

Echols, Mabel E.

From: Stuart Gordon
Sent: Tuesday, March 31, 2009 1:22 PM
To: FN-OMB-OIRA-Submission
Subject: SNHPA Comments on Federal Regulatory Review Process
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Attachments: Comments on Regulatory Review 3-31-09.doc

Dear Ms. Echols:

The Safety Net Hospitals for Pharmaceutical Access (SNHPA) thanks the Office of Information and Regulatory Affairs (OIRA) for the opportunity to offer comments on OIRA's role in the federal regulatory process and the opportunities afforded for public participation in that process. SNHPA believes the role of OIRA in the regulatory process would be greatly enhanced through additional transparency during the centralized review of agency guidance documents. This could be accomplished if Executive Order 13422 of 2007 were amended to expand the required web-based public notice of OIRA review of agency regulations to include agency guidance documents with a significant impact. Such an extension of public notice requirements would provide greater transparency and facilitate a more rapid centralized review of these documents.

Our written comments are attached.

We thank you for the opportunity to comment on this important issue. If you have any questions, please contact SNHPA's Director of Legal and Regulatory Affairs, Stuart Gordon, at

Stuart Yael Gordon
Director, Legal and Regulatory Affairs
Safety Net Hospitals for Pharmaceutical Access (SNHPA)



Safety Net Hospitals for Pharmaceutical Access

March 31, 2009

Office of Information and Regulatory Affairs
Office of Management and Budget
Records Management Center
Attn: Mabel Echols
10th Floor New Executive Office Bldg.
725 17th Street, NW.
Washington, DC 20503

Dear Ms. Echols:

The Safety Net Hospitals for Pharmaceutical Access (SNHPA) thanks the Office of Information and Regulatory Affairs (OIRA) for the opportunity to offer comments on OIRA's role in the federal regulatory process and the opportunities afforded for public participation in that process. SNHPA believes the role of OIRA in the regulatory process would be greatly enhanced through additional transparency during the centralized review of agency guidance documents. This could be accomplished if Executive Order 13422 of 2007 were amended to expand the required web-based public notice of OIRA review of agency regulations to include agency guidance documents with a significant impact.

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an organization of over 500 public and private non-profit hospitals and health systems throughout the U.S. that participate in the Public Health Service 340B drug discount program. SNHPA, which was originally named the Public Hospital Pharmacy Coalition, was formed in 1993 to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. When Congress was creating the 340B program in 1992, SNHPA took the lead role in ensuring that hospitals were included in the program and the organization has been representing the interests of 340B hospitals ever since. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA is dedicated to educating its members and others about the 340B program and creating new opportunities for members to improve access to pharmaceutical care.

Extending Public Notice Requirements to Significant Guidance Documents

SNHPA understands there are organizations advocating for changes to the regulatory process that they believe would reduce or eliminate delays that are perceived to arise out of OIRA's centralized review of proposed and final agency regulations. The Center for American Progress, for instance, argues in its March 2, 2009 comments that the size of the OIRA staff makes it difficult for OIRA to process every rule in a timely manner. However, SNHPA believes it could be just as easily argued that the review of agency actions and documents would be performed more expeditiously if there is greater transparency and public notice injected into the review process, so that the public is fully

aware of what factors or what agency personnel might be delaying the drafting or finalization of a regulation or guidance document.

Executive Order 13422 of 2007 applied the principles of transparency and public notice inherent in Executive Order 12866 of 1993 to significant agency guidance documents generally, in an attempt to make agency guidance practices more transparent, consistent, and accountable. This was done, we believe, in recognition that agencies increasingly rely on the use of guidance documents to implement policies that broadly impact affected parties, and that these agencies could be seen as evading their responsibilities under the Administrative Procedure Act and Executive Order 12866 when they implement agency action through the less formalistic guidance document process.

The 2007 Executive Order largely accomplished its purposes, but it failed to address one significant step in the OIRA review process. Pursuant to Sec. 6 of Executive Order 12866, OIRA gives notice via the OMB website when it is performing a 30-day review of a proposed, final, or interim final formal regulation, or when an OIRA review of a formal regulation has been completed within the last 30 days. Unfortunately, similar notices are not posted on the OMB website when OIRA reviews a significant agency guidance document, leaving affected parties uninformed about the status of significant agency documents or OIRA review of those documents. SNHPA believes that OIRA could achieve increased transparency by providing public notice of guidance documents through a posting on its website, and that this increased transparency could work to increase the speed with which guidance documents are reviewed. We also believe that giving notice of OIRA's review of guidance documents would not impose an unreasonable burden on OIRA's limited resources or staff.

Conclusion

SNHPA applauds the Obama Administration efforts aimed at improving the regulatory process, and we believe that public notice on the Internet of OIRA review of significant agency guidance documents, identical to that now being provided for formal regulations, would achieve a significant improvement in the process. Such an extension of public notice requirements would provide greater transparency and facilitate a more rapid centralized review of these documents.

We thank you for the opportunity to comment on this important issue. If you have any questions, please contact SNHPA's Director of Legal and Regulatory Affairs, Stuart Gordon, at

Sincerely,



William von Oehsen
President and General Counsel



Stuart Yael Gordon
Director, Legal and Regulatory Affairs