DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Care Financing Administration

[HSQ–219–GNC]

RIN 0938–AG87

CLIA Program; Fee Schedule Revision

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

ACTION: General Notice with comment period.

SUMMARY: This notice updates the certificate fees for laboratories established under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) consistent with the methodology set forth in 42 CFR part 493. Section 353(m) of the Public Health Service Act requires that fees be collected to recoup costs of general administration of the CLIA Program. By economizing at every opportunity, the CLIA program has managed to maintain the fees established in 1992 and has absorbed all increases in costs. Revisions to the fees are necessary because the current fees are no longer sufficient to support the administration of the CLIA program. This restructuring of fees will more equitably distribute fees across all sizes and complexity of laboratories. For purposes of simplification, this notice announces a flat fee of $100 for a certificate of registration.

DATES: *Effective Date:* The updated fee schedule is effective for certificate fees assessed as of January 1, 1998, unless we announce changes in response to public comments in a subsequent notice.

Comments: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 28, 1997. We will not consider comments concerning any other issue.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–219-GNC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–219–GNC. 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 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. 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**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

FOR FURTHER INFORMATION CONTACT: Judith Yost (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. CLIA replaced in its entirety section 353 of the Public Health Service (PHS) Act and applies to every laboratory in the United States and its territories that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings subject to the requirements established by the Department of Health and Human Services (HHS). These requirements apply whether or not a laboratory receives reimbursement for services, participates in the Medicare or Medicaid program, and whether or not it tests specimens in interstate commerce. Section 353 of the PHS Act requires HHS to establish certification requirements for any laboratory that performs tests on human specimens. An amendment to the Social Security Act also requires laboratories to meet the CLIA requirements if they choose to participate in the Medicare or Medicaid programs.

On February 28, 1992, we published regulations (57 FR 7002) that contain the CLIA standards that all laboratories must meet. Also on that date, we issued regulations (57 FR 7188) concerning CLIA fees and their collection. Section 353(m) of the PHS Act requires HHS to impose fees sufficient to cover the general costs of administration incurred by HHS in implementing the CLIA program.

The preamble to the final regulations published on February 28, 1992, stated that, as experience was gained from administering the CLIA program, the fee schedules would be revised as necessary. The regulations themselves provide for periodic updating (§ 493.638(b)).

The statute requires that CLIA be a self-funded program with two separate types of fees: (1) Certificate fees and (2) additional fees for laboratory specific monitoring activities. Of these two types of fees, this notice revises only certificate fees, which is the only type of fee authorized by the statute to cover general administrative program costs.

- *Certificate fee* means a fixed charge for the issuance and renewal of certificates. Section 353(b) of the PHS Act requires that every laboratory have in effect a certificate issued by the Secretary applicable to the nature and scope of tests performed. The categories or types of certificates are described in the regulations at Part 493. Section 353(m) of the PHS Act requires that certificate fees must be sufficient to cover the Federal administrative costs of the program. These Federal administration costs to be recouped include costs incurred by HCFA, the Centers for Disease Control and Prevention (CDC) and contractors for both agencies. Administrative activities

include locating and registering laboratories, issuing and reissuing certificates, developing regulatory standards, evaluating States' requests for exemption and accrediting organizations' petitions for deemed status, reviewing, approving and monitoring proficiency testing programs, evaluating which procedures, tests, or examinations meet the criteria for inclusion in the appropriate complexity category, carrying out special public health research studies required by law, providing public information, training surveyors, developing and maintaining a comprehensive CLIA data system, and developing and overseeing the fiscal management of the program.

This notice updates the fees associated with issuance of certificates, consistent with the applicable statutory requirements and regulations. Certificate fees, as required in part 493 subpart F, support the Federal CLIA administration activities.

- *Additional fees* are the fees associated with the inspection of laboratories found in § 493.643 of the CLIA regulation. These fees are to be used for the costs associated with the inspection of laboratories and to assess compliance with CLIA requirements. This notice does not increase these fees.

II. Current Types of Certificates and Fees

Laboratories must pay the following applicable fees biennially depending on the type of certificate they receive. (These fees and certificates do not apply to laboratories licensed in States which are CLIA-exempt under subpart E of this part. In this case the State pays a fee for CLIA administrative costs.)

- *Certificate of Waiver (§ 493.638).* A laboratory that performs only tests categorized as waived must obtain a certificate of waiver. The certificate of waiver fee, established in 1992, is $100.
- *Certificate for Provider-Performed Microscopy (PPM) Procedures (§ 493.638).* A certificate for PPM procedures is required for a laboratory that performs:

1. Only tests specified as PPM procedures, or
2. Only tests specified as PPM procedures and tests categorized as waived.

The certificate fee for PPM procedures, set in 1993, is $150, which is $50 more than the fee for certificates of waiver and Schedules LVA, A, B, and C laboratories. (See Section IV Volume and Scope of Laboratory Services.) This fee reflects the additional expenses involved in reviewing moderate complexity tests to determine if they meet the criteria for classification as PPM procedures. (NOTE: This subcategory was first established in a rule published January 19, 1993, (58 FR 5212) and subsequently revised in a rule published April 24, 1995 (60 FR 20035).)

- *Certificate of Registration (part 493, subparts B and C)*

The CLIA regulations, issued on February 28, 1992, and revised April 24, 1995, describe the fees charged for a certificate of registration. Every laboratory is required to obtain a certificate of registration (subparts B and C) except for the following: laboratories performing only those tests categorized as waived; laboratories performing only tests specified as PPM procedures or performing PPM procedures and waived tests; and laboratories located in and licensed by a State which has a CLIA exemption, as specified in subpart E. In the 1992 regulations the cost to the laboratory for the certificate of registration varied with the volume and specialties of services of the laboratory. The fees for the certificate of registration, established by the February 28, 1992 regulations, are: $100 (Small volume laboratories), $350 (Medium volume laboratories), and $600 (Large volume laboratories). (See Table I)

- *Certificate of Accreditation (§ 493.638).* Any laboratory performing testing beyond waived and PPM procedures may request a certificate of accreditation based on its accreditation by a HCFA approved accrediting body. The laboratory must initially pay a fee for a certificate of registration. The certificate of registration fee is based on the laboratory's volume and number of specialties. The certificate of registration is valid for a period of no more than 2 years or until such time as the laboratory shows proof of compliance with the requirements of the accreditation organization. Once compliance is established through the accreditation program, the laboratory must pay the appropriate certificate fee based on volume and number of specialties, prior to the issuance of the certificate of accreditation. The fees, set in 1992, for these certificates are: $100 (Small volume laboratories), $350 (Medium volume laboratories), and $600 (Large volume laboratories).
- *Certificate of Compliance (§ 493.638).* All laboratories performing testing beyond waived and PPM procedures and requesting a certificate of compliance must initially pay a fee for a certificate of registration. The certificate of registration fee is based on the laboratory's volume and number of specialties. The certificate of registration is valid for no more than 2 years or until such time as an inspection by HCFA or a HCFA agent establishes compliance with the CLIA requirements. Once compliance is established, the laboratory must pay the appropriate certificate fee based on volume and number of specialties, prior to the issuance of the certificate of compliance. The fees for these certificates, set in 1992, are: $100 (Small volume laboratories), $350 (Medium volume laboratories), and $600 (Large volume laboratories).

III. Revisions to Certificates

If a laboratory issued a certificate, changes its name, location, or meets any conditions specified in § 493.639 of our regulations before the certificate expiration date, the administrative fee to issue the revised certificate is $50. (The categorization of laboratories by scope and volume (see below) was discussed in detail in the preamble to the February 28, 1992 rule (at page 7194) and is specified in our regulations at § 493.643(c).)

IV. CLIA Schedules Defined by Number of Specialties and Volume (See Table II)

Section 493.643(c), lists the schedules based on the laboratory's number of specialties and volume of testing (including PPM procedures but excluding tests performed for quality control, quality assurance, and proficiency testing purposes). These schedules, as set forth below, are used to establish the certificate fees, as well as fees associated with monitoring activities.

- *Schedule A Low Volume (LVA).* The laboratory performs not more than 2,000 laboratory tests annually.
- *Schedule A.* The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 2,000, but not more than 10,000 laboratory tests.
- *Schedule B.* The laboratory performs tests in at least four specialties of service with a total annual volume of more than 2,000, but not more than 10,000 laboratory tests.
- *Schedule C.* The laboratory performs tests in no more than three specialties of service with a total annual volume of more than 10,000, but not more than 25,000 laboratory tests.
- *Schedule D.* The laboratory performs tests in at least four specialties with a total annual volume of more than 10,000, but not more than 25,000 laboratory tests.
- *Schedule E.* The laboratory performs more than 25,000, but not more than 50,000 laboratory tests annually.
- *Schedule F.* The laboratory performs more than 50,000, but not

more than 75,000 laboratory tests annually.

- *Schedule G.* The laboratory performs more than 75,000, but not more than 100,000 laboratory tests annually.
- *Schedule H.* The laboratory performs more than 100,000, but not more than 500,000 laboratory tests annually.
- *Schedule I.* The laboratory performs more than 500,000, but not more than 1,000,000 laboratory tests annually.
- *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

For purposes of assessing certificate fees in 1992, we considered laboratories in Schedules LVA through C as small volume ($100 fee), in Schedules D through G as medium volume ($350 fee), and Schedules H through J as large volume ($600 fee).

V. Need for Increased Fees

After careful review of CLIA administration costs and revenues generated from the current certificate fees, we have concluded that current certificate fees are not sufficient to satisfy the requirements of section 353 of the PHS Act. According to our regulations at § 493.638, the total of fees collected must be sufficient to cover the general costs of administering the CLIA program. The total cost of the CLIA program is estimated to be approximately $37.5 million annually. CLIA generates about $25 million in total revenue annually, through a combination of certificate fees and additional fees, leaving a projected shortfall of approximately $12.5 million annually.

The shortfall in revenue is the result of two factors. First, more than half of all registered laboratories now pay fees based on their performing only waived tests or performing only PPM procedures, or both. When the initial fees were established in February 1992, there were no national data available on the number or types of testing performed. We projected that only 15 percent of all laboratories would have a certificate of waiver, and the PPM procedures category had not yet been established. Second, our revenue projections were based on an initial estimate of 180,000 to 250,000 registered laboratories. In fact, less than 150,000 laboratories are currently registered. This number does not include laboratories in CLIA exempt States.

This shortfall has been exacerbated by the lack of appropriations for start up costs at the inception of the program in 1988. As a result, we have taken a number of steps to curtail CLIA costs and administrative activities in order to meet the statutory mandate which requires CLIA revenues to cover the costs of administering the program. These steps have included: implementing survey efficiencies, improving the fee collection process, limiting or postponing CLIA research projects, restricting hiring of additional staff and delaying some other Federal administrative activities. Overall Federal administrative costs have been reduced significantly by decreasing staff positions and reducing costs for travel, printing, subscriptions, and training.

Even though we have reduced administrative costs, a portion of CLIA's administrative expenditures remains fixed and cannot be reduced without seriously undermining the effectiveness of the program. These costs are associated with activities such as: evaluating test systems for appropriate complexity categorization under CLIA; revising survey procedures, such as instituting the Alternate Quality Assessment Survey (AQAS); providing training and consultation to States, other Federal agencies, professional organizations, and laboratories; mailing information and application materials to laboratories; and operating and maintaining the accounting and data systems needed to provide accurate and timely information about laboratory registration and about CLIA receipts and expenses. Other costs are those associated with collecting unpaid fees and administration of the enforcement process.

In order to comply with statutory requirements requiring that CLIA be self-funded, we have already made substantial efforts to decrease Federal administrative costs. Now, we must also seek additional revenues within the authority of the statute and existing regulations to eliminate an anticipated CLIA shortfall.

While this increase in fees will have a varying impact on laboratories, depending on the size and volume of testing performed and other market place factors, it will ultimately provide for a more effective and efficient management of the CLIA program and be a cost effective investment. For example, research projects will enable us to identify, expand and develop innovative, less burdensome survey processes, appropriate personnel qualifications, effective quality control requirements, and could ultimately reduce costs to individual laboratories.

VI. Revised Fees

The CLIA regulations require laboratories to pay a fee for the issuance of a CLIA certificate. In updating the certificate fee levels to meet statutory revenue requirements, the methodology set forth in § 493.638(b) has been retained. This is consistent with the intent to allocate fees to avoid any undue burden and to maintain site neutrality among all laboratories. This means that laboratories performing similar types and volumes of testing despite the location of testing have the same fees imposed upon them. Currently, there are three certificate fees for small, medium and large volume laboratories. This notice sets forth a $150 certificate fee for Schedules LVA, A and B laboratories. It also establishes eight other certificate fees based on volume differences in laboratories.

Registration Fee—Currently, a laboratory pays the same amount for a certificate of registration and its certificate of compliance or certificate of accreditation. Schedules LVA, A, B, and C laboratories pay $100. Schedules D, E, F, and G laboratories pay $350; and Schedules H, I, and J laboratories pay $600. To be consistent, a set registration fee of $100 will be charged to every laboratory applying for a certificate of accreditation or certificate of compliance. Therefore, this notice provides for a reduction in certificate of registration fees for Schedules D through J laboratories. The fee for Schedules LVA, A, B, and C laboratories will remain $100. (See Table I). We invite comments if there are other alternatives which might be adopted in place of this flat registration fee.

Fee for Revised Certificates—The regulations require laboratories to provide notification of certain changes such as name, location, director, and deleting or adding services as outlined in § 493.639. Prior to the expiration of the certificate, these changes require payment of a fee for the issuance of a revised certificate. Based on the costs involved to issue a revised certificate, this fee will increase from $50 to $75. It should be noted that, to date, no fees have been charged for issuing revised certificates, due to changes in the CLIA program such as the addition of PPM procedures; categorization of additional waived tests and revisions to other federal regulations pertaining to laboratory ownership.

Biennial Certificate Fees—The statute requires fees be imposed to cover the costs of administering the CLIA program. Even though significant cost reductions in the program have already occurred, the certificate fees must be increased to maintain program integrity. In order to equitably distribute the biennial certificate fees, the average annual testing volume for laboratories in

Schedules LVA through J were considered. Table III in this section lists average annual testing volumes for the various schedules of laboratories.

The regulations at § 493.643(c) require that certificate fees be based on the ''number of specialties and volume of testing.'' It was determined that an equitable manner to spread costs while conforming to regulatory requirements would be to set certificate fees for Schedules C through J laboratories on an average per-test basis. Fees for Schedules LVA, A, and B laboratories would be set at a minimum amount—$150. Use of this basis to determine fees is expected to result in a more appropriate allocation of cost across all fee schedules. (See Table III).

Economies of scale among laboratories are accounted for by applying reductions in the per-test rates as the number of specialties and volume of a laboratory increases. New fees for laboratory Schedules C through J are calculated by multiplying the average testing volume by the corresponding per-test rate. This will result in a fairer allocation of costs than the current flat fees for small, medium and large laboratories. The revised fees are summarized below.

• *Certificate of Waiver (§ 493.638).* The biennial fee for this certificate is being increased from $100 to $150. This increase is necessary to cover added administrative costs to the CLIA program as more tests are waived. Laboratories may perform these tests at any volume and pay only $150 biennially.

• *Certificate for Provider-Performed Microscopy (PPM) Procedures (§ 493.638).* The biennial fee for the certificate is being increased from $150 to $200. This increase in fees is required to cover administrative costs associated with this subcategory of testing. This certificate allows a laboratory to conduct both PPM procedures and waived tests, at any volume and pay no other fee.

• *Certificate of Compliance and Certificate of Accreditation (§ 493.638).*

• *Schedule A Low Volume.* If the laboratory performs not more than 2,000 laboratory tests annually, the biennial certificate fee will be $150.

• *Schedule A.* If the laboratory performs tests in no more than three specialties of service with a total annual volume of more than 2,000, but not more than 10,000 laboratory tests, the biennial certificate fee will be $150.

• *Schedule B.* If the laboratory performs tests in at least four or more specialties of service with a total annual volume of not more than 10,000 laboratory tests, the biennial certificate fee will be $150.

• *Schedule C.* If the laboratory performs tests in no more than three specialties of service with a total annual volume of more than 10,000, but not more than 25,000 laboratory tests, the biennial certificate fee will be $430.

• *Schedule D.* If the laboratory performs tests in at least four or more specialties with a total annual volume of more than 10,000, but not more than 25,000 laboratory tests, the biennial certificate fee will be $440.

• *Schedule E.* If the laboratory performs more than 25,000, but not more than 50,000 laboratory tests annually, the biennial certificate fee will be $650.

• *Schedule F.* If the laboratory performs more than 50,000, but not more than 75,000 laboratory tests annually, the biennial certificate fee will be $1,100.

• *Schedule G.* If the laboratory performs more than 75,000, but not more than 100,000 laboratory tests annually, the biennial certificate fee will be $1,550.

• *Schedule H.* If the laboratory performs more than 100,000, but not more than 500,000 laboratory tests annually, the biennial certificate fee will be $2,040.

• *Schedule I.* If the laboratory performs more than 500,000, but not more than 1,000,000 laboratory tests annually, the biennial certificate fee will be $6,220.

• *Schedule J.* If the laboratory performs more than 1,000,000 laboratory tests annually, the biennial certificate fee will be $7,940. The revised certificate fees in schedule C through J are based on the average annual number of tests performed.

The following examples illustrate how these fees are determined:

• The average annual test volume for laboratories in Schedule D is 16,445 tests each year. The certificate fee, rounded to the nearest $10, for those laboratories is $0.0269 times 16,445 annual tests, or $440.

• Similarly, the average annual test volume for Schedule J laboratories is 2,886,393. At a per-test rate of $0.00275, Schedule J laboratories will pay a biennial certificate fee, rounded to the nearest $10, of $7,940.

TABLE I.—REDUCTIONS IN MOST REGISTRATION FEES

Type of lab	Current registration fee	Reduction in registration fee	New registration fee
Waived	N/A	N/A	N/A
PPM	N/A	N/A	N/A
Low Vol A	$100	$0	$100
Schedule A	100	0	100
Schedule B	100	0	100
Schedule C	100	0	100
Schedule D	350	250	100
Schedule E	350	250	100
Schedule F	350	250	100
Schedule G	350	250	100
Schedule H	600	500	100
Schedule I	600	500	100
Schedule J	600	500	100

TABLE II.—CLIA LABORATORY SCHEDULE

Type of lab	Number of specialties	Annual test volume	Current biennial certificate fee	New biennial certificate fee
Waived	N/A	N/A	$100	$150
PPM	N/A	N/A	150	200

TABLE II.—CLIA LABORATORY SCHEDULE—Continued

Type of lab	Number of specialties	Annual test volume	Current biennial certificate fee	New biennial certificate fee
Low Vol A	N/A	Less than 2,000	100	150
Sch. A	3 or Fewer	2,000–10,000	100	150
Sch. B	4 or More	2,000–10,000	100	150
Sch. C	3 or Fewer	10,001–25,000	100	430
Sch. D	4 or More	10,001–25,000	350	440
Sch. E	N/A	25,001–50,000	350	650
Sch. F	N/A	50,001–75,000	350	1,100
Sch. G	N/A	75,001–100,000	350	1,550
Sch. H	N/A	100,001–500,000	600	2,040
Sch. I	N/A	500,001–1,000,000	600	6,220
Sch. J	N/A	Greater than 1,000,000	600	7,940

TABLE III.—CLIA LABORATORIES BY TESTING VOLUME

Type of lab	Current biennial cert. fee	Number of labs as of 3/96	Average annual testing volume	Biennial per test rate	New biennial cert. fee
Waived	$100	70948	N/A	N/A	$150
PPM	150	26707	N/A	N/A	200
Low Vol A	100	18307	852	N/A	150
Sch. A	100	11204	4911	N/A	150
Sch. B	100	2864	5509	N/A	150
Sch. C	100	3599	15969	$0.027	430
Sch. D	350	1840	16445	0.0269	440
Sch. E	350	2990	35928	0.0181	650
Sch. F	350	1417	61669	0.0179	1,100
Sch. G	350	938	87145	0.0178	1,550
Sch. H	600	3566	226237	0.0090	2,040
Sch. I	600	988	711213	0.00875	6,220
Sch. J	600	1058	2886393	0.00275	7,940

VII. Comment Opportunities and Alternatives Considered

We are publishing this as a general notice with opportunity to comment because it relates only to the application of § 493.638 by the agency, and is limited to the issue of the amount of the CLIA certificate fee. While we will be accepting public comment on this notice, a fee increase is required by statute because section 353(m)(3)(A) of the PHS Act mandates that certificate fees cover the cost of general CLIA program administration. Moreover, we believe this fee increase is consistent with the methodology set forth in our regulations at §§ 493.638 and 493.649.

We will consider all comments received within 60 days of the date of publication of this notice, and if necessary, we may revise the certificate fees laid out in this notice based on issues raised by commenters. Other alternatives to the changes in fee schedules may exist, and we will consider options suggested by commenters. If we determine that changes in the certificate fees are required in response to public comments, we will announce the changes in a subsequent notice. Otherwise, the certificate fees announced in this notice will become effective on January 1, 1998.

We considered several options before establishing the certificate fees. The first option we considered was to establish a single registration and certificate fee for all laboratories, regardless of their size. This option was first presented in the proposed rule on CLIA program fees in May 1990 (55 FR 31758). After further discussion and consideration of public comments, it was rejected because a single certificate fee would create an unfair burden on small laboratories.

The second option we considered was to retain separate registration and certificate fees for small, medium, and large laboratories, using the existing size categories; that is, for purposes of assessing fees, we considered laboratories in Schedules LVA through C as small volume, in Schedules D through G as medium volume, and in Schedules H through J as large volume. We dismissed this option because, in order to generate adequate revenue, the increase in fees from one category to another would be too extreme. Laboratories with nearly identical test volumes could, under this option, pay extremely disparate fees.

We also considered basing certificate fees on each laboratory's annual revenue, but dismissed this option because accurate information regarding revenues for each laboratory is not readily available. Therefore, after careful evaluation of these options, it was determined that a set fee would be assessed for certificates of waiver, PPM procedures, registration and Schedules LVA, A and B laboratories. Certificate of compliance and certificate of accreditation fees, for Schedules C through J laboratories, are based on the average annual test volume and number of specialties. This was the most equitable and practical method for determining fees. This approach has the merit of assessing larger fees to large volume laboratories, while setting their cost per test performed at a lower rate than that of smaller laboratories to acknowledge economies of scale. This approach is based on the fee methodology already set forth in the CLIA regulations.

We will continue to review these certificate fees and may adjust the fee amounts in the future as additional experience in program implementation is gained. We are considering whether to establish a mechanism to adjust fees periodically for inflation and invite specific suggestions on mechanisms, including specific indices, which could be used to accommodate adjustments

based on inflation and changes to the program. Any future changes in the fees will be preceded by an announcement in the **Federal Register**.

VIII. Impact Analysis

A. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final 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. Although this notice would not have a significant economic impact on a substantial number of small entities, we are preparing the following voluntary regulatory flexibility analysis.

This notice revises the fees for all CLIA certificates. The effect of this notice will vary widely among laboratories. This notice is projected to generate certificate fees of $50 million on a biennial basis or $25 million annually.

Section 353(m) of the PHS Act, as amended by CLIA, requires HHS to impose fees for the issuance and renewal of certificates and for determining program compliance. The statute requires that all certificate holders share in the costs that the government incurs in administering the CLIA program. The statute states that the fees imposed vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant. Hence, the imposition of fees is not a discretionary action on the part of HHS or HCFA.

The CLIA fee collection rule, published on February 28, 1992, established 12 classifications of laboratories based on volume and scope of services. (A thirteenth schedule, certificate for PPM procedures, was added January 19, 1993.) These classifications are unchanged by this notice. Previously, laboratories applying for certificate of waiver or certificate of PPM procedures paid a set fee. Laboratories applying for certificates of compliance or accreditation paid one of three registration and certificate fees determined by number of specialties and volume of services.

In developing the CLIA regulations and implementation policies, we were cognizant of the costs and attempted to avoid unnecessary burden on laboratories due to unreasonable costs of regulation, particularly on small providers in rural areas. The graduated fee amounts also were adopted in order to avoid any undue burden on small laboratories and represented our best attempt, using the limited data available at the time, to apportion the estimated costs of administering CLIA while maintaining site neutrality among the projected universe of laboratories.

In the comprehensive regulatory impact analysis of the February 28, 1992, regulations implementing CLIA, we presented several assumptions regarding the universe of laboratories and the projected distribution of laboratories by certificate fee category. Our most conservative assumption estimated a universe of 180,000 laboratories, with 50 percent of the laboratories paying the lowest fee of $100 by virtue of being classified as waived or small, and 50 percent paying either $350 or $600, depending on whether they were classified as medium or large.

Our 1992 projections have proven to be incorrect. At that time, there was no way to accurately predict that the total number of laboratories registering under CLIA would fall short of our estimate, and the number of waived and small laboratories would exceed our projection. Recent data indicate that approximately 90 percent of the registered laboratories pay minimum fees because they hold certificates of waiver, PPM procedures, or are categorized as small based on volume of testing. The remaining 10 percent (Schedules C through J) have average annual testing volumes greater than 10,000.

Current total CLIA revenues generated are approximately $25 million annually and are not sufficient to fully support the continued operation of the CLIA program and retain the intended goals of the program. Even with the reduction in administrative activities, we estimate that the cost of the program will be approximately $37.5 million annually or $75 million biennially. After enactment of this certificate fee schedule, we estimate that annual CLIA revenues, through a combination of certificate fees and additional fees, will maintain the viability of the program.

Once this notice is effective, there will be a set fee for certificates of registration, waiver, PPM procedures and the certificates for Schedules LVA, A and B laboratories. For Schedules C through J laboratories, the certificate fee changes in this notice result in increases in fee amounts from one schedule to another, based on test volume. These changes also retain the policy of allowing the laboratories doing the least amount of testing to pay the lowest certificate fee necessary to cover the costs of implementing the CLIA requirements. This is a minimal change because laboratories holding a certificate of waiver, certificate for PPM procedures, or laboratories falling in Schedules LVA through B will each see an increase of only $50 over a 2 year period, amounting to less than $.07 per day.

Currently, laboratories pay $100, $350, or $600 for a certificate of registration, depending on their volume of testing. The new certificate of registration fee for all laboratories will be $100, regardless of testing volume. We believe this approach is in keeping with our policy of attempting to minimize fee increases for laboratories performing a smaller volume of testing, and at the same time, simplifies the registration process.

A certificate of registration allows the laboratory to begin performing testing before compliance is assessed. We will maintain the policy of not requiring a certificate of registration for laboratories seeking a certificate of waiver or a certificate for PPM procedures; therefore, these laboratories' will not have to pay a certificate of registration fee. We will assess these laboratories fees biennially only for their respective certificate of waiver or certificate for PPM procedures.

We are soliciting comments on whether assessing even a new minimal $100 registration fee for laboratories seeking a certificate of compliance or certificate of accreditation creates a barrier into the market place. If so, specifically how do such fees create a barrier into the market place?

When we examined total fees related to the volume of tests performed, we concluded that disproportionally small fees were being collected from large laboratories. Under the current certificate fees, laboratories holding a certificate of waiver, certificate for PPM procedures and laboratories falling in Schedules LVA, through B (approximately 130,000 or 89 percent of the total number of laboratories) pay 70 percent of the administrative costs of the CLIA program through the certificate fees. Under the new certificate fees, the same laboratories pay only 42 percent of the administrative costs. We were conservative in raising the certificate fees for small laboratories in order to be sensitive to their need to provide direct patient care and not impede access to quality laboratory testing. Larger laboratories, based on the volume of tests, reap a greater financial benefit than the smaller laboratories due to the conceivable economies of scale and, therefore, have unlimited potential to provide service to a larger share of the

market. In an effort to distribute costs more equitably among the various types and sizes of laboratories, while generating sufficient revenue, we now rely more heavily on average annual test volumes to determine certificate fees. The fees for certificate of waiver or PPM procedures have been, and will continue to be, a flat fee irrespective of volume of testing performed. The $50 fee increase for these laboratories is based on expenditures related to these types of certificates. These costs include: reviewing test systems for categorization as waived or PPM procedures; maintaining and updating the data systems; issuing certificates; issuing test categorization notices; collecting fees; and analyzing data.

For other certificate types, instead of using the three-tiered fee schedule based on general ranges of test volume, we are maintaining the 11 laboratory schedules, LVA through J, previously established on February 28, 1992. The new biennial certificate fees for each schedule are computed using a decreasing per test rate as the volume of tests increases. This per-test rate is multiplied by the average annual test volume performed in each schedule, with the exception of the smallest laboratories, LVA through B, being charged a certificate fee of $150. Laboratories in Schedules C through G, which encompass test volumes up to 100,000, each will pay a certificate fee based on the per-test rate. (See Table III) Between Schedules G and H laboratories, the per-test rate is being reduced by almost one half, because of the dramatic increase in volume for Schedule H laboratories. These test volumes range from more than 100,000 to 500,000. Another very large increase in volume occurs for Schedule J laboratories, which perform over 1 million tests annually. Between Schedules I and J laboratories, the per-test rate is being reduced by approximately three-fourths, in recognition of the large increase in the test volume of these laboratories.

The revisions to the CLIA certificate fees will significantly alter the biennial certificate fees for some laboratories. Table III presents the approximate number of laboratories in each laboratory type and their new biennial certificate fees.

The effect of this new fee schedule will vary widely among clinical laboratories. Nearly 62 percent of the laboratories now hold certificate of waiver or certificate for PPM procedures and pay a flat certificate fee. For certificates of waiver, laboratories will pay $150 biennially and for certificates for PPM procedures, the biennial fee will be $200. These $50 biennial increases amount to less than $0.07 per day per laboratory. The new fees take into account the increased number of tests that may be performed under these types of certificates.

Laboratories with a change in name, location or in any of the conditions specified in § 493.639 of our regulations will find the fee for a revised certificate increased by $25, from $50 to $75.

As previously stated, we are required by statute to establish fees to support the CLIA program. Although certificate fees increase proportionately, we believe that by relating the fee more precisely to the number of tests a laboratory performs each year, the costs of administering CLIA will be distributed more equitably across all laboratories. The laboratories bearing the largest increase in certificate fees, Schedules C through J, account for more than 90 percent of the annual test volume in this country. Because of their large test volumes we have applied the lowest possible per-test rates to those laboratories, consistent with generating sufficient revenues. We concluded that basing certificate fees on the average annual test volume for each schedule and a decreasing per-test rate was the most equitable and practical method for constructing the fee schedule. (See Table III) This approach has the merit of charging larger laboratories less per test performed, while still basing the overall fees directly on the volume of testing. These fees will result in large increases in certificate fees for the laboratories with the highest test volumes. These differences are directly proportional to test volumes, resulting in laboratories with similar volumes paying similar fees.

For the reasons given above, we certify that this proposed fee schedule would not have a significant effect on a substantial number of small entities and that a regulatory flexibility analysis is not needed.

B. Rural Hospital Impact Statement

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. This 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. We are not preparing a rural impact statement since we have determined, and certify, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

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

(Catalog of Federal Domestic Assistance Program No. 93–778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93–774, Medicare—Supplementary Medical Insurance Program)

Dated: December 20, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 11, 1996.

David A. Satcher,

Director, Centers for Disease Control and Prevention.

Dated: March 26, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–23084 Filed 8–28–97; 8:45 am]

BILLING CODE 4210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Translation Advisory Committee for Diabetes Prevention and Control Programs: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Translation Advisory Committee for Diabetes Prevention and Control Programs.

Times and Dates: 9 a.m.–6 p.m., September 16, 1997. 9 a.m.–12 noon, September 17, 1997.

Place: Crown Plaza Ravinia, 4355 Ashford-Dunwoody Road, Atlanta, Georgia 30346, telephone 770/395-7700.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with advising the Director, CDC, regarding policy issues and broad strategies for diabetes translation activities and control programs designed to reduce risk factors, health services utilization, costs, morbidity, and mortality associated with diabetes and its complications. The Committee identifies research advances and technologies ready for translation into widespread community practice; recommends broad public health strategies to be implemented through public health interventions; identifies opportunities for surveillance and epidemiologic assessment of diabetes and related complications; and for the purpose of assuring the most effective use and