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General Accounting Office
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Health, Education, and
Human Services Division

B-284285

February 4, 2000

The Honorable Ron Wyden
United States Senate

Subject: Laboratory Quality: Financing the Clinical Laboratory Improvement Act (CLIA) Program

Dear Senator Wyden:

The Clinical Laboratory Improvement Act amendments (CLIA), implemented in 1992, expanded the federal quality assurance program for laboratory testing. Although all clinical laboratories are subject to CLIA requirements, some states have been approved by the Department of Health and Human Services (HHS) to operate their own laboratory quality assurance programs in lieu of the federal program. Because CLIA is funded entirely by user fees, these approved states are required to pay a fee to the Health Care Financing Administration (HCFA) for CLIA activities that will benefit them. Laboratories in all other states pay fees to support these activities as well as for inspection and certification of their facilities. In July 1999, HCFA announced an increase in the fees charged to the three approved states; this action follows a 1998 increase in fees for laboratories in all other states. In light of these fee increases, you asked us to review (1) the CLIA program budget history, including the rationale for recent fee increases; (2) the allocation of increased fees across laboratories and states; and (3) the information HCFA provided to states on CLIA program operations and the recent increase in fees.

To analyze budget trends, we obtained data from federal agencies onCLIA program collections and disbursements between fiscal years 1992 and 2000 (estimated). To determine HCFA's justification for increasing fees, and how those fee increases were distributed, we held discussions with agency officials, reviewed agency documents, and examined CLIA legislation and regulations. To describe the information provided to states about CLIA activities and fees, we interviewed officials in the approved states–Oregon, Washington, and New York–and reviewed their correspondence with HCFA. We also contacted states that are seeking approval–California, Florida, and Georgia–and associations representing public and private laboratories. We

performed this review from October 1999 through January 2000 in accordance with generally accepted government auditing standards.

In summary, when HCFA first implemented the CLIA amendments, the agency overestimated the numbers and types of laboratories in the United States, and set user fees too low to cover all planned program activities. Anticipating a shortfall, HCFA officials accelerated billing to meet the program's cash flow needs and curtailed expenditures through efficiencies and deferred program operations. As a result, the funding shortfall did not materialize. However, to avoid long-term loss in CLIA's capacity to ensure laboratory quality, the agency increased laboratory user fees in 1998, and began funding deferred program activities. The largest increases were assessed on the highest-volume laboratories. The following year, fees were increased for approved states, requiring them to pay a greater proportion of CLIA's total administrative costs than had been the case in the past. Officials in these states have questioned HCFA's legal authority to impose these fees. In response, HCFA officials maintain that approved states derive benefits from the national program and note that they are required by regulation to pay a prorated share of general administrative costs. In communicating with state officials regarding CLIA, HCFA was generally responsive to requests for program and budget information, but the agency did not provide timely notification of the amount of the recent fee increase.

BACKGROUND

Congress enacted CLIA in 1967 to improve the quality of medical laboratory testing in hospital and interstate laboratories. CLIA was amended in 1988 to broaden its coverage to all clinical laboratories. Three agencies within HHS administer the program: HCFA (which has primary responsibility for managing the CLIA program), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).[1] Because it is a self-funded program, user fees must be sufficient to cover the costs of administration these agencies incur in implementing CLIA.

The CLIA program established standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the country.[2] Laboratories in the national program are subject to a system of federal oversight that includes inspecting laboratories and assessing their compliance with CLIA requirements. HCFA

[1]Representatives from these agencies, along with experts in laboratory science and other fields, make up a CLIA advisory committee that informs the Secretary of HHS on technical and regulatory developments.

[2]A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease; or for the purpose of providing information on the impairment or assessment of health. Research and certain other laboratories remain unregulated under CLIA.

generally contracts with state agencies (often the state Department of Health) to conduct laboratory surveys. Laboratories in the national program are required to pay two types of fees: (1) certificate fees to cover general administrative program costs, and (2) additional fees to cover the costs of laboratory-specific monitoring activities.

The volume and types of testing performed determine the level of oversight required and the fees charged each laboratory.[3] Individual laboratory tests are categorized as waived, provider performed microscopy (PPM), or moderate or high complexity. These are described below:

- Waived tests are considered the simplest to administer.[4] Laboratories that conduct only waived tests are not routinely subject to federal oversight and they must pay a certificate of waiver fee. Of the 162,044 laboratories registered with the CLIA program in non-approved states, 53 percent conduct only waived tests.

- PPM tests are a subset of the group of moderate complexity tests. Laboratories in which a physician, midlevel practitioner, or dentist performs only PPM (or waived) tests are not subject to survey and certification.[5] The 21 percent of laboratories that are in this category pay a certificate of microscopy fee.

- Tests designated as moderate or high complexity must be administered by trained personnel who follow quality control procedures. Laboratories conducting such tests are subject to survey and certification by a HCFA contractor or accreditation by a HCFA-approved private organization.[6] They are also subject to proficiency testing, a means of checking the accuracy of test results from a laboratory by sending samples with known properties to the laboratory for testing. This group of laboratories must pay a registration fee and a biennial certificate fee. If they undergo HCFA inspection, they also pay HCFA a compliance fee to cover the cost of their

[3]The highest level of testing done by a laboratory determines the level of oversight required. Laboratories classify themselves on HCFA's CLIA application. This information is not validated by HCFA for waived and PPM laboratories, although HCFA verifies the information provided by other labs during their initial survey.

[4]Nearly 600 laboratory tests have waived status, and 8 of the top 10 laboratory tests (by volume) used in physician office laboratories can be conducted with a waived product.

[5]Laboratories that conduct PPM tests are subject to proficiency testing. To date, however, HCFA has not approved any proficiency testing providers for this group.

[6]Laboratories subject to survey under CLIA may choose whether they wish to be surveyed by HCFA or by one of the six private, nonprofit accrediting organizations that have been approved by HCFA. In 1999, 39 percent of such laboratories chose accreditation to meet their requirement. For more information on HCFA's use and oversight of these organizations, see Medicare: HCFA's Approval and Oversight of Private Accreditation Organizations (GAO/HEHS-99-197R, Sept. 30, 1999).

survey. If they choose the accreditation option, they pay a similar fee to the accreditation organization as well as a fee to HCFA to cover the cost of validation surveys. Excluding PPM laboratories, this category accounts for 26 percent of laboratories in the national program.

CLIA legislation allows the Secretary of HHS to exempt laboratories from federal inspection if HCFA has determined that they are subject to a state program of licensing and oversight that is as rigorous as the CLIA requirements. In such cases, the state pays a fee to HCFA to cover the cost of conducting validation surveys for laboratories within the state as well as a prorated share of the total administrative costs of the national CLIA program. Typically, approved states collect fees from their laboratories to cover both the state's cost of licensing and oversight and the amount owed to HCFA. In 1999, there were 7,514 laboratories registered in three approved states (Oregon, Washington, and New York[7]); Oregon has since given up its approved status. HCFA has granted conditional approved status for Florida and California (pending acceptance of the approved state fee and publication in the Federal Register) and Georgia has also submitted an application for approval that is under review.

FEE INCREASES INTENDED TO SUPPORT IMPLEMENTATION OF CURTAILED PROGRAM ACTIVITIES

HCFA officials told us that, soon after the program began, they determined that user fee collections at the originally set levels would not be sufficient to cover projected costs. As a short-term response to avoid operating with a deficit, they made various program adjustments, including limiting several areas of program operations. As a result, although expenses slightly exceeded revenues in 3 of the 5 years between 1993 and 1997, revenues carried over from previous years kept the budget in balance. In 1998, to implement activities deemed necessary to assure quality laboratory operations, HCFA increased CLIA laboratory fees. Revenues increased sharply in fiscal years 1998 and 1999, exceeding expenditures. Currently, nearly all collections derive from fees paid by laboratories for survey and certification and about half of all disbursements are paid to states that contract with HCFA to conduct laboratory surveys.

[7]Not all of New York's laboratories are exempt from federal oversight; physician office laboratories remain part of the national CLIA program.

Anticipated Revenue Shortfall Spurred Program Modifications and Fee Increases

As early as 1993, HCFA officials realized that the fee schedule originally established would not generate revenue sufficient to cover the costs of a comprehensive program. They told us that, at the time CLIA was implemented, no national data were available on the number and type of laboratories in operation. In 1992, HCFA officials estimated a universe of 312,000 laboratories, and user fee amounts were developed based on this estimate. In fact, only about 90,000 laboratories registered that year–less than one-third the number expected. In addition, HCFA estimated that 50 percent of laboratories would pay the lowest fee amount, by virtue of being classified as waived or small-volume.[8] In 1993, after one year of program operations, agency officials estimated a shortfall of as much as $120 million over the first 4 years of CLIA's implementation.

To avoid a budget shortfall, HCFA officials made several program adjustments during the early years of CLIA operations. The agency took steps to contain CLIA costs by restricting program operations in several areas, including reduced staffing levels, elimination of regular training for state agency surveyors, limited funding for research studies, and delayed implementation of validation surveys for both accreditation organizations and approved states. HCFA also pursued efficiencies, such as permitting selected laboratories to conduct their own surveys under specific circumstances. Finally, HCFA initiated a prebilling system that required laboratories to pay their certificate fees in advance of the next survey cycle. According to agency officials, implementation of these measures early in the program's development forestalled the predicted funding shortfall.

HCFA officials told us they were concerned that, if these restrictions were continued over a long period of time, the quality of program operations could decline. Therefore, in 1998, HCFA raised fees to allow the implementation of deferred program operations.[9] According to program managers, by increasing fees in 1998, CLIA solvency was assured until 2002.

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[8]The numbers of waived and PPM labs have increased due to additional approved tests in these categories and improved technology. Specifically, the number of laboratories subject to HCFA survey has declined from 45,000 in fiscal year 1992 to about 27,000 in fiscal year 1999, creating an estimated reduction in fee receipts of $18 million.

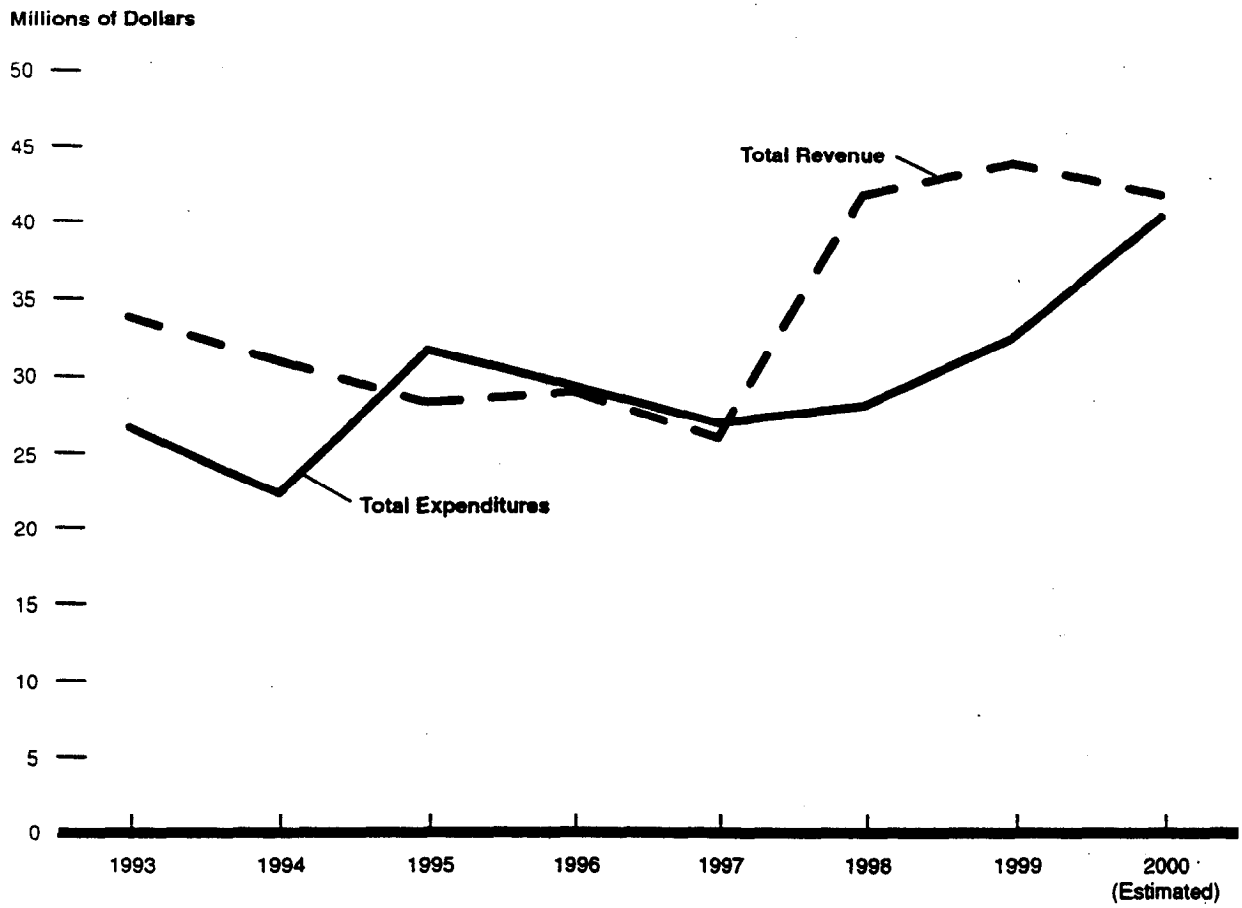
[9]Believing that additional revenues were essential for effective operations, CLIA program officials began seeking approval to increase laboratory user fees in 1994. In 1997, senior HCFA officials approved an increase in the fees, which was implemented in 1998.

Fee Increases Allow for Expansion of CLIA Spending

For much of the period before 1998, expenditures for the CLIA program slightly exceeded revenues. Since that time, revenues have risen dramatically, while expenditures are growing more slowly. HCFA expects the gap to narrow by fiscal year 2000. Currently, the vast majority of collections–about 95 percent of total revenues–derive from fees paid by laboratories for survey and certification. The largest cost category—about half of all CLIA disbursements–has been for payments to states for conducting laboratory surveys. Expenses for items such as billing and data management, validation surveys, test categorization, research, and administration account for the remainder.

Total revenues for CLIA averaged $29.6 million between fiscal year 1993 and fiscal year 1997, while total expenditure averaged $27.4 million over the same period (see figure 1). The 1998 fee increase raised revenues by about 68 percent from $26 million in fiscal year 1997 to almost $44 million in fiscal year 1999. Total expenditures have increased more slowly, rising from $27.0 million in fiscal year 1997 to $32.6 million in fiscal year 1999, and are projected to reach $40 million in fiscal year 2000.

Figure 1: Total CLIA Revenues and Expenditures, Fiscal Years 1993-2000 (estimated)



Note: Expenditure data through fiscal year 1999 do not include indirect costs– CLIA's portion of total HCFA administrative costs–that should have been charged to the program by HHS but were not billed. Expenditure data for fiscal year 2000 include $3.85 million in indirect costs that HCFA expects to be billed. Revenue data in millions, from 1993 to 2000 (anticipated) are, respectively: $33.84, $30.99, $28.31, $29.01, $26.01, $41.75, $43.80, and $41.80. Expenditure data, in millions, for the same years 1993 to 2000 (anticipated) are, respectively: $26.66, $22.27, $31.69, $29.42, $26.99, $28.16, $32.58, and $40.38.

Source: HCFA, Center for Medicaid and State Operations, Jan. 2000.

As shown in table 1, CLIA revenues are derived from a variety of fees,nearly all of which are paid by laboratories. Fee levels vary widely, from a $100 registration fee to several thousand dollars charged for some certificate fees. About a quarter of laboratories in the national CLIA program account for most of the program revenues. In fiscal year 1999, the 26 percent of laboratories that conduct tests designated as moderate and high complexity paid 82 percent of the $43.8 million in CLIA revenues through certificate, compliance, and validation fees.

Table 1: CLIA Sources of Revenue by Type of Fee, Fiscal Years 1997-2000

Dollars in millions

Type of fee	FY 1997	FY 1998	FY 1999	FY 2000 (estimated)
Certificate fee	$7.82	$10.03	$24.51	$14.15
Waiver certificate fee	1.65	8.88	4.51	9.49
Microscopy certificate fee	1.01	5.06	2.61	5.0
Survey/compliance fee	14.15	16.08	10.69	11.53
Accredited/compliance fee	1.19	0.81	0.92	0.54
Registration fee	0.11	0.80	0.33	0.31
Approved state fee	0.09	0.09	0.23	0.61
Complaint/follow-up fee[a]	0.00	0.00	0.00	0.17
Total	**$26.01**	**$41.75**	**$43.80**	**$41.80**

[a] HCFA has conducted complaint investigations in the past. It is now developing a system to collect related fees from laboratories.

Source: HCFA, Center for Medicaid and State Operations, Jan. 2000.

The allocation of expenditures by program activity has been relatively constant, with the direct cost of surveying laboratories representing about half of program costs each year. Table 2 shows how CLIA expenditures have been allocated among state agencies (under contract to HCFA), HCFA (including central and regional offices), CDC, and FDA.[10] The $5.6 million growth in CLIA expenditures between 1997 and 1999 was focused largely on two areas: additional funding for CDC activities and contracts with state agencies for conducting laboratory surveys. HCFA estimates additional CLIA expenses of $7.8 million in fiscal year 2000, due to anticipated expenditures of $3.8 million for the HHS indirect cost allocation, an additional $2.7 million for a new accounting system, and greater staff training costs.

[10] FDA's allocation of expenses will increase slightly in 2000 as it assumes responsibility for the categorization of laboratory tests, a key CLIA function that has been CDC's responsibility since 1994. All laboratory tests and devices approved by the FDA must be given a complexity designation for the CLIA program. Agency officials told us that FDA is assuming responsibility for test categorization largely at the request of device manufacturers, who have had to submit two sets of paperwork for new devices--one to FDA for new product approval, and another to CDC for test categorization. By moving test categorization to FDA, the two functions will be consolidated within one agency.

Table 2: CLIA Expenditures, by Agency, Fiscal Years 1997 to 2000

Dollars in millions

Agency and activities	FY 1997	FY 1998	FY 1999	FY 2000 (estimated)
Contracted state agencies	**$13.62**	**$14.51**	**$17.04**	**$16.28**
Biennial laboratory surveys	13.62	14.51	17.04	16.28
HCFA	**6.76**	**7.09**	**6.82**	**14.00**
Indirect cost allocation[a]	0.00	0.00	0.00	3.85
Fiscal and administrative services	2.14	2.16	2.37	2.87
Billing and data systems for non-approved states	0.89	0.54	0.60	2.90
Billing and data systems for approved states	0.88	1.49	0.81	1.22
Regional office surveys	1.21	1.26	1.50	1.51
Development of certification standards	0.84	0.84	0.79	0.84
Training and public information	0.79	0.80	0.75	0.82
CDC	**6.61**	**6.56**	**8.20**	**8.58[b]**
Scientific and technical review and monitoring	2.74	3.76[c]	3.74	N/A
Research to evaluate quality standards and outcomes	3.01	3.52[c]	3.51	N/A
Development of information and educational materials	0.86	0.99[c]	0.95	N/A
FDA	**0.00**	**0.00**	**0.52**	**1.52[b]**
Test categorization and waiver determination	0.00	0.00	0.52	1.52
Total expenditures	**26.99**	**28.16**	**32.58**	**40.38**

[a] Every program administered by HCFA is required to pay a share of HCFA administrative costs but, in the past, the CLIA program was not billed by HHS for this expense.

[b] HCFA disbursements for FY 00 to CDC and FDA combined will not exceed $10.1 million. The actual amounts to each will depend on completion of the transfer of the test categorization function from CDC to FDA.

[c] Includes amounts in excess of HCFA disbursements to CDC.

Source: HCFA, Center for Medicaid and State Operations, Jan. 2000.

RECENT FEE INCREASES MOST AFFECT LARGE LABORATORIES AND STATES WITH APPROVED STATUS

The recent fee increases to allow implementation of certain program activities involved modest changes for most laboratories but significantly increased user fees for the nation's largest labs. Similarly, HCFA has substantially raised the fees approved states must pay because the original fees established for these states did not include a full share of CLIA's administrative costs. Officials in these states have questioned these fees, arguing that they should not have to support CLIA administrative expenditures since they administer their own state programs. However, the CLIA regulations explicitly provide that approved states are required to pay a share of general administrative costs.

Increase in Certificate Fees Paid by Laboratories

In 1997, HCFA published a notice in the Federal Register that certificate fees would be increased for all laboratories–small increases for most laboratories (those conducting only waived or PPM tests, or a low volume of other types of tests), but much larger increases for high-volume laboratories. Certificate fees increased from a biennial rate of $100 to $150 for waived labs and those with an annual volume of 10,000 or fewer tests, and from $150 to $200 for PPM labs. In contrast, the largest laboratories faced much steeper increases, with the biennial fee increasing from $600 to $6,220 for laboratories with an annual volume of 500,001 to 1 million tests, and from $600 to $7,940 for laboratories with an annual volume of over 1 million tests. Table 3 shows the old and new fee levels for each type of laboratory.

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Table 3: Increase in Biennial Certificate Fees, by Type of Laboratory

Type of laboratory	Annual test volume	Number of laboratories[a]	Previous fee (dollars)	New fee (dollars)
Waived	N/A	86,675	$100	$150
PPM	N/A	35,934	150	200
Low volume A	Under 2,000	13,738	100	150
Schedule A	2,000 to 10,000	9,460	100	150
Schedule B	2,000 to 10,000	2,463	100	150
Schedule C	10,001 to 25,000	3,423	100	430
Schedule D	10,001 to 25,000	1,762	350	440
Schedule E	25,001 to 50,000	3,028	350	650
Schedule F	50,001 to 75,000	1,495	350	1,100
Schedule G	75,001 to 100,000	973	350	1,550
Schedule H	100,001 to 500,000	3,443	600	2,040
Schedule I	500,001 to 1,000,000	944	600	6,220
Schedule J	Over 1,000,000	989	600	7,940

Note: For laboratories in schedule A through D, fees vary by the number of different tests performed as well as by volume of testing.

[a] Includes laboratories in nonapproved states only.

Source: HCFA, Center for Medicaid and State Operations, Jan. 2000.

The new fee levels shift financial support for CLIA from waived,PPM, and smaller laboratories to the largest laboratories. HCFA data show that, prior to 1998, the 8 percent of laboratories with medium- to high-volume testing[11] had been paying 25 percent of total CLIA administrative costs. Under the new fee structure, HCFA expected that group of laboratories to pay 51 percent of total administrative costs. Trade association representatives told us that the industry--especially large laboratories subject to the highest fees--responded to HCFA's 1997 notice of the new fees with concern, but that the higher fee amounts have since been absorbed without disruption.

The CLIA statute specifies that, in establishing certificate fees, HHS may only charge a nominal fee for issuance and renewal of certificates ofwaiver (which are issued to roughly half the laboratories in the program). Under the new fee structure, HCFA established small, nominal fees not only for certificate of waiver labs, but also for laboratories with an annual volume of up to 10,000 tests. The statute further authorizes HHS to vary certificate fees based on the dollar volume and scope of testing being performed by the laboratories.[12] The

[11]Defined by HCFA as all laboratories in schedules D through J.

[12]In a 1997 notice in the Federal Register, HCFA justified the increase and shift in collections by noting that high-volume laboratories "reap a greater financial benefit than the smaller

fees charged to medium- and high-volume laboratories represent, at most, a few pennies per test performed.

Increase in Fees Paid by Approved States

After increasing laboratory certificate fees, HCFA reevaluated CLIA fees for approved states. HCFA's review showed that fees for approved states were limited to the cost of conducting validation studies in those states, as well as a prorated share of a small portion of the national program's administrative costs. In letters sent to approved states in 1999, HCFA indicated that all states, including those with approved status, should share total CLIA administrative costs (including billing and data systems fornonapproved states). The reasons cited were (1) approved states remain part of the national program and can use any of the innovations designed or implemented for the national program,[13] (2) the original fees for approved states allowed labs in these states to be billed much lower fees for CLIA administrative costs than labs in all other states, creating "an unfair imbalance among states," and (3) all HCFA functions related to CLIA continue regardless of the number of approved states, and thus as more states began to seek approval to run their own programs, the continued financial viability of CLIA was at risk.

As a result of HCFA's change in the fee computation, approved states now pay a prorated share of total CLIA administrative costs, rather than a share of only some CLIA administrative costs. Under the previous fee structure, about three-fourths of the total administrative costs for thenational CLIA program were excluded before the approved state's share was calculated. For example, in the 1998 and 1999 billing cycles, total administrative costs for the 2 years were $42.27 million, representing all program costs except the direct costs of conducting laboratory surveys innonapproved states. Of that amount, $30.75 million was excluded,[14] leaving a "national chargeable base" of $11.53 million. The share of the base to be paid by each approved state was then computed using the proportion of labs in each state relative to the total nationwide.[15]

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laboratories due to the conceivable economies of scale and, therefore, have unlimited potential to provide service to a larger share of the market."

[13]The benefits cited by HCFA include the categorization of approved tests, research on laboratory quality, and the approval of proficiency testing programs and accreditation organizations.

[14]Total program costs for fiscal and administration, regional office costs, training and public information, certification standards, indirect costs, cytology, and the billing and data system costs assessed to nonapproved states were excluded. In addition, one-half of the costs for CDC expenditures and billing and data system costs for approved states were excluded.

[15]For example, in the fiscal year 1998-99 billing cycle, there were 1,928 laboratories in Oregon or 1.16 percent of the 165,968 laboratories nationwide. Therefore, Oregon's portion of the base for that billing cycle was 1.16 percent of the national base of $11.53 million, or $133,884. In addition, each approved state is charged for the cost of validation surveys conducted by

Under the new fee structure, each state is still required to pay the same proportionate share, but there are no exclusions from program administrative costs prior to calculation of the approved state's share. Approved states were notified in 1999 that their fees would be increased, based on the new fee system, resulting in increases of about 275 percent. The increased fee amounts are to be phased in over a 3-year period to allow approved states time to adjust their laboratory collections; states are allowed to complete their current 2-year billing cycles under the old fee levels. Table 4 shows the fee increases for approved states and states with pending applications.

Table 4: Increase in Biennial Fees For States with Approved Status

	FY 1999 fee (dollars)	FY 2000-01 fee (dollars)
States with approval		
New York	$225,145	$844,021
Washington	194,662	749,526
Oregon[a]	150,114	560,888
States with approval applications pending		
California	1,273,470	4,797,097
Florida	832,083	3,129,306
Georgia	131,632	499,962

[a] Oregon allowed its CLIA approval to expire at the end of calendar year 1999.

Source: HCFA, Center for Medicaid and State Operations, Jan. 2000.

Officials in approved states have questioned HCFA's basis for imposing this fee. Specifically, they question the legal basis for requiring approved states to assume program administrative costs. For example, in a March 8, 1999, letter to the Deputy Secretary of HHS, the Administrator of the Oregon Health Division noted that the Washington and Oregon assistant attorneys general had concluded that "there is no statutory authority for assessing an ongoing fee beyond program validation costs." In a separate letter, Washingtonstate officials argued that the new fee calculation shifts the cost of the national CLIA program to states that do not participate in CLIA.

In response, HCFA officials note that the CLIA program must be fully supported by user fees established by the agency. In addition, CLIA regulations permit states to opt out of the national program provided they agree to pay for validation surveys, complaint investigation surveys, and a prorated share of the general administrative costs. In responding to

HCFA in their state, based on the number of hours spent conducting each state's validation surveys and multiplied by the federal hourly rate. For Oregon, HCFA estimated a cost of $16,230, which was added to their share of the national base for a total fee of $150,114.

Washington's attorney general, HCFA reported that "non-exempt laboratories are being asked to shoulder their fair share of [administrative] costs, and states with approved licensure programs must do the same . . . regardless of the number of approved states, the costs of administration and other elements of the CLIA program remain constant."

Furthermore, approved states point out that CLIA legislation specifically restricts the financing of CLIA general expenses to one type of fee, the certificate fee. Since certificate fees are only applied by HCFA to labs in the national program, these states believe they should not have to pay any administrative costs. On this point, HCFA officials respond that the legislative restriction applies only to states participating in the national program and does not preclude them from collecting administrative costs from approved states. They also note that approved states are required by regulation to pay a share of general administrative costs.

HCFA DID NOT PROVIDE TIMELY NOTICE OF FEE INCREASES TO APPROVED STATES

Following notification in late 1998 that an increase in the CLIA fees for approved states was under discussion, Washington and Oregon state officials asked HCFA to provide information about how CLIA program administrative funds were being used, and the basis for HCFA's legal authority to charge approved states for any portion of CLIA's ongoing administrative expenses. During June and July 1999, HCFA responded by providing specific information about CLIA program administrative expenditures and the source of their authority to charge approved states for ongoing administrative expenses. HCFA also reported CLIA expenditures by agency and by activity for fiscal years 1998, 1999, and (projected) 2000. Agency officials also provided a step-by-step description of the method for calculating CLIA fees for approved states. In response to state questions about HCFA's legal authority to charge approved states for a portion of CLIA's ongoing administrative expenses, the agency provided the justification for including these costs in the state fees, discussed in the previous section of this report.

Although HCFA had informed approved states that an increase in fees was being considered, the agency did not notify them of the likely magnitude of the increase. HCFA officials discussed the fees with state officials on numerous occasions during the spring and summer of 1999, including a telephone conference call in early July, but did not disclose that states would be billed for a fee increase of about 275 percent within weeks. On July 12, HCFA notified the approved states that their fees would be about 275 percent higher during their next billing cycles (for example, Washington's fee increased from $194,662 to $749,526).

Faced with substantially higher fees, Oregon officials let the state's approved status expire. The Oregon program had been financed by fees charged to

laboratories as set by state law, and thus required legislative action before the higher HCFA fees could be passed on to in-state laboratories. Because HCFA's announcement of the new fees occurred shortly after the state's biennial legislature had adjourned, the state notified HCFA that it would not reapply for approved status when its approval expired on December 31, 1999. Officials in Washington state have expressed concerns about the new fee amount, noting that to maintain their approved status under the new fee, laboratories in Washington would have to pay higher fees than would be required for participation in the national program. In New York, citing concerns about its $618,876 increase in fees, officials are considering cutbacks in program operations, such as reducing training, limiting travel or equipment purchases, or imposing a hiring freeze, rather than increasing fees to laboratories.

The states that have applied for approved status but have not yet started their laboratory quality assurance programs--California, Florida, and Georgia--are also affected by the new fees. To maintain program operations at their current level, Florida officials have estimated they would need to raise an additional $1.4 million from fees charged to their 10,500 laboratories. Similarly, California officials reported needing an additional $1.6 million from its 16,000 laboratories.

AGENCY COMMENTS

We provided a draft of this report for comment to HCFA, which generally concurred with the information presented but said that states were provided with adequate notice that a fee increase was coming. The agency noted that the approved states were informed in September 1998 that a substantial fee increase was under discussion. However, HCFA acknowledged that it provided limited time between the formal fee increase announcement and the phase-in of the increase. The agency also noted that without actual figures, it would be difficult for the approved states to anticipate the magnitude of the increase.

HCFA also said that it believes that, in any event, states generally have the authority to assess laboratory fees that are sufficient to cover all expenses, including HCFA's approved state fee. HCFA said that it anticipated that the fees which states must set to recover their costs of operation would not differ substantially from fees paid by laboratories in non-approved states.

In addition, the agency provided technical comments, which we have incorporated where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after the date of the letter. At that time, we will send copies to interested parties and make copies available to others upon request.

If you have any questions about this correspondence, please call me at (202) 512-7119. This report was prepared by Jenny Grover under the direction of Rosamond Katz, Assistant Director.

Sincerely,

Janet Heinrich
Associate Director, Health Financing
and Public Health Issues

(201002)

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