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August 9, 2010

Sherry Glied, Ph.D.
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Attention: CER Inventory
Hubert H. Humphrey Building, Room 447–D
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Request for Information on Development of an Inventory of Comparative Effectiveness Research (Docket ID: HHS-OS-2010-0017)

Dear Dr. Glied,

On behalf of the American Society of Clinical Oncology (ASCO), I am pleased to submit these comments in response to the request for information issued in the *Federal Register* entitled "Request for Information on Development of an Inventory of Comparative Effectiveness Research." With more than 28,000 members, ASCO is the leading specialty society in the United States and throughout the world for physicians who treat patients with cancer and conduct cancer research to improve patient outcomes. ASCO is committed to ensuring that high-quality, evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans. We appreciate the opportunity to comment on the important questions you raise about how to create an inventory of comparative effectiveness research (CER).

ASCO is pleased with the growing federal investment in the field of CER. Because of the incremental way in which cancer therapies are developed, CER is embedded into the fabric of how we conduct clinical trials. In addition, cancer encompasses several hundred complex illnesses that touch many aspects of the health care system. Therefore, oncology serves as an important laboratory for how to conduct CER studies. The extensive federally-funded clinical trials network is a gold-standard for CER. However, there are many questions relevant to the prevention, diagnosis and treatment of cancer that cannot be readily addressed by randomized clinical trials, and the myriad methods of CER serve as important tools for bringing the highest quality care and best outcomes to our patients.

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Sources for CER – Fundamental to CER is the goal of obtaining and reviewing the totality of evidence on specific, clinically relevant questions, including both current and past studies. It is important that the full range of study types be incorporated into the analysis, including but not limited to randomized controlled trials (RCTs), meta-analyses, population studies, patient registries, administrative databases, decision models, etc. Because these studies are reflected in multiple databases, ASCO strongly encourages HHS to develop linkages that allow information to be pulled from existing sites, such as ClinicalTrials.gov and sites listing NIH and AHRQ-funded research. This would enable researchers to go to a *single* site to register a study and then upload the information to other sites. A single registration site with links to the CER inventory will not only ease the registration process but also help avoid overlapping data sets in multiple sites.

Encouraging Participation/Submission – The CER Inventory would facilitate understanding the landscape of CER projects. ASCO believes that having access to information about studies that are underway – not just those that have been completed or published – will enable researchers to build on the work of others, as well as avoid duplication. Like the registration requirement for ClinicalTrials.gov, it would be ideal if researchers would register their study at initiation. Registration at the outset will provide a thorough understanding of the field, since not all studies result in publication. Since this is a newly emerging field, it will also enable a more objective analysis of CER data and help guard against publication bias. Finally, registration at the beginning of the project will help researchers who are looking for opportunities to be involved know whom to contact about a specific project.

HHS raises a critical question on what will motivate researchers to enter abstracts or summaries of their studies. Hopefully, the ability to see what colleagues are doing, highlight one's own work, and solicit research strategies from those conducting similar studies will serve as incentives. For federally funded CER studies, the federal government could require registration in the inventory prior to the expenditure of funds. An additional incentive could involve a requirement that federal applicants link to their studies in the inventory of CER projects as part of their application. This would make researchers aware that peer review panels will be looking at the inventory as a method of determining the applicants' expertise. HHS could also encourage journal editors to make prior registration a required element of eligibility for publication, as editors did to promote use of ClinicalTrials.gov. Given the breadth of CER, it will be critical to clearly define the criteria of research that would require registration.

Categorization – ASCO encourages HHS to be broad in its scope and inclusion of studies. However, as not all evidence is equally defined or valid, HHS should establish a ranking or stratification to indicate the type of study design, e.g., RCT, meta-analysis, prospective cohort, retrospective, etc. In addition, the categorization should indicate whether the study is ongoing or complete. If complete, information should indicate whether the results are available and whether the data has undergone peer review – either by a data monitoring committee or as part of the publication process. Creation of the inventory is a good opportunity to bring the field together to agree on a workable process that will guide the users of this database both to find the appropriate evidence but also to guide the utilization of the information in proportion to its validity.

Data Elements – If the inventory includes ongoing studies, ASCO encourages HHS to include study goals and subject matter. This will enable researchers to access sufficient information to gain an

understanding of the project. It is important, however, that the information not be overly detailed, in order to preserve the ability to publish and protect the researcher's original work.

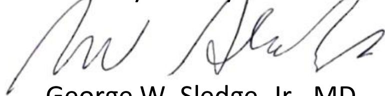
While the Institute of Medicine (IOM) CER priority list reflects a snapshot in time, we believe that it may be useful for the inventory to reflect whether a particular study relates to one of the one hundred priorities. This will provide useful information for policymakers, as they reflect on the original intent motivating the $1.1 billion investment in CER and whether priorities were addressed.

Sustainability – Linking the inventory to the newly created Patient-Centered Outcomes Research (PCOR) Institute may be one method to enable sustainability. The establishment of the PCOR Institute provides dedicated funding through the PCOR Trust Fund and incorporates a public-private partnership. This format may create more buy-in among stakeholders in the research community for sustaining and enhancing the inventory for the long-term. Providing long-term funding for the inventory is an important issue associated with sustainability. The PCOR Trust Fund may be a source worthy of examination.

Additional Consideration:
Timing in Relation to Establishment of and Coordination with PCOR Institute – ASCO urges HHS to delay finalization of plans for the inventory until it can seek input and feedback from the PCOR Institute's Board of Governors and Methodology Committee. The early work of the Board and Methodology Committee will help answer the questions that HHS proposes. In addition, we believe (as stated above) that creation of the inventory is an important opportunity for collaboration with the PCOR Institute.

Thank you again for the opportunity to comment on this important issue. ASCO looks forward to continuing to work closely with HHS to enhance patient-centered approaches to CER. If you have any questions, please contact Suanna Bruinooge, ASCO's Director of Research Policy, at 571-483-1613 or suanna.bruinooge@asco.org.

Thank you for your consideration,



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