

The Next President's Prescription for Action on Drugs

Obama and McCain Positions Similar—with One Major Difference

Stephen Barlas

Regardless of whether Senator John McCain or Senator Barack Obama is sitting in the Oval Office on January 20, 2009, the door there will be swinging outward as a series of health care proposals—all with prescription drug and pharmacy implications—fly up Pennsylvania Avenue to Congress. Both presidential candidates have talked up differently structured proposals aimed at providing health insurance for the 43 to 47 million Americans who are without coverage, but the two men almost resemble conjoined twins on some key drug matters.

That Oval Office door will be swinging inward, too, as Democrats on Capitol Hill start salvaging pharmaceutical-oriented legislation—some of which sank during the 2007–2008 session because of a veto threat by President George W. Bush—and send those resurrected bills to the new president. Either man will probably be waiting with the famous presidential pen in hand.

Both candidates, for example, are likely to sign bills that would make major changes in the Medicare Part D outpatient drug program, including allowing the federal government to negotiate prices with drug companies, a proposal that the House passed early in 2007 but that floundered in the Senate because of that threatened veto and a lack of Republican support in the upper house.

The problem with federal negotiation, according to Bill Hermelin, Director of Government Affairs and General Counsel of the Academy of Managed Care Pharmacy (AMCP), is that it constrains formularies. He says it is “almost a no-brainer” that Congress will pass a Medicare Part D reform bill as one of its first orders of business. He explains that the “800-pound gorilla” in the room is the question of whether any legislation provides for eliminating the ability of prescription drug plans (PDPs), authorized under Part D, to negotiate prices with drug companies and giving that negotiation authority to the federal government.

The House passed a “direct federal negotiations” bill right off the bat, in January 2007, which passed by a largely partisan vote of 255 to 170. The Senate Finance Committee then passed a similar bill in April 2007, but the full Senate never passed that bill. When the bill came before the Senate on April 18, 2007, it captured 55 votes, five short of what was needed to shut off debate. Senator Obama voted for it.

“Once again, a minority of the Senate has allowed the power

and the profits of the pharmaceutical industry to trump good policy and the will of the American people,” Obama said on the floor of the Senate.

John McCain did not vote that day, but in November 2003, as the House and Senate were adopting a conference agreement establishing the Part D program, he complained that providing an outpatient drug benefit to senior citizens without first getting drug costs under control was like “rearranging the deck chairs on the Titanic.” He expressly bemoaned the absence of a negotiation provision. He said:

“Taxpayers should be able to expect Medicare, as a large purchaser of prescription drugs, to be able to derive some discount from its new market share. Instead, taxpayers will provide an estimated \$13 billion a year in increased profits to the pharmaceutical industry.”

Neither candidate has directly addressed formularies, much less P&T committees, either in the context of Part D reform or in their plans for providing health insurance to the currently uninsured. McCain’s health insurance access proposal

centers on eliminating the tax subsidies for employers to provide health insurance, instead giving individuals and families tax credits of \$2,500 and \$5,000 with which to purchase insurance in the private market. Mr. Obama would create a national insurance program, run by the federal government, that the uninsured could buy into if they preferred.

Of course, every sector in the pharmaceutical industry—from manufacturers to wholesalers to pharmacy benefit management companies (PBMs) to retail and hospital pharmacies—supports the concept of universal health insurance. An expansion of access to health insurance would lift all boats in the pharmaceutical distribution chain, even though it might create some waves, too.

Kevin J. Colgan, MA, RPh, FASHP, President of the American Society of Health-System Pharmacists and Senior Vice President of Health Economics and Outcomes Research at EPIQ, Inc., says:

“I don’t have a preference for the Obama plan over the McCain plan. My preference is that we go about getting that taken care of.”

Despite their frequent reference on the campaign trail to expanding access to health insurance, neither candidate would expect quick action on that priority upon election to the White House. But discussions between the new President and Congress are sure to get off the ground quickly. Charles Cote, Director of Public Affairs of the Pharmaceutical Care Management Association, has stated: “There is much more demand to get things done [for] the uninsured than 10 to 15 years ago.”



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COMMENTARY: Prescription for Action on Drugs

A serious attempt to expand coverage for uninsured Americans opens the door to both wider drug availability as well as pressure to keep drug costs down. So PBMs will have a large role in any new initiative, whether it involves broader access to private plans via new tax credits (the McCain approach) or whether it involves a new voluntary federal program with implied subsidies, on a par with the Massachusetts universal health care model (the Obama preference). (The Massachusetts plan was discussed in the September 2008 issue of *P&T*, page 544.)

In terms of how legislation extending health insurance to the uninsured might affect formularies, it is too early to tell. However, the skeletal Obama plan looks a lot like the Healthy Americans Act, at least in concept. That bill was introduced early in 2007 by Senators Ron Wyden (D-Ore.) and Bob Bennett (R-Utah), and it has considerable bipartisan support. The Wyden bill does not specifically address the extent to which drugs would have to be made available by the Healthy Americans Private Insurance Plans that the bill would create. There is no drug mandate of any kind or a reference to federal price negotiation. The bill anticipates competition among Medicare Part D-style drug plans.

The AMCP's Hermelin says that one probable component of any "uninsured" legislation will be the creation of some sort of "Comparative Effectiveness Institute" which would be charged with making judgments on the cost effectiveness of various drugs in clinical categories. He adds,

"That could be a plus in the context of formularies since such an institute would hopefully provide credible information, which is consistent with the notion that a P&T committee needs as much information as possible to make rational decisions."

Senator Obama endorses such a comparative institute; in fact, a bill that passed the House in 2007 included a provision for a Center for Comparative Effectiveness Research. In July, Senate Finance Committee Chairman Max Baucus (D-Mont.) and Budget Committee Chairman Kent Conrad (D-N.D.) introduced a free-standing bill called "The Comparative Effectiveness Research Act of 2008." (This program is also covered in the Prescription: Washington column on page 569 in this issue of *P&T*.)

The House bill that included the comparative research center was called the Children's Health and Medicare Protection (CHAMP) Act (H.R. 3162). The main purpose of that bill was to extend the number of low-income children covered by the Medicaid Children's Health Insurance Program (CHIP), whose legislative lease on life expires in March 2009. President Bush vetoed two CHIP expansion bills. With CHIP's authorization expiring, a CHIP bill will land on the new president's desk early on—and it might include not just a comparative research amendment but also many other non-CHIP provisions. The CHAMP Act, for example, included a provision allowing Medicare to update the Part D formulary requirements by adding compendia to the U.S. Pharmacopeia, which is currently the only compendium cited in Part D.

In general, then, it's possible that either a CHIP reauthorization or a Medicare Part D reform bill could include formulary provisions even if the latter did not include a federal negotiation provision. The AMCP, for example, is looking for an

opportunity to redress the damage done by a provision in the Medicare reform bill Congress passed in June 2008—whose main purpose was to avert cuts in fees to physicians—and that strengthened the "all or substantially all" policy within the Part D benefit. Part D requires prescription drug plans (PDPs) to make all drugs in six clinical categories available to PDP subscribers. In addition, Representative Henry Waxman (D-Calif.), chairman of the House Oversight and Government Reform Committee, presided over the issuance of two critical Part D reports in the past year. He will probably push for provisions limiting federal reimbursement for PBM administrative costs.

Some key drug bills from previous sessions of Congresses will also rear their heads again, either as stand-alone proposals or as part of a Part D or CHIP bill. Reimportation of brand-name drugs and a legal pathway for approval of biogenerics, two issues that have gained traction in earlier congressional sessions, will come back, not just with a vengeance but with considerably higher odds of approval. Senators Obama and McCain agree on these two issues; they both support reimportation and biogenerics, although they might quibble about the fine print. In fact, the Democratic presidential platform specifically mentions biogenerics, sometimes called "biosimilars."

A Senate committee passed the Biologics Price Competition and Innovation Act in 2007. This act would create a pathway at the Food and Drug Administration (FDA) for approval of biologic generics; these would be "comparables," not copies, under the Public Health Act. This is the law under which almost all major biologics are approved, such as rituximab (Rituxan, Genentech), adalimumab (Humira, Abbott), trastuzumab (Herceptin, Genentech), natalizumab (Tysabri, Biogen Idec), and interferon beta-1a (Avonex, Biogen Idec). Conventional chemical drugs and a handful of biologics are approved under the FDA Act, which includes the Hatch-Waxman pathway for generics, which has been well trod. ASHP's Kevin Colgan says his group supports the concept.

"But since the comparables would not be exactly the same as the originals, it seems important to use risk evaluation and mitigation strategies with approved biological generics," he states. "The patient safety piece would be important."

One Democratic Senate aide involved in readying health care legislation for 2009 says that Democrats want health care to be a "top priority" next year.

Given the Democrats' expected expanded control of Congress and the certainty that the new occupant of the White House, whether Obama or McCain, will be much more hospitable to health care expansions than his predecessor, the current veto-wielding occupant, pharmaceutical industry players would be well advised to have high-magnification field glasses in hand when the health care race begins on January 20, 2009. ■