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Phase II of Federal Health Reform: Executive Branch Implementation and Health Care Industry Participation *Now*

BY LYNN SHAPIRO SNYDER

Health reform is a process, not an outcome. The health care industry needs to treat Phase II of health reform——implementation by the Executive Branch—with the same focus and zeal as they did with Phase I—deliberation and passage by the Legislative Branch. It may not be as sexy as Capitol Hill but industry participation in shaping implementation through the Executive Branch could have an even greater impact for industry efforts. Phase II is when the rubber of ''the law'' meets the road of ''the real world.'' We are one month into implementation so ***now*** is the time for the health care industry to step up to the plate and continue to shape the details of federal health reform currently being developed and implemented by the Executive Branch.

As with any topic of public policy, proposed laws are discussed in Congress. Final laws are sent to the Executive Branch for interpretation and rulemaking within something called ''congressional intent.'' Public comments hopefully are considered by the relevant agencies writing the regulations. Challenges to the regulatory process may occur when the regulations go too far from the words and intent of the statute. Eventually, issues may be sent back to Congress to amend the law. The federal Medicare program has worked this way for over 43 years.

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However, in the implementation of federal health reform, we are seeing new creative elements to the implementation process. The Obama administration is asking industry to take steps that are not in the statute. For example, on April 19 Department of Health and Human Services Secretary Kathleen Sebelius sent letters to health insurance companies asking them to continue to cover young adults so that they can remain on their parents' policies notwithstanding the terms of the policies (18 HCPR 604, 4/26/10). This health reform provision does not take effect until Sept. 23, 2010. She was seeking collaboration with industry on a topic that could make sense for all involved.

Sebelius also recently sent a letter to the health insurance industry trade group, America's Health Insurance Plans, challenging the group's interpretation of a section of the statute related to the coverage for children with pre-existing health conditions even before any regulations were published (18 HCPR 469, 4/5/10). The statute appears to nullify pre-existing illness exclusion contractual provisions for enrolled children later this year but there was a question whether guaranteed issue of health insurance for these and other children had to wait until after 2013. Nevertheless, the administration obtained a promise from private health insurers for guaranteed issue this year for this particular population notwithstanding what some believe are the words in the statute.

Successful implementation of the 2000+ pages of the federal health reform law requires collaboration between the Executive Branch and the health care industry stakeholders. This is because the law is based upon actions to be taken by key health care industry stake-

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holders, such as health insurers to increase access, and health care providers to achieve Medicare savings.

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And since we never had a federal department of health insurance before this new law—health insurance had been regulated mostly at the state level—the Executive Branch's need for continuous public input and collaboration with industry is even more compelling. The same is true for some of the creative new pilot programs designed to customize the Medicare payments for certain providers.

A big part of implementation is in the Executive Branch's federal rulemaking activities. That is when the public has the formal opportunity to collaborate with the administration on federal health reform. Not all provisions in the recently enacted Patient Protection and Affordable Care Act (Pub. L. No. 111-148) and its companion, the Health Care and Education Reconciliation Act (Pub. L. No. 111-152), require a federal regulation. Some provisions are self-executing while others specifically require a designated federal official to publish regulations on a particular topic. For other provisions, it depends.

Regulations interpret and implement the law, but are not supposed to change the substance of the law. In publishing federal regulations, federal agencies are supposed to stay within the bounds of what the law requires. Even where there are some ambiguities, there are limits to an agency's exercise of its discretion. In drafting regulations, agencies rely on the plain language of the law and to congressional intent during the enactment of the law.

Unfortunately, due to the unique path that federal health reform took in Phase I on Capitol Hill, these laws came out of Congress without the vetting process achieved from melding a House bill and Senate bill into one conference bill. Consequently, there are likely to be holes in the law that were going to be filled by portions of the House bill. Rulemaking may be the avenue for both the administration and the stakeholders to fill at least some of those gaps.

The uniqueness of congressional procedures use to pass these laws also means that these laws came out of Congress without the traditional congressional reports relied upon for determining congressional intent. Consequently, it is unclear what documents the federal agencies are using to determine congressional intent. Statements by Congress after enactment may have political weight but have little merit in a court of law. The industry can play a role in the debate as to the four corners of congressional intent for this new law.

As implementation of federal health reform unfolds by the Executive Branch, the public is likely to hear more about how something in the law is ''ambiguous.'' Ambiguity gives the federal agency the opportunity, through rulemaking, to further ''shape'' the law. The agency's solution to ambiguities in the law likely will be to publish a federal regulation to provide the clarity needed. (Otherwise, the solution would be to go back to Congress to amend the law and, at this particular time, that is not likely to be a desired option.)

In writing regulations, the Administrative Procedure Act plays an essential function in providing industry stakeholders with the formal opportunity to interact with federal agencies on such key issues as whether the regulations are true to the law and how practical the proposed regulations may be in real world situations.

Of course, most would prefer not to spend time in court challenging regulations. The public should have the opportunity to voice its comments and concerns to the relevant federal agency as part of the meaningful federal rulemaking process by that agency. Issuing ''interim final regulations with an opportunity to comment'' should be used sparingly by agencies and only in very rare circumstances. Proposed rules should be the norm. But, with the deadlines in the law, agencies may not necessarily use proposed rules for getting federal health reform up and running.

Interestingly, two of the earliest health reform *Federal Register* notices published on April 14 may be harbingers of what is to come this year in rulemaking. They both are formatted as a ''Request for Information.'' The first notice relates to medical loss ratios by insurers pursuant to Section 2718 of the Public Health Service Act (PHSA) as it was amended by the federal health reform legislation. In this announcement, the Internal Revenue Service, Department of Labor, and Department of Health and Human Services (HHS) are seeking comments and information about key aspects of medical loss ratios for the health insurance industry. The departments are ''inviting public comment to aid in the development of regulations regarding Section 2718 of the PHS Act.''

This section of reform not only affects insurers, but also affects other companies that sell to the insurers since their costs will need to be categorized within these key definitions within the ratio. Examples include health IT, disease management, and other health benefit management companies. This same *Federal Register* edition included an HHS ''Request for Information'' about the proposed health insurance premium review process pursuant to Section 2794 of the PHSA. Responses from the public for both of these notices are due ***by May 14, 2010***. It is unclear whether these notices are going to be the norminstead of proposed rulemaking and whether such topics will become interim final rules as the next step in their respective rulemaking.

That is why interested members of the public should get involved ***now*** in making their comments known to the relevant federal agency—before the agency puts pen to paper to draft proposed regulations. Stakeholders from private industry should educate the agency earlier in the process about how the law may impact the real world or where the law requires further deliberation and policy outcome. Agencies may become wedded to a certain position by the time the agency presents its proposed regulation in the *Federal Register*. Public comments may only change the proposed regulation on the edges when, perhaps, the regulation would have been quite different had interested members of the public educated the federal agency with the real world facts and positions on the law earlier in the agency's work. This is especially true here where several of the regula-

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tions will require two or even three federal agencies to sign off on them.

There also are over a dozen new boards and commissions within the federal health reform law. These boards and commissions provide another formal opportunity for industry stakeholders to continue to shape health reform by having this formal collaborative role within the Executive Branch in connection with implementation.

Let's respect and capitalize on the APA rulemaking process and use it to accomplish everything that the federal health reform laws have to offer and seek amendments from Congress where there are significant differences that need further consideration. Successful implementation requires a public/private partnership of collaboration between the Executive Branch and the relevant health care industry stakeholders. Collaboration also requires an energized health care industry focused as much on Phase II as they were on Phase I. After all, health reform is a process, not an outcome.