Medicaid Attestation Form: SMCH Interim Workflow

SMCH + SHC Compliance + the University are working to come up with a standardized workflow across all three entities, however in the interim, SMCH has developed the below process for the required Medicaid Attestation Form.

In January 2023, Medi-Cal published guidance on a new attestation form required for providers to bill Medicaid for routine care in qualifying clinical trials.

The Medicaid Attestation Form:

- Must be signed by PI and provider.
- Must include the clinical trial registry number.
- Is required for all patients with any Medicaid coverage on a qualifying clinical trial.
- Must be appended to authorizations and claims.
- Applies to both SMCH and SHC
- Is retroactive to July 2022

Failure to obtain and submit this form for eligible patients may result in Medicaid’s denial of coverage for the patient.

**Interim process**: For all patients who are enrolled in qualifying clinical trials.

1. School of Medicine Research Coordinators identify that participant and trial are eligible to require form.
2. School of Medicine Research Coordinators obtain both PI and Provider signature on form.
   a. **For new enrollments**: This form should be signed by the PI and Provider at the time of consent. The form is required to be completed and submitted to SMCH **no more than one business day** following obtaining of informed consent.
   b. **For eligible patients already enrolled in a qualifying clinical trial**: This form should be signed by the PI and Provider at the time of the patient’s next visit (whether that visit is study-related or not) and submitted to SMCH.
3. Research Coordinators should save a PDF of the signed form with the following naming convention.
   a. “Patient First and Last Name MRN and NCT number”
4. E-mail completed/signed form to HIMS DL DL-HIMS-RESEARCH@stanfordchildrens.org via SECURE email and request that the form be uploaded to Epic as “Study Consent and have the description of Medicaid Attestation.”
   a. Hospital billing will complete the “Medicaid ID” field for all participants

Frequently Asked Questions

- Participants will require a signed Medicaid Attestation Form for **all qualifying clinical trials in which they are enrolled**. If a patient is enrolled in multiple qualifying clinical trials, they will need one form signed for each trial.
• If participants will have any services provided at SHC during their participation in the trial, the completed Medicaid Attestation Form should also be sent to SHC.

• To determine if a study is a qualifying clinical trial and requires this form: If a study has an NCT number, it is considered a qualifying clinical trial:
  o Medicare Coverage- Clinical Trials: Medicare Coverage ~ Clinical Trials (cms.gov)

• Can you put 2 NCT numbers on one form?
  o If the qualifying studies have the same Health Care Provider and PI, then both NCT numbers can be added to one form; however if the two NCT numbers have different Health Care Providers and/or PIs, then a separate form will be required for each qualifying NCT.

• “My participant doesn’t have Medicaid coverage. Why is this form still required?”
  o We are obtaining this form for all participants enrolled in qualifying clinical trials regardless of insurance coverage. This way if a patient’s coverage changes and they acquire Medicaid coverage, we have all required documentation in place. In addition, it will reduce the need for Research Coordinators to monitor the insurance status of all research participants to collect the form if/when insurance status changes.

• “Can I make changes to this form?”
  o No, this is a CMS-issued form and any modifications are not permitted.

• “Is the Medicaid ID the same as the medical record number? How do I find the Medicaid ID”
  o The Medicaid ID is a separate number from a patient’s medical record number. Hospital billing will fill in the Medicaid ID field on the form for all participants.

• For questions, please contact: crso@stanfordchildrens.org

• More information on this requirement can be found here: https://mcweb.apps.prd.cammis.medical.ca.gov/news/32043