
SPECIALTY PHARMACY NEWS

Some Early Efforts Under Obama Could Impact Specialty Pharmacy

Several specialty pharmacy observers agree that the upcoming Barack Obama presidential administration will propose more changes affecting health care than a John McCain administration would have. And everyone who spoke with *SPN* agreed that because of the current economic situation, health care will not be at the top of the new administration's list of priorities. Still, there eventually may be some significant changes that could impact the specialty pharmacy industry.

The high costs for health care services may be scrutinized, says Al Heaton, Pharm.D., director of pharmacy at Blue Cross and Blue Shield of Minnesota. If this happens, expect specialty drugs to be in the crosshairs. "We are already seeing model legislation in Minnesota" for capping specialty drugs, he points out. The Minnesota House of Representatives introduced H.F. No. 4069 in early 2008. It calls for "limiting excessive co-payments on drugs to treat multiple sclerosis" and would not allow plans to charge a copay of more than \$50 for a 30-day supply of an MS drug. While the bill was not passed, "expect a new one in January," Heaton says. And the more Democratic-controlled the U.S. Congress is, the more likely it is that something similar could happen nationwide, he contends.

Follow-on Biologics May Be Reality in U.S. Soon

Most of the people who spoke with *SPN* agree that there may finally be legislation approved to provide for an approval pathway for follow-on biologics. Some contend this may occur later in the administration, but "given the House leadership, and [California Rep. Henry] Waxman's work with the FDA on follow-on biologics, we could see action within the first year," says Heaton.

"The availability of generic medications has had a tremendous effect on the affordability of drugs through health plan formularies, and allowing for safe competition in this marketplace will allow more Americans to access the drugs they need at an affordable cost," says Edmund Pezalla, M.D., national medical director and chief clinical officer for Aetna Pharmacy Management.

Another action that could occur within the first year of the new administration is the passage of legislation to allow Medicare to negotiate prices on Part D drugs, says **Kevin Gorman**, managing partner and founder of Put-

nam Associates, a pharmaceutical and biotech consulting firm. With this shift could also come "the power to delist a drug from Medicare if the manufacturer won't play ball" in pricing negotiations. Still, with "a lot of pharma companies in blue states...it may be hard for Democrats to restrict and rein in" Part D benefits, maintains **Domenick Bertelli**, a principal with Putnam.

If the federal government does get involved in price negotiations with manufacturers, commercial insurers may try to do the same thing, says Craig Kephart, president and CEO of Centric Health Resources, Inc. "Whatever the government does, private industry often follows," he says. And while price controls would be better for health plans and patients, some specialty pharmacies and PBMs may suffer. "Independents and smaller companies may be cut out of the system," according to Kephart. "The big boys will trade whatever margin is left for volume, which will put independents at a disadvantage."

Another Part D change that may occur a bit early in the new administration is reimbursement for administrative services and supplies for home infusion, Kephart says (*SPN 10/08, p. 6*). Currently, only the drug is reimbursed.

Attorney Jayson Slotnik, who is with Hogan & Hartson LLP and was formerly director of Medicare reimbursement and economic policy at the Biotechnology Industry Organization, said that the "evolution of fail-first policies" within Medicare may be on the horizon. For instance, coverage of drugs under Medicare Part B may be subject to "why don't you show me you failed on an oral drug before I pay for this infusion?" he said Oct. 6 at the Center For Business Intelligence's Effective Oncology Benefit Management Conference in Chicago.

Expect to see more of a focus on drugs' comparative effectiveness, say various sources. "Indirectly, I believe that the potential of using comparative-effectiveness studies to determine if a drug makes it to market may have an impact on specialty pharmacy due to the potential that fewer drugs will be approved for use," says Atheer Kaddis, M.D., vice president of managed markets at Diplomat Specialty Pharmacy. Pezalla agrees. "With so many new high-price drugs and devices coming to market, consumers, physicians and health plans all need to know that they are getting

the best value for their hard-earned health care dollars," he says.

Within the new Congress, says Gorman, it will be interesting to see if Sen. Hillary Clinton (D-NY) "takes a leadership role." If that happens, he says, "we may see a hard push early on" regarding health care initiatives.

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