

To: Docket No. 2004S - 0170

Kaiser Permanente's response to Request for Comments on Section 1013 of the Medicare Modernization Act

Date: May 8, 2004

Kaiser Permanente appreciates the opportunity to submit these comments, including a series of recommendations for HHS to consider in developing its research agenda as directed by the MMA.

KP is the nation's largest nonprofit integrated health care system and is among the nation's largest Medicare Advantage providers, with long experience in providing prescription drug benefits to Medicare beneficiaries. Overall, KP prescribes and dispenses to its members more than \$2.5 billion in prescription drugs annually. Because relatively little of its pharmacy services are provided on a fee-for-service basis, KP's interest in high quality and cost-effective drug selection and use are closely aligned with those of other private and public health care payers.

HHS's priorities should be focused on research that would provide the greatest value in terms of guiding good prescription drug benefit management for taxpayer-funded health care systems. Because the MMA will greatly expand the federal government's role in providing these services through the Medicare program, we believe that research should be targeted in areas that potentially have the greatest long-term impact on the Medicare program. With that in mind, KP makes the following recommendations for prioritization of comparative research that needs to be done.

High Priority

Cancer – comparison of cancer prevention effectiveness of NSAIDs vs. Cox-2 inhibitors.

Cancer – comparison of the effectiveness, optimal duration of therapy, and adverse effects related to treatment of anemia for chemotherapy patients.

Cancer – comparison of tumor stimulating effects (e.g., comparing progression or survival in patients with similar tumors) of different exposure levels of erythropoietin therapy.

Cardiovascular Disease – comparison of cardiovascular outcomes related to treatment with different combinations of lipid-lowering agents (e.g., statin and niacin, statin and resin, statin and ezetimibe, statin and fibrate).

Diabetes – comparison of the benefits of adding insulin versus newer oral antidiabetic agents in patients taking metformin and a sulfonylurea.

Mental Health – comparison of effectiveness of the selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, and benzodiazepines in alleviating

depression. Special attention to relative value for older adults (e.g., faster onset, lower relapse rates, fewer treatment failures) and whether certain ones are better tolerated. Comparison of long term use of antidepressants, antipsychotics and benzodiazepines as well as in combination.

Osteoarthritis – Comparison between Cox-2 inhibitors and other NSAIDs with respect to relative safety (GI, cardiovascular, renal).

Rheumatoid Arthritis – comparison of effectiveness Enbrel, Humira, and Remicade and appropriate dosing. Evaluation of a stepwise approach for escalating drug therapy.

Priority

Incontinence – comparison of overall effectiveness and compliance of immediate release, sustained release prescription drugs, and various treatment regimens.

Pain – comparison for the treatment of neuropathic pain of gabapentin, pregabalin, and tricyclic antidepressants (nortriptyline, desipramine).

Pain – comparison of long-acting opioids to determine which one should be used as first-line therapy.

Prostate Cancer – comparison of effectiveness of testosterone-based Depo-Lupron dosing.

Psoriasis – Comparison of outcomes, compliance, duration of therapy, and remittive potential of traditional therapies and newer biologics.

We are more than happy to provide any additional input. If you have any questions, please do not hesitate to contact either Steve Cole in our Washington, D.C. office (202) 296-1314, or Anthony Barrueta in our Oakland offices (510) 271-6835.

Thank you for your consideration of Kaiser Permanente's views.

Sincerely,

/s/

Anthony Barrueta
Vice President, Government Relations
Kaiser Foundation Health Plan, Inc.
One Kaiser Plaza
Oakland, California 94612
anthony.barrueta@kp.org