

A Look Ahead: the 2009 U.S. Health Legislative Agenda

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While systemic health reform promises to be a top U.S. policy priority in any new administration, Congress' first health policy focus in 2009 will be on already identified and targeted health initiatives. Some are time-sensitive measures that demand attention early in the new year. Others are front-and-center concerns that will also command immediate attention. All of these health proposals invariably will become vehicles for a variety of "bite-sized" provisions, either as a means to offset the cost of the underlying proposal (e.g., restrictions on physician-owned hospitals have recently been offered up in this context) or as unrelated provisions seeking a legislative ride to enactment.

This article highlights key measures that Congress is likely to consider early in 2009: State Children's Health Insurance Program (SCHIP), Medicaid, Medicare, health information technology, "follow-on" biologics and the Medicare prescription drug benefit.

Health industry stakeholders immediately have opportunities to weigh in on these initiatives and either affect their shape or capitalize on them as vehicles for accomplishing other health-related goals apart from the specific focus of the legislation. In addition, understanding the health legislative and regulatory landscape remains a critical element of sound legal and business strategy and decision-making.

Time-Sensitive Measures

Congress faces three separate time-sensitive health matters in 2009 that are certain to be addressed early in the next congressional session regardless of who is president, and regardless of the timing of broader health care reform endeavors. Critically, any of these items could become a vehicle for enacting other unrelated health provisions, extending the impact beyond the matters directly implicated.

SCHIP

The Issue

Unless Congress acts by March 31, 2009, the federal SCHIP program will expire. SCHIP provides federal matching funds to states to cover uninsured children and some adults with family incomes too high to qualify for Medicaid. The debate around SCHIP will shed light on attitudes to systemic health reform as it revolves around how and whether the federal government should extend coverage to the uninsured. Senator McCain voted against SCHIP expansions when they came before the Senate in 2007; Senator Obama voted in favor of SCHIP reauthorization and expansion, foreshadowing the bent each would take if elected president. Indeed, Senator Obama has called for expansion of the SCHIP program as a key element of his health overhaul proposal.

Direct Impact

SCHIP reauthorization, and possibly expansion, would help providers that serve the uninsured, especially children. Some benefits may be expanded, such as dental, which also would help providers in that sector.

MEDICAID REDUCTIONS

The Issue

On April 1, 2009, steep Medicaid payment reductions will go into effect unless Congress or the new president extends the moratoria on six Medicaid regulations established by the Bush administration and recently suspended by the Democratic Congress. Affected payment areas include graduate medical education, coverage and payment for rehabilitation services, treatment of targeted case management services and allowable provider taxes. An additional regulation not suspended by Congress relates to outpatient hospital services.

Direct Impact

Providers that receive Medicaid reimbursement for the services subject to reduction will be affected if the moratoria are not extended. Public and other safety-net hospitals that serve a significant Medicaid population will also be affected.

MEDICARE REDUCTIONS

The Issue

Physicians face dramatic Medicare payment reductions of at least 20 percent unless those reductions are averted by Congress before January 1, 2010. If Congress does rescue physicians from these cuts, the cost will be between \$40 and \$100 billion, depending on whether Congress replaces the reductions with a payment increase, and the size of the increase, forcing cuts from other sources. Democrats have recently looked to the Medicare Advantage program as a source of funding, but efforts to slash funding to the program have been blocked by the Bush administration. A McCain administration could be the new firewall, as Senator McCain has traditionally opposed cuts to the Medicare Advantage program. Senator Obama, on the other hand, has supported efforts to strategically cut spending for Medicare Advantage to support other Medicare priorities.

Even if cut, the Medicare Advantage program will not provide ample funds to avoid physician payment reductions. Congress will have to look to other funding sources, which could include payment reductions for hospitals, skilled nursing facilities, durable medical equipment suppliers and new restrictions on physician ownership of hospitals.

Direct Impact

Physicians will be significantly affected by the scheduled 20 percent payment reduction should it be realized, or by a positive update instead. To the extent that Congress decides to reverse the negative update, other providers will feel the bite from reductions that will be needed to offset increases to doctors.

Other Pressing Priorities

HEALTH INFORMATION TECHNOLOGY

The Issue

Lawmakers widely view the U.S.-wide implementation of interoperable health information technology as critical to efforts to improve efficiency in the health sector. Senator Obama was an original co-sponsor of the principal Senate health information technology bill in the 110th Congress; Senator McCain also supports accelerated adoption of health information technology.

Areas of controversy include how to incentivize providers to adopt health information technology and whether to penalize them for failure to do so, whether patient privacy and security protections would need to be expanded and/or refined, and how to manage the investment costs in new health information systems and in new privacy and security protections.

Direct Impact

The ability of pharmaceutical companies, academic medical centers and health systems to use data to improve care for specific patients and to use and work with aggregated data for quality improvement at the population level could be undermined by new privacy and security provisions that may accompany health information technology legislation.

All providers could face new cost and standards of practice flowing from new requirements, incentives or penalties related to adopting health information technology, and accompanying privacy and security measures. Amongst the questions that will be on the table is whether certain entities (*e.g.*, hospitals or pharmaceutical companies) could financially support physician acquisition of the hardware and software that will be needed.

“FOLLOW-ON” BIOLOGICS

The Issue

Both Senators McCain and Obama have called for an approval pathway through the U.S. Food and Drug Administration for generic or “follow-on” versions of biologics. Congress began to entertain proposals in this regard in 2008, setting the stage for stand-alone consideration in early 2009.

A key area of concern is how long manufacturers of brand name biologics would have market exclusivity.

Direct Impact

Brand name manufacturers seek to protect their market exclusivity for as long as possible. Some of these manufacturers may be able to make a case for singling out specific types of products that should not be subject to market exclusivity established timeframes.

MEDICARE PRESCRIPTION DRUG BENEFIT

The Issue

Both presidential candidates have identified the Medicare prescription drug benefit as an arena ripe for early legislating. Key areas of debate include the importation of prescription drugs from other countries, how to craft federal authority to negotiate drug prices and whether to expand the benefit. Both candidates agree that reimportation should be allowed provided that safety is assured, but they differ on how to approach federal negotiation of drug prices, with McCain focusing on market competition and Obama favoring federal negotiation authority. In addition, Obama favors and McCain opposes expanding the benefit to eliminate the so-called “doughnut hole” into which beneficiaries fall when their total drug spending exceeds a certain amount each year.

Direct Impact

Pharmaceutical manufacturers are vulnerable both to price negotiation authority and also to re-importation from other countries. As with “follow-on” biologics, certain manufacturers may have the opportunity to seek carve-outs from these provisions for products with certain distinct characteristics.

Conclusion

Health issues will be center stage on the congressional and administration agenda in 2009. Indeed, at this writing, Congress may return in mid-November 2008 after the elections for a lame-duck session, which may well include consideration of some health-related matters. We also expect to see later in 2008 the release and promotion of legislators’ health reform proposals, as jockeying for advantage in the systemic reform debate is clearly underway.

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HEALTH APPOINTEES IN THE NEW ADMINISTRATION

The new president will not only appoint a new secretary of Health and Human Services (HHS), but will also be responsible for filling more than 400 senior positions within the department and the agencies it oversees, including the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). The new secretary likely will have considerable discretion about how to staff his or her immediate office. The current secretary chose to surround himself with several counselors, each with specific portfolios; these counselors work to ensure that the administration's priorities and philosophies permeate the agencies within their portfolio.

New presidents often look to those who have advised them during their campaigns when deciding how to fill these top positions. Senator McCain's key outside health advisors include two former directors of the Congressional Budget Office—Dan Crippen and Douglas Holtz-Eakin—as well as Gail Wilensky, former Medicare administrator. Names circulating for the top HHS post in a McCain administration include Senator Tom Coburn, M.D. (R-OK); former Arkansas Governor Mike Huckabee (R); former CMS Administrator and former FDA Commissioner Mark McClellan, M.D., Ph.D.; and Louisiana Governor Bobby Jindal (R). Names circulating for CMS administrator in a McCain administration include the aforementioned Wilensky, as well as Stephen Parente, a health economist, and David McIntyre, Jr., a former McCain health aide who is now an Arizona-based health care executive.

Senator Obama has turned primarily to two Harvard professors for health policy advice, David Cutler and David Blumenthal, M.D., as well as Heather Higginbottom, Melody Barnes, Neera Tanden and former South Dakota Senator and Senate Democratic Leader Tom Daschle, who is frequently discussed as a possible contender for HHS secretary in an Obama administration. Other names circulating as contenders for the top job at HHS include Tennessee Governor Phil Bredesen (D), Kansas Governor Kathleen Sebelius (D) and Representative Rosa DeLauro (D-CT-New Haven).

CONTROL OF CONGRESS

The outcome of the U.S. presidential contest between Senators John McCain (R-AZ) and Barack Obama (D-IL) remains too close to call, although Senator Obama currently holds a slight lead in U.S. polls. Observers and pundits, however, appear to be more confident predicting outcomes of many congressional elections. There is widespread consensus that Democrats will maintain control of both the House of Representatives and the Senate, and perhaps expand their majorities in both bodies.

Democrats currently occupy 49 Senate seats. Republicans also occupy 49 Senate seats. Independent Democrat Joe Lieberman of Connecticut and Independent Bernard Sanders of Vermont typically caucus with the Democrats, which gives Democrats a working majority of 51 to 49. While Democrats hope to attain a filibuster-proof 60-seat majority, most Congress watchers predict a gain of between five to seven Senate seats, which would leave Democrats just shy of a filibuster-proof majority, but still with substantial margins with which to control the agenda.

On election day, Senate Republicans must defend 23 seats compared with the Democrats' 12. Moreover, while only 10 of the 23 GOP seats are considered "safe," all of the Democrats' 12 seats are considered secure, with the exception of South Dakota's Tim Johnson and Louisiana's Mary Landrieu, and both those races are leaning to the incumbent. Key Senate races to watch on election day are the six "toss-up" races. Five incumbent Republican senators are in races too close to call: Senators Coleman (MN), Dole (NC), Smith (OR), Sununu (NH) and Wicker (MS). The race in Colorado for the open seat of retiring Republican Senator Allard is also considered a toss-up.

In the House of Representatives, the current composition is 235 Democrats to 199 Republicans with one vacancy. Of the 33 incumbents, 26 voluntarily retiring from the House are Republicans, leaving Democrats with enhanced opportunities to convert open seats. Congress watchers believe that Democrats will expand their majority in the House of Representatives by 12 to 17 seats.

If, as expected, Democrats retain their majority in both the House and Senate, they will chair all committees, control the legislative agenda and set the schedule for floor action in the 111th Congress.