identified in this section. The State Medicaid/CHIP agency will report the existence of a system to collect all information needed to determine and redetermine eligibility for Medicaid and CHIP. The State Medicaid/CHIP agency will attest to using the PARIS system in determining beneficiary eligibility in Medicaid or CHIP benefit programs. *Form Number:* CMS–R–74 (*OMB control number:* 0938–0467); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 55; *Total Annual Responses:* 3,241; *Total Annual Hours:* 1,071. (For policy questions regarding this collection contact Stephanie Bell at 410–786–0617.)

Dated: December 13, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–27337 Filed 12–28–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3356–NC]

RIN 0938–AT56

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period announces the increase of certain fees established under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Public Health Service Act (PHSA) requires the Secretary to impose certificate fees to cover the general costs of administering the CLIA program, as well as additional fees, including Inspection fees for non-accredited laboratories. We are increasing these fees to cover the cost of administering the CLIA program as required by statute. We seek public comment regarding this increase, which we believe is necessary to meet the statutory requirements.

DATES: *Comments:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 1, 2019.

ADDRESSES: In commenting, refer to file code CMS–3356–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3356–NC, P.O. Box 8016, Baltimore, MD 21244–8016. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3356–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For policy related questions, please contact Cindy Flacks, 410–786–6520, and Caecilia Blondiaux, 410–786–2190.

For the Budget and Financial Impact, please contact Jeffrey Pleines, 410–786–0684.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

I. Background

A. CLIA Fees

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which replaced in its entirety section 353 of the Public Health Service Act (PHSA). Section 353(m) of the PHSA requires the Secretary to impose two separate types of fees: ''certificate fees'' and ''additional fees.'' Certificate fees are imposed for the issuance and renewal of certificates and must be sufficient to cover the general costs of administering the CLIA program, including evaluating and monitoring approved proficiency testing (PT) programs and accrediting bodies and implementing and monitoring compliance with program requirements. Additional fees are imposed for inspections of non-accredited laboratories and for the cost of performing PT on laboratories that do not participate in approved PT programs intended to cover the cost of evaluating a laboratory to determine overall if an accreditation organization's standards and inspection process is equivalent to the CLIA program. These evaluations are referred to as validation inspections. The additional fees must be sufficient to cover, among other things, the cost of carrying out such inspections and PT. Certificate and additional fees vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories, and only a nominal fee may be required for the issuance and renewal of Certificates of Waiver (CoWs).

The regulations provide for a methodology for determining fee amounts (§ 493.649) and periodic updating of the certificate fee amounts (§ 493.638(b)) and compliance fee amounts (§ 493.643(b)). Under § 493.645(b)(1), laboratories that are issued a certificate of accreditation (CoA) are assessed a fee to cover the cost of validation inspections. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting non-accredited laboratories.

B. CLIA Budget Process

With the exception of the ''CLIA Program; Fee Schedule Revision'' notice published in the August 29, 1997 **Federal Register** (62 FR 45815 through 45821), the fees imposed to cover the costs of administering the CLIA program have not been updated since 1992. The fee amounts currently collected under the CLIA regulations are based on preliminary assumptions made in 1992 about future program operations and workload requirements. After decades of actual program experience, we have determined that it is necessary to increase certain CLIA fees to fund current and future program operations as required by section 353(m) of the PHSA. Specifically, as discussed in section II. of this notice with comment period, we are increasing those CLIA fees collected under § 493.638(b) (hereinafter referred to as ''Certificate Fees''), with the exception of fees for

issuing a Certificate of Registration (CoR); § 493.643(b) (hereinafter referred to as ''Compliance Fees''); and § 493.645(b)(1) (hereinafter referred to as ''Additional Fees'') (collectively referred to hereinafter as ''CLIA Fees'').

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 operation of the CLIA program, including state survey agency (SA) awards, CMS administrative costs, other federal agency costs, and contract support. Over the past several years, we have observed that the total amount of incurred obligations in a given fiscal year has outpaced the corresponding amount of CLIA Fees collected over the same timeframe, leading to decreases in the level of budgetary resources available to support program operations. Factors contributing to the increased obligations incurred by the CLIA program include 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, as well as the overall inflation of the economy. Based on our observations, we performed a retrospective comparative analysis of federal fiscal year (FY)-end CLIA Fee collections and incurred obligations over the prior six FYs (FY 2012 through FY 2017). As shown in Table 1, the amount of incurred obligations in each fiscal year has exceeded the corresponding amount of collected CLIA Fees.

TABLE 1—CMS COMPARATIVE ANALYSIS FYS 2012 THROUGH 2017

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Certificate Fees Collected	$36,343,753	$42,169,869	$41,173,724	$41,185,755	$42,369,451	$41,544,575
Compliance Fees Collected	13,213,680	13,040,589	12,823,731	12,466,102	13,468,981	12,527,235
Sequester [1]	0	(2,760,521)	(3,887,817)	(3,916,586)	(3,795,483)	(3,730,969)
Total, CLIA Fees Collected [2]	49,557,433	52,449,907	50,109,639	49,735,271	52,042,948	50,340,842
Total, CLIA Obligations [2 3]	54,539,917	54,169,837	57,360,315	56,404,651	56,778,918	59,680,186
Total, CLIA (Shortfall)/Surplus	(4,982,484)	(1,719,930)	(7,250,677)	(6,669,380)	(4,735,970)	(9,339,344)

[1] Sequester is a reduction in budget authority authorized by Public Law 112–25, the Budget Control Act of 2011.
[2] Collections and obligations data taken from FY-end Healthcare Integrated General Ledger Accounting System (HIGLAS) reporting. Exempt State Fees are categorized as Certificate Fees, because the state surveys their own laboratories and State Fees charged go to the state.
[3] CLIA obligations include FY-end obligations for CMS administration (payroll, travel, training, supplies, contracts), other federal agencies (CDC, FDA, Treasury, DHHS/OGC), and SA awards (surveys, PT, etc.).

Over the past few years, we have been diligent in controlling administrative costs, including use of carryover funds, in an attempt to avoid a fee increase. For example, we have controlled costs by enhancing monitoring and control over funds awarded to SAs for surveys, reducing federal travel and training expenses, as well as imposing strict oversight of incurred contract costs. Despite these efforts, a portion of CLIA's administrative obligations and expenditures remains fixed and cannot be further reduced without significant disruption in program operations (for example, limiting planned regulatory and enforcement actions). Taking into account annual inflation in the overall economy, we anticipate that program costs and concurrent obligations will continue to increase, further contributing to a projected shortfall in collections. Moreover, our ability to continue using carryover funds is limited since we have used this carryover to supplement shortfalls in new collections over a number of years.

We project that without a fee increase, the CLIA program would cease to be self-sustaining at some point in FY 2020, as shown in Table 2.

TABLE 2—CMS PROJECTIONS FYS 2018 THROUGH 2020

[No Fee Increase]

	FY 2018	FY 2019	FY 2020
Prior Year Carryover (SOY) [1]	$43,494,763	$29,469,649	$14,464,636
Projected CLIA Fee Collections	51,900,306	51,900,306	51,900,306
Projected Sequester (6.6%, 6.2%)	(3,425,420)	(3,217,819)	(3,217,819)
Budgetary Resources	91,969,649	78,152,136	63,147,123
Projected Obligations	62,500,000	63,687,500	65,024,938
Projected Carryover (EOY) [2]	29,469,649	14,464,636	(1,877,815)

[1] Start of year balances.
[2] End of year balances.

Based on these projections, absent a fee increase, our ability to maintain effective program operations may be jeopardized, potentially comprising public health and safety. As a result, we need to increase currently assessed CLIA Fees to ensure effective program operations.

C. CLIA RFI Feedback

In January 2018, we published the ''Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988'' (83 FR 1004). As part of the general solicitation for comments related to the CLIA Fees, more than a few commenters noted the CLIA Compliance and Additional fees have not been updated since 1992 and supported increasing the fees. Some of these commenters suggested the CLIA Fees be reviewed annually and updated as needed to cover the program costs of performing biennial surveys.

One commenter raised concerns related to increases to the CLIA Fees, linking them to the recent changes to

the Clinical Laboratory Fee Schedule (CLFS) (see 81 FR 41036). While we appreciate this commenter's concerns, we note that changes to the CLFS are issued by Medicare and are separate and distinct from changes to CLIA Fees.

As a result of the feedback received from the 2018 RFI, as well as through assessing the current program needs, we are increasing the fees as outlined in section II of this notice with comment period. Additionally, we will consider the comments received in response to the 2018 RFI as well as this notice with comment period in future rulemaking.

II. CLIA Fees Increase

For the reasons discussed in section I. of this notice with comment period, we are increasing the following CLIA Fees: Certificate Fees (collected under § 493.638(b), with the exception of fees for the issuance of a CoR); Compliance Fees (collected under § 493.643(b)); and Additional Fees (collected under§ 493.645(b)(1)). These increases are based on our review of historical revenue and expenditure data, which have shown that expenditures in comparison to collections are insufficient to keep pace with the CLIA program costs.

As shown in Table 1, we must close the $9.3 million gap between incurred obligations and CLIA Fee collections in FY 2017 to keep the program on a sustained solvent basis projected over time. To close this $9.3 million gap, we first determined the appropriate fee drivers, as shown in Table 3, and then added the results together, along with current State-Exempt Fees at about $1.1 million, to calculate the total projected fees.

TABLE 3—CMS PROJECTED LABORATORY POPULATION AND SURVEY WORKLOAD, FY 2018

	Waived	PPMP [1]	LVA [2]	Schedule Codes										Total
				A	B	C	D	E	F	G	H	I	J	
Non-Accredited ..	0	0	6,466	4,245	183	2,022	249	1,493	793	497	1,721	200	167	18,036
Accredited	0	0	2,103	2,700	184	1,895	228	1,631	959	599	3,081	1,107	1,794	16,281
Other	178,616	33,411	0	0	0	0	0	0	0	0	0	0	0	212,027
Total, CLIA Lab Population	178,616	33,411	8,569	6,975	367	3,917	477	3,124	1,752	1,096	4,802	1,307	1,961	246,344
Total, CLIA Compliance Surveys	0	0	3,500	2,330	110	1,124	145	839	445	285	995	141	144	10,058

[1] Provider-Performed Microscopy Procedures Laboratories (PPMP).
[2] Low-Volume Laboratory (LVA).

For Certificate Fees, the driver used in our calculations is one half of the projected laboratory population for FY 2018 (123,172 CLIA laboratories), broken out by state and laboratory schedule code. We used one half of the projected laboratory population to determine an average annual collection because all CLIA laboratories are billed on a biennial basis. For Compliance Fees, the driver used in our calculations is the projected number of surveys budgeted for FY 2018 (10,058 total surveys). For Additional Fees for accredited laboratory validation inspections, the driver used in our calculations is the projected number of validation surveys budgeted for FY2018 (about 407). Using this methodology, we project increased CLIA Fee collections at $61.0 million in FY 2018, as opposed to the currently collected $50.8 million, plus the collection of $1.1 million in State-Exempt Fees, for a total projected collection of $62.1 million.

We have projected that we need to increase the CLIA Fees described previously by at least 18.6 percent ($9.339 million/$50.341 million, per Table 1). In calculating projected collections for FYs 2018 through 2021, we rounded up to a 20 percent increase to ensure a sufficient level of carryover to maintain operations in the first two quarters of FYs 2019 and 2020. Generally, carryover funds are needed to support program operations at the start of any given FY, until a sufficient amount of current FY collections is accumulated and made available for obligation. In rounding up to the 20 percent increase, we projected increased FY 2018 collections at $62.1 million, enough to reasonably approximate projected FY 2018 obligations. To calculate the $62.1 million in projected collections, we multiplied the increased fees by the appropriate fee drivers, as shown in Table 3, and then added the results together, along with current State-Exempt Fees at about $1.1 million, to calculate the total projected fees.

The total of fees collected by HHS must be sufficient to cover the general costs of administering the CLIA program, and as indicated in Table 4, upon publication of the final notice, we project that the 20 percent increase will be sufficient to fund the CLIA program into FY 2022.

TABLE 4—CMS PROJECTIONS FYS 2018 THROUGH 2021

[With 20 percent fee increase]

	FY 2018	FY 2019	FY 2020	FY 2021
Prior Year Carryover (SOY) [1]	$43,494,763	$29,469,649	$20,855,892	$14,052,629
Projected CLIA Fee Collections	51,900,306	58,714,011	62,070,016	62,070,016
Projected Sequester (6.6%, 6.2%)	(3,425,420)	(3,640,269)	(3,848,341)	(3,848,341)
Budgetary Resources	91,969,649	84,543,392	79,077,566	72,274,303
Projected Obligations	62,500,000	63,687,500	65,024,938	66,390,461
Projected Carryover (EOY) [2]	29,469,649	20,855,892	14,052,629	5,883,842

[1] Start of year balances.

[2] End of year balances.

With this notice, we are increasing all currently assessed CLIA Fees by 20 percent to close the gap between current obligations and current collections, and to account for a small increase in costs for the current fiscal year. Fees for the issuance of registration certificates would not be increased as these increases would not have substantial impact.

The 20 percent increase would apply to the following CLIA fee types:

1. Certificate Fees—collected under § 493.638(b), with the exception of fees for the issuance of a CoR. Under § 493.638(b), the fee amount is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and PT purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649(b) and (c). Under § 493.649(a), the fee for issuance of a CoR or CoC is based on the laboratory's scope and volume of testing. The current Certificate Fees are already based on each laboratory's schedule's scope and volume of testing, including test complexity and specialties tested. Following the application of a uniform 20 percent increase to Certificate Fees across all schedules, with the exception of fees for the issuance of a CoR, the new Certificate Fees will continue to satisfy §§ 493.638(b) and 493.649(a).

2. Compliance Fees collected under § 493.643(b). Under § 493.649(a), the amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in § 493.649(b), the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity.

As discussed in section I. of this notice with comment period, current Compliance Fees were established in 1992 based on estimates as to the average time a survey would take, the cost of the surveyor salary per hour, as well as the size of the laboratory. Based on FY 2017 available compliance fee collections, we estimate that current Compliance Fee collections cover approximately 55 percent of current and future compliance determination costs. Following the application of a uniform 20 percent increase to Compliance Fees across all schedules, in combination with the aforementioned increase to Certificate Fees, the new Compliance Fees will continue to satisfy § 493.649(a).

3. Additional Fees collected under § 493.645(b)(1). Under § 493.645(b)(1), laboratories that are issued a CoA are assessed an additional fee to cover the cost of validation inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories. As discussed in section I. of this notice with comment period, current Additional Fees were established in 1992 based on estimates as to the average time a survey would take, the cost of the surveyor salary per hour, as well as the size of the laboratory. Following the application of a uniform 20 percent increase to additional fees across all schedules, in combination with the aforementioned increases to Certificate Fees and Compliance Fees, the new Additional Fees will continue to satisfy §§ 493.645(b)(1) and 493.649(a).

While we recognize that the 20 percent increase to CLIA Fees across all schedule codes can be perceived as a major increase for laboratories, we intend for this approach to be a one-time adjustment to address the projected shortfall to ensure the program can remain self-sustaining into FY 2022. We will continue to review our obligations and collections and may make future adjustments as needed to avoid shortfalls. We considered multiple options prior to this notice with comment period, including limiting the increase to varying percentages and timeframes across a single fee type, specifically Compliance Fees. For example, we considered the following options:

- Update the existing Compliance Fees by updating the hours for all classifications (schedules) of laboratories and the hourly rates for all states and territories.
- A one-time 70 percent increase in Compliance Fees alone to meet projected obligations, with a phased-in two 35 percent Compliance Fee increases over a two biennial survey cycles.

As discussed previously, in regard to the estimates established in 1992, we are proposing the one-time 20 percent increase across most CLIA Fees, including Certificate (excluding CoR fees) and Compliance Fees based on our comparison of FY 2017 obligations and collections (see Table 1). Analysis indicates that the difference between collections and obligations results primarily from inflationary increases incurred since Compliance Fees were set in 1992 and since Certificate Fees user fees were last increased in 1997. Furthermore, analysis shows that the relative proportions of the certification and compliance work to total program obligations has remained virtually consistent over time, at about 34 percent for compliance and 66 percent for certification. We believe the original methodology for calculating CLIA fees was reasonable at the time, with the exception of excluding adjustments for inflation, which has remained relatively constant. Therefore, we determined that a one-time 20 percent increase across most currently assessed fees is the most appropriate approach. The 20 percent increase also meets our policy objectives to keep any increase reasonably limited, given the elapsed time since the CLIA Fees were last updated.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

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

V. Regulatory Impact Statement

A. Statement of Need

As discussed in section I. of this notice with comment period, when CLIA was enacted, and its implementing regulations were finalized in 1992, CLIA Fees were established based on estimates as to the average time a survey would take; cost of the surveyor salary per hour; as well as the size of the laboratory (schedules A, B, etc.). As discussed in section III. of this notice with comment period, we are increasing

certain CLIA Fees based on our analysis of the overall level of collections relative to the costs of maintaining the CLIA program, which project a shortfall to begin in calendar year 2020.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) is required for economically-significant regulatory actions that are likely to impose costs or benefits of $100 million or more in any given year.

This notice with comment period is not economically significant within the meaning of section 3(f)(1) of the Executive Order since the estimated cost alone is not likely to exceed the $100 million annual threshold. Our upper limit of estimated impact is under the threshold of $150 million for the year of 2018 under Unfunded Mandates Reform Act (UMRA). This notice with comment period increases certain CLIA Fee requirements and will affect approximately 251,010 clinical laboratories, resulting in some budget implications.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we assume that the great majority of clinical laboratories are small entities, either by virtue of being nonprofit organizations or by meeting the Small Business Administration definition of a small business by having revenues of less than $7.5 million to $38.5 million in any one year. For purposes of the RFA, we believe that approximately 82 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2017 (*https://www.aha.org/system/files/2018-01/fast-facts-us-hospitals-2017_0.pdf*). Individuals and states are not included in the definition of a small entity. We are voluntarily preparing a Regulatory Impact Analysis and are requesting public comments in this area to assist us in making this determination.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. 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 100 beds. We do not expect this notice with comment period will have a significant impact on small rural hospitals. Laboratories in small rural hospitals are already subject to CLIA Fees. We are requesting public comments in this area to assist us in making this determination.

C. Anticipated Effects

This notice with comment period impacts approximately 251,010 CLIA certified laboratories.

TABLE 5—CURRENT AND NEW NATIONAL AVERAGE OF COMPLIANCE FEE UPDATE

[Compliance fee updates at 20 percent increase]

Laboratory classification (schedules)	Current average (c)	New average (n)
LVA	$300	$360
A	994	1,192
B	1,325	1,591
C	1,657	1,988
D	1,947	2,336
E	2,237	2,684
F	2,527	3,032
G	2,817	3,380
H	3,107	3,728
I	3,397	4,076
J	3,673	4,408

Table 5 reflects the national average of compliance fees for each classification of laboratories (schedules) that requires inspection. Specifically, Table 5 represents the national average for each schedule for the current Compliance Fees (noted with a ''c'') as paid biennially by laboratories that hold a CoC and the national average for each schedule for the new Compliance Fees (noted with a ''n'') that will be paid biennially by laboratories that hold a CoC. As discussed section II. of this notice with comment period, Table 5 reflects a total increase of 20 percent across all schedules.

TABLE 6—CURRENT AND NEW NATIONAL AVERAGE OF ADDITIONAL FEES FOR ACCREDITED LABORATORIES UPDATE

[Additional fee updates at 20 percent increase]

Laboratory classification (schedules)	Current average (c)	New average (n)
LVA	$15	$18
A	50	60
B	60	80
C	83	99
D	97	117
E	112	134
F	126	152
G	141	169
H	155	186
I	170	204
J	184	220

Table 6 shows the national average of Additional Fees for each schedule of accredited laboratory. Specifically, Table 6 represents the national average fees for each schedule for the current Additional Fees (noted with a ''c'') as paid biennially by laboratories that hold a CoA and the national average for the new Additional Fees (noted with a ''n'') that will be paid biennially by laboratories that hold a CoA. As discussed in section II. of this notice with comment period, Table 6 reflects a total increase of 20 percent across all schedules.

TABLE 7—CLIA BIENNIAL CERTIFICATE FEES

Type of CLIA certificate	Laboratory schedule	Current fee	New fee
Certificate of Waiver (CoW)	Not applicable	$150.00	$180.00
PPM	Not applicable	200.00	240.00
CoC and CoA	LVA	150.00	180.00
CoC and CoA	A	150.00	180.00
CoC and CoA	B	150.00	180.00
CoC and CoA	C	430.00	516.00
CoC and CoA	D	440.00	528.00
CoC and CoA	E	650.00	780.00
CoC and CoA	F	1,100.00	1,320.00
CoC and CoA	G	1,550.00	1,860.00
CoC and CoA	H	2,040.00	2,448.00
CoC and CoA	I	6,220.00	7,464.00
CoC and CoA	J	7,940.00	9,528.00

Table 7 depicts the current and new Certificate Fees, which reflects the 20 percent increase across all schedules, with the exception of fees for the issuance of a CoR.

D. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' It has been determined that this notice with comment period is not a ''significant regulatory action'' under E.O. 12866 and thus is not considered regulatory action under Executive Order 13771.

E. Conclusion

Although the effect of the changes will increase laboratory costs, implementation of these changes will be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.

We have determined that this notice with comment period would not have a significant economic impact on a substantial number of small entities or a significant impact in the operations of a substantial number of small rural hospitals and for these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

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

Dated: December 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–28359 Filed 12–28–18; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Physician-Focused Payment Model Technical Advisory Committee; Meetings

ACTION: Notice of meetings.

SUMMARY: This notice announces the 2019 meetings of the Physician-Focused Payment Model Technical Advisory Committee (PTAC). These meetings will include deliberation and voting on