

**America's Health
Insurance Plans**

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March 20, 2009

Mabel Echols
Office of Management and Budget
Office of Information and Regulatory Affairs
Room 10102, NEOB
725 17th Street, NW
Washington, DC 20503

Re: Request for Comments – Executive Order on Federal Regulatory Review

Submitted via e-mail: oira_submission@omb.eop.gov

Dear Ms. Echols:

America's Health Insurance Plans (AHIP) is writing in response to a request from the Office of Management and Budget (OMB) for public comments on recommendations for a new Executive Order on Federal Regulatory Review. As discussed below, a transparent and consistent regulatory process is critical for AHIP's member health insurance plans, which are subject to extensive state and federal oversight.

AHIP is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, vision, disability, and supplemental coverage. AHIP's members also have a strong track record of participation in Medicare, Medicaid, and other public programs.

We believe Executive Order (E.O.) 12866, issued by President Clinton, establishes a clear set of principles and processes to ensure that federal regulations are developed in a manner that “protects and improves [the public’s] health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society . . .” (E.O. 12866, October 4, 1993, 58 Fed. Reg. No. 190). While that E.O. provides a foundational template for rulemaking, we have comments relating to the following four issues:

- the current extensive regulatory oversight of health insurance plans;
- recommendations for making the regulatory process more transparent;
- recommendations for assuring procedural and substantive fairness; and
- recommendations for achieving value in the rulemaking process.

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Comprehensive Regulation of Health Insurance Plans

Health insurance plans operate in highly regulated markets, both federal and state. Because of the extensive and overlapping state and federal oversight of health insurance plans, it is critical that regulations provide consistency between federal and state policy objectives and not place unreasonable financial and administrative burdens on health insurance plans -- costs that are ultimately passed on to consumers.

At the federal level, the Departments of Labor and the Treasury provide oversight of employee health and welfare benefits offered to over 177 million employees and their dependents.¹ The Office of Personnel Management oversees health and welfare benefits provided to 4 million federal workers, retirees, and their family members. The Department of Health and Human Services is responsible for a broad range of regulatory activities impacting our members, including supervision of the Medicare Advantage, Medicare Part D prescription drug, and Medicaid programs; rules for health information technology, privacy, and data security; oversight of the individual and group insurance markets; regulation of prescription drugs and medical devices; and support for health care quality and comparative effectiveness initiatives.

In addition, states have broad authority under the McCarran-Ferguson Act (15 U.S.C §1001 *et seq.*) to regulate insurance products and require oversight of virtually every aspect of an insurer's business operations, including licensure of insurers and insurance producers, enrollee information disclosures, access to medical services, health care provider contracting issues, financial solvency, rate filings, benefit mandates, quality assurance and utilization review, and grievances and appeals.²

Assuring a Transparent Regulatory Process

Transparency assures the public that governmental agencies are acting in an open manner and considering all available, relevant information when making decisions. Transparency is a critical component of the rulemaking process and a central requirement of the Administrative Procedure Act (5 U.S.C. §500 *et seq.*) and E.O. 12866. A transparent regulatory process is achieved through public notice of agency rules and guidance documents, providing an opportunity for public comment, and the disclosure of all relevant information considered by the agency as part of the decision-making process.

¹ U. S. Census Bureau, *Health Insurance Coverage Status and Type of Coverage by Selected Characteristics: 2007*.

² For a full discussion of state regulatory oversight, see: *Essentials of Managed Health Care*, Peter R. Kongstvedt, Fourth Edition, (2001), *NAIC Compendium of State Laws on Insurance Topics, Volumes I – III*, (November 2007), www.naic.org., and *How Private Health Coverage Works: A Primer 2008 Update*, Kaiser Family Foundation (April 2008).

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Transparency, however, is not an end in itself, but rather a means of providing regulatory agencies and stakeholders with relevant, useful information that adds value to the decision-making process. For example, it has been suggested that the regulatory record include all “significant” oral and written communications between agency staff and OMB. Constructing such a detailed record could be administratively burdensome and potentially chill consultation among professional staff at the regulatory agencies and OMB and should not be required. In addition, we recommend that the extent of “transparency” in rulemaking should be considered in a particular context and should revolve around the answers to three key questions: (1) how will the disclosures provide benefit to the public; (2) how much administrative complexity will be added; and (3) whether the transparency may have an anti-competitive effect because of the disclosure of sensitive proprietary information, such as pricing data or trade secrets.

Assuring Procedural and Substantive Fairness

An open rulemaking process is dependent on both procedural and substantive fairness. In other words, the development of rules and other regulatory requirements must be based on a clear set of procedures that are followed consistently (procedural fairness) as well as a careful consideration of relevant information from many sources (substantive fairness). In general, while we believe federal regulatory agencies provide procedural and substantive fairness in their decision making, we have highlighted below examples of three concerns with the rulemaking process that we believe should be addressed.

- *Delays in Issuing Regulations*

Federal agencies may lack the resources and technical expertise in some situations to issue rules in a timely manner. For example, the process to release new health care transaction standards as required by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) has been slowed, which in turn delays the adoption of new administrative systems and processes to more efficiently exchange health care information between health care providers and health plans. The lack of predictability in the adoption of new and revised HIPAA standards negatively impacts the ability of health care providers, health insurance plans, and clearinghouses to budget and plan for implementation of the significant and costly administrative changes that are required.³

³ Implementing the HIPAA standards has a significant impact on the health care industry. For example, it is estimated that the health care industry will need at least five years to implement the new code sets for hospital claims (the International Classification of Diseases, Tenth Revision or “ICD-10”) at a cost of \$1.8 billion (*see: Department of Health and Human Services, Final Rule, Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS, January 16, 2009, 74 Fed. Reg. 3328*).

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- *Insufficient “Front End” Analysis*

In some cases, agencies need to conduct more comprehensive information gathering and analysis prior to the release of rules to determine if a problem exists and whether the proposed regulation is the best approach to address any concerns. The recently proposed (and subsequently withdrawn) rules on service provider contracts from the Department of Labor, Employee Benefits Security Administration (EBSA), are a case in point.⁴ The EBSA conducted hearings and identified concerns regarding the administration of pension funds and adequacy of information disclosure to pension plan participants. As a result of these hearings, the EBSA developed regulations governing the activities of entities that provide administrative services to plan fiduciaries (“service providers”).

However, the proposed rule inexplicably included extensive requirements not only for pension plans, but also for health and welfare plans – even though no complaints or issues were raised during the hearings with respect to health and welfare plan service providers. We believe that the proposed rule in fact attempted to “put a round peg in a square hole” by applying pension plan standards to health and welfare plans and imposing sweeping new requirements on fully-insured health and welfare plans that are already subject to significant oversight by the states. After the proposed rule was published, the EBSA conducted additional hearings to receive public input, including testimony regarding health and welfare plans, which highlighted the inappropriate application of a single regulatory formula to both types of plans. Such fact-finding and analysis with respect to health and welfare plan service providers would have been more appropriate prior to the release of the proposed rule.

- *Poor Planning and Coordination*

In most situations, rules are not issued in a vacuum – rulemaking is frequently part of an overall regulatory and policy strategy by an agency that impacts multiple industries as well as other state and federal regulatory functions. Some agencies may lack a coherent regulatory vision and planning process. For example, federal agencies use the Unified Regulatory Agenda as a planning tool to provide the public with a schedule of anticipated regulatory actions such as the publication date for rules. Unfortunately, the timeframes given in the Agenda are frequently not followed.

In addition, some agencies do not provide a clear understanding of how a particular rule fits within the agency’s overall policy objectives and the correlative objectives of other agencies working toward the same goal. For example, the HIPAA transaction standards discussed above are part of an integrated series of criteria for electronic health care transactions including data formats; health plan, health care provider, and employer identifiers; claim attachment

⁴ The proposed rule was published in the *Federal Register* on December 13, 2007 (72 Fed. Reg. 70988).

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requirements; and electronic prescribing standards. The standards apply not only to commercial transactions, but are also included as part of the contracting requirements for Medicare and Medicaid. As a result, it is important that the health care industry have a clear understanding of when the various rules will be released, how those regulations are integrated, and how the standards fit within the overall contracting administration strategy for government programs.

Recommendations for Achieving Value in the Regulatory Process

AHIP believes that E.O. 12866 provides clear and consistent standards for the development of rules and guidance. We have the following recommendations on how that process can be further improved.

Strengthen Cost-Benefit Analysis – Cost-benefit analysis gives agencies a tool to determine if a proposed regulatory action meets the needs of the public without imposing unreasonable burdens and costs. In addition, cost-benefit analysis data can often assist compliance activities. For example, information developed by HHS as part of the cost-benefit analysis for the ICD-10 rule is being used by the health care industry for planning and resource allocation in support of implementing the new code sets requirements.

E.O. 12866 requires agencies to conduct cost-benefit analysis as part of the development of significant rules and to make such information available when a proposed rule is released. We believe cost-benefit analysis is a critical tool for agency review of potential approaches to rulemaking and should be retained. In addition, the release of cost-benefit data by agencies should include references to all data and other information sources used as part of that analysis.

Clarify the Process for Agency Review of Significant Guidance – Agency guidance is a way to inform regulated industries of their compliance responsibilities on a timely basis without going through a rulemaking process. OMB should provide agencies with a general framework for the development of significant guidance documents through a process that includes solicitation of stakeholder comments, to assist the agencies in identifying anticipated operational implications while ensuring the release of timely guidance by the agency.

Improve Transparency -- The government should provide a primary website or web portal where all public comments and other information related to regulations are located on a searchable database. Currently, the website Regulations.gov serves as the main access point for information about regulations, but not all public comments and other information related to a particular regulation are available or searchable on the website. Regulations.gov should be updated to serve as the primary access point to search for regulatory activity and comments. In addition, other related information (such as reports, testimony or other information considered during the rulemaking process) should be linked to the public record maintained on the Regulations.gov website.

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Strengthen Agency Planning and Coordination of Rules – OMB should work with agencies to improve the rulemaking process and coordinate rules that impact across multiple agencies. For example, agencies need clear guidance from OMB on how to conduct “fact finding” in advance of rulemaking and how to analyze if the proposed rule is meeting a specific public need. This process should ensure that all affected stakeholders have an opportunity to provide input during the fact-finding and regulatory development stages.

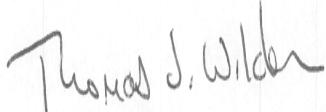
Establish Clear Guidelines for Timely Release of Rulemaking – The delays in the release of regulations causes problems for regulated industries. Better allocation of internal agency staff to rulemaking and other agency actions is needed, as well as realistic assessments when scheduling anticipated rules. In addition, OMB should work with agencies to make sure the publication dates in the Unified Regulatory Agenda are met as frequently as possible.

Build in Feedback Loops – OMB should require agencies to periodically complete a retrospective review of selected rules to see if the rulemaking process worked as intended or if a rule is no longer necessary. Such a process would allow the agencies and public to better understand how the rulemaking process can be improved. For example, was the cost-benefit analysis accurate? Did the rule actually solve the problem being addressed? The retrospective review process should include input from public stakeholders as appropriate.

Conclusion

AHIP supports OMB’s efforts to coordinate the regulatory process and to promote efficient and cost-effective government. In general, we believe E.O. 12866 provides an important framework for the development of rules and federal agencies are engaging in a procedurally and substantively fair rulemaking process. We also believe that process can be improved as set out in our recommendations and look forward to working with you on this important issue. Please feel free to contact us if you have any questions.

Sincerely,



Thomas J. Wilder
Senior Regulatory Counsel