Society for Clinical Research Inquiry(s)

1. **SCRS Medicaid Question/Comment:** The form and its guidance should clearly specify that the Principal Investigator can also sign as the Health Care Provide, provided it is not the intent to delay the participant's enrollment in the study and add cost to the Medicaid system for them to have to see a second physician.

CMS Response: The attestation form has been revised to include a signatory option for the principal investigator as well as the Health Care Provider. See the attached attestation form for details. This update has no impact on the currently approved burden estimates.

2. **SCRS Medicaid Question/Comment:** The form and its guidance should specify that in the event the Principal Investigator is not the same person as the Health Care Provider, then the form can be signed in counterparts and that faxes/scans are OK. This will prevent the beneficiary from the need to cover transportation resources to carry the form around.

CMS Response: The attestation form contains two signature lines, one for the Health Care Provider and another for the principal investigator. Since the state will manage the attestation forms, CMS defers to the state on how they want to handle the signatory obligations in the event the Principal Investigator is not the same person as the Health Care Provider. See the revised attestation form for details. This update has no impact on the currently approved burden estimates.

3. **SCRS Medicaid Question/Comment:** The form and its guidance should eliminate the need for gathering "Name/Subject of qualified clinical trial". First this information is not required by the law, which only requires the form "includes the option to reference information regarding the qualifying clinical trial that is publicly available on a website maintained by the Secretary, such as clinicaltrials.gov (or a successor website)" and the proposed form already has a blank to link to the trial (e.g., on ClinicalTrials.gov) that meets the requirements of the law. Second, not only will asking for additional trial identifiers cause extra-regulatory burden to Medicare beneficiaries and their providers, but it will also facilitate confusion on uniquely identifying the clinical trial across Medicaid beneficiaries and providers. Clinical trials almost always have other identifiers, such as Sponsor-assigned protocol identifiers, IRB approval numbers, internally assigned institution numbers, full titles, abbreviated titles and the like to which many of these are not even publicly accessible. The single, publicly accessible and universally accepted unique identifier is the NCT number (which CMS already recognizes for Medicare coverage) is the NCT number from clinicaltrials.gov. No other trial identifying information should be gathered other than the NCT number from clinicaltrials.gov.

CMS Response: The attestation form no longer includes the Name/Subject of the qualified clinical trial and instead includes the National Clinical Trial Number. See the revised attestation form for details. This change has no impact on the currently approved burden estimates.

4. **SCRS Medicaid Question/Comment:** The form and its guidance should replace "link to the qualified trial" to be the NCT number on clinicaltrials.gov, specifically "NCT# (from clinicaltrials.gov):_____". This makes the form unambiguously compliant with the law as it provides the required reference to the Secretary's website. Otherwise, the provider may assume that alternate links are acceptable such as a link to the sponsoring manufacturer's website or a social media recruitment advertisement.

CMS Response: The attestation form replaced the link to the qualified trial with "NCT (form clinicaltrials.gov)". See the revised attestation form for details. This change has no impact on the currently approved burden estimates.

5. **SCRS Medicaid Question/Comment:** The request for NPI number should be eliminated. It is not required by the law and thus the additional data gathering and quality control costs to Medicaid beneficiaries and their providers is an unnecessary burden.

CMS Response: The NPI number has been eliminated from the attestation form. See the revised attestation form for details. This update has no impact on the currently approved burden estimates.

6. **SCRS Medicaid Question/Comment:** The name and Medicaid ID of the beneficiary is gathered twice. This information should only be gathered once at the top of the form to assure consistency of the information throughout the form.

CMS Response: The attestation form now request the name and Medicaid ID of the beneficiary once opposed to twice. See the revised attestation form for details. This change has no impact on the currently approved burden estimates.

7. **SCRS Medicaid Question/Comment:** It is not clear what the providers and/or Principal Investigators are supposed to do with this form. The form should specify in the footer if it is only to be stored in the patient medical record of the billing provider or if it is to also be submitted to the state Medicaid office and if so, when and how.

CMS Response: CMS defers to the state Medicaid agency on how they will handle the form in terms of storage/placement since the state Medicaid agencies will manage the attestation forms. This has no impact on the currently approved burden estimates.

8. **SCRS Medicaid Question/Comment:** The form should be condensed to one single page. In this case of this form the second page has the most relevant content and, pragmatically

speaking, the second page of a two-page form has more chance of getting lost and/or not electronically scanned.

CMS Response: The attestation form has been condensed to one single page. See the revised attestation for details. This change has no impact on the currently approved burden estimates.

9. **SCRS Medicaid Question/Comment:** As the requirement and form was supposed to be in effect January 1, 2022, but the form had and has yet to be finalized by CMS, once the form is finalized and published it should be stated that the form is not required for patients enrolled prior to the form's publication date.

CMS Response: CMS will alert states that the attestation form is not required for patients enrolled prior to the form's publication date. This will have no impact on the currently approved burden estimates.

10. **SCRS Medicaid Question/Comment:** The form and its instructions should be clearer that the signatures do not have to be obtained and dated before items and services are rendered for the patient's routine care. Specifically, beneficiaries should not be denied benefits for otherwise billable routine care items and services that are medically necessary for their serious or life-threatening condition or disease but rendered prior to both or one signature(s) being obtained and dated on the form.

CMS Response: The attestation form is collected prior to any services rendered to a beneficiary as the attestation form is attesting to the appropriateness of the clinical trial. This has no impact on the currently approved burden estimates.

11. **SCRS Medicaid Question/Comment:** The form and its guidance should make accommodations for circumstances where one signatory is unavailable to physically sign for a period of time but verbally agrees. This can be done via documentation that the future signatory has verbally made the attestation and will sign later.

CMS Response: CMS will defer to the state Medicaid agency to determine signatory accommodations/requirements since the state Medicaid agency will manage the attestation forms. This has no impact on the currently approved burden estimates.