CLIA standard'' is insufficient.

Accordingly, I must concur with the initial determination reached by HCFA with regard to the technical supervisors qualifications. I find that the qualifications for technical supervisor represent a condition-level requirement and that the Commonwealth has not produced existing regulations demonstrating the existence of standards equal to or more stringent than those required by 493.1447.

3. Clinical Consultants. Section 493.1453 requires that all laboratories performing high complexity testing must have a clinical consultant meeting the requirements of § 493.1455 and who provides clinical consultation in accordance with § 493.1457.

In its application, the Commonwealth stated that, with the exception of hospital laboratories, it did not require laboratories to have a clinical consultant. On this basis, HCFA made an initial determination that the Commonwealth did not demonstrate that it had laws equal to or more stringent than the CLIA regulations regarding clinical consultants.

In the Feliciano letter and in the Position Paper, the Commonwealth argues that clinical consultants have no role in Puerto Rico since the clinical laboratories use the physician who orders the test as the clinical consultant. (Position Paper, p. 19; Feliciano letter, p. 7). The Commonwealth believes that requiring independent clinical consultants interferes with the physician-patient relationship and could cause ethical conflicts. *Id.* However, notwithstanding these concerns, the Commonwealth has offered to amend its regulations to include a requirement relating to clinical consultants *if* the request for exemption is granted.

As discussed above, a future offer to amend the regulations to meet or exceed CLIA requirements may not be considered in a request for CLIA exemption. Thus, on the issue of clinical consultants, I concur with the determination reached by HCFA. I find that the Commonwealth has failed to demonstrate that it has in effect regulations regarding clinical consultants that are equal to or more stringent than those required by § 493.1453.

4. General Supervisor—Cytology. Section 493.1467 sets as a condition-level standard for the subspecialty of cytology, that the laboratory must have a general supervisor who meets the qualification requirements of section 493.1469 and who provides supervision in accordance with section 493.1471. In reviewing the Commonwealth's submission, HCFA noted that the application failed to address certain requirements for cytology general supervisors, including the requirement that the individual have at least three years of full-time experience as a cytotechnologist within the preceding ten years.

In its Position Paper, the Commonwealth concedes that its regulations at Regulation 83, Chpt. 5, Art. IV, Sec. 1(a)(5) do not mandate that cytology general supervisors have the same number of years of experience as a cytotechnologists. (Position Paper, pg. 31). To resolve this deficiency, the Commonwealth offers to amend their regulations to correct this ''oversight.'' *Id.*

As stated, a future offer to amend regulations to meet or exceed CLIA standards can not be considered when evaluating a request for exemption. The Commonwealth acknowledges that its current regulations establishing the qualifications for cytology general supervisors are not equal to the CLIA regulations. Thus, I concur with the initial determination reached by HCFA and find that the Commonwealth has failed to document the existence of regulations equal to or more stringent than those set forth at § 493.1467.

5. Cytotechnologists. Section 493.1483(b)(4) of the CLIA regulations requires that cytotechnologists seeking the benefit of the ''grandfathering'' provisions must have completed two years of full-time supervised experience in cytotechnology before January 1, 1969. Section 493.1483(b)(5), in turn, allows an individual to be ''grandfathered'' in if, on or before September 1, 1994, they had two years of full-time experience within the preceding five years under the supervision of a physician and on or

[9] July 26, 1995 Letter from Dr. Carmen A. Feliciano de Melecio to Anthony J. Tirone.

before September 1, 1995, either have graduated from an accredited cytotechnology school or become certified in cytotechnology.

HCFA informed the Commonwealth as one of the grounds for denial that their personnel qualifications for cytotechnologists wanting to be ''grandfathered'' into the program were less stringent than these CLIA requirements. Specifically, HCFA noted that the regulations cited by the Commonwealth did not require an additional two years of full-time supervised experience in cytology before January 1, 1969. The Commonwealth's regulations also did not require an individual to have graduated from cytotechnology school or have certification in addition to possessing the requisite number of years of full-time experience.

In responding to these issues in its Position Paper, the Commonwealth did not dispute the existence of a difference in qualifications. The Commonwealth avers that the applicable provisions in Regulation 83, Chpt. 5, Art. IV, sec. 1(a)(5) contains an error, causing one to read these qualifications in the alternative rather than as cumulative, that will be corrected at some time in the future. (Position Paper, p. 31).

However, to the extent that the language of the current regulatory provision is lacking when compared to §§ 493.1483(b)(4) and (b)(5), I concur with the determination reached by HCFA. I find that the Commonwealth has failed to demonstrate the existence of regulations setting forth cytotechnologist qualifications equal to or more stringent than those required by §§ 493.1483(b)(4) and (b)(5).

6. Testing Personnel. § 493.1487 requires that laboratories performing high complexity testing have a sufficient number of individuals meeting the qualification requirements of § 493.1489 to handle the volume and complexity of testing performed. The qualification standards set forth at section 493.1489 apply to all individuals performing such high complexity testing. In its initial determination, HCFA stated that the Commonwealth did not provide assurances that individuals given special licenses, such as hemodialysis technicians, nursing personnel and emergency medical technicians, would have to meet these CLIA level standards. The Commonwealth has stated that all testing performed in the Commonwealth is treated as high complexity testing. Thus, even individuals granted special licenses by the Commonwealth would need to possess qualifications equal to or more stringent than those set forth at § 493.1489.

The Commonwealth cites Regulation 83, Chapter 2, Section 2 as the currently applicable regulation governing the qualifications of individuals accorded special licenses. That regulation allows a laboratory to undertake responsibilities for training personnel working under a special license and allows the laboratory to certify proficiency through a written and practical tests. (Position Paper, p. 32). However, there is no indication that these individuals are required to complete any accredited laboratory training program or that they must attain any particular educational level.

By contrast, § 493.1489 of the CLIA regulations sets forth in detail the licensing, accreditation and educational requirements for personnel who perform high complexity testing. Nothing in the documentation provided by the Commonwealth represents similar regulatory requirements.

The Commonwealth states in its Position Paper that ''the personnel authorized under special license to perform certain testing shall either comply with Puerto Rico's stricter testing personnel requirements or at a minimum, comply with the less stringent C.L.I.A. requirements.'' (Position Paper, pp. 31–31.) However, as with other personnel qualification requirements, the Commonwealth's proposed manner of assuring the application of such standards is by taking regulatory action in the future.

Thus, I agree with the determination made by HCFA regarding the qualifications for testing personnel. I find that the Commonwealth has not produced evidence of existing regulations that are equal to or more stringent than the CLIA regulations on testing personnel qualifications set forth at § 493.1489.

H. Comparison of Test Results

Section 493.1709 of the regulations provides that if a laboratory performs tests that are not included in a proficiency testing program, the laboratory must have a system for verifying the accuracy of its test results at least twice a year. Upon reviewing the Commonwealth's application, HCFA determined that it failed to demonstrate the existence of an equivalent regulation.

In its Position Paper, the Commonwealth draws our attention to the text of Regulation 83, Art. XI, Chpt. 9, sec. 5(b). (Position Paper, p. 34.) That section, which is entitled ''Evaluation of the Comparison of the Test Results,'' states in pertinent part that ''(t)he Institution must develop mechanisms to verify the accuracy and reliability of the processed tests through different methods at least twice a year.''

However, the Commonwealth acknowledges, and we must note, that this regulation does not specifically require that laboratories maintain the accuracy of a testing procedure at least two times a year for tests for which proficiency testing is not available. In order to ensure that its regulations correspond more closely with § 493.1709, the Commonwealth has offered to amend its regulations accordingly.

This change, necessary to ensure that the Commonwealth has in effect a law equal to or more stringent than § 493.1709, has not yet been made. Hence, I concur with the initial determination of HCFA and find that the Commonwealth has not satisfied the requirements of § 493.513(a) with regard to the comparison of test results.

I. Subpart R—Enforcement

1. Relationship of Proprietor to Owner/Operator. When apprising the Commonwealth of its initial determination, HCFA generally noted that ''(t)he relationship of the proprietor to the owner/operator is unclear. This is important because, under CLIA, certain consequences to the owner-operator of a laboratory occur when the laboratory loses its certificate.'' No particular section of the CLIA regulations was cited and no additional information on the ''consequences'' at issue was provided in the notice of denial. Indeed, other than the above-cited two sentences, there is no indication that the Commonwealth was advised of the specific basis for HCFA's problems with the manner in which the Commonwealth defined the duties of the proprietor/owner.

Section 493.1840(a)(8) allows HCFA to initiate adverse actions to suspend, limit or revoke any CLIA certificate if the laboratory's owner or operator, within the preceding two year period, owned or operated a laboratory that had its CLIA certificate revoked. An ''owner'' is defined at § 493.2 as ''any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded.'' Section 493.2 defines an ''operator'' as the ''individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory.''

By comparison, the Commonwealth uses the term ''proprietor'' or ''owner'' to mean the person to whom a license is issued for the operation of a

laboratory. Reg. 83, Art. III, (51). The ''supervisor'' of the laboratory is identified as the ''[p]erson in charge of ensuring that the operation and/or administrative procedures are performed in compliance with the established standards of the institution.'' *Id.* at (58). The laboratory ''director'', in turn, is the ''[p]erson in charge of a facility in which any type of clinical analysis, pathological study and/or Blood Bank's service is provided.'' *Id.* at (15).

While there apparently is incongruence between the terms used in the CLIA regulations and the Commonwealth's regulations, the initial determination did not explain the basis for HCFA's concerns in anything but the vaguest form. Perhaps because of this failure to specify the nature of the problem insofar as concerns ''proprietors,'' ''owners,'' and ''operators,'' the Commonwealth did not address this issue in its Position Paper.

It is also noteworthy that HCFA did not actively solicit additional guidance on how the Commonwealth allocated duties between proprietors, owners and operators during the hearing.

Hence, because the Commonwealth was not fully apprised of the nature of HCFA's concerns with regard to the issue of the duties of proprietors, owners and operators, I have elected to disregard this issue in reaching a decision in this reconsideration.

2. Ensuring Timely Correction of Deficiencies. The Commonwealth was informed by HCFA that one of the grounds for the initial determination to deny the request for exemption from CLIA was that the application failed to explain fully how the Commonwealth enforced the timely correction of deficiencies. More specifically, the Commonwealth was advised:

> (T)he ability to take enforcement action in cases of immediate and serious jeopardy before the laboratory receives a hearing must be demonstrated. The Commonwealth must provide information concerning the type of sanction imposed, time frames for correction, and the actions taken when deficiencies are not corrected for * * * immediate and serious threat to public health and safety; condition level deficiencies, and deficiencies below the condition level.[10]

Thus, HCFA's evaluation of the application for exemption indicated a dearth of basic information necessary to establish the existence of adequate enforcement measures.

In its Position Paper, the Commonwealth overlooks an opportunity to educate us regarding this important aspect of the basis for denial and instead merely references sundry regulations and laws, without meaningful explanation on how the laws and regulations respond to the concerns identified in the initial denial. (Position Paper, p. 34) However, testimony was given during the Hearing that may help explain how the Commonwealth knits together these various laws to fashion enforcement proceedings. We will use this testimony to attempt to respond to the particular concerns identified by HCFA in its initial determination.

As stated, HCFA generally noted that the Commonwealth needed to demonstrate the ability to take prehearing enforcement action in cases of immediate and serious jeopardy. To respond to this deficiency, the Commonwealth refers us to Regulation 83, Chapter 10, Art. VI, sec. 10, which explains the procedures the Department may use in cases where there is an existing situation which is imminently dangerous to the health, safety and well being of the public. While this regulation is imprecise, it does demonstrate an ability to take enforcement action in such cases, and when read together with other parts of Regulation 83, such as Chapter 2 and Chapter 4, would seem sufficient to respond to the first concern expressed by HCFA.

Testimony offered at the hearing also pointed to the UAPA as an important element of the Commonwealth's enforcement authority. Section 2167 of the UAPA allows an agency to take immediate action in cases involving threats to the public health. Witnesses for the Commonwealth explained that these proceedings are *ex parte* and an order addressing the threat may be issued by the Secretary of the Department of Health after receipt of a complaint. (Testimony, pp. 90–91). If a laboratory ignores the Secretary's order, the Department of Law may petition the court for an injunction directing the laboratory to close. (Testimony, p. 91).

We note that the UAPA and the relevant provisions of Regulation 83 were cited in the Crosswalk submitted by the Commonwealth together with its application. However, it is also apparent that the testimony offered at the Hearing helped explain how these various laws should be read together. Based upon the information I have reviewed, I must partially reverse the determination of HCFA insofar as concerns this aspect of the initial determination. I find that the Commonwealth has produced documentation demonstrating the ability to take prehearing enforcement actions in cases of immediate and serious jeopardy.

HCFA also found lacking the Commonwealth's submission of documentation concerning sanctions, time frames for corrections and actions taken when deficiencies are not corrected for all levels of deficiencies. Again, because the Commonwealth relies upon several regulations to address enforcement and did not prepare a Crosswalk that corresponded exactly to the CLIA regulations, appraising the sufficiency of the Commonwealth's laws has been difficult. However, we believe that a very close reading of the documentation submitted with the initial application, including sections not explicitly identified by the Commonwealth, provides some of the information needed by HCFA.

Regulation 83, Chpt. 2, Art. VII sets forth the principal sanctions: suspension, revocation or limitation of tests. Puerto Rico also has alternative sanctions such as plans of correction, explained at Regulation 83, Chpt. 4, Art. III, sec. 1(f), and civil monetary penalties, set forth at section 2201 of the UAPA and Regulation 83, Chpt. 2, Art. VIII. A civil suit, seeking immediate closing of a laboratory, may be commenced in cases of immediate jeopardy and criminal prosecution may be sought in cases involving intentional violations. Reg. 83, Chpt. 2, Arts. IX and X. Thus, with the exception of State onsite monitoring, the Commonwealth has in effect laws that correspond generally to the CLIA regulations at section 493.1806.

However, although these laws exist, they nevertheless fail to address certain key elements and are, in some instances, less stringent than the CLIA regulations. For example, the regulations do not address the amount of time a laboratory is given to make corrections. Although Regulation 83, Chpt. 4, Art. III, Section 1(f) explains that deficiency reports are issued ten days after an inspection discloses deficiencies and indicates that correction plans must be submitted by the laboratories, the regulations do not specify when the laboratory must complete any noted corrections. Neither do the regulations make clear that the Commonwealth may send someone to visit the laboratory at any time to evaluate progress in correcting noted deficiencies. *See* § 493.1820(a).

Similarly, while the Commonwealth has in effect laws that allow for the assessment of civil monetary penalties for certain violations, the amounts are markedly less than those authorized under the CLIA regulations. As stated, section 2201 of the UAPA allows the imposition of an administrative fine of up to $5,000 for each violation of the

[10] See May 22, 1996 Denial Letter.

agency's regulations and has been cited by the Commonwealth as the key penalty provision for cases involving immediate jeopardy. However, this must be compared with 42 CFR 493.1834(d)(2) which allows HCFA to impose a penalty amount from $3,050 to $10,000 per day of noncompliance or per violation for condition level deficiencies that represent immediate jeopardy.

Lastly, with the exception of information provided concerning cases of immediate jeopardy, the Commonwealth cannot be said to have submitted comprehensible documentation of what actions are taken when less severe deficiencies are not corrected.

In summary, while I disagree with HCFA's initial determination that the Commonwealth did not demonstrate an ability to take enforcement action in cases of immediate and serious jeopardy, I concur with their assessment that the Commonwealth did not adequately explain certain key aspects of their enforcement proceedings. I find that the Commonwealth has not demonstrated the existence of regulations to ensure the timely investigation of and correction of deficiencies. I also find that the amount of civil monetary penalties that the Commonwealth may assess in cases of immediate and serious jeopardy is insufficient when compared to the CLIA regulations. For these reasons, I find that the Commonwealth has failed to document the existence of regulations equal to or more stringent than § 493.1820 of the CLIA regulations.

3. Laboratory Registry. Section 493.1850 of the regulations requires HCFA to make available once a year specific information that is useful in evaluating the performance of laboratories. The regulation explicitly mandates that this information include a list of laboratories convicted under laws relating to fraud and abuse, false billing, or kickbacks. In its initial determination, HCFA found that the Commonwealth did not evidence the existence of a regulation or law that would require it to make available to physicians and the public, via HCFA, a list of laboratories convicted of fraud and abuse, false billing, or kickbacks, under Puerto Rican law.[11]

The Commonwealth in its Position Paper indicates that it does not have any information about any laboratory convicted under Puerto Rican laws sanctioning fraud and abuse, false billing or kickbacks. (Position Paper, p. 34). As concerns its future duty to report pursuant to § 493.1850, the Commonwealth ''guarantees'' submission of such information and the future amendment of its regulations, if necessary. (Position Paper, p. 34).

We are unsure of how one should interpret the Commonwealth's lack of information in this regard. One interpretation is that there have been no laboratories in the Commonwealth of Puerto Rico have been convicted of fraud and abuse, false billing or kickbacks. Another interpretation is that the Secretary does not obtain information or maintain a record of the disposition of fraud and abuse, false billing or kickback cases involving laboratories.

In any event, to the extent that the CLIA regulations specifically require disclosure of this information to the public, any State seeking exemption from CLIA must show the existence of a corresponding reporting mechanism. As conceded by the Commonwealth, it does not currently have regulations that require it to collect and submit this data to HCFA. Without such current regulations, I have no alternative but to concur with the initial determination reached by HCFA. For the above-noted reasons, I find that the Commonwealth has failed to demonstrate the existence of a regulation equal to or more stringent than the CLIA regulation requiring laboratory registry.

IV. Findings

After undertaking an exhaustive and complete review of the documentation submitted by the Commonwealth in connection with its application for exemption, HCFA determined that Puerto Rico did not satisfy the requirements of § 493.513(a)(1) and could not be granted exemption from CLIA. I have considered the record, supplementary information provided by the Commonwealth, the Position Paper and testimony in preparing this decision. I hereby make the following findings:

1. Section 493.513 of the regulations sets forth the general requirements for States seeking exemption from CLIA program requirements.

2. Subsection 493.513(a)(1) provides that HCFA may grant a State exemption from CLIA if the State has in effect laws that provide for requirements equal to or more stringent than CLIA condition-level requirements.

3. The application for exemption and supporting documentation submitted by the Commonwealth of Puerto Rico was evaluated by HCFA using this standard.

4. In fourteen instances involving condition-level requirements, HCFA properly determined that the Commonwealth was unable to demonstrate the existence of laws providing for requirements equal to or more stringent than the CLIA regulations. These deficiencies have been thoroughly discussed in this decision.

Legal Conclusion

For the reasons discussed herein, and based upon the above-referenced findings of fact, I conclude that the initial determination reached by HCFA to deny the Commonwealth of Puerto Rico's application for exemption from CLIA was consistent with the applicable laws and regulations. It is recommended that the initial determination denying the Commonwealth's application for CLIA exemption be affirmed.

Dated: September 27, 1996.

Richard W. Besdine,

Hearing Officer, Health Care Financing Administration.

[FR Doc. 97–2761 Filed 2–4–97; 8:45 am]

BILLING CODE 4120–03–P

[11] See also § 493.513(d), which requires exempted States to provide HCFA with certain information, including license approvals, revocations, sanctions and withdrawals.

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A35, Rockville, MD 20857, (301) 443–6593.