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January 31, 2022

Submitted Online at http://www.regulations.gov.
RE: CMS-10398/OMB #0938-1148

Dear OMB Reviewers,

We are hereby providing comment on proposed form number CMS-10398/OMB #0938-1148 entitled "APPROPRIATENESS OF THE QUALIFYING CLINICAL TRIAL" (a copy of which is attached below as Exhibit A).

The Society of Clinical Research Sites has over 9,000 clinical trial site members, many of which will be the very ones who will have to utilize this form and directly discuss it with the Medicaid beneficiaries and providers. While we understand that a new form is to be required by CMS as a result of section 210(a)(3)(c) of the Consolidated Appropriations Act of 2021, we strongly believe based on our members' feedback that the form will have the opposite effect of the intention of the law. It is our expectation that the proposed form will in fact actually decrease enrollment of the Medicaid population in clinical trials and also have a negative effect on our increased efforts of diversity and inclusion in clinical trials enrollment by making it more difficult for this population to enroll than any other socio-economic populations (i.e., those with private insurance and Medicare). We strongly hope CMS does everything possible to decrease burden on its Medicaid beneficiaries' enrolling in qualifying clinical trials while this law is in effect and are available for further discussion on this issue.

Regarding the proposed form itself we hope that OMB and CMS will respect and accommodate the feedback from its intended users who directly care for the Medicaid beneficiaries whose lives this form is intended to improve. While we see that the form seemingly meets the required law passed by Congress, in its present state there are still a number of outstanding questions and concerns from the forthcoming end users that we have collected and listed below. [Note that in the below items we use the term "Principal Investigator" instead of the form's use of "Principle Investigator" in an effort for us to remain consistent with the FDA regulatory language governing clinical trials]. Overall, we hope that the law gets changed to bring both equality to and equity in the Medicaid population for their enrollment in clinical trials and the advancement of medical science, however in the interim we hope these items below can either be addressed in a revision to the form and/or in guidance issued about the form.

1) 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.

2) 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.
3) 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.
4) 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.
5) 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.
6) 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.
7) 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.
8) 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.
9) 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.

10) 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.
11) 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.

As always, we are happy to work with OMB and/or CMS as a liaison to the clinical trial site community on this and other issues for better access and healthcare equity of the Medicaid beneficiaries.

Sincerely,

Allyson Small
Chief Operating Officer

cc: Kirsten Jensen, Director, Benefits and Coverage CMS (via email Kirsten.Jensen@cms.hhs.gov)