



Kaiser Permanente

**Institute for Health Policy**

# **Establishing a National Comparative Effectiveness Research Capacity: Overview of Key Issues**

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## For discussion

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- **Why is comparative effectiveness research (CER) on everyone's agenda?**
- **What does “establish CER capacity” mean?**
- **Where is there broad-based agreement?**
- **What are some of the unresolved legislative issues?**
- **What issues need to be resolved later?**
- **Some preliminary thoughts on where to get going**

# Why is CER on the policy agenda?

- **Status quo in health care is not sustainable, not desirable**
  - Spending growth exceeds income growth
  - World's highest spending not reflected in health outcomes
  - Quality of care falls short of knowledge
  - Care patterns exhibit substantial unwarranted variation
- **How could comparative effectiveness research help?**
  - Inform head-to-head (or head-to-head-to-head) comparisons of treatments—benefits, risks, costs—not now possible
  - Enable clinicians to make better treatment recommendations, patients to make informed decisions
  - Help payers tailor reimbursement and cost sharing to value, avoid “zero-one” decisions

# What “establishing CER capacity” means

- **Creation/designation of an entity to:**
  - **Prioritize among health conditions for research**
  - **Develop evidentiary standards**
  - **Evaluate research findings**
  - **Disseminate results/recommendations**
- **Creation/designation of some entity to undertake (and/or fund) comparative effectiveness research**
  - **Evidence reviews**
  - **New trials, registries, and so on**
- **What “establishing CER capacity” does not mean**
  - **Entity would not make coverage decisions**
  - **Entity would not negotiate prices**



## Areas of agreement

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- **Clinicians, patients, payers need better information about what works and what does not**
- **CER should be condition-based and have wide scope: drugs, devices, biologics, and medical procedures**
- **Priority setting and evaluation should obtain input from stakeholders with diverse perspectives and expertise**
- **Trust is crucial—need transparent process, credible results**
- **Funding should be stable and broad-based**
- **CER should not stifle productive innovation**

# Legislative issues on the table

- **Scope**: Will research on comparative cost effectiveness be part of the new entity's mandate?
  - Is addressing unsustainable spending an objective or not?
- **Governance**: How can the process be protected from political meddling and/or undue stakeholder influence?
  - Need accountability for funding, independence of judgments
  - Want expertise, buy-in without impairing integrity or paralysis
- **Funding**: What is the appropriate amount and source?
  - How much research to inform \$2+ trillion in health spending?
  - Appropriation or trust fund?
  - How (and when) should private funds be in the mix?



# Issues the new entity will need to address

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- **Accounting for differences across technologies**
  - Product life-cycles (evolutionary vs. revolutionary)
  - Amenability to randomized controlled trials or not
  - Sorting out roles of clinicians, technology, patients
- **Developing an analytic framework**
  - What evidentiary standards will determine “better?”
  - How will benefits and risks be measured?
- **Confronting worries about “zero-one” decision-making**
  - How will findings and recommendations be characterized?
  - To whom will they be conveyed?
- **None of these trivial, none of these a show-stopper**



## Priority setting

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- **Address conditions with alternative treatments available**
- **Address conditions with significant clinical or financial implications**
- **Choose research areas with a reasonable expectation that results will influence provider and/or patient behavior**
- **Choose research areas with a reasonable expectation of getting usable results**
- **Avoid researching conditions for which treatment is self-evidently necessary (see next page)**

## Avoiding the obvious ...



For further reading: Gordon C S Smith, Jill P Pell, *Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials*, BMJ 2003; 327:1 459-461