



March 1, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-3356-NC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

Dear Administrator Verma:

The American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA) submit the following comments regarding CMS's proposal to increase CLIA certificate, compliance, and additional fees published in the December 31, 2018, Federal Register, Vol. 83, No. 249, pp. 67726 – 67728.

While we appreciate the opportunity to comment on the proposed CLIA fee increase, AAB and NILA maintain that there is not enough public information about the financial management of the CLIA program to provide substantive comments on the need for an increase in CLIA fees.

Before moving forward with an increase in CLIA fees, AAB recommends the following actions:

1. Conduct and publish complete financial reports of the CLIA program's income and expenses for Fiscal Years 1992 – 2018.
2. Publish an explanation of how the "Carryover Fees" were generated and managed.
3. Fully publicize and disclose the amount of funds subject to Sequestration, and how those funds are used.

CLIA Fees

The basic rule in Section 493.638 of Title 42 for determining CLIA fees is that "the total fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under Section 353 of the PHS Act."

Note that the "basic rule" only includes fees that are for the general costs of the CLIA program.

Section 493.638(b) states that CLIA's fee amounts are to be set annually, and that the amount of the fee in each schedule is to be a function of the costs for all aspects of general administration of CLIA as set forth in Section 493.649(b) and (c). However, CMS's December 31, 2018, notice does not specify what those costs were or provide a breakdown of those costs for Fiscal Years 1992 – 2018.

AAB has repeatedly requested this breakdown and was informed by CMS that the only way to obtain the data is through a Freedom of Information Act (FOIA) request. AAB filed a FOIA request for this information (for just the last three Fiscal Years) on June 14, 2018, which has still not been answered by CMS.

It is impossible for us and other stakeholders to evaluate the CLIA program's costs because CMS has not provided the detailed financial information necessary to evaluate those costs.

It is clear, though, that CMS has collected fees that not only cover the costs of the CLIA program but are clearly in excess of the CLIA program's costs. This excess is referred to as "Carryover Fees." At the beginning of Fiscal Year 2018—according to Table 2—the Carryover Fees totaled \$43,494,763. According to Table 1, the CLIA program's shortfalls for Fiscal Years 2012 – 2017 totaled \$34,697,785. Therefore, we can assume that the Carryover Fees of \$43,494,763 is what remains after addressing these budget shortfalls in FYs 2012 – 2017, which means the program had a Carryover Fees balance of \$78,192,548 at the beginning of Fiscal Year 2012.

The Carryover Fees balance could be higher for FYs 1992 to 2011, but CMS did not provide the data for those years, even though the CLIA regulations require such a calculation annually. CMS admits that it used the Carryover Fees "to supplement shortfalls in new collections over a number of years" (p. 67724), but does not say how many years and the total amount of the Carryover Fees since 1992. We see no legitimate reason for CMS to withhold this information, and no explanation is provided for why CMS is withholding this information.

It is clear that CMS collected fees far in excess of the costs of the CLIA program for Fiscal Years 1992 to 2018. It is also clear that CMS knew that it was collecting fees far in excess of the CLIA program's administrative costs because, on p. 67724, CMS states:

"We routinely monitor incoming CLIA Fee collections and compare them on a monthly basis with the corresponding amounts of obligations and expenditures for all costs required to support the operations of the CLIA program..."

In addition, the Carryover Fees cash balance of \$78,192,548 at the beginning of Fiscal Year 2012 should have been earning interest (we do not know if it was because there is no public financial report on the CLIA program's finances). Just 1% interest (in U.S. Treasury Bills), would yield \$781,925 for Fiscal Year 2012. Extended over 10 years, the interest earned on the Carryover Fees could be as high as \$7,819,254. And that is just at a rate of 1% interest.

Regarding the need for Carryover Fees, CMS claims that these funds "...are needed to support program operations at the start of any given Fiscal Year, until a sufficient amount of current Fiscal Year collections is accumulated and made available for obligation." This is the reason given for rounding up what CMS says is the amount of money it needs, \$9.339 million (18.6%),

to \$10.068 million (20%), an increase of \$729,200 to support program operations in the first 6 months of any given Fiscal Year.

Yet the Carryover Fees balance **with no fee increase** at the beginning of Fiscal Year 2019 is \$29,469,649 and \$14,464,636 at the beginning of Fiscal Year 2020 (Table 2, p. 67724). It is difficult to understand why CMS needs an additional \$729,200 in Carryover Fees at the beginning of Fiscal Year 2019 and Fiscal Year 2020 given these Carryover Fees projections. CMS does not explain the CLIA program's cash flow position during the first two quarters of any given Fiscal Year, so again it is not possible to determine why CMS needs to charge 1.6% more than it needs for CLIA fees as a "rounding" procedure.

As is the case with other user fee programs, CMS should publish an annual CLIA financial report, with a detailed breakdown of the CLIA program's income and expenses. Then CMS could propose a CLIA fee increase, or decrease, for the following Fiscal Year, thereby adjusting the CLIA fees once a year, or once every two years, if that is more practical and consistent with the regulations.

In addition to publishing this report going forward, AAB requests that CMS provide complete financial information for Fiscal Years 1992 to 2018 to reveal the actual amounts of the Carryover Fees and the interest that should have been earned during those years. We do not believe it should be necessary to file a FOIA request to obtain this information.

Table 2 (p. 67724) projects a total shortfall of \$45,372,578 for Fiscal Years 2018 – 2020, of which \$9,861,058 (21.73%) is for the Sequester for Fiscal Years 2018 to 2020. Adding the Sequester for Fiscal Years 2018 to 2020 to the Sequester for Fiscal Years 2013 – 2017 (\$18,091,376) yields Sequester "taxes" of \$27,952,434 for Fiscal Years 2013 – 2020, which equals 61.61% of the CLIA program's projected shortfall for Fiscal Years 2018 – 2020.

If several million dollars are factored in for interest on the cash balance of the Carryover Fees for Fiscal Years 2013 – 2020, it is entirely possible that more than two-thirds of the CLIA program's projected shortfalls for Fiscal Years 2018 – 2020 are due to Sequester "taxes" and interest not credited or earned on the Carryover Fees cash balances. **Therefore, the major reason for CLIA's projected shortfalls seemingly has little to do with CLIA's Administrative Costs.**

The fact that the CLIA program collected fees well in excess of annual program costs for 10 – 25 years also raises the issue of whether the CLIA program managed its costs well. Having such a large surplus, and not reporting that surplus to the laboratory community may, or may not, have led to lax management of the CLIA program's costs over the years. The point is that we don't know because CMS is not providing the financial data that would allow us to make a determination. Moreover, the justification in the proposed notice does not clarify matters either. In one instance, the reason for increasing the fees is attributed to "an increase in the amount of time it takes to perform surveys in laboratories that are using more complex testing platforms and laboratory developed tests" (p.67724), but in another instance the justification in the obligations "results primarily from inflationary increases" (p.67726). It is even more confusing whether increased time is a contributing factor by the statement that "analysis shows that the relative proportions of the certification and compliance work to total program obligations has remained virtually consistent over time." (p.67726). It is therefore impossible to know whether a 20% across-the-board fee increase in CLIA fees is justified.

CLIA Fees and Sequestration


Table 1 in the proposed rule shows that, in Fiscal Years 2013 – 2017, CMS collected \$18,091,376 (with an additional \$9,861,058 projected for Fiscal Years 2018 – 2020) for "Sequester." While sequestration was originally proposed as an across the board cut to all federal spending, it was only implemented for certain mandatory programs. As these funds are clearly not used for purposes having to do with the general costs of the CLIA program, AAB and NILA would like additional clarification on when the CLIA program was sequestered and why.

Using CLIA certificate "fees" for sequestration is different from using the fees for the general cost of administrating the CLIA certificate program. Therefore, monies used for sequestration should be considered a "tax," not a "fee," and the increase in the proposed rule should be referred to as an increase to CLIA certificate fees and taxes related to Sequester.

Conclusion

In summary, the opaqueness of financial information about the administration of the CLIA program should be replaced with a system that is transparent. Only then can the laboratory community, Congress, CMS, and interested members of the public evaluate the necessity of a 20% across-the-board increase in CLIA fees.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Administrator, AAB/NILA