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healthcare reform: time to attend to the details

Now that healthcare reform legislation is the law of the land—at least version 1.0 of healthcare reform—the real work starts.

As is the case for most new legislation, rules and regulations will need to be developed that implement the many aspects of the legislation that are not completely developed in the statutory language. Many of these new rules will come from the Centers for Medicare & Medicaid Services (CMS), but certainly not all of them. Important rules will also come from other areas within the Department of Health and Human Services (HHS), and several important rules will be developed by the states.

Near-Term Challenges

Among the significant early challenges associated with implementing healthcare reform is the need to provide guidance for the 2010 changes to various parts of the Medicare and Medicaid programs, as well as for the various changes affecting private insurance in 2010 and early 2011. The scope of this challenge is apparent when one considers that guidance is required for, among other considerations:

> Establishing a temporary high-risk pool
> Implementing prohibitions against annual and lifetime limits on insurance
> Setting restrictions on medical loss ratios
> Eliminating cost-sharing for certain preventive services
> Establishing tax credits for certain small employers
> Creating a temporary reinsurance program
> Developing a premium rate review process
> Expanding Medicare coverage to limited populations
> Setting limits on physician-owned hospitals
> Establishing new state options for Medicaid
> Creating a process for public notice and comment for section 1115 waivers for Medicaid and the children's health insurance program
> Establishing a new patient-centered outcomes research institute
> Forming a commissioned regular medical corps and a ready reserve corps
> Establishing a process for the FDA to approve generic versions of biologic drugs

For perspective on the sheer size and level of complexity of the issues that must be resolved in the next few months, consider just a couple of these areas that are already receiving attention: the temporary reinsurance program and the restrictions on medical loss ratios.

Temporary insurance program. HHS is responsible for creating the temporary reinsurance program by the end of June for employers that provide health insurance to retirees over the age of 55 who are not eligible for Medicare. This temporary program will end Jan. 1, 2014, when subsidized insurance will be available through the exchanges and after the Medicaid expansions will have gone into effect. The proposed rule will need to clarify many considerations, including exactly who will be eligible, the obligations of the employer during this period in terms of maintenance of effort or continued benefits, and how the available subsidies will be distributed to beneficiaries. Moreover, because the $5 billion that has been allocated for this purpose is widely believed to be inadequate to fund all of the expected claims, the rule will also need to indicate how this funding will be distributed.

Medical loss ratio. The legislation requires health plans to report the proportion of premium dollars spent on clinical services, quality initiatives,

and other cost areas, and to rebate money to consumers if the amount spent on clinical services and quality is less that 85 percent for plans in the large group market and less than 80 percent for plans in the individual and small group market. The plans are required to report the information in 2010 and to provide rebates by 2011.

The question is how to determine which services should qualify under the terms *medical services* or *quality-enhancing services*. The larger and more comprehensive these terms, the easier it will be for plans to comply. Not surprisingly, hospitals and some consumer advocates have been pushing for more narrow definitions while the plans have been pushing for more expansive definitions. And the definitions will likely be of interest not only to insurance companies, medical providers, and consumer advocates, but also to companies that market products to insurance companies for use with quality assurance and other quality improvement programs, because the tightness of the definitions is likely to affect the willingness of plans to purchase their services.

How Will the Rules Be Written?

Generally, such issues are hashed out in the rule-making process. The Administrative Procedures Act (APA) provides a mechanism for all of those affected by a proposed rule to weigh in with the relevant federal agency to make their views known. Although the agency writing the rule doesn't have to accept all of the comments made by the affected parties, it does have to indicate how all of the issues raised are dealt with and provide justification for the decisions that are made for each of the issues raised.

In the case of the medical loss ratio, however, the notice in the *Federal Register* was for a "request for information" rather than a proposed rule per se. HHS, the IRS, and the Department of Labor announced they are inviting public comment to aid in the development of the relevant regulations.

Whether such nontraditional approaches will be used to develop the first rules implementing healthcare reform is not yet clear, but departures from traditional rule-making would not be surprising given the enormity of the tasks ahead. Writing rules that implement new legislation is always a challenge for the agency or agencies charged with the implementation. The constrained time available for implementation and the lack of clarity in terms of congressional intent make the rule-writing for healthcare reform particularly difficult.

A Big First Step: Determining Congressional Intent

The strategy that was used to secure passage of healthcare reform makes it even more challenging with this legislation. There is always some ambiguity as to what the Congress intended to do when it passes legislation. Usually that ambiguity is made clearer during the process of reconciling the differences between the bills passed by the House and the Senate in the conference bill. Absent such clarification, there also are congressional reports that help indicate or clarify congressional intent. Without either type of guidance, however, the agencies face a serious challenge in determining congressional intent.

Given the unusual circumstances surrounding the passage of healthcare reform legislation, with greater-than-usual ambiguity surrounding congressional intent, all interested parties should follow this next phase of healthcare reform as closely as they followed events leading to passage of the legislation, if not more closely. Lobbyists can be especially effective at this time—making it all the more important for interested parties to watch closely what unfolds over the next 12 to 18 months. ●

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