July 16, 2012

Gary Cohen, JD
Director, Oversight Group
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7501 Wisconsin Avenue
Chevy Chase Trust Building-West Tower
Bethesda, MD 20814

Dear Mr. Cohen,

The undersigned organizations are pleased to submit these comments in follow-up to our April 16th meeting regarding implementation of Section 2709 of the Public Health Service Act as enacted under the Affordable Care Act (ACA). Section 2709 establishes strong new federal safeguards to protect patient access to clinical trials by requiring group health plans and insurance issuers to cover routine patient care costs incurred when individuals enroll in clinical trials for the prevention, detection, or treatment of cancer and other life-threatening diseases.

The following comments and enclosed attestation form address points that were raised during our April 16th meeting. We have also enclosed the original recommendations that we submitted to Acting Administrator Tavenner earlier this year. We hope these three documents will be of assistance as you draft the regulations that will implement Section 2709. The comments in this letter address:

- A template for a proposed attestation form
- Statutory authority for recommendation to establish a geographic safeguard to limit the distance that enrollees would have to travel to access a clinical trial
- Nuances in the statutory language
- Clarification why there is explicit preemption language in Section 2709
- Recommendation of a timeline in which the regulation should be released to ensure implementation by January 2014

The undersigned organizations would be pleased to serve as a resource for CMS' ongoing work involving clinical trials, as well as any other issues involving the prevention, diagnosis, and treatment of cancer. To discuss these issues further, please contact Allison Baer at 571-483-1624 or Allison.Baer@asco.org with any questions.

Sincerely,

American Association for Cancer Research (AACR)

The AACR, representing 34,000 laboratory, translational, and clinical researchers; other health care professionals; and cancer survivors and patient advocates, is the world's oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research.

American Cancer Society Cancer Action Network (ACS CAN)

ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society that supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

American Society for Radiation Oncology (ASTRO)

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapy. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy.

American Society of Clinical Oncology (ASCO)

The American Society of Clinical Oncology (ASCO) is the national organization representing more than 30,000 physicians and other health care professionals committed to conquering cancer through research, education, prevention, and delivery of high quality cancer care.

American Society of Hematology (ASH)

The American Society of Hematology (ASH) is the world's largest professional society concerned with the causes and treatments of blood disorders. The mission of the Society is to further the understanding, diagnosis, treatment, and prevention of disorders affecting the blood, bone marrow, and the immunologic, hemostatic and vascular systems, by promoting research, clinical care, education, training, and advocacy in hematology.

Association of American Cancer Institutes (AACI)

The Association of American Cancer Institutes (AACI) is dedicated to promoting the nation's leading cancer research institutions' efforts to eradicate cancer through a comprehensive and multidisciplinary program of research, treatment, patient care, prevention, education and community outreach.

Association of Community Cancer Centers (ACCC)

The Association of Community Cancer Centers (ACCC) promotes the entire continuum of quality cancer care for our patients and our communities. Since 1974, ACCC has been helping oncology professionals adapt to the complex changes of delivering quality cancer care while responding to regulatory and legislative changes. ACCC's core purpose is to be the leading education and advocacy organization for the cancer team.

Coalition of Cancer Cooperative Groups

The Coalition of Cancer Cooperative Groups is an independent non-profit service organization working to improve physician and patient access to cancer clinical trials through broad-based education and outreach, advocacy at the federal level on behalf of the public cancer clinical trials system, and direct regulatory support services to the National Cancer Institute-sponsored Cooperative Groups and their network of 14,000+ clinical research professionals in over 3,100 medical facilities nationwide, who collectively enroll about 25,000 patients annually in clinical trials and monitor another 150,000 patients in follow-up care.

LIVESTRONG, Lance Armstrong Foundation

LIVESTRONG serves people and families fighting cancer and empowers communities to take action. It provides free, one-on-one, confidential consultation to cancer survivors for the host of challenges that

accompany a diagnosis, including insurance questions, fertility issues, legal and career concerns and emotional support.

National Coalition for Cancer Research (NCCR)

NCCR is a coalition that is comprised of 24 national cancer organizations. Its mission is to advocate on behalf of public policies that will enhance and expand basic, translational and clinical research, and ensure that the infrastructure and reimbursement mechanisms are in place to support the translation of research from the laboratory to the bedside. The NCCR supports these goals in the broadest terms, emphasizing national priorities essential to progress in cancer research, prevention, education, early detection and treatment.

National Comprehensive Cancer Network (NCCN)

The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives.

National Lung Cancer Partnership

The National Lung Cancer Partnership is the only lung cancer advocacy organization founded by doctors and researchers working together with survivors and advocates to increase lung cancer awareness and research funding.

Oncology Nursing Society (ONS)

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing.

Ovarian Cancer National Alliance

The Ovarian Cancer National Alliance is the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the organization advocates at a national level for increases in research funding for the development of an early detection test, improved health care practices, and life-saving treatment protocols. The Ovarian Cancer National Alliance educates health care professionals and raises public awareness of the risks and symptoms of ovarian cancer. The Ovarian Cancer National Alliance is a 501 (c) (3) organization established in 1997.

Pancreatic Cancer Action Network

The Pancreatic Cancer Action Network is a nationwide network of people dedicated to working together to advance research, support patients and create hope for those affected by pancreatic cancer.

Prevent Cancer Foundation

The Prevent Cancer Foundation is a national non-profit that advocates and supports the prevention and early detection of cancer through advocacy, research, education and community outreach.

Research Advocacy Network

The mission of the Research Advocacy Network is to develop a network of advocates and researchers who influence cancer research—from initial concept to patient care delivery— through collaboration, education and mutual support.

Society of Gynecologic Oncology (SGO)

The Society of Gynecologic Oncology (SGO) is the premier medical specialty society for physicians trained in the comprehensive management of gynecologic cancers. SGO unites all members of the women's cancer care team. Our 1,500+ members include gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, hematologists, surgical oncologists, nurses, physician assistants, obstetrician/gynecologists, fellows-in-training and residents. Our members practice in a variety of settings, including academic institutions and hospitals, major regional cancer centers, and private practice.

Susan G. Komen for the Cure Advocacy Alliance

The Susan G. Komen for the Cure® Advocacy Alliance is the nonprofit, nonpartisan advocacy arm of Susan G. Komen for Cure®, the largest breast cancer organization in the world. With a network of more than 300,000 advocates, the Alliance is the voice for the 2.6 million breast cancer survivors and those who love them, working to ensure that the fight against breast cancer is a priority among policymakers in Washington, D.C., and every Capitol across the country.

Detailed Recommendations

1) Template for proposed attestation form-

At our April 16th meeting, we offered to provide CMS a template that CMS could use to develop a standardized form for health care providers participating in a clinical trial to use to verify with an insurer that a proposed clinical trial meets the statutory requirements of Section 2079 and the individual is qualified under the terms of Section 2079. We believe the attached form provides sufficient information and would ensure that patients receive timely information regarding the clinical trial in which they are considering enrollment. Throughout the document, words in quotation marks are taken verbatim from the statute. Our rationale for each section of the form is explained below:

- Introductory Statement- The introductory statement on the form asserts that the content on the form is sufficient information for a provider to attest that the clinical trial meets the section 2709 coverage requirements and that the insurer should not require additional information to confirm the attestation. This statement is an important element of the form because requests for excessive information serve as a barrier to participation on clinical trials. In some cases, the additional information requested (i.e., a full clinical trial protocol) cannot be provided due to confidentiality or is unnecessary (i.e., signed consent form). A standard form that all insurers are required to accept will greatly facilitate prompt clinical trials participation and initiation of patient treatment.
- Demographics Section- This section includes information routinely included in correspondences between providers and insurers. This section also includes a space for the ClinicalTrials.gov identifier. As discussed in the recommendations we previously submitted in January 2012, ClinicalTrials.gov listings are publically accessible and provide a robust amount of information regarding registered trials.
- **Determining if a trial is "approved"-** Questions number 1 through 3 on the form address the elements in section 2709(d) that explicitly define an "approved clinical trial." The language includes a statement about supportive care trials due to the importance of symptom management with anti-cancer therapies. We strongly believe that the investigator, serving as the referring health care provider, is in the best position to confirm that that the clinical trial meets the statutory criteria for an approved clinical trial.
- **Determining if a person is a "qualified individual"** Question number 4 enables the provider to attest that the individual meets the definition of "qualified individual" because their participation is "appropriate" as defined in section 2709(b)(2)(A). We strongly believe that the investigator is best poised to make the determination of whether a patient meets the clinical trial eligibility criteria. We included the parenthetical statement because it is possible that the investigator or patient may need confirmation from the insurer that the

trial meets the coverage requirement before completing specific final diagnostic testing to determine eligibility for a trial. Some of the test results are time sensitive, so it is necessary to avoid delay between results and trial initiation.

• Insurer Affirmation- the second page of the form is to be completed by the insurer and returned to the provider as confirmation that the insurer acknowledges that clinical trial participation for the patient meets the statutory requirements. This section includes space for the contact information for the person completing this section of the form. This information will help expedite the resolution of any questions or discrepancies between the provider and insurer. Noted in italics is a statement requiring that the insurer respond within 48 hours. Lack of response will indicate that the clinical trial meets the statutory requirement. This statement is important because individuals with cancer are extremely vulnerable to delays in clinical interventions due to the nature of their illnesses and the time sensitivity associated with initiating treatment.

We urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- Group health plans and insurance issuers must accept a standardized electronic form developed by CMS and submitted by individuals or health care providers as affirmation that the clinical trial meets the criteria in Section 2709 for a Phase I, II, III or IV clinical trial. Group health plans and issuers also must accept this standardized electronic form as affirmation that the patient is a "qualified individual" as that term is used under Section 2709.
- Our recommended template for this form is attached.
- For additional information, please see the recommendations under Section I of the attachment to the coalition's letter to Marilynn Tavenner from January 18, 2012.
- 2) Statutory authority for recommendation to establish a geographic safeguard to limit the distance that enrollees would have to travel to access a clinical trial

At our April 16th meeting, CCIIO staff asked for assistance in identifying potential rationales within the Affordable Care Act to support the establishment of a geographic safeguard to preserve local access under such a scenario. Specifically, we urge CMS to protect patients with out-of-network health insurance benefits from being forced to travel more than 25 miles to seek care in a clinical trial from an in-network provider if a local provider participating in the same clinical trial is available to care for the patient.

As we discussed at the meeting, there is a potential loophole in the safeguards established for patient access to clinical trials. As enacted, a health insurance company could undermine the intent of Section 2709 by requiring a patient to travel an unreasonable distance to participate in a clinical trial with an in-network provider, potentially bypassing an opportunity in the local community for

the patient to participate in the same clinical trial with an out-of-network provider. For many individuals fighting life-threatening illnesses, extensive travel presents a physical and economic barrier to care.

When consumers purchase insurance products that provide both in-network and out-of-network benefits, their objective is often to ensure access to the most appropriate specialist or therapy in the event of a life-threatening illness. A health insurer that sells a policy with both in-network and out-of-network benefits should not be able to undermine the safeguards of Section 2709 by allowing coverage only if an individual travels hundreds of miles to participate in a clinical trial through an in-network provider. For such instances in which the same clinical trial is available through an out-of-network provider in the patient's local geographic area, CMS should establish a safeguard that prevents unreasonable travel requirements.

One or more of the following provides adequate rationale for such a geographic protection within the Affordable Care Act.

First, through enactment of Section 2709, Congress highlighted the importance of providing access to clinical trials for individuals with cancer and other life-threatening conditions. Given the plain meaning and spirit of Section 2709, CMS has the authority and obligation to address the oversight of the statutory language and ensure that health insurers are unable to undermine Congress' clear intent.

Second, Section 6003 of the ACA made changes to the In-Office Ancillary Services Exception to the physician self-referral ("Stark") law by imposing enhanced disclosure requirements. This provision of the ACA requires that at the time of referral for certain imaging services, including MRI, the referring physician inform the patient in writing that the patient may obtain the service from someone other than the referring physician or his or her practice group. Part of this notification must include a list of suppliers who furnish the service "in the area in which the patient resides."

This statutory provision was implemented by a final rule issued by CMS on November 29, 2010 (75 Fed. Reg. 73170). The final rule includes a requirement that the suppliers included on the list have to be "located within a 25-mile radius of the physician's office location at the time of the referral" (75 Fed. Reg. 73170 at 73443). Accordingly, CMS interpreted the statutory language that requires services in the area in which the patient lives as being within a 25 mile radius. This provides further support for the recommended local geographic safeguard protecting patients from being forced to travel more than 25 miles to seek care in a clinical trial.

Third, under Section 1311(c)(1)(B) of the Affordable Care Act, Congress directed CMS to "ensure a sufficient choice of providers" within certified health plans and to "provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers." Access to health providers participating in clinical trials is critically important (as demonstrated by enactment of Section 2709) but administratively difficult to determine on a prospective basis. However, CMS can protect consumers in a manner consistent with the intent of Section 1311(c)(1)(B) by implementing Section 2709 with a local geographic safeguard.

Finally, under Section 1401 of the Affordable Care Act, Congress established subsidies in the form of tax credits so that low-income families can obtain access to qualified health insurance plans, which include coverage for clinical trials for the treatment of cancer and other life-threatening conditions. However, if health insurers are able to require extensive travel under the loophole described above,

low-income families will experience the greatest adverse impacts. Low-income patients and their families/caregivers are much less likely to be able to afford the costs associated with long-distance travel, hotels and extended periods away from work. CMS can protect consumers in a manner consistent with the intent of Section 1401 by implementing Section 2709 with a local geographic safeguard.

We urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- CMS should adopt one or more of the following rationales to support the establishment of a
 geographic safeguard to preserve local access to clinical trials: 1) Section 2709 of the Public
 Health Service Act; 2) the 25-mile limit used in implementing Section 6003 of the Affordable
 Care Act; 3) Section 1311(c)(1)(B) of the Affordable Care Act; and 4) Section 1401 of the
 Affordable Care Act.
- For additional information, please see the recommendations under Section III of the attachment to the coalition's letter to Marilynn Tavenner from January 18, 2012.
- **3)** Nuances in the statutory language- At the April 16th meeting, CCIIO staff asked for feedback on any aspects of the statutory language that may merit additional consideration in the regulatory process. Clarifications regarding the definitions of "qualified individuals," "conditions for the departments" and "approved clinical trials" follow below.
 - a. "Qualified Individual Defined" [Section 2709(b)(2)(A)] Subsection (b) defines the patients who will be the "qualified individuals" protected under the clinical trials safeguards of Section 2709. We urge CMS to clarify that Section 2709(b) shall be satisfied in full when a physician who is an investigator participating in a clinical trial concludes that the patient satisfies the eligibility requirements for a particular clinical trial. Although the concepts are simple and clear to those who study the statutory language, we urge CMS to clarify the meaning of the statutory language in this section in a manner that will be clear to all stakeholders, including patients with cancer and other life-threatening conditions.

Paragraphs (1) and (2) must be read in conjunction with one another to define the qualified individuals who are protected under Section 2709. Specifically, the language in (b)(2) clarifies the two ways in which the requirements in paragraph (b)(1) are met. Both paragraphs (2)(A) and (2)(B) make explicit reference to paragraph (1).

Paragraph (1) means that the patient must be eligible to participate in the clinical trial under the terms of the clinical trial. Additionally, the clinical trial must be an "approved trial" as defined under section 2709(d).

Paragraph 2(A) describes one way that patients will satisfy paragraphs (1) and (2). Under the terms of paragraph 2(A), there must be a "referring health care professional," and the referring health care professional must be participating in the clinical trial.

In general, whether or not the referring health care professional is participating in the clinical trial is determined by the trial sponsor and investigators running the clinical trial. This determination is never made by the insurance company. Thus, there is no need to distinguish between in-network and out-of-network status with respect to the referring health care professional and the determinations made under subsection (b), although subsection (c) states that insurers are not required to cover out-of-network clinical trials unless the plan would otherwise cover out-of-network services.

Under subsection (b), the referring health care professional does not have to be the principal investigator for the clinical trial, but the referring health care professional must be one of the physicians who are permitted to treat patients as part of the clinical trial.

Using (2)(A) to satisfy (b)(1) and (b)(2), the referring health care provider must conclude that the patient's participation would be appropriate based on the individual meeting the eligibility requirements established for the particular clinical trial as established by the clinical trial protocol. The "protocol" is the document created by the investigators conducting the clinical trial. The full protocol document is often subject to confidentiality requirements; although a general description of the patient eligibility criteria are typically summarized on the federal government's website at ClinicalTrials.gov.

In addition, we also urge CMS to clarify that the language in paragraphs (1) and (2) of the statute does not create a separate authority for the insurer to demand the protocol documents or to delay the process by attempting to make a redundant review of the patient's medical record and the study protocol. Our experience indicates that insurers are not equipped to make these nuanced determinations, and the clear meaning and intent of the statutory language bases qualification only on whether a physician participating in the clinical trial makes such a conclusion.

In practice, there has been much concern that when insurers attempt to require the submission of protocol documents and large volumes of medical records, the process delays decision making and places patient health in jeopardy. Congress established paragraph (2)(A) to streamline the process and avoid the delays and administrative burdens associated with large paperwork requests from insurers.

As a general rule, the eligibility decisions made by physicians participating in clinical trials are carefully weighed and closely scrutinized by clinical trial investigators. We believe the interests of insurers are more than adequately protected by ensuring that the patients ultimately are accepted by the clinical trial. Even in instances where insurers make significant document requests, we believe the common practice today is for insurance companies ultimately to defer on eligibility issues to the physicians participating in the clinical trial. Determining patient eligibility for a clinical trial is a specialized undertaking,

and as a result, the physicians participating in a particular clinical trial frequently undergo specialized training regarding the enrollment criteria and clinical protocols for the specific clinical trial.

Paragraph (2)(B) provides a second (alternative) pathway for patients to satisfy the requirements in paragraphs (1) and (2). We believe it is important for CMS to clarify that the patient decides whether or not to pursue the pathway under (2)(B) as an alternative to the pathway under (2)(A). Under (2)(B), the patient provides scientific and medical information to the insurer.

With respect to the definition of qualified individuals, we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- CMS should clarify that eligibility of the patient is determined by the "referring health care provider," and the "referring health care provider" is a physician who is participating in the clinical trial by enrolling patients and treating patients under the clinical trial. The investigators running a particular trial make the determination whether or not a particular physician can participate in a clinical trial, and insurers do not make determinations whether a physician is participating in a clinical trial. Whether or not a physician is an in-network or out-of-network provider for an insurance plan has no bearing on whether or not that physician can serve as the referring health care provider under Section 2709.
- CMS should clarify that Congress established paragraph (2)(A) to streamline the process
 and avoid the delays and administrative burdens associated with large paperwork
 requests from insurers. Subsection (b) does not create an independent authority for
 insurers to make burdensome document requests that delay straightforward
 determinations regarding patient eligibility for clinical trials. If the physicians
 participating in the clinical trial find that the patient qualifies to enroll in the clinical trial,
 CMS should clarify that insurers are not expected to engage in burdensome document
 requests that are likely to waste resources and interfere with access to care under the
 clinical trial.

CMS should clarify that the patient decides whether or not to pursue the pathway under (b)(2)(B) as an alternative to the pathway under (b)(2)(A) of Section 2709.

b. "Conditions for the Departments" [Section 2709(d)(2)]— We suggest that CMS work with the Departments of Defense, Veterans Affairs and Energy to develop a process whereby the Secretary can make an overarching assurance that all clinical trials approved, conducted or funded by one of the three Departments meet the standards described in Section 2709(d)(2) of the Affordable Care Act. We strongly urge against an approach that relies upon a case-by-case ruling for each clinical trial to determine whether the terms of Section 2709(d)(2) are met. It is in the best interest of the three Departments to adjust their standard

procedures, if necessary, and clarify that Section 2709 applies to all studies approved, conducted or funded by one of the Departments.

With respect to the conditions to be met for studies conducted by the Departments of Veterans Affairs, Defense or Energy, we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- CMS should urge these Departments to certify that the process used to evaluate all clinical trials meets the criteria set forth in (d)(2) of Section 2709. This may or may not require modification to the current procedures used by each Department.
- c. "Approved Clinical Trial" Subsection (d) defines the term "approved clinical trial" to mean a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition." With respect to the federally funded trials referenced under (d)(1)(A), the plain meaning of the language and the intent is to include studies that involve a wide range of approaches and modalities. This could include devices, biologics, imaging, radiation therapy, surgery, and other modalities, which are all used in the prevention, detection and treatment of cancer or other life-threatening disease or condition. There is nothing that would limit the studies referenced in (d)(1)(A) to only those studies involving drugs.

With respect to the definition of "approved clinical trials," we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- CMS should clarify that federally funded trials referenced under (d)(1)(A) of Section 2709 are not limited to drug trials and can include clinical trials that evaluate devices, biologics, imaging, radiation therapy, surgery and other modalities for the prevention, detection, or treatment of cancer or other life-threatening disease or condition.
- We believe that it would be consistent with the spirit and intent of Section 2709 if CMS
 extended the scope of (d)(1)(B) and (d)(2)(C) to include modalities beyond drugs for the
 prevention, detection, or treatment of cancer or other life-threatening disease or
 condition.

4) Reason why there is language explicitly stating that Section 2709 does not preempt state laws that are more protective-

CCIIO staff asked whether the preemption language under (h) is intended to address any specific issues beyond what otherwise may be addressed in preemption language for the Public Health Service Act.

We do not believe that there is any nuanced meaning underlying the language in this provision. This provision sets a floor regarding clinical trials coverage but explicitly specifies that it does not preempt state laws that are more robust. The drafters likely included this wording to ensure that the

issue was covered, since 30 states have clinical trials coverage laws that are already in existence. However, we do not believe there was any intent by Congress to differentiate the safeguard against preemption for clinical trials from other provisions on preemption under the Public Health Service Act. If a state does go above and beyond the protections established under Section 2709, there is clear confirmation that the state mandate can stand in its current form and does not have to be rolled back in any way to match the threshold coverage required under the ACA.

5) Recommendation of a timeline in which the regulation should be released to ensure implementation by January 2014-

CCIIO staff asked whether we have any recommendations regarding the timing of rulemaking for Section 2709. We recommend that the final regulation be available by the summer of 2013. Release of a proposed final rule ideally should occur in the fall of 2012 or the timeline the CCIIO determines sufficient to meet the summer 2013 timeframe.

Date& Time of Submission:

Clinical Trial Participation Attestation Form

For submission to a group health plan or health insurance issuer offering group health insurance coverage

This form encompasses in full the information that is to be used under Section 2709 of the Public Health Service Act as established by the Affordable Care Act to attest that a clinical trial meets the criteria of an "approved clinical trial" and that a patient is a "qualified individual." Group health plans or health insurance issuers should not require additional information beyond what is included on this form.

Patient Name	Patient DOB
Diagnosis	Diagnosis Code
Insurance Name and Policy Number	
Provider Name	Provider's Tax ID#
Office Contact, Phone, and Fax	
ClinicalTrials.gov Identifier	
(The identifier is typically 11 chara	acters in length and begins with "NCT")

Questions 1 through 4 to be completed by a physician participating in the clinical trial described above. Please answer "yes" or "no" to each of the following questions-				
1.	Is the trial "a phase I, phase II, phase III or phase IV clinical trial"?	Yes	No	
2.	Is the trial "conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition," including trials of supportive care?		No	
3.	 Does the clinical trial satisfy at least one of the following: (A) federally "approved or funded", OR (B) is either: 1. "Conducted under an investigational new drug application reviewed by the Food and Drug Administration, OR 2. "A drug trial that is exempt from having such an investigational new drug application" 	Yes	No	
4.	Is the individual's participation in the clinical trial "appropriate" (i.e. the patient satisfies all trial eligibility criteria, subject to any additional testing that may be required by the protocol)?	Yes	No	

Confirmation to be completed by the insurer and returned to the provider-**

C	1 1	rance issuer concurs that clinical trials participation for thi ection 2709 of the Public Health Service Act.
	Yes	
0	No	
	Rationale must be provided	if no:
Contact Pers	on for Health Plan or Insura	ance Issuer:
Name	·	Title:
Phone	:	Email:

** NOTE: If a health plan or insurance issuer believes clinical trials participation does not meet the statutory requirement, they must respond within 48 hours of receiving this attestation. Lack of response will be considered confirmation that clinical trials participation meets the statutory coverage requirement.

Footnotes-

¹42 USCS 300gg-8 (2012): Coverage for individuals participating in approved clinical trials.

²The term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

³"Federally funded trials"-The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

- (i) The National Institutes of Health.
- (ii) The Centers for Disease Control and Prevention.
- (iii) The Agency for Health Care Research and Quality.
- (iv) The Centers for Medicare & Medicaid Services.
- (v) A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.
- (vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
- (vii) Any of the following if the conditions described in paragraph (2) are met:
 - (I) The Department of Veterans Affairs.
 - (II) The Department of Defense.
 - (III) The Department of Energy.

⁴Definition of "exemptions" according to the Code of Federal Regulations (21 CFR§ 312.2(b)):

- "(b)Exemptions. (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:
 - (i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
 - (ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the Investigation is not intended to support a significant change in the advertising for the product;
 - (iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
 - (iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
 - (v) The investigation is conducted in compliance with the requirements of 312.7."