Research Medicaid Attestation FAQ's

1. Why do we need to collect/sign Medicaid Attestation forms for individual study participants?
   A. To meet the requirements of a federal law, the Consolidated Appropriations Act of 2021, all healthcare organizations/providers which engage in clinical research are required to submit an attestation form for each Medicaid or Medicaid Managed Care coverage participant being enrolled into a specific type of clinical research study, known as a "Qualifying Clinical Trial" (QCT) prior to beginning any treatment on a research study.

2. What is a Qualifying Clinical Trial (QCT)?
   A. In general, if a study has therapeutic and/or diagnostic intent in the context of prevention, detection, or treatment of any serious disease or condition, then it is likely considered to be a QCT. By extension, this includes any Investigational Device Exemption (IDE) or Investigational New Drug (IND) study. If you are unsure whether your study meets this criteria, please reference your current Billing Grid/Coverage Analysis document and then reach out to the UW Medicine Clinical Trials Office (uwcto@uw.edu) if you have any questions.

3. What date do we need to begin completing/submitting the Medicaid Attestation forms into Epic?
   A. Any Medicaid Attestation form collected with a signed date on or after January 13, 2025 will need to be collected through, or entered, in Epic.

4. When does this form need to be completed?
   A. This form should be completed for potential Medicaid or Medicaid Managed Care coverage participants **prior** to beginning study related services, ideally prior to, or at, consent.

5. Does this form need to be completed for all patients on the study?
   A. No. The form only needs to be completed for patients with Medicaid or Medicaid Managed Care coverage.

6. Which patients must have an attestation form?
   A. Any patient on a QCT with Medicaid or Managed Medicaid coverage where they will have any billable study related services on or after 1/13/25.

7. Are there any exceptions to the Medicaid Attestation form requirement?
   A. Yes. If your study is not considered to be a QCT (as described in #2 above), then the form is not required. Additionally, for UWM or FHCC studies in which the study sponsor is covering 100% of all billable study-related items/tests/services (i.e., there is no study-related billing whatsoever to patients/insurers), Medicaid attestation forms are not required. This is a rare exception. So, if you are unsure whether your study meets this

criteria, please reference your current Billing Grid/Coverage Analysis document and then reach out to the UW Medicine Clinical Trials Office (uwcto@uw.edu) if you have any questions.

8. Who is responsible for the completion of this form?
    A. The form should be initiated by a study team member (coordinator, nurse, etc..) in Epic, signed by the Principal Investigator (PI) in Epic, and will be sent to the Medicaid or Medicaid Managed Care coverage by either the UW Clinical Trials Office (CTO) or the FHCC Financial Clearance Team.

9. Where can we find the patient's insurance information?
    A. Insurance information can be found in the patient's storyboard in Epic. Alternatively, you can ask the patient what kind of insurance they have, or if they have Medicaid or Medicaid Managed Care coverage, instead of looking in Epic.

10. How quickly would we expect PIs to sign the form?
    A. The UWM and FHCC standard require the form to be completed prior to services being provided to the patient. While there is no specific timeline set in the workflow, the best practice is to complete the form as soon as the patient is identified as a potential study participant and it is determined that the patient has Medicaid or Medicaid Managed Care coverage (i.e., based on #4 above), or when it is discovered that the patient has Medicaid or a Medicaid Managed Care coverage.

11. If services need to be provided emergently, do we delay services until the form is signed?
    A. Services should never be withheld for urgent or emergency care situations. In such situations, it would be expected that the Medicaid Attestation form is completed as soon as possible.

12. Can the PI delegate signing of the form?
    A. Yes - The PI or their delegated authority can sign if they have a documented process for delegation of authority. However, the PI should be the person who signs the form whenever they are able to do so in a timely manner. For example, if the PI is off-site at a conference, they should still be able to access Epic remotely and could therefore still sign the form. Alternatively, if the PI is on sabbatical or is taking a similarly long-term absence, then the PI would already be in need of reassigning their PI responsibilities to another investigator. That person would therefore assume all of the PI's responsibilities under COMP.202, including but not limited to signing Medicaid Attestation Forms.
        i. If the PI has to take a defined leave of absence, they should already have established their delegated authority to handle regulatory trial related issues.

    B. Delegated Authority may sign only in rare exceptions

C. Where a delegated authority needs to sign the Medicaid Attestation form you will need to utilize the paper form workflow.

13. When the patient doesn't have Medicaid or Medicaid Managed Care coverage to begin with but later switches to Medicaid or Medicaid Managed Care coverage-how do study teams know to collect the form at that time?
    A. You can run Reporting Workbench Report 'RSH Patients on My Studies Without a Medicaid Attestation Form' to identify patients on your studies with Medicaid or Medicaid Managed Care coverage that do not have an attestation form completed, it is suggested to run this report weekly. These patients will likewise need a Medicaid Attestation Form filled out/submitted as soon as possible after their eligibility for Medicaid or a Medicaid Managed Care coverage shows in Epic.

14. My PI does not have Epic access, how do they sign the form?
    A. PIs should always seek Epic access as the default. To request Epic access submit a [UW Medicine Account Activation Request Form](#) or email **mcsos@uw.edu** for assistance.

15. How do we handle/initiate these forms for patients that utilize Doe aliases in Epic?
    A. We would not collect the form until we identify that the patient has Medicaid or Medicaid Managed Care coverage.

16. Are we able to utilize a paper document and scan it into Epic?
    A. Yes, however it is recommended to utilize the electronic Epic workflow to capture Medicaid Attestations except where:
        i. A delegated authority must sign the document instead of the PI
        ii. A PI needs another provider to sign as the HealthCare Provider
        iii. The PI does not have access to Epic

    Once the paper form has been signed it needs to be scanned into Epic and emailed to the appropriate billing team for delivery to the Medicaid or Medicaid Managed Care coverage.

17. How do we scan signed paper documents into Epic?

    A. Documents will need to be scanned into Epic via Express Scan. Using Express Scan, you can upload documents electronically from a file on your computer, or physically from a Fujitsu scanner.
        a. Tip Sheets on how to scan documents into Epic can be found here: [Records Scanning (uwmedicine.org)](#)
        b. [The Medicaid Attestation barcoded coversheet can be found here.](#)
        c. If Express Scan training is needed, you can request this by email or Unite ticket:
            i. Email: [erhicontentintegrity@uw.edu](#)
            ii. [Unite Ticket](#) > I Need Something Else > Couldn't Find What I Was Looking For
                1. Set Assignment group on request to 'RIG-CONTENT INTEGRITY'

For additional questions:

- Epic Workflow Questions/Issues: Submit an Epic Research Request in UNITE
- Questions about coverage or form delivery to Medicaid
  - ο UWM CTO Billing – crbills@uw.edu
  - ο FHCC Financial Clearance Team
    - General Oncology - pfsclintrials@fredhutch.org
    - BMT - pfstror@fredhutch.org
    - Immunotherapy - pfsimtx@fredhutch.org
- Compliance/COMP.202 Policy Questions:
  - ο UWM Compliance - comply@uw.edu
  - ο FHCC Compliance – integrity@fredhutch.org