Medicaid Attestation Requirements

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IU School of Medicine • IU Health • Indiana CTSI

Background Information

- Effective January 1, 2022, there are additional requirements to ensure coverage of routine patient costs for items and services furnished to a State plan beneficiary (Medicaid) while participating in a qualifying clinical trial. (H.R.133 - Consolidated Appropriations Act, 2021)
- In response to the new law, on July 1, 2022, CMS released the required Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.
- On October 4th, 2022, Indiana FSSA released a Medicaid Bulletin: BT202286 to provide additional guidance on compliance with this requirement.
    - Indiana Medicaid requires that the completed form be placed in the medical record to be provided during the prior authorization or coverage determination process as needed.
- It is the research team's responsibility to provide a completed form to the health care system for all Medicaid beneficiaries enrolled in a qualifying clinical trial.
- It is the health care system's responsibility to store or provide this form to Medicaid in accordance with the law.

MEDICAID ATTESTATION FORM ON THE APPROPRIATENESS OF THE QUALIFIED CLINICAL TRIAL

Participant

Participant Name: _____

Medicaid I.D.: _____

Qualified Clinical Trial

National Clinical Trial Number (from clinicaltrials.gov): _____

Principal Investigator Attestation

Principal Investigator Name: _____

- ☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.
- ☐ The Principal Investigator is also the Health Care Provider and hereby attests to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of principal investigator*) (*month, day, year*)

Health Care Provider Attestation

Health Care Provider Name: _____

- ☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of health care provider*) (*month, day, year*)

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-0193. Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

IU Health Medicaid Attestation Process

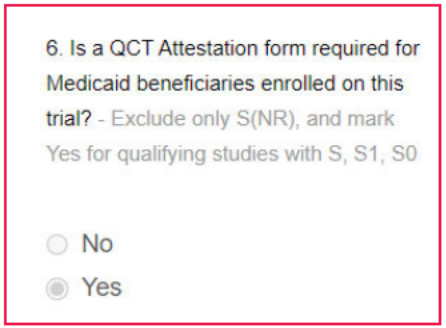
- The Medicaid Attestation form is required for Medicaid beneficiaries that have consented to a Qualifying Clinical Trial with routine services planned as billable to the patient.
- Previously, we provided guidance on how the study team could locate information in OnCore and Cerner to determine whether completion of this form would be required at time of consent.
- Today we are introducing a process that is intended to leverage the information already available in OnCore and streamline this requirement by:
    - Identifying the patients who are Medicaid beneficiaries when they consent to a QCT
    - Notifying the study team that a Medicaid Attestation Form is required
    - Allowing for completion of this form directly in PowerChart using auto text
- The identification and notification pieces of this process apply only to studies with the IU Health RCS Management Group.

Identifying the Patients

- During the Coverage Analysis process, a trial's qualifying status is documented in the OnCore QCT Checklist.

6. Is this a Qualifying Clinical Trial based on Medicare guidelines?	Yes
7. Comments:	It is a Qualifying Clinical Trial according to NCD 310.1. Routine items and services may be billed to patient insurance.

- For each QCT, if any protocol required items or services are designated as billable to the patient (S1/S0) on the Coverage Analysis billing grid, the requirement to submit the Attestation form is noted on the Billing Annotations tab.
- This indicator is provided to IU Health RCS along with your consented patient information because the IU Health RCS Management Group is present.
- Insurance information will be reviewed for participants consented to studies marked as 'Yes' and notification of Medicaid beneficiaries will be sent to the study team.



Notifying the Study Team

- When consented participants are identified as a Medicaid beneficiary, a secure email will be sent to the Study Site Contact, as listed on the OnCore Staff tab.

#Secure Research Attestations

N NoReply@IUHealth.org
To

Encrypt-Only - This message is encrypted. Recipients can't remove encryption.
Permission granted by: NoReply@IUHealth.org
If there are problems with how this message is displayed, click here to view it in a web browser.

You are receiving this message because the participant(s) listed below has been identified as a Medicaid beneficiary.
As the study site contact, you are being notified so that you can ensure completion of the mandatory Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial.

MedicalRecordNBR	NationalClinicalTrialNBR	FirstNM	LastNM	MiddleNM	ProtocolNBR	MemberNBR

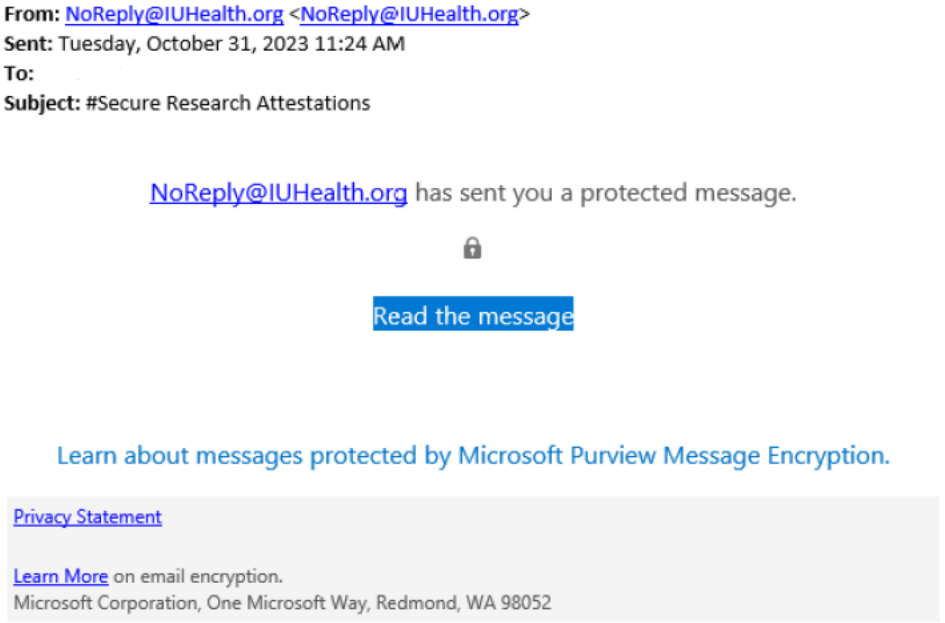
Additional information and instructions are located on the OCR website at https://ocr.iu.edu/medicaid-attestation/
If you have questions related to this requirement, please contact ocrfin@iu.edu and clinicaltrials@iuhealth.org

Report & Email Notifications

- An initial report was run on Monday, October 30th. This report cross-referenced current insurance information for all patients that were active on a Qualifying Clinical Trial retroactive to July 1, 2022 (this is when the form was made available by CMS). The first email notifications were sent on October 31st.
- The report will be run daily to check the insurance status of *newly* consented patients as well as *existing* patients who may have had a change in coverage.
- The report does not factor whether the form has previously been completed. If you are notified about a patient and the Attestation is complete, no further action is required.
- The email notification is sent to the Study Site Contact. You may only list one Study Site Contact in OnCore, and you will only be notified once for each patient.
- If more than one participant is identified in a single day on the same study, they will be grouped by OnCore Protocol ID and one email notification will be sent per study.
- The email will include the NCT# and the patient's Medicaid ID # that are required for completion of the Medicaid Attestation Form. It will also contain a link to the OCR website where Medicaid Attestation guidance is located.

IU Health Secure Medicaid Attestation Emails

- Some confusion about how to view the message – click on the blue "Read the message" not the attachment.
- A handful of users have received an error message indicating they should refresh the application. If you receive this error message, reach out to your IT helpdesk for assistance.

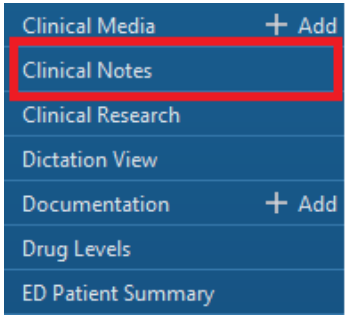


Completing the Form in PowerChart

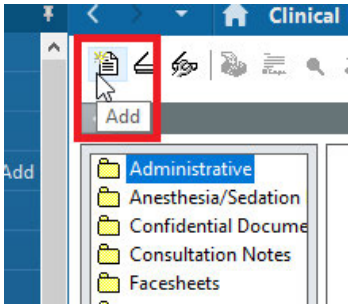
- Within PowerChart, the Medicaid Attestation Form is now an available AutoText so that it can be electronically signed by the investigator. A step-by-step guide to completing the form in PowerChart can be found here and is included in the Appendix section of this presentation.
- If the PI is an IU Health physician, you will only need to complete the information under the Principal Investigator Attestation and only the PI will need to sign. If the PI is not an IU Health physician, completion of the Medicaid Attestation form can be formally delegated to a clinical co-investigator.
- If the PI is not an IU Health physician and there is not a formal delegation to a clinical co-investigator, the form will require two signatures.
- If completion of the Medicaid Attestation form cannot be formally delegated to a clinical co-investigator, study teams should:
    - Complete a paper copy of the form (PDF fillable form version is available on the OCR website)
    - Obtain Signature(s) and dates from the PI and a treating physician.
    - Using Cerner Scanner, scan into the Research/Clinical Trials folder (Found in Clinical Notes > Progress Notes > Research/Clinical Trials)

Adding Medicaid Attestation Note to Clinical Notes section in Cerner PowerChart

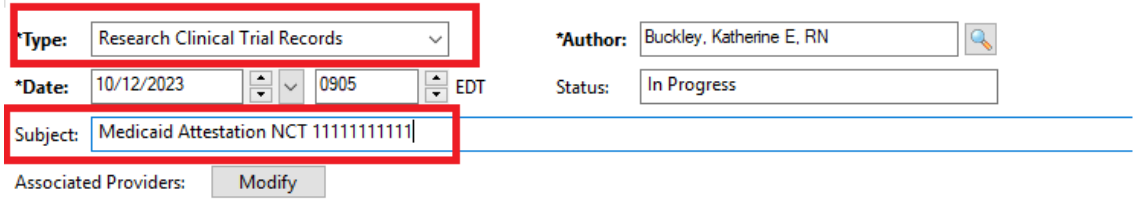
1. When you receive the automated email that indicates that you must complete the Medicaid Attestation, open the subject's account in PowerChart and select the Clinical Notes Band:



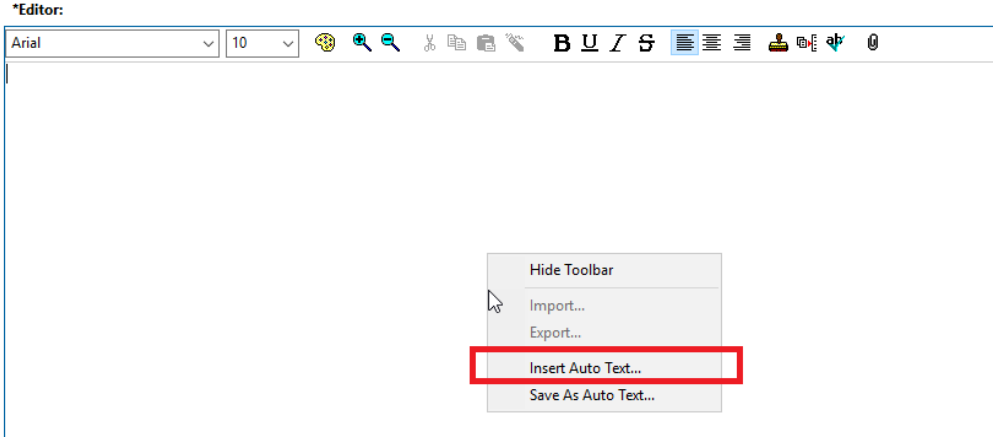
2. Click the icon that looks like a piece of paper to add a clinical note:

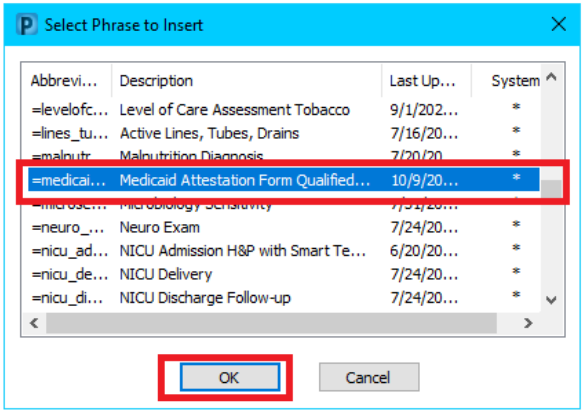


3. The note Type should be “Research Clinical Trial Records” (the Type may default for you), and the Subject should be “Medicaid Attestation NCT xxxxxxx”:

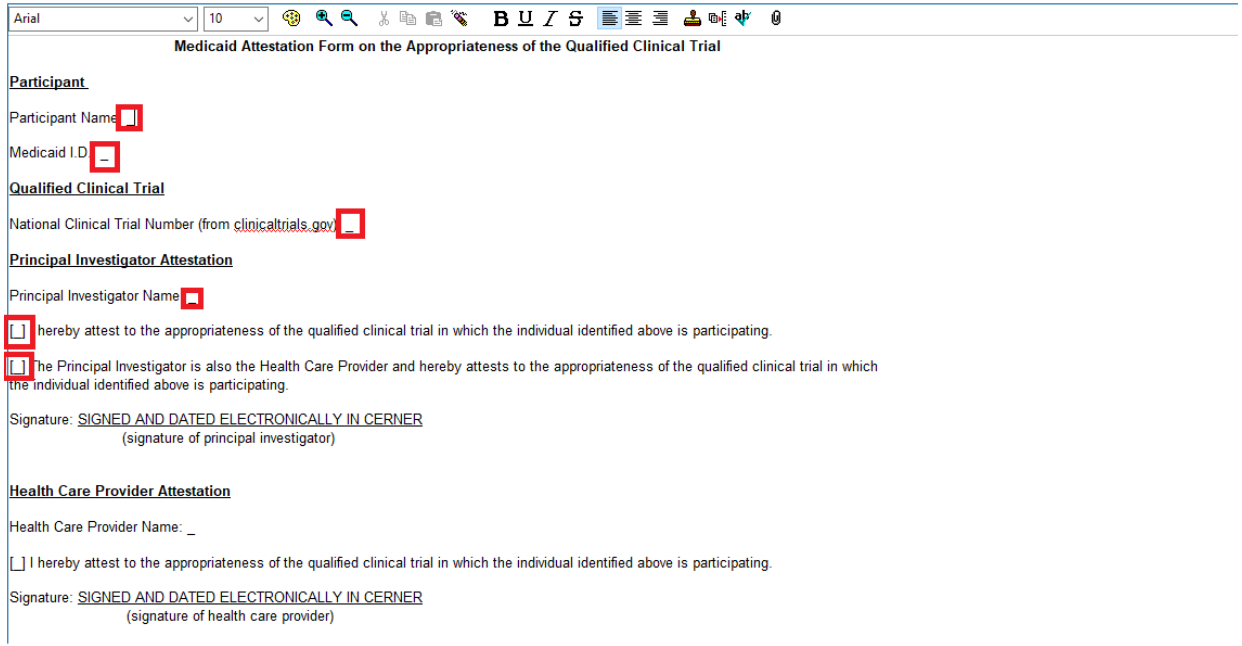


4. In the body of the Note, right click and select “Insert Auto Text.” From this menu, search for “Medicaid Attestation Form,” select it, and click OK:





5. Within the form, the areas with blanks _ or brackets [] need to be completed. Once you have typed an answer, you can move to the next blank by hitting the F3 key. If the PI is an IU Health physician, you will only need to complete the information under the Principal Investigator Attestation.



Arial 10

Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial

Participant

Participant Name: _

Medicaid I.D.: _

Qualified Clinical Trial

National Clinical Trial Number (from clinicaltrials.gov): _

Principal Investigator Attestation

Principal Investigator Name: _

[_] I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

[_] The Principal Investigator is also the Health Care Provider and hereby attests to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: SIGNED AND DATED ELECTRONICALLY IN CERNER
(signature of principal investigator)

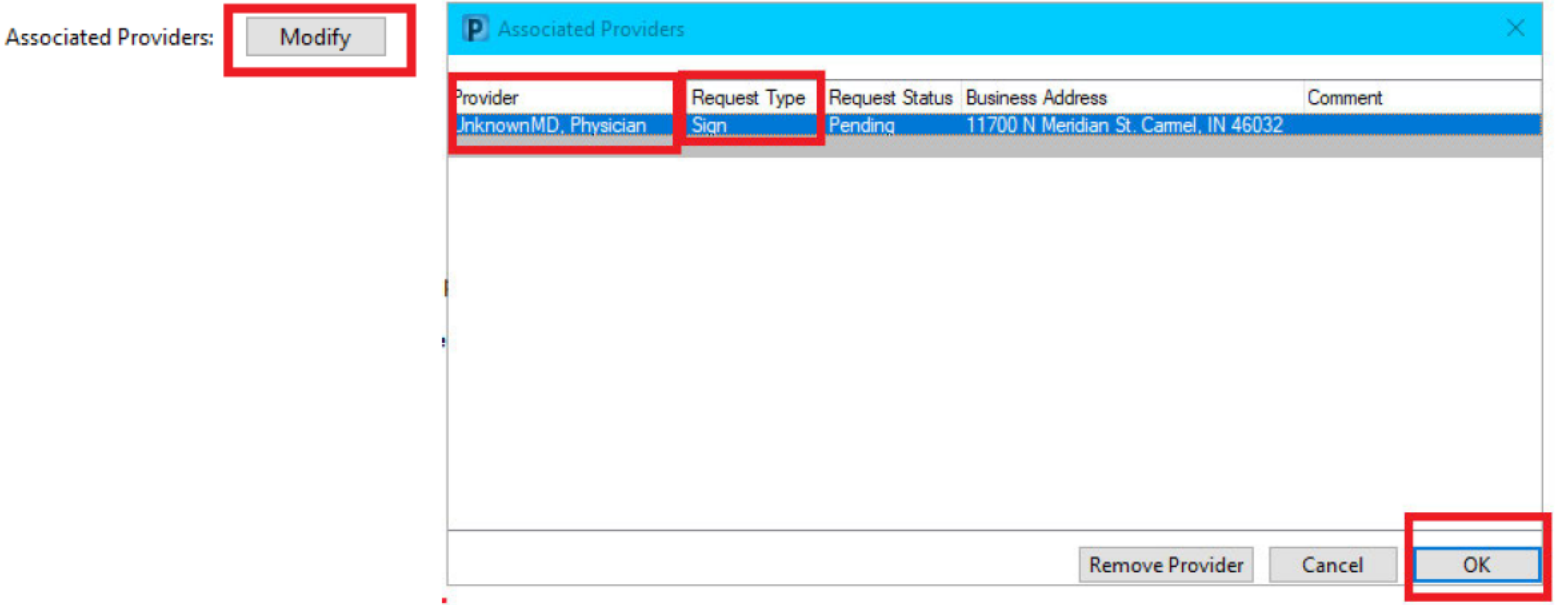
Health Care Provider Attestation

Health Care Provider Name: _

[_] I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: SIGNED AND DATED ELECTRONICALLY IN CERNER
(signature of health care provider)

6. Once you have completed the required information, click Modify at the top of the note. Search for the PI, choose Request Type “Sign,” then click OK:



7. At the bottom of the of the note, click Sign. This will sign the note and send to the provider you requested for their signature.

To review…

- For IU Health patients consented into studies that have IU Health RCS Billing:
  - Study team adds consented patients into OnCore.
  - If RCS determines a patient consented to a Qualifying Clinical Trial is a Medicaid beneficiary, the Study Site Contact will receive a secure email notification.
  - The Medicaid Attestation form should then be completed in PowerChart using the new Auto Text and sent to the PI or clinical Co-I for signature.

- For studies that predate the IU Health RCS Management group process, you will need to self-identify these patients. Guidance for this will remain on the OCR website. However, completion of the attestation form should can still be done in PowerChart.

Eskenazi Health
Manual Medicaid Attestation Form Process

Patricia Noblet: Patricia.Noblet@eskenazihealth.edu

- Completion of the Medicaid Attestation Form is a Medicaid Regulation.
- EH is following the same Medicaid regulations as IUH.
- EH is using the same Medicaid Attestation form as IUH.
- Delinquent forms from July 1, 2022, to present will be collected by EH.
- Email reminders to submit delinquent forms will be sent to the Principal Investigator repeatedly until delinquent forms have been submitted to EH.
- Thank you in advance for submitting the delinquent forms.

Eskenazi Health
Manual Medicaid Attestation Form Process

- All completed forms [pdf] should be emailed to Jessica Broughton at: Jessica.Broughton@eskenazihealth.edu
- Each pdf form MUST be emailed as a single individual file/document.
    - The patient's individual document/form will be uploaded into the patient's Epic record by EH [Jessica Broughton].
    - EH CANNOT accept a pdf file/document that contains multiple forms, we CANNOT process a file/document that contains more than 1 [ONE] completed form.

Epic Process for Medicaid Attestation Form

- The process for managing the completion of the form within Epic is currently being developed.
- The form within Epic will look like the “Manual” form.
- When the Epic process is available an announcement will go out.
- Tip sheets will be made available for both Coordinators and Investigators.
- EH will audit the Epic Research Study Records for compliance with the Medicaid Regulation.