



April 13, 2009

Federal Coordinating Council on Comparative Effectiveness Research
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RE: Written statement for the Coordinating Council’s consideration

Dear Council Members,

First, thank you for providing an open forum to listen to the concerns of stakeholders in this important initiative. We firmly believe this is a critical point in the US health care delivery system, and that the American Recovery and Reinvestment Act (ARRA) is the beginning of a positive shift toward reshaping healthcare.

Premier is an organization that is owned by approximately 200 not-for-profit hospital and healthcare systems, and serves over 2100 hospital members and more than 54000 other healthcare sites. Our core purpose is “To improve the health of communities”, and to do that we collect and standardize data in a manner that allows our members and others to use it to perform research, work on quality improvement initiatives, and work in collaborate interventions to improve quality, safety, and the cost of care delivery in their facilities.

Regarding the ARRA, Premier would like for this council to ensure that the funding for comparative effectiveness research goes not to administrative activities, but to true research, which addresses areas of greatest clinical significance that have the most impact on quality and efficiency of care in the acute care setting. To that end we ask that you ensure the research aligns with 5 key principals:

1. **Patient Focused: Each study should be conceived with the ultimate goal of identifying optimal patient care.**
 - o Comparative effectiveness research should not solely focus on identifying which treatment works the best in an ideal environment as in a clinical trial setting, but which treatment provides the greatest benefit to the patient, in the real-world healthcare environment. To that end, results for the comparative effectiveness research should be used as a guide for the best



available treatment based quality, safety and efficiency, but not a substitute for provider and patient judgment.

2. Leverages Proven Data Sources and Methodologies: Only valid, field tested data sources and scientifically appropriate methodologies should be used to assess alternative treatment approaches.

- An assessment of treatment performance begins with the selection of the data source and the methodology used to evaluate the outcomes of care. The use of various data sets or various methodologies to compare the same two patient groups will ultimately provide different results without even changing the intervention. To that end, it is imperative that the Federal Coordinating Council provide broad guidance to ensure methodologies employed in comparative effectiveness studies reflect current scientific practice and is based upon epidemiologically sound principals. Additionally, the Council should ensure a peer review process is in place.

3. Effectiveness Must be Defined Broadly with an Inclusive Scope: In other words quality, safety and efficiency of care should be considered independently, such that there is no trade-off between them in studies, and consideration is given to each in evaluating appropriate care.

- When evaluating comparative methods of treatment, research must be able to account for the quality, safety and efficiency of care in a manner that will allow the care provider and the consumer the opportunity to fully weigh each when selecting the best care pathway for a specific patient. We are not against incorporating those measures into a single result (e.g., a cost effectiveness measure); however, the inputs into such as measure must be clearly defined and transparent.

4. Collaboration: The experience and involvement of stakeholders, such as hospitals and health care systems, must be considered in the development of research priorities so that the transition from research to practice can be completed in a collaborative manner.

- It is essential that all stakeholders in the care process have a voice in the selection of comparative effectiveness research priorities so that the likelihood of adopting of best practices will be higher. As we have found in the CMS/Premier Hospital Quality Incentive Demonstration project, when all parties have a voice in setting a goal for care improvement, they will be much more engaged in efforts to disseminate and adopt best practices identified via research efforts.

5. Transparency: All aspects of comparative effectiveness research must be transparent and disseminated by a central independent body to the, provider, the patient, and the payer; and synthesized in a manner that is understandable by all.

- It goes without saying that this is one of the most important aspects of comparative effectiveness research. Patients, providers, and payers can only make decisions based on the information they have available and can understand. The

Federal Coordinating Council needs to ensure that all research is disseminated in a format that allows the users of that information to clearly understand the comparators, the information and methods used to compare them, and the meaning of the results in terms of quality, safety, and efficiency so that they can assess the return on investment for each care pathway.

Once again, on behalf of Premier and its members, thank you for this opportunity to comment on such an important issue.

Sincerely,



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