Doug Owens <owens@smi.stanford.edu>
04/15/2003 10:31:37 AM

Record Type:Record

To: John Graham/OMB/EOP@EOP, owens@stanford.edu

cc: Lorraine D. Hunt OIRA ECON GUIDE/OMB/EOP@EOP
Subject: Re: .pdf copy of cost-benefit report fed register notice

At 01:35 PM 2/27/03, John_Graham@omb.eop.gov wrote:

>---------------------- Forwarded by John Graham/OMB/EOP on 02/27/2003 03:29 PM
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>
>John Graham
>02/27/2003 01:37:49 PM
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>Record Type: Record
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>To: owens@stanford@dartmouth.edu, Anna.N.A.Tosteson@dartmouth.edu @ inet
>
>cc: John F. Morrall III/OMB/EOP@EOP, Arthur G. Fraas/OMB/EOP@EOP
>Subject: .pdf copy of cost-benefit report fed register notice
>
>Doug and Anna:
>
>OMB has recently released for public comment and peer review our guidelines on
>regulatory analysis. These guidelines cover the analytic activities of
>federal
>health and safety agencies. Historically, the guidelines have emphasized
>benefit-cost analysis but for the first time we are considering a requirement
>that agencies also present a cost-effectiveness perspective. Given each
>of your
>experience with CEA, we would appreciate your service as a peer reviewer.
>Comments on all aspects of the draft Report and guidelines are welcome but we
>are particularly interested in your advice on how we should frame the
>cost-effectiveness requirement.
>
>Any comments you can provide by April 15 would be appreciated. John
>Morrall or
>Art Fraas on my staff can answer any contextual or format questions you might
>have. Your review will be made part of the public record. Once the
>guidelines
>are finalized, they will serve as the basis for our review of rulemaking
>packages submitted to OMB by agencies such as FDA, NHTSA, EPA, CDC and others.
>
>Although we cannot offer you the compensation for this activity that you
>deserve, we respectfully request that you perform the review as a public
>service. Many thanks and please contact me if you happen to come to
>Washington
>in the near future. Take care.
>---------------------- Forwarded by John Graham/OMB/EOP on 02/27/2003 01:24 PM
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>Bryon P. Allen
>02/03/2003 10:59:02 AM
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>Record Type: Record
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>To: John Graham/OMB/EOP@EOP, Paul R. Noe/OMB/EOP@EOP, Veronica
>   Vargas/OMB/EOP@EOP
>
>cc: Mary M. Chuckerel/OMB/EOP@EOP
>Subject: .pdf copy of cost-benefit report fed register notice
>
>(See attached file: cost benefit fed register notice.pdf)
>
>Attached is the Federal Register notice that was printed today.
>

Dear John,

Many thanks for sending me the draft OMB guidelines on regulatory analysis. I've attached my comments - the guidelines are very impressive. I've directed my comments toward some technical aspects of cost effectiveness analysis. My comments are my personal views, not related to any official comment from the VA. I hope this is useful. Please let me know if I can be of further help.

Best wishes,
Doug

Douglas K. Owens, MD, MS
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Associate Professor of Medicine and of Health Research and Policy
Director, Program on Clinical Decision Making and Guideline Development
Center for Primary Care and Outcomes Research
Stanford University


OMBceaReview.doc

April 14, 2003

Below are my comments on the OMB draft guidelines on regulatory analysis. The guidelines are an impressive and laudable effort to increase the consistency and sophistication of regulatory analyses. I have several main comments.

1. I strongly endorse the use of cost effectiveness analysis (CEA) as an important and legitimate tool for public policy decision making. CEA is a very useful method that is complementary to benefit-cost analysis (BCA), and may provide advantages for certain problems.

2. For CEAs that assess regulations that affect both mortality and morbidity, use of quality-adjusted life years should generally be the preferred outcome measure, when feasible. Use of QALYs provides a common metric that allows for the "apples to apples" comparison across interventions as requested in the draft guideline. Quality adjustments should generally be made with utility-based (or preference-based) assessments of quality of life (such as the standard gamble, or time-tradeoff method as noted on p. 5521). Because such assessments may not exist, or there may be uncertainty about the magnitude of appropriate quality adjustments, regulatory analyses can also report life-years saved, although such outcomes may over- or underestimate true cost effectiveness depending on the impact of a regulation on morbidity.

3. I'd suggest that the guidelines more strongly encourage use of incremental cost effectiveness comparisons, and note that average cost effectiveness is virtually never appropriate for decision making. Although the guideline urges caution about average cost effectiveness, there is still some ambiguity. On p. 5517, column 3, the guideline suggests presenting both total benefits and costs relative to the same baseline. Although this may be appropriate to estimate total costs and benefits, the cost effectiveness ratio should be incremental. The alternatives should be ranked from worst to best in terms of benefit, and the cost effectiveness ratio of the best should be compared to the next best, and so on. Several alternatives should *not* be compared to the baseline or status quo. Alternatives that are dominated by strict or extended dominance should be removed from consideration.

Perhaps the easiest way to assess cost effectiveness when there are numerous alternatives is to plot each alternative on a plot with health outcomes on the y-axis and and costs on the x-axis. Alternatives on the cost effectiveness frontier can then be compared appropriately by calculating cost-effectiveness ratios, and alternatives that are dominated can be eliminated.

4. Treatment of uncertainty is particularly important and the approach outlined in the guideline is rigorous and will ensure that the importance of assumptions and uncertainty in regulatory analyses is clear to policymakers and the public.

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