REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (I-08)
Comparative Effectiveness Research
(Reference Committee J)

EXECUTIVE SUMMARY

At the 2007 Annual Meeting, the House of Delegates adopted the recommendations of Council on Medical Service Report 8, "Strategies to Address Rising Health Care Costs" (Policy H-155.960[4], AMA Policy Database). The Council on Medical Service has prepared this report on comparative effectiveness research (CER) as part of its ongoing efforts to further develop AMA policy related to value, costs and improving health care decision-making. This report defines relevant terminology; examines the need for comparative effectiveness research; outlines the key issues in establishing a CER entity; highlights the role of physicians; and discusses the relationship between comparative effectiveness and cost effectiveness. The report recommends a series of principles for comparative effectiveness research. The principles were jointly developed by the Council on Medical Service, the Council on Legislation and the Board of Trustees in response to a growing need for and imminent legislation concerning comparative effectiveness research.

There is a lack of comparative effectiveness research on the effects of alternative services and treatments which has led to a lack of knowledge about whether new treatments outperform existing treatments. With an increased investment in comparative effectiveness research, the evidence gained could be used to promote the delivery of quality care as well as effective and efficient utilization of limited resources in order to slow rising health care spending. Although there is consensus that an increased investment in comparative effectiveness research is needed, key concerns about CER remain, including disagreement about the composition, funding and structure of a federally supported CER entity, and what role cost-effectiveness will have in the entity's mission and activities.

The Council believes the principles outlined in this report provide AMA with a sound policy foundation to guide its future advocacy efforts on comparative effectiveness research and the creation of a federal CER entity. Accordingly, the Council recommends that these principles be adopted as AMA policy.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5 - I-08

Subject: Comparative Effectiveness Research

Presented by: David O. Barbe, MD, Chair

Referred to: Reference Committee J
(Jack J. Beller, MD, Chair)

At the 2007 Annual Meeting, the House of Delegates adopted the recommendations of Council on Medical Service Report 8, "Strategies to Address Rising Health Care Costs," which established the following policy:

> Our American Medical Association (AMA) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers (Policy H-155.960[4], AMA Policy Database).

The Council on Medical Service has prepared this report on comparative effectiveness research (CER) as part of its ongoing efforts to further develop AMA policy related to value, costs and improving health care decision-making. This report defines relevant terminology; examines the need for comparative effectiveness research; outlines the key issues in establishing a CER entity; highlights the role of physicians; discusses the relationship between comparative effectiveness and cost effectiveness; and recommends a series of principles for the creation of a centralized CER entity.

THE NEED FOR COMPARATIVE EFFECTIVENESS RESEARCH

The June 2007 report of the Medicare Payment Advisory Commission (MedPAC) stated "there is not enough credible, empirically based information for health care providers and patients to make informed decisions about alternative services for diagnosing and treating most common clinical conditions." This lack of timely and credible information has contributed to the United States falling behind in several health indicators, such as infant mortality and life expectancy, and having the highest per capita health expenditures in the world.

Most research on medical treatments to date has focused on comparing the effects of a given treatment to no treatment, rather than comparing alternative treatments to each other. For example, for prescription drugs to gain Food and Drug Administration (FDA) approval, prescription drug manufacturers conduct research that compares their drug to a placebo in the majority of cases, versus comparing their drug to similar drugs. The lack of comparative research on the effects of alternative services and treatments has led to a lack of knowledge about whether new treatments outperform existing treatments. In cases in which there are multiple, alternate interventions to treat

a health condition that have been proven to be effective, studies have also shown that the treatment patients receive often depends on where they live. Contributing factors to such geographic variation include the lack of availability of data and information on the clinical effectiveness and costs of alternative interventions, as well as a lack of physician consensus on the optimal treatment.

Council on Medical Service Reports 8-A-07 and 7-A-08 emphasized that AMA efforts to address rising health care costs should focus on achieving better value for health care spending and promoting value-based decision making. Increasing value is inextricably linked to possessing knowledge and information about the outcomes of health care services, treatments and interventions. Ultimately, having evidence that compares outcomes of alternative treatments, as well as treatment costs, will not only increasingly integrate value into the health care decision making process, but will also equip physicians with the ability to achieve the right care for each patient.

FEDERAL ACTIVITY

Legislation has been introduced in the 110th Congress that addresses funding for comparative effectiveness research and the creation of a centralized CER entity. In May 2007, Representative Thomas Allen (D-ME) introduced H.R. 2184, the Enhanced Health Care Value for All Act, with Representative Jo Ann Emerson (R-MO). If enacted into law, the bill would provide increased funding to finance research on comparative effectiveness and establish a new infrastructure to support a national strategy on comparative effectiveness research. In August 2007, the House of Representatives passed the Children's Health and Medicare Protection (CHAMP) Act, which included CER provisions that were substantially similar to the Allen-Emerson bill. The CHAMP Act provisions on CER were never signed into law.

In July 2008, Senators Max Baucus (D-MT) and Kent Conrad (D-ND) introduced the Comparative Effectiveness Research Act of 2008. The Baucus-Conrad bill would establish an independent comparative effectiveness research institute. The research methodology would not use cost and health plan design factors. A Board of Governors comprised of 21 members appointed by the US Comptroller General would provide the institute's oversight. There were a number of changes made to the legislation from a previous version of the bill that was introduced in March 2008 and subsequently withdrawn (e.g., with respect to the analysis of cost-effectiveness and health plan design as well as the funding sources to support the CER entity). The next Congress is likely to revisit CER legislation as part of comprehensive health system reform and the presidential candidates have included CER in their health proposals.

As a result of this legislative activity, the Council on Medical Service met with the Council on Legislation in March 2008 to establish guiding principles for CER. At its meeting in April 2008, the AMA Board of Trustees reviewed the principles developed jointly by the Councils and agreed to interim principles to guide AMA advocacy efforts when legislative action on CER appeared imminent. Due to the strength and comprehensiveness of these principles, the Council on Medical Service concurs with the Board of Trustees and recommends the adoption of these principles as AMA policy at the conclusion of this report.

CURRENT STATE OF COMPARATIVE EFFECTIVENESS RESEARCH

In September 2007, the Institute of Medicine (IOM) defined comparative effectiveness research as "the direct generation of clinical information on the relative merits or outcomes of one intervention

in comparison to one or more others, and secondary comparative effectiveness research involves the synthesis of primary studies to allow conclusions to be drawn. Secondary comparisons of the relative merits of different diagnostic or treatment interventions can be done through collective analysis of the results of multiple head-to-head studies, or indirectly, in which the treatment options have not been directly compared to each other in a clinical evaluation, and inferences must be drawn based on the relative effect of each intervention to a specific comparison, often a placebo."

There is currently no single federal agency dedicated to CER. Of the few agencies that conduct comparative effectiveness research, their initiatives, in general, are limited in terms of their scope and funding. More than $2 trillion is spent on health care annually in the United States, nearly half of which is publicly financed. Although five percent of annual health expenditures are dedicated to research, less than 0.1% is spent on CER. In the private sector, although private health plans often conduct their own reviews of existing evidence and treatments, they often treat such findings as proprietary and keep their findings confidential. In addition, private sector investment in CER to date has been limited, as the health plan funding such research will likely only capture a portion of the benefits resulting from the findings. Consequently, the investment in CER has not kept pace with new and rapidly emerging health technologies, and new and innovative treatments. Importantly, the research has not been widely disseminated to the medical community.

Under Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Agency for Healthcare Research and Quality (AHRQ) was granted the authority to conduct and support evidence syntheses and research on topics of highest priority to Medicare, Medicaid, and the State Children's Health Insurance Program. In response, AHRQ launched the Effective Health Care Program in 2005. Having had an annual appropriation of $15 million since its creation, the annual appropriation for the program doubled to $30 million in 2008. The program uses AHRQ's Evidence-based Practice Centers (EPCs), institutions in the US and Canada which are awarded contracts to synthesize existing scientific literature about important health care topics and promote evidence-based practice and decision-making. Current EPCs include universities, institutes and associations representing health plans. As of June 2008, the program's EPCs have issued 14 comparative effectiveness reviews, with eight additional reviews in progress.

The National Institutes of Health (NIH) supports comparative effectiveness research by sponsoring head-to-head clinical trials. However, CER has not been the agency's main research focus. As of June 2008, NIH has conducted at least nine head-to-head clinical trials. More than $575 million has been directed toward CER activities within NIH since 1982. This amount, however, is a fraction of the agency's budget in only one year, which was $28.8 billion in FY 2007. NIH has also partnered with the Centers for Medicare and Medicaid Services (CMS) on CER. Currently, the agencies are jointly sponsoring a trial that may compare the effects of daily dialysis for kidney disease patients with the standard treatment of dialysis three times a week.

The Department of Veterans Affairs (VA) also conducts CER as part of its Research and Development Program, which includes 15 Centers of Excellence. Many of these Centers of Excellence carry out comparative effectiveness research. The VA's investment in CER is also rather limited. The FY 2007 budget for the health services research area of the VA's Research and Development Program was $61 million, and not all of this amount was used for CER.

The need for a centralized, adequately funded CER entity is apparent. Some groups, such as the AMA-convened Physician Consortium for Performance Improvement, have established workgroups to study and address this issue further. With an increased investment in CER, the

evidence gained as a result can be used to promote the delivery of quality care as well as effective and efficient utilization of limited resources in order to slow rising health care spending. Although there is consensus that an increased investment in CER is needed, key concerns about CER remain, including disagreement about the composition, funding and structure of a federally supported CER entity, and what role cost-effectiveness will have in the entity's mission and activities.

STRUCTURE OF COMPARATIVE EFFECTIVENESS RESEARCH ENTITY

Comparative effectiveness research ultimately will produce information that is a public good. Accordingly, it is widely expected that the federal government will have a significant role in the funding and oversight of the comparative effectiveness entity. Although private industry (e.g., insurance companies and manufacturers of health care products) has been successful in lobbying for involvement with CER, a CER entity that is solely funded by the private sector would be unduly influenced by its funding entities and organizations, which have a clear economic interest in the research outcomes.

A federal CER entity could be structured in several ways, with each governance approach having advantages and disadvantages. One possible option for structuring a federal CER entity is establishing an independent federal agency within the executive branch, similar to the Federal Reserve and the Securities and Exchange Commission. These agencies, due to their structural independence, are regarded as less vulnerable to political pressures. However, these entities have been criticized for not being as transparent due to their independence. In addition, if the members of the board of these agencies are political appointees, they can become subject to political pressures, which would only be exacerbated by receiving funding through the congressional appropriations process.

Another option is to house an independent CER entity within the legislative branch, with a structure similar to those of the Government Accountability Office (GAO) and MedPAC. One of the main concerns with this approach is that the CER entity would not be independent of political influences. However, some note that the GAO and Congressional Budget Office have maintained their ability to be nonpartisan and objective despite their linkage to the legislative branch.

A federal CER entity also could be structured as a federally-funded research and development center (FFRDC), a nonprofit private sector organization that is sponsored by an existing executive branch agency. Current examples of FFRDCs include the Center for Naval Analyses and the National Cancer Institute at Frederick. Proponents of this option recommend that an existing agency within the Department of Health and Human Services, such as AHRQ or NIH, should sponsor and be responsible for the FFRDC's general oversight. Advantages of FFRDCs include their general protection from outside and political interests, and their ability to be flexible in terms of their structure and staffing. Disadvantages of FFRDCs include their possible lack of stability and close alignment with an executive branch department, which could jeopardize their independence and objectivity.

Another alternative would be for Congress to charter a federal CER entity as a non-profit organization, similar in structure to the National Park Foundation and the Legal Services Corporation. There have been specific proposals to house a federal CER entity within the Institute of Medicine, which is part of the National Academy of Sciences, a congressionally chartered nonprofit private corporation. Although Congress stipulates the charter for such nonprofit private

corporations, concerns with this approach include a possible lack of accountability, reduced transparency and inability to act in a timely manner.

In evaluating all of the options of structuring a federal CER entity, the Council believes that the entity needs to have the independence necessary to remain objective and produce scientifically rigorous research. However, the entity must also have transparent processes for setting research priorities, establishing accepted methodologies and disseminating findings.

FUNDING LEVEL AND OPTIONS

Creating a CER entity raises questions regarding the level at which such an entity should be funded and financing options. Proposed funding levels vary depending on the type of research the CER entity is expected to sponsor. The funding will need to be higher if it sponsors mostly primary research, including head-to-head clinical trials, versus systematic reviews of existing literature. Some researchers have proposed basing the entity's funding on the nation's annual yearly expenditures on health care services, which results in expenditures of $1 billion to $3 billion per year. Legislative proposals to date have also varied in terms of their funding levels, with annual funding levels for the CER entity ranging from $5 million to $900 million. If the entity mainly sponsors head-to-head clinical trials, the clinical trial budget of NIH can be used as a guide.

The long-term stability of a federal CER entity ultimately depends on its financing. Financing could be mandatory, discretionary or voluntary. The entity could also be publicly or privately financed, or a combination of the two. Regarding public funding, options that are mandatory in nature have been favored in recent discussions, versus having the entity being funded by the appropriations process, which is discretionary in nature and can be susceptible to political pressures over disputed research findings. Some mandatory public financing options include establishing a trust fund for CER supported by a mandatory appropriation of general revenue funding, or by dedicating a small percentage of the Medicare Part A Trust Fund.

Proposed public-private funding approaches have included blending a contribution from the Medicare Trust Fund with set-asides from private health insurance premiums and/or manufacturer expenditures for research and development. One example that has been used to illustrate a public-private financing approach is the funding of the FDA's new drug review process, as a result of the Prescription Drug User Fee Act (PDUFA). This process is partly funded by user fees the FDA collects from drug and biologic manufacturers to ensure adequate resources to facilitate the timely review of such products. In this example, user fees currently fund about half of new drug review costs, which are more than $515 million annually. Using this model for a centralized CER entity, it has been proposed, would draw financial support from those who would use or benefit from the evidence produced by CER. Because voluntary contributions from the private sector are seen as being unstable and susceptible to political and budget pressures, proposed mandatory private financing mechanisms have included a levy on private sector organizations.

In considering the options to fund a federal CER entity, the Council believes that the entity needs to have secure and sufficient funding to ensure the entity's long-term sustainability and the resources necessary to produce high quality CER. Funding sources must support and safeguard the independence of a federal CER entity from political pressures, especially those resulting from disputed research findings.

COMPOSITION OF COMPARATIVE EFFECTIVENESS RESEARCH ENTITY

The configuration and composition of the CER entity's governing board must be carefully determined to avoid conflicts of interest. Legislation creating a federal CER entity needs to detail how a board of experts should be structured, whether the board is full- or part-time, the ethics rules of the board, how individuals are appointed to the board, and to what extent physicians, patients, researchers, payers and other groups are represented on the board. In terms of ethics rules, the Council believes that conflicts of interest must be disclosed and minimized to safeguard the integrity and legitimacy of the CER entity's research findings and conclusions. In addition, safeguards should be developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders do not undermine or unduly influence the entity's activities and research findings.

The composition of the governing body of a CER entity is crucial, as it impacts the objectivity and direction of the research taking place, and how the findings are used and disseminated. To ensure science and the well-being of patients are prioritized in the entity, the Council believes that physicians, researchers and patients should have substantial and central representation on the governing body. As key decision-makers, physicians and patients are uniquely motivated to promote the delivery of quality care while maximizing value. However, other stakeholders, including payers and drug and device manufacturers, also have advocated for representation on the governing body, which raises concerns regarding conflict of interest, the prioritization of cost issues, and whether the entity will impact coverage and payment decisions.

The appointment process for the governing body also serves as a guide for the entity's objectivity. Although the appointment process may depend on how the CER entity is structured and where it is housed, many proposals have supported granting appointment authority to a neutral individual, such as the US Comptroller General, to help ensure the board's stability and objectivity.

MISSION AND THE ROLE OF COST EFFECTIVENESS

There is not consensus as to what the mission of the centralized CER entity should be or what activities it should carry out. At the most basic level, there is a need for the CER entity to prioritize interventions, treatments and technologies for scientific evaluation. Proposals thus far have included several criteria to use in prioritizing the CER entity's research activities, including volume, cost, high variance in practice patterns and other factors. The Council believes that the priority areas of CER should include high volume, high cost diagnosis, treatment and health services for which there is a significant variation in practice. In addition, CER should not be limited to new treatments.

Proposals vary regarding whether the CER entity should only fund studies of comparative effectiveness, or conduct the actual research itself. Related is how much the entity should focus on primary research such as head-to-head trials versus secondary research, such as systematically reviewing existing evidence.

In addition, there is disagreement on the role of cost-effectiveness in CER, and how the evidence and information resulting from CER should be used. Some stakeholders have supported the inclusion of cost-effectiveness in CER, and support linking CER findings to payment and coverage decisions. Others have advocated that although CER findings can impact and inform cost-effectiveness research, the two goals should remain separate and the entity should not make

coverage and payment decisions. The Council shares the concern that incorporating cost into comparative effectiveness research may undermine the science and credibility of the research and findings, as comparative effectiveness research and cost-effectiveness research have different purposes and measures. Specifically, the Council is concerned that cost considerations may bias the goal of the research toward cost containment instead of maximizing clinical effectiveness and improving patient care. Therefore, the Council stresses that the composition of the governing body needs to include an appropriate balance of stakeholders to minimize and properly address conflicts of interest within its membership, including vested economic interests. This would be especially vital if the entity were also to conduct cost-effectiveness research. MedPAC has acknowledged that CER findings could potentially increase costs in some cases, because the most effective intervention could be the one that is the most costly.

AMA POLICY

In recent years, the House of Delegates has supported the adoption of several policies that provide a strong foundation for the establishment of policy on comparative effectiveness research. Council on Medical Service Report 8-A-07 established the policy that supports funding that gives priority to studies that collect both clinical and cost data; evaluation criteria that takes into account cost impacts as well as clinical outcomes; and research findings that are translated into widely-disseminated, usable information on the relative cost-effectiveness of alternative diagnostic services and treatments (Policy H-155.960[4]).

Council on Medical Service Report 7-A-08 established Policy H-450.938, which provides principles to guide physician value-based decision-making, including:

- Physicians should have easy access to and consider the best available evidence at the point of decision-making, to ensure that the chosen intervention is maximally effective in reducing morbidity and mortality.
- Physicians should have easy access to and review the best available data associated with costs at the point of decision-making. This necessitates cost data to be delivered in a reasonable and useable manner by third party payers and purchasers. The cost of each alternate intervention, in addition to patient insurance coverage and cost-sharing requirements, should be evaluated.
- Physicians can enhance value by balancing the potential benefits and costs in their decision-making related to maximizing health outcomes and quality of care for patients.

Council Report 7-A-08 also established the policy that our AMA advocate for third-party payers and purchasers to make cost data available to physicians in a usable form at the point of service and decision-making, including the cost of each alternate intervention, and the insurance coverage and cost-sharing requirements of the respective patient (Policy D-155.994).

Evaluation should include the development of information on safety, effectiveness, and indications for use, and be based upon a rigorous scientific methodology. This complete information should be delivered to physicians to enhance appropriate utilization (Policy H-480.984). Policies H-480.984 and H-480.990 support the use of cost-effectiveness considerations, but notes that cost-effectiveness is subordinate to the consideration of safety and effectiveness. The policies also define the central role of physicians in determining cost-effectiveness, and oppose the use of cost-effectiveness by payers to preclude or limit the availability of a safe and effective technology. These policies, both of which relate to technology assessment, also state the need for reevaluating

health care technologies on a continuing basis, and using cost-effectiveness and cost-benefit analysis in such evaluation. Policies H-460.926, H-460.999 and H-460.986 support ample funding of medical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research. Policy H-335.964 supports AHRQ funding and Policy H-460.975 supports NIH funding. Policies H-320.949, H-285.954, and H-285.920 note the importance of recognizing individual patient variation, an important factor to consider when conducting clinical trials. Policy H-460.924 recognizes that race and ethnicity are valuable research variables when used and interpreted appropriately.

DISCUSSION

Due to the likelihood of imminent legislation on comparative effectiveness research, the Council believes that AMA principles governing CER are needed to guide AMA advocacy on the implementation of CER. One of the most critical issues of CER legislation for patients and physicians is the membership of the governing board of the CER entity. Accordingly, the Council believes that physicians, medical researchers and patients should have primary and substantial representation on the governing body. This will ensure subject matter experts and primary decision makers in health care have a central and significant role in directing and supporting objective CER, which will ultimately inform health care decision-making, and health service and treatment utilization.

Although the Council believes that the wide implementation of CER will lead to the adoption of cost-effective care, the primary goal of CER should not be to contain costs. The goal of CER should be to enhance physician clinical judgment and foster the delivery of quality patient-centered care. In certain cases, the most effective intervention could be the one that is the most costly. Once the clinical effectiveness of alternative services is compared, it may be appropriate to consider costs. However, CER should not be a tool for indiscriminately cutting costs by reducing physician payment and instituting coverage decisions based solely on cost.

The impact of CER will ultimately depend on how the findings are disseminated and used. Information and evidence resulting from CER should be easily available to physicians in a useable format. Findings of CER should be incorporated into the latest communications vehicles and technologies, such as electronic medical records, to ensure physicians have complete information and evidence at the time of decision-making. Finally, the Council notes that physicians have a key role in disseminating comparative effectiveness information to patients.

The Council believes the following principles for CER, jointly developed by the Council on Medical Service, the Council on Legislation and the AMA Board of Trustees, will provide the AMA with a sound policy foundation to guide its future advocacy efforts on comparative effectiveness research and the creation of a federal CER entity. Accordingly, the Council recommends that these principles be adopted as AMA policy.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of this report be filed:

1. That our American Medical Association adopt the following principles for creating a centralized comparative effectiveness research entity:

a. Value. Value can be thought of as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information. Quality comparative clinical effectiveness research (CER) will improve health care value by enhancing physician clinical judgment and fostering the delivery of patient-centered care.

b. Independence. A federally sponsored CER entity should be an objective, independent authority that produces valid, scientifically rigorous research.

c. Stable Funding. The entity should have secure and sufficient funding in order to maintain the necessary infrastructure and resources to produce quality CER. Funding source(s) must safeguard the independence of a federally sponsored CER entity.

d. Rigorous Scientifically Sound Methodology. CER should be conducted using rigorous scientific methods to ensure that conclusions from such research are evidence-based and valid for the population studied. The primary responsibility for the conduct of CER and selection of CER methodologies must rest with physicians and researchers.

e. Transparent Process. The processes for setting research priorities, establishing accepted methodologies, selecting researchers or research organizations, and disseminating findings must be transparent and provide physicians and researchers a central and significant role.

f. Significant Patient and Physician Oversight Role. The oversight body of the CER entity must provide patients, physicians (MD, DO), including clinical practice physicians, and independent scientific researchers with substantial representation and a central decision-making role(s). Both physicians and patients are uniquely motivated to provide/receive quality care while maximizing value.

g. Conflicts of Interest Disclosed and Minimized. All conflicts of interest must be disclosed and safeguards developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders with such conflicts of interest do not undermine the integrity and legitimacy of the research findings and conclusions.

h. Scope of Research. CER should include long term and short term assessments of diagnostic and treatment modalities for a given disease or condition in a defined population of patients. Diagnostic and treatment modalities should include drugs, biologics, imaging and laboratory tests, medical devices, health services, or combinations. It should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data. The priority areas of CER should be on high volume, high cost diagnosis, treatment, and health services for which there is significant variation in practice. Research priorities and methodology should factor in any systematic variations in disease prevalence or response across groups by race, ethnicity, gender, age, geography, and economic status.

i. Dissemination of Research. The CER entity must work with health care professionals and health care professional organizations to effectively disseminate the results in a timely manner by significantly expanding dissemination capacity and intensifying efforts to communicate to physicians utilizing a variety of strategies and methods. All research

findings must be readily and easily accessible to physicians as well as the public without limits imposed by the federally supported CER entity. The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

j. Coverage and Payment. The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

k. Patient Variation and Physician Discretion. Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition, patient autonomy and choice may play a significant role in both CER findings and diagnostic/treatment planning in the clinical setting. As a result, sufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative. (New HOD Policy)

Fiscal Note: Staff cost estimated to be less than $500 to implement.

References for this report are available from the AMA Division of Socioeconomic Policy Development.