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April 14, 2009

TO: Federal Coordinating Committee for Comparative Effectiveness Research

FROM: David Lansky, PhD – Pacific Business Group on Health

RE: Public testimony

Purchasers have led many of the healthcare quality improvement initiatives of the past thirty years: accreditation and systematic measurement of managed care plans, rewarding performance through Bridges to Excellence, CMS, and many regional initiatives, hospital safety and quality programs like Leapfrog, and national measurement systems under the auspices of National Quality Forum, NCQA, and FACCT. PBGH, a coalition of over 50 large California purchasers that provide coverage to more than 3 million employees, retirees, and dependents, has participated in many of these national efforts and has also applied them on the ground in California – through vehicles such as public reporting websites, the Integrated Healthcare Association pay-for-performance program, HHS' Better Quality Information for Medicare Beneficiaries, and the Hospital Value Initiative. With decades of experience in promoting quality improvement and accountability, we are now focused on understanding the relative value of various treatments, programs, and systems of care in improving health. **We believe that a sustainable health care system will require all Americans to make health care decisions that reflect the relative likelihood of favorable outcomes and the commitment of personal and societal resources.**

PBGH and its members are unequivocally supportive of comparative effectiveness research and the use of that research to improve health care decision-making and planning. We believe that the long-term welfare of the American public and the sustainability of the healthcare system itself depend upon an honest, transparent, and evidence-informed discussion about the benefits and risks afforded by different treatment strategies coupled with information on resource use. Too many therapies have value for some but are applied to many, without regard to the relative value and risk associated with the broad use of these treatments. The new federal commitment to comparative effectiveness research provides us with an opportunity to compile and review the evidence needed to support better decision-making in the real world.

As purchasers, we wish to encourage federal attention to both the infrastructure needed to support on ongoing system for using comparative effectiveness and outcomes research and several aspects of comparative effectiveness research and its use. Below are comments addressing these two broad areas.

1. Infrastructure to Support Ongoing Comparative Effectiveness and Outcomes Research

Every day, millions of American patients and their doctors must make decisions based on limited information and a vast, poorly organized, inaccessible body of evidence. They can not wait for randomized controlled trials for every combination of factors and patient characteristics – and probably would be unable to locate and apply them if they existed. Instead, doctors and patients need access to relevant, sound information to inform real-world decisions. **It will be important to think of the comparative effectiveness enterprise less as a library of research studies, and more as an information-rich decision-making environment, supported by continuous learning from the results of routine care.** Let's not produce 1,000 more good research papers but fail to create a robust, durable, and modern information infrastructure for continuous learning. The ARRA mandates the Secretary to address our absent infrastructure by encouraging the "development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data". The Federal Coordinating Council should act aggressively to outline a national information infrastructure approach that will allow us to compile and apply effectiveness information continually. Such an infrastructure should be:

1. **Federated:** Providers who are participating in structured registries and other clinical systems should maintain control of their patient data, but have the ability to federate with

others to answer questions of mutual interest. For example, PBGH is working to link all of the total joint replacement registries in California in a federated network of this kind, so that investigators can compare the effectiveness of various implants across the community.

2. **Standardized:** Cooperating local data sources should agree to conform to content and messaging standards for a core subset of data, as determined by their professional society and other stakeholders. The American Academy of Orthopedic Surgeons, the American College of Cardiology, and the American Society of Clinical Oncology, for example, are well positioned to propose such standards to enable their members to aggregate and analyze practice-level results.
3. **Integrated:** The network of federated registries and data systems should also have a well-structured interface to large aggregate data sets, including health plan and CMS claims data, RxHub and Surescripts dispensing data, and major laboratory results reporting systems.
4. **Rich in feedback:** This infrastructure should not simply support a one-way trip of data to central repositories with feedback reports delayed by months or years. In the era of Google and Twitter, and emerging platforms like ca-GRID and I2B2, we should deploy a many-to-many environment, in which any authorized user can query the network to answer an appropriate question, and in which structured feedback is frequently provided to health professionals and to the public.

Principles for the Development and Use of Comparative Effectiveness Research (CER)

1. *The criteria for defining which subject areas and priorities will be addressed by CER should be clearly articulated and patient-centered:* CER investments should be focused on topics with the highest potential to help assure that all patients receive the right care at the right time, every time. Criteria for priority focus should include:
 - The magnitude of the potential differences in patient outcomes driven by the selection of alternative interventions and pathways of care;
 - The extent of unexplained variation in the use of specific interventions or pathways of care across geographic regions and across racial and socio-demographic groups;
 - Clinical conditions related to categories of technology that do not currently have a robust history of evidence-based care; and
 - The amount of healthcare expenditures related to alternative interventions and care pathways for the condition.

Current examples that meet these criteria include total joint replacement, back surgery, caesarean section and VBAC, elective catheterization and PCI procedures, and some chemotherapy.

2. *The scope of CER should be designed to support better care delivery:* CER should be framed and designed to support improved care decision-making by both patients and clinicians, as well as to inform public and private policy making. To achieve this broad scope, CER should generate results in the following measurement realms:
 - Clinical outcomes
 - Functional status and quality of life
 - Patient experience
 - Impact on health system utilization
 - Expense of all care delivered to the patient for the particular care pathways
 - Disparities across all patient populations, providers, and practice settings
3. *There should be a clear and transparent processes for input in developing CER priorities and policies:* There is an urgent need for results from CER to be generated as quickly as possible, but at the same time it must be assured that the results are robust and that priorities are established with input from consumers, patients, employers, clinicians, researchers and others. The Federal government should establish processes that assure:
 - There must be transparent and open processes that assure CER is (1) answering important/appropriate questions and (2) is doing so with the right methodologies and scope;
 - The multiple federal efforts to fund CER should be coordinated not only with one another, but with other public and private sector CER efforts;

- Part of the coordination among NIH, AHRQ and HHS should consider the mix across these CER-funders of methodologies; priorities and when results would be available.
 - Each of the ARRA-supported CER funders (AHRQ, NIH and NIH) should publish a calendar of funded projects, and there should be a consolidated roster across all funders, that would detail:
 - Funded entity
 - Subject and scope of CER funded
 - Methodology
 - Date of results
 - Efficiency in the development of CER results. The US federal effort should take advantage of international and private sector experience, both in terms of successful processes used elsewhere and the body of substantive findings already developed from valid and transparent institutions like the United Kingdom's NICE program. Additionally, structured observational data can help doctors and patients in real-time and real-world determine which treatments to pursue, unlike random control trials.
4. *Comparative effectiveness research should be relevant to users: patients, clinicians, researchers and purchasers:* CER's value will only be realized through its use by clinicians, researchers, patients and purchasers. When determining the scope of CER, it is important to keep in mind the nature of efforts that may be taken to promote and encourage CER's use through strategies such as:
- Wide dissemination of CER results;
 - Design of CER such that it can support and inform patient-clinician decision-making;
 - Provisions for CER to be used in practice guidelines; and
 - Tools and strategies to link CER to reimbursement, such as value-based insurance design and performance-based payment.
5. *Comparative effectiveness research must address the resources required to deliver various therapies:* In no other market do consumers look only at quality and not the cost of a product when making a purchasing decision. Sometimes small net benefits come at great costs – and can consume resources that could provide greater benefits in some other way. We need information to enable everyone involved to understand these tradeoffs as they make these judgments.

Purchasers like the members of PBGH are impatient to see the health care system create the information rich environment that has long been expected in other industries like aviation, finance, and manufacturing. The proliferation of electronic health records – even interconnected through health information exchanges – will not provide the information platform needed for continuous improvement in the knowledge base to guide therapeutic decisions. We must also create an infrastructure for data aggregation and analysis that allows the many millions of engaged patients, families, and health professionals to fully participate in the decisions that will affect their health and their finances. We look forward to working with the Federal Coordinating Committee and other bodies to create such an infrastructure.