

All-State CLIA Call January 22, 2024, Q&A

The new fees for revised certificates are below (from the [Federal Register](#)):

We proposed the following fees for issuing **revised certificates**:

TABLE 6: CMS Proposed Fee for Issuance of Revised Certificate

Certificate Type	Fee
CoW	\$95.00
CoA	\$95.00
CoR	\$150.00
CoC	\$150.00
PPM	\$150.00

Please note that these are the Revised Certificate Fees that did go into effect.

The cost for a Replacement Certificate is \$75.

The Schedule Code Chart for the new Certificate Fees has also been updated in ASPENWeb.

The new Certificate of Registration fee is \$123.

Please note that Revisit survey fees are assessed using the average SA hourly rate of \$111.81/hour x the hours it takes to perform the revisit (including all travel time).

1. For the new fees, how long after the new fee is issued before CMS will take action for non-payment?

Answer – if there are unpaid fees, the certificate will not be able to take the next step in its certificate cycle, and just like if a lab failed to pay their survey bill or certificate bill, the certificate will be allowed to expire due to non-payment.

2. For cert of waiver is there an 18% increase plus a \$25 increase. So new CoW fee is \$238? or is it just a \$25 increase, so it is \$205?

Answer – the COW fee will now be \$248, new certificate fees will be posted to CMS.gov on Friday 1/26/24.

3. When a CoW files a 116 to meet the renewal requirement in §493.37(f)(1) how will the system identify this as part of the renewal and not an "update or revised" certificate? This would be similar to the update on COC done under "survey".

Answer –The automated renewal process and the new certificate that will be sent will not generate a fee. Only if the lab requests a revised or replacement certificate be generated will a fee be assessed. The generate certificate drop-down is on the Certificate/ Billing Inquiry tab.

SA staff do not currently have access to this drop-down menu and will need to work with their Location/data liaison to generate a replacement/revised certificate.

4. The final rule indicates implementation of additional fees to be effective 1/27/2024 but is dependent on the new system being implemented. Is there an estimate of when that will happen?

Answer – the new system will be up and running on Monday January 29, 2024. The new billing process will start on Tuesday January 30, 2024. We (CMS) will put a hold on sending the new bills for a few days so we can ensure everything works as designed.

5. Will CMS be sending notice to PPM labs regarding the new requirement for competency assessment? Also, has it been determined how SAs will enforce/track compliance?

Answer – There are no specific notice plans to PPM labs, it was in the Federal Register. There is no PPM Project at this time, so the only surveys you could potentially do in a PPM are complaint surveys that have been approved by CMS (your Branch Location).

6. What's the new PPM fee? If you add 18% it would be 283.20 which seems unlikely
Answer - \$297.

7. Will a memo be sent to facilities about the fee increase or will they just see it on their next invoice?

Answer – No, it was published in the Federal Register, a ListServ announcement was sent out, it will be on the CMS.gov website next week (week of January 29, 2024), and the Model Letters in BOX will be updated to include revisit survey fees.

8. What specialty additions will CMS require a survey to add?

Answer - CMS-3326-F does not change when a specialty addition may require a survey. The SA should not change their current practice. The SA should continue to determine whether a separate revisit needs to be performed. Timing normally allows for the new specialty to be reviewed during the recertification survey. If a revisit needs to be performed, the SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab. SA should contact CMS for further guidance if needed. If a SA performs an onsite revisit, the laboratory will be charged a fee.

9. Will there be an update to SOP Appendix C?

Answer –We are currently updating Appendix C right now. It is on track to get an advance copy to the State Agencies this year.

Appendix C contains interpretative guidance on regulations. CMS may consider updating the SOM Chapter 6 with additional advice to the SA. For guidance on how to enter a revisit survey for the addition of a specialty, please see page 172 of CMS 116 and Certification 12.4.4.2 Procedures Guide.

10. Will surveyors be going out to perform specialty/subspecialty addition-only surveys or will these be done offsite by desk review?

Answer -

The SA should continue to determine whether a separate revisit needs to be performed. Timing normally allows for the new specialty to be reviewed during the recertification survey. If a revisit needs to be performed, the SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab. SA should contact CMS for further guidance if needed.

11. es^ please explain how this changes expansion surveys. this has a huge impact on billing. The LC codes are subject of a lot of heartache right now—add a specialty LC codes tied to Medicare for specialty surveys

Answer –

CMS-3326-F does not change when a specialty addition may require a survey. The SA should not change its current practice. The SA should continue to determine whether a separate revisit needs to be performed. Timing normally allows for the new specialty to be reviewed during the recertification survey. If a revisit needs to be performed, the SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab. SA should contact CMS for further guidance if needed. If a SA performs an onsite revisit, the laboratory will be charged a fee.

12. Will SAs have an option to generate a fee coupon in CMS-116?

Answer – in the current system (QIES) the State Agencies do not have the option to generate a new fee coupon. But the new system under development – iQIES will have that functionality.

13. When we add an email for electronic certificates (and fees) will it automatically be available on the lab demographics search feature or will we still have to request a certificate be issued for the link to show up?

Answer – All electronic certificates generated will be available as a link on QCOR regardless of whether electronic notifications have been selected by the laboratory. However, a certificate is only generated outside the normal process if a revised or replacement certificate is requested. For example, a laboratory requests an address change. The SA makes the change in Aspen Web. The new address change will display in QCOR but the link to the certificate will continue to have the old address unless a revised certificate is requested and generated.

In the screenshot below, a new address may be reflected in the details below. However, the new address may not be displayed when the Certificate URL is selected. The Certificate URL will only display the new address if a revised certificate is generated.

CLIA Laboratory Details

CLIA Identification Number:	21D0881027
Facility Name:	HOWARD COUNTY PEDIATRICS, LLC
Lab Director:	DR. MARY CATHERINE MAILANDER
Address:	11055 LITTLE PATUXENT PKWY #103 COLUMBIA, MD 21044-6335
Phone Number:	410 992-9339
Certificate Type:	Waiver
Certificate Effective Date:	09/29/2023
Certificate Expiration Date:	09/28/2025
Facility Type:	Physician Office
Certificate URL:	https://iqies.cms.gov/api/clia/v1/public/assets/CLIA-Certificate-21D0881027-2023-09-29.pdf

14. when would a replacement certificate be chosen vs revised
Answer – a replacement certificate is one requested with no changes (i.e. the lab contacts your State Agency because they lost their certificate). A revised certificate is one where the lab makes updates to their certificate.

15. Will the lab need to pay whenever making a change in order to get a new certificate, even an electronic one?
Answer – yes. Any time a lab wants a certificate re-issued, there will be a charge. There are no fees associated with a certificate issued because it is “time” in its cycle to move it to the new 2-year cycle (like after the successful recertification survey). If something is changed mid-cycle, the certificate link on QCOR will NOT be updated UNLESS they request a revised certificate.

16. backtracking a little... do Chiropractic Doctors qualify as a provider, or as a earned doctoral degree?
Answer – a degree such as a Chiropractic Doctor would go through what we call the doctoral degree equivalent educational pathway, which is for those individuals who do not have a traditional doctoral degree. You would have to evaluate their CE/CME credits, experience, and courses. Thesis and research can also count in this pathway.

17. In regards to the new fees for onsite revisits, add on specialty surveys, and substantiated complaint surveys, what happens with those fees? Will they go to the general CLIA fund, or will they be awarded to the SA performing those surveys?
Answer – all funds CLIA collects (except for Civil Money Penalties) are used to fund the CLIA program, which includes State Agencies.

18. don't understand your explanation on what will void the fees? The requestor clarified – what happens when a bill isn't paid? (like if they revise their certificate but never pay the fee) but they pay their renewal fees? Will the revised certificate fee be voided?
Answer – Yes. If there is an outstanding revised or replacement certificate fee during the recertification cycle (that starts 6 months before expiration), the fee will be voided.
19. will these changes be communicated to labs in a similar way that IQCP letters were mailed out ahead of the changes? If not, can CMS provide some messaging the SA can provide to the public?
Answer - No, it was published in Federal Register, a ListServ announcement was sent out, it will be on the CMS.gov website next week (week of January 29, 2024), and the Model Letters in BOX will be updated to include revisit survey fees.
The SA may use the language in the model letter if needed.
20. how can we get updated amount for CMP that are listed in our model letters?
Answer – the link to the current Civil Money Penalties is:
<https://www.cms.gov/medicare/health-safety-standards/civil-monetary-penalties>
21. can we get a copy of the power point presentation, and also a copy of the document Zuleika was referring to please?
Answer – Penny's PowerPoint will be uploaded to BOX.
22. Onsite follow-up and PTDR fees - will these apply to all sites dated 01/27/24 forward? For example condition level deficiencies we've already performed the initial survey, but follow-up not yet completed?
Answer – any survey with an exit date after January 27, 2024, will generate the fee.
23. Will these presentations and word documents be in BOX for reference?
Answer – yes. Penny's presentation and the memos are embedded in the agenda.
24. how long will the Demographic information be reflected if labs want to print with their updates? on QCOR
Answer - available until the next certificate is issued. The electronic notification link will work for at least six years. Please encourage labs to elect to receive electronic notifications!
25. I'm new. Can someone please inform in what system the remaining questions will be answered? Is it DBAC?
Answer – BOX.
26. The model letter noted something to the effect of..fees may not be collected until a new data system is online. Is that a reference to iQIES? Is there an update on when CLIA is scheduled to onboard with iQIES?
Answer – see previous answers.

27. We have never requested a 116 for a CoW renewal. Is this something we are supposed to do? The PPM section doesn't list a renewal application requirement like the CoW section does.
Answer – no, you do not need to do this. If a CoW or a PPM does not request any changes (revisions) to the certificate, and they pay their certificate fee when billed, they will be issued a new certificate as usual (in the manner they have elected – electronic notification or mailed via USPS).
28. So if processing a renewal we would select no charge?
Answer - if no changes to the certificate, then yes, there is no charge or change in your procedure
29. 297 is not \$240 + 18%. Is 18% incorrect? This is really confusing.
Answer – the Final Rule is a combination of the fee increase plus an inflation adjustment that is also new.
30. If a laboratory does not wish to pay for a replacement/revised certificate, may we continue to provide a Verification of Certification letter?
The SA should suspend sending verification letters. The laboratory may use QCOR for verification of their CLIA certificate. Demographic and LD changes are reflected in QCOR without a revised certificate being generated.
31. Can we get some more information on specialty addition surveys? Information on them and what to and the process and how to add them in ACO
Answer - The SA should continue to determine whether a separate (specialty addition) revisit needs to be performed. Timing normally allows for the new specialty to be reviewed during the recertification survey. If a separate (specialty addition) revisit needs to be performed, the SA determines whether the separate (specialty addition) revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab. SA should contact CMS for further guidance if needed.
How to add a separate (specialty addition) survey can be found in the QTSO guide “ASPEN CLIA 116 And CERTIFICATION Procedures Guide” at https://qtso.cms.gov/system/files/qtso/CLIA_116_Cert_PG_12.4.4.2_FINAL_0.PDF
See “Addition of Specialty Surveys”, page 172 & 173:

Addition of Specialty Surveys

Addition of Specialty surveys may be entered as revisits. The revisit can be left as the default standard/routine survey or changed to an offsite survey. The SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab.

To enter an Addition of Specialty survey:

1 In the most recent certification kit for the lab within the last two years, scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.

2 Click the **Create Revisit** button to create a revisit survey.

If the selected survey already has revisits assigned, select the latest revisit before selecting Create Revisit.

Note: No tags should carry forward to the revisit since they all should have already been corrected.

3 In the **Survey Properties** window, select **S-Add of Specialties** for Type of Survey.

172

12/11/23

CLIA 116 and Certification

4 Select survey extent:

- For an **offsite** Addition of Specialty survey, select **F-Offsite/Paper** as the Extent for the survey.
- For an **onsite** Addition of Specialty survey, select **A-Routine/Std Survey** or **D-Other Survey** as the Extent.

5 Enter 670 hours:

- For an **offsite** survey, enter **Pre-Survey Hours** and/or **Off Site** hours. Do *not* enter On-Site and Travel hours.
- For an **onsite** survey, enter applicable 670 hours. Pre-Survey Hours and/or Off Site hours are not required.

The kit is automatically re-uploaded if created on or after 07/01/2014. Otherwise, you should manually upload the kit again.

More ...

[Screen: "Survey List" on page 343](#)

[Procedure: "Create Revisit Survey Shells" on page 166](#)

[Screen: "Create Health Survey/Survey Properties window" on page 362](#)

[Screen: "CMS 670 Workload Detail window" on page 369](#)

[Procedure: "Upload Certification Kits" on page 149](#)

32. If we update laboratory demographics will lab receive an email (if signed up) with link to print revised CLIA certificate? —if mid cycle, QCOR will not reflect the changes.

Answer - The laboratory will only receive a link to a new certificate if a revised certificate is generated. Demographic changes will be displayed in QCOR. The link to the certificate in QCOR will have the old demographics unless a revised certificate is generated. For example, a laboratory requests an address change. The SA makes the change in Aspen Web. The new address change will display in QCOR but the link to the certificate will continue to have the old address unless a revised certificate is requested and generated.

33. Can the CLIA certificate be updated to reflect if the lab holds a multiple site exception? And can QCOR be updated to list the multiple sites that are listed in ASPEN Web? This is a request we often receive from our laboratories.

Answer - currently QIES does not have the capability, and we will add to list for new system—

34. Will labs receive a fee coupon when we request a replacement or revised certificate?
Answer - yes, they will.
35. Any recommendation for dialogue with laboratories that need multiple onsite revisits and they lab says, "CLIA is just trying to generate extra money for all these revisits."
Answer -CMS would suggest using that statement to focus the discussion on the laboratory's plan to come back into compliance.
36. If the lab wants a replacement and has their certificate on QCOR and go and print it out, they will not receive an additional charge?
Answer - correct, they will not receive a charge for printing out a certificate from the link in QCOR.
37. How long does it take QCOR to update after changes are made in 116?
Answer – QCOR has relative data and data is available after the night upload—one day after the changes. Data no longer takes up to eight days to be available.
38. A lab is found out of compliance - we prioritize an onsite revisit. When does the fee for the onsite revisit drop? will revisit changes apply to validation surveys as well?
Answer - The fee coupon will not be generated until the revisit is completed and the kit is uploaded. For validations - yes, revisit fees will also apply.
39. For onsite revisits, will the fees have to be paid before the revisit occurs?
Answer – no, fees are based on the 670 hours for the revisit. The bill will not be generated until the revisit is completed and the kit is uploaded
40. If a lab changes director but doesn't request a replacement certificate will the new lab director show in the demographics on QCOR?
Answer – the pop-up on QCOR will show the new name, but the link to the electronic certificate will not unless the lab requests a revised certificate.
41. What if there was a typo on the SA end when a certificate was entered and the error is not caught until a QA review. Can we just select replacement so the lab is not charged for the changes?
Answer – yes. The drop-down box to generate a certificate includes a no-change option.
42. Just a comment on listing multiple sites...some qualified laboratories have >50 sites which change frequently and as such consider it as an option.
Answer – Thank you for the additional insight into the multiple-site issue.
43. what if they made a revision in the middle of a survey cycle, such as a lab director, we would update and indicate a revision to the certificate and they would be charged even if they are not requesting a copy of the new certificate with the change.

Answer –The pop-up on QCOR will show the new LD name, but the link to the electronic certificate will display the old LD name unless the lab requests a revised certificate. The laboratory is only charged if a revised certificate is requested

44. So if a lab does not choose to pay the fee for a revised certificate, then the SA must issue a letter with the correct dates and information on it, correct? Otherwise they are out of compliance for not displaying a current CLIA cert. or do I have this wrong?

Answer – No, the SA does not need to provide verification of CLIA certification letters. QCOR will display all current demographics and may be used to verify CLIA certification. There are no federal regulations that require a CLIA certificate to be displayed.

45. For those asking about the fee calculations for CoW and PPM: page 89984 of the FR notices says there is a 2-part increase of both 0.0495% and 18%.

Answer – correct, see also Q #50

46. In Basic Training, it stated that transcripts are required with qualification form. Should we be asking for transcripts for new laboratory director?

Answer – if the laboratory director cannot be qualified based on the degree they possess (for example, a Clinical Laboratory Science degree for a moderate-complexity lab), then yes, you will need to evaluate their transcripts.

47. I'm still confused about the CoW fee, it's currently $\$180 + \$25 = \$205$ so where did $\$248$ come from?

Answer – see Q #45 & #50

48. How do we determine when a specialty survey is required?

Answer – The SA should continue to determine whether a separate revisit needs to be performed. Timing normally allows for the new specialty to be reviewed during the recertification survey. If a revisit needs to be performed, the SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab. SA should contact CMS for further guidance if needed.

49. $180 \times (18\% + 4.96\%) + 25 = 246.33$

Answer – see Q #45 & #50

50. What documentation should we ask for when a lab is requesting a replacement/revised certificate? 1st they added the 18% increase of $\$180.00$. $180 \times .18 = 32.4$. $180 + 32.4 = 212.4$. From the 212.4 they added the biennial increase of 4.96%. Which is 10.53504. $212.4 + 10.53504 = 222.93504$. To that they added the 25. $222.93504 + 25 = 247.93508$

Answer – There is no change in the process. See Admin Info 23-05-CLIA for more information on changes that require a new form CMS -116 or written notification. See also Q #45. The new fee chart is posted on the cms.gov website.

51. when is CLIA going to iQIES?

Answer – we are actively working on developing iQIES right now and will release it as soon as we are able to.

52. Are there a certain section(s) of the 670 that is used to calculate on-site revisit fees?

Answer – the revisit fees will be calculated based on the hours that are entered into the 670 under the revisit kit.