Pushing an Expanded Role for Pharmacists

Medicare, SCHIP, and Health Insurance Debates

Present Ample Opportunities

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The pharmaceutical industry will be facing a radically different political environment in Washington in 2009 compared with any time in the recent past, but opportunities and threats differ from sector to sector. Barack Obama’s ascension to the White House, the fattening of the Democratic majority in Congress, and the shift in leadership of at least one key committee signals the acceleration of three trends: an emphasis away from the treatment of disease to one of disease prevention, a switch from brand-name drugs to generics, and a movement toward comparative research that will address the question of which brand-name drugs really work. These trends are likely to highlight the value of pharmacists, for example, and to undercut the appeal of brand-name drugs, just to mention two of the sectors likely to be affected.

What will be a new emphasis on prevention and better-informed patients presents the opportunity for pharmacists to receive federal backing to elevate their role to health care advisors. John M. Coster, Vice President of Federal Affairs and Public Policy at Rite Aid, says:

There is going to be an emphasis on prevention in any legislation targeting the uninsured and that means there will be opportunities for advancing the health care role of pharmacists. There will be a concerted effort in 2009 among pharmacy groups to push for direct payment of pharmacists for medication therapy management (MTM) and immunization services, including by Medicare.

But the health insurance industry is expected to lobby hard against new, discrete payments to pharmacists, because, with Medicare, the insurance industry receives payments directly for MTM services that any health care professional, not just a pharmacist, can provide.

There will be numerous legislative opportunities for pharmacists to expand their roles in both private and federal health programs. A Medicare Part D “reform” bill will probably move much more quickly than an “uninsured” bill. The House did pass such a bill in 2007, only to see it derailed in the Senate by Republican opposition and a veto threat by President George W. Bush. Its main feature had allowed the federal government to negotiate Medicare drug prices directly with drug manufacturers.

At this writing, the Democrats have—with the occupants of two seats still in doubt—58 votes in the Senate, including those of two independents, Senators Joe Lieberman (D-Conn.) and Bernie Sanders (D-Vt.), who caucus with the Democrats. In addition, a couple of Senate Republicans remaining in Congress voted for the Medicare Part D reform bill in 2007. The question for that bill—as with the State Children’s Health Insurance Program (SCHIP), which is a “must pass” because of the impending expiration of the program’s authorization in March—is just how many pharmaceutical amendments will be attached to those legislative vehicles.

As with the potential expansion of the role of pharmacists, the tightening or loosening of restrictions on Medicare formulary policies is probably also up for grabs in the form of amendments to either a Part D or a SCHIP bill. The issue cropped up in 2008 because of the passage of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) last summer. The main purpose of that bill was to eliminate a big cut in Medicare pay for physicians in the second half of 2008 and for calendar year 2009 and to replace the Medicare pay cut with a minimal increase. The bill was introduced in June and passed within weeks, without any hearings being held, because of a June 30 deadline for a precipitous decline in physicians’ pay. The frenzy surrounding the bill made it an appealing target for all sorts of amendments that Congress—had it acted in a more purposeful manner—might not have considered, much less passed.

Drug manufacturers, aligned with patients’ and some physicians’ advocacy groups, used the chaotic environment to get an amendment attached to the MIPPA, which has the potential to expand the Part D formulary program. Currently, Medicare has a limited “mandated” formulary, established by way of guidance issued by the Centers for Medicare and Medicaid Services (CMS), which says that every Part D drug plan is required to provide “all or substantially all” medications within six classifications: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.

That guidance was issued at the beginning of 2006, when the Medicare outpatient drug benefit kicked in. The guidance was established to protect the stream of fragile Medicaid recipients who were being transferred to the Part D program; these recipients were the so-called “dual eligibles,” so that even if they were being treated for depression, psychosis, or any of the other four conditions, they would not be required to stop taking their current medication.

Patients’ groups and drug manufacturers wanted a more permanent, and potentially broader, Medicare formulary pro-
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The American Pharmacists Association (APhA) is part of a broad coalition called the Leadership for Medication Management. The coalition has developed an MTM legislative agenda that includes payment to pharmacists for activities outside the current scope narrowly defined by the MMA. Payments to pharmacists could be approved for such things as collaboration with the physician to provide feedback on drug therapy and development and implementation of a medication management plan, in collaboration with the caregiver and others.

But questions have been raised about the effectiveness of MTM services. MedPac, the group that advises Congress on Medicare policy, issued a report on November 6, 2008, noting no data existed to indicate that MTM services are effective. MedPac recommended some actions that Medicare could take, such as setting minimum standards for MTM programs and requiring outcomes reporting. Both those ideas leave the APhA queasy.

“We are concerned that a minimum could become the maximum and could remove the discretion of the health care providers, working with patients, to determine the needs of an individual patient,” says John A. Gans, PharmD, Executive Vice President and APhA’s Chief Executive Officer.

Any legislation expanding MTM services and payments would have to be negotiated with Tom Daschle, the new secretary of DHHS. The former leader of Senate Democrats, who has been out of Congress for a few years, was a leading supporter of federal negotiation with drug companies over Part D prices and, as an analogy to that, development of a national Medicare formulary. Besides wrestling with Medicare reform efforts, though, he will confront congressional efforts to toughen up regulation of the drug industry by the FDA, which is part of DHHS.

As for FDA oversight and legislation, the House has a new drug czar, Representative Henry Waxman (D-Calif.). He replaces Representative John Dingell (D-Mich.) as chairman of the House Energy and Commerce Committee, which has considerable authority over health policy. Mr. Dingell, who remains at the committee, is “an old bull,” the longest-serving member of the House, a bit crotchety and better known these past few years for his dyspeptic questioning of committee witnesses than for getting bills passed.

Henry Waxman is a ball of energy. Moreover, he has been a pesky antagonist of the brand-name drug industry, constantly investigating its drug pricing policies and highlighting questionable aspects. In 2008, as chairman of the House Oversight and Investigations Committee, he had no legislative authority. In 2009, he has more legislative authority than almost anyone in the House, and he is closer to House Speaker Representative Nancy Pelosi (D-Calif.) than John Dingell is.

The flip side of Mr. Waxman’s antipathy to the brand-name industry is his support for greater use of generic drugs. It was Waxman who last year teamed up with Senator Charles Schumer (D-N.Y.) to introduce a bill (the Access to Life-Saving Medicine Act) that created a pathway at the FDA for approving generic versions of the most advanced types of biotechnology drugs, such as various interferons.

The point is that the Waxman bill is considerably more generous than a rival bill that actually passed a Senate committee last June—the Biologics Price Competition and Innovation Act. Its chief sponsor is Senator Edward Kennedy (D-Mass.).
The Pharmaceutical Care Management Association preferred the Waxman bill because it conferred no market exclusivity on innovator biologic drugs. The Biologics Price bill gave innovator companies 12 years plus the possibility of additional time through minor changes to its preferred product.

Henry Waxman’s increased prominence and Barack Obama’s presence—he had made wider use of generics a major plank in his platform to assist the uninsured—means not only the likely passage of a biopharmaceuticals bill but also the passage of legislation allowing re-importation of brand-name drugs from other Western countries, a proposal the Pharmaceutical Research and Manufacturers of America (PhRMA) has hotly opposed.

But President Obama and his allies in Congress will be shoveling a quite bit down the throat of PhRMA in 2009. Fortunately, pharmacists face a more promising fate in spite of the inevitable challenges for organizations such as PhRMA.