Every sector in the pharmaceutical industry has a horse in the race as Congress jockeys to finish a health care reform bill. This bill promises expanded drug coverage for millions of Americans and new responsibilities for pharmacy industry providers that are handling those prescriptions.

Whichever bill Congress passes later this fall will provide health insurance for up to 46 million Americans who don’t have it today. Each plan will have a minimum drug benefit. Forty million Medicare recipients will receive subsidies from pharmaceutical companies for drugs purchased when the beneficiary falls into the dreaded “doughnut hole,” a coverage gap in the Part D drug benefit plan. Patients who fall into the doughnut hole must now pay 100% of prescription costs after their annual cost for drugs exceeds $2,700. Medicaid eligibility will be expanded to 133% of the current baseline earnings limit, and childless couples will qualify for the first time and will have first-time drug plans too.

In all, millions of prescriptions that would otherwise not have been written will be filled. However, this health care legislation is not just about expanding access to drugs; it is about insuring that these prescribed drugs will be the most effective for each patient, that excessive drug costs will be brought to heel, and that using brand-name or generic prescription drugs will reduce future physician and hospital costs.

David B. Nash, MD, MBA, Dean and Dr. Raymond C. and Doris N. Grandon Professor at the Jefferson School of Population Health in Philadelphia, concedes that drug costs account for perhaps 10% of the nation’s health bill, so they aren’t rivals to the main cost drivers—physician and hospital expenditures. However, pharmaceuticals do have the potential to actually lower mammoth hospital costs.

This point was made in the July 23 issue of the New England Journal of Medicine,¹ which looked at Medicare Part D drug costs. The authors concluded that greater drug access lowers the cost of noncompliance.

“That was a very important conclusion,” notes Dr. Nash. Noncompliance costs would accrue when a Medicare beneficiary who should be taking a heart medication, for example, stops taking it because of the cost and ends up in the hospital.

The legislation’s tentacles reach into every corner of the pharmaceutical industry.

Any legislation will open a new pathway at the FDA for the approval of biosimilars (follow-on biologics), which are nearly identical copies of expensive biotechnology drugs that can cost consumers (and insurers) tens of thousands of dollars each year. Medicaid reimbursement to pharmacies for generic drugs, which was tightened like a vise by a 2005 law, may be loosened, but not by much. Pharmacists, as a result of providing medication therapy management (MTM) services to patients, will get new recognition and payment for their role in prescription cost containment. Yet given that only 10% to 15% or so of health care costs are prescription-related, Congress will squeeze physician and hospital costs even harder.

F. Randy Vogenberg, Principal at the Institute for Integrated Healthcare in Sharon, Massachusetts, says that drug use in hospitals will be a major focus in the legislation. Congress is almost sure to endorse, at a minimum, pilot programs that provide incentives to hospitals for cutting down on the number of readmissions of patients who have a second or third bout of the same illness or who pick up an infection in the hospital and have to be rehospitalized.

Related to that will be a push for “global” payments, in which “accountable care organizations”—such as the Mayo Clinic—are paid one fee for managing a patient’s illness from start to finish. Both of these concepts place hospital P&T committees in the spotlight.

“They will have to rethink the value proposition of what a product will bring to the table,” Mr. Vogenberg states.

Today, P&T committees in hospitals might meet 10 times per year for an hour at a time. Being a committee member is a voluntary position; no one gets paid for serving. In developing the formulary, the 20 or so committee members generally rubber-stamp recommendations made by a subcommittee or the hospital pharmacy.

Mr. Vogenberg adds, “In the future, the P&T committees will have more of a responsibility to look at a broader issue, not just the particular drugs on the formulary, but how those drugs are used. The utilization review component will be much more important.”

It is impossible to say at this moment—in late September—whether the House and Senate will agree on a compromise health reform package. The final details, if an agreement is reached, will be hammered together in what is likely to be a fractious conference committee free-for-all that will probably take place in October or November, after the House and Senate pass their separate bills.

However, there is substantial political support from many groups—some of them frequent antagonists in Washington, such as business and labor—that want a bill that can change the way in which health care is delivered in the U.S., reduce costs, improve the effectiveness of that care, and cover many of the 46 million Americans who are without insurance. Individuals whose employers don’t provide insurance will have to get insurance from state-run exchanges or cooperatives (these are different concepts), and Congress is still making deci-

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sions about how this will be handled. Private insurers would compete for that business and might have to contend with a federally sponsored plan called the “public option.”

Congress will probably prescribe a minimum benefit package for individuals, but it is unlikely to reveal details about what such a plan should look like. Neither the House nor the Senate bill specifically addresses drug benefits; the issue is simply being passed to an independent commission whose structure differs from that of the House and Senate bills. It is this commission that would ostensibly set the exact minimum benefits.

With regard to a drug benefit for any public option, the concern is that the Democrats would fulfill a long-held desire and would allow the federal government to set pharmaceutical prices for those federally administered plans offered by state health exchanges. Democrats tried to institute federal pricing for Medicare during the latter years of the George W. Bush administration, but those legislative efforts fell short. Drug manufacturers in particular are worried that the Democrats will come back to the issue within the context of health care reform, now that a Democrat is in the White House and substantial Democratic majorities are in the House and Senate.

Kathleen Buto, Vice President for Health Policy at Johnson & Johnson, explains:

A government plan that negotiates prices of pharmaceuticals would be more likely to use price controls that would undermine risky and long-term research in important new treatments. From our industry, there’s concern that a public plan could undermine a market-based system that provides incentives for the long-term research we will need if we are to find cures for cancers, Alzheimer’s disease, and other debilitating and costly conditions.

Price controls within a public option or within Medicare Part D don’t appear to be in the offing, however. Part of the reason is that Part D drug costs have not been as high as predicted, and pharmacy benefit managers (PBMs) have been able to tame costs to an extent that was unforeseen in 2005, when the drug benefit first went into effect.

The New England Journal of Medicine article points out that in 2004, Medicare actuaries projected that net Part D benefit payments would be $66 billion in 2007. Yet actual payments that year were considerably lower, at $40 billion. However, the journal report warned that favorable drug expenditure totals within Part D might erode as generic dispensing rates level off and as new, expensive specialty drugs are approved.

Mark Merritt, President and Chief Executive Officer of the Pharmaceutical Care Management Association, says: “It would be hard to develop a system with more efficiency and choice than Medicare Part D. If anything, we should look to see how we can make Part D better.”

One way to do that, he suggests, is to allow a greater use of mail-order delivery. In his view, Congress ought to simply drop the entire Medicare Part D apparatus straight into the drug portion of any public option if, in fact, Congress creates a public option. This possibility is far from certain, given the heated opposition of Republicans, whose votes will be needed in the Senate. If there is a public plan, groups such as the National Community Pharmacists Association (NCPA) will push to have the drug benefit run by a pharmacy benefit ad-

ministrator (PBA), not a PBM. Medicaid plans, for example, are run by PBAs that have no role in developing formularies or in obtaining discounts from drug manufacturers.

The biggest issue for the NCPA, and high on the list of nearly every other pharmacy group, is the expansion of MTM services. Currently, pharmacists are paid for MTM services only in the context of a limited number of Medicare Part D prescriptions and rarely by private plans. Studies have clearly demonstrated that community-based MTM, provided by pharmacists to senior populations, improves health care outcomes and reduces spending.

In North Carolina, the ChecKmeds NC program, which offers eligible elderly patients one-on-one MTM consultations with pharmacists, saved an estimated $10 million in health care costs and avoided numerous health problems in the first year of the program for the more than 15,000 of these patients receiving MTM.

The Minnesota Medication Therapy Management Care Program, which is designed for low-income residents who take four or more prescription drugs to treat or prevent two or more chronic medical conditions, generated total savings of approximately $2.11 million, with the state share estimated at $1.05 million during the period from 2006 to 2007. Approximately 62.2% of the total savings were the result of overall decreases in the number of hospitalizations, clinical office visits, emergency department visits, and urgent care visits.

Pharmacy groups have been pushing for inclusion, in any final health reform bill, of the Medication Therapy Management Benefits Act of 2009. This bill was introduced by Representative Mike Ross (D-Ark.), who happens to be chairman of the Democratic House Blue Dog Health Care Task Force. The generally fiscally conservative Blue Dog Coalition has been chiefly responsible for forcing Democratic leaders in the House to include more cost-containment measures in their bill. The Ross bill requires Medicare to expand its current MTM services to include:

- an annual comprehensive drug review, furnished person to person (as opposed to via telephone or e-mail), by a licensed pharmacist.
- at least quarterly targeted medication reviews, also furnished in person by a licensed pharmacist.
- follow-up interventions, in person or through other interactive means, on a schedule and frequency recommended by the prescriber or a licensed pharmacist.

The bill would also allow pharmacists or other qualified health care providers to identify enrollees for MTM interventions who are not targeted beneficiaries or are not otherwise offered MTM services. Additional incentive payments for pharmacists meeting quality measures would be available.

However, neither the emerging House nor Senate bills appear to adopt a Ross-like expansion of MTM services within Medicare or in a public plan. The emerging bills have some provisions that dance around the issue, albeit lightly. For example, the bill produced by the Senate Health, Education, Labor, and Pensions (HELP) Committee endorses the creation of a Patient Safety Research Center within the Agency for Healthcare Research and Quality (AHRQ) that would provide...
grants to support local health providers for MTM services. The program would evaluate and determine the best practices and develop quality measures specific to this service provided by pharmacists and other types of health care professionals.

A second provision in the Senate bill endorses community health “teams” that would go into certain homes (not yet defined) to offer comprehensive, community-based, coordinated care (the “medical home” pilot) (please see this month’s editorial on the Patient-Centered Medical Home, p. 462). Again, federal grants would be provided for this. Pharmacists are not expressly endorsed as members of these new teams, but the NCFA believes that pharmacists should be included because the average individual takes 11.5 prescription drugs every year. A pharmacist can help patients manage and utilize their medications appropriately to achieve the best outcomes.

Although Congress is not likely to endorse a major expansion of MTM services, any final legislation will open the door to much broader access to preventive care and wellness programs, both for the newly insured and for employees of companies that already provide coverage. It is only sensible that someone who doesn’t go to a physician isn’t going to get a medication for an illness or a condition. Wellness care is a bit different, in that an insurance company or an employer would give patients or employees with a specific condition (e.g., diabetes, obesity, or cardiovascular disease) an incentive to take certain positive actions, such as exercise or a change in diet. The incentive is often a rebate in health care premiums. These wellness programs have started to dot the corporate horizon and have proved beneficial in restraining cost growth in employer health plans. J&J’s Kathleen Buto says that her company was able to reduce smoking among health plan members from 12% in 1995 to 4.3% in 2007, thus saving $250 million over a period of 10 years.

Some drug companies are getting into the wellness business although probably not overtly as a way to increase sales of their products, yet one could certainly see that result in some instances. As an example, last October J&J acquired HealthMedia, Inc., a privately held company in Ann Arbor, Michigan. HealthMedia creates Web-based interventions designed to encourage changes in behavior, acting somewhat like a “Web health coach.” One of the main responsibilities of the coach is to instill a commitment to medication adherence.

Whether in the context of a wellness program or MTM services, pharmacists need to be paid for whatever extra time they devote to medication adherence, counseling, and associated duties. However, pharmacy and pharmacist reimbursements in Medicaid have been heading in the opposite direction ever since Congress passed the Deficit Reduction Act of 2005, which resulted in drastic cuts to pharmacy reimbursement in order to save Medicaid funds for both federal and state governments. That change had to do with how the average manufacturer’s price (AMP) was defined.

“Getting this fixed is the biggest issue for us in the context of the health care reform debate,” says Chrissy Koppel, spokesperson for the National Association of Chain Drug Stores (NACDS).

The House bill makes some positive changes to that calculation by eliminating PBM discounts, which go to the manufacturer, not the drugstore. However, sales of certain drugs to hospitals, physicians, and clinics would remain part of the AMP definition.

Steven C. Anderson, IOM, CAE, President and NACDS Chief Executive Officer, says that the changes don’t go far enough.

“We are concerned that this reimbursement will end the incentives to dispense generic medications, which are so critical to reducing prescription drug expenditures in the Medicaid program,” he explains.

In terms of generic drugs, the biggest political controversy on Capitol Hill has been not about Medicaid but about follow-on biologics, or biosimilar drugs. Congress has been in a dogfight regarding biosimilars for the past two years. One faction (Democrats have been fighting other Democrats on this one), allied with seniors’ and consumers’ groups, has been fighting another faction, allied with drug manufacturers, over legislation. The problem is the expense of these biotechnology drugs, which are made from cell cultures, not chemicals. Examples include etanercept (Enbrel), infliximab (Remicade), epoetin alfa (Epogen, Procrit), rituximab (Rituxan), adalimumab (Humira), and bevacizumab (Avastin), the current top sellers. These agents cannot be duplicated, thus complicating the process of developing a generic version that has the same action as the original. A one-year course of the breast cancer biologic trastuzumab (Herceptin) costs about $48,000.

Representative Frank Pallone (D-N.J.), Chairman of the Health Subcommittee in the House Energy & Commerce Committee, states:

Currently, brand biologics account for approximately 15% of total U.S. prescription drug sales, and the industry is growing at a rate of around 20% annually. In a couple years, we could be spending over $100 billion just on biologic drugs. According to data from the Centers for Medicare and Medicaid Services, just four biologics account for 30% of all Medicare Part B spending. Obviously, these drugs are costing the health system a lot of money.

Follow-on biologics cannot be approved by the FDA, which administers the Hatch–Waxman Act for traditional chemical generics. But any health care reform bill will create a new pathway for FDA approval outside Hatch–Waxman, inside the Public Health Service Act, under which Enbrel and the other biologics are approved. The big issue is whether a generic company can use the data generated by the brand-name company, and when. This is the “data exclusivity” issue, and the two sides have differed considerably on a legislative proposal. The health care reform bill from the Senate HELP committee grants companies like Genentech and Biogen 12 years of data exclusivity, a big victory for BIO (Biotechnology Industry Association), the biotech trade organization.

“Because this proposal would grant manufacturers almost twice the monopoly pricing power that the President requested and ignores the Federal Trade Commission report which found that not even one year is necessary to protect incentives to innovate, it is hard to conceive that it will be part of any final ‘reform’ legislation in its current state,” says the PCMA’s Mark Merritt.

No one in the pharmaceutical industry has been so brazen
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as to (publicly) add up the potential revenue and profit gains from health care reform. But the advantages for manufacturers, pharmacies, and PBMs are likely to be huge. One indication of the promise is that PhRMA (Pharmaceutical Research and Manufacturers of America), the drug manufacturers’ trade association, volunteered to cut the prices of drugs sold to elderly patients who must deal with Medicare’s doughnut hole. Patients pay 100% of the cost of prescriptions after their annual drug costs reach $2,700. Coverage picks up again after patient out-of-pocket costs reach $6,100.

PhRMA’s commitment reputedly equals $80 billion in lost revenue to drug companies over 10 years. The companies probably did not make that commitment out of the goodness of their hearts. There is much to gain for pharmacies and PBMs too. Like the manufacturers, however, they might have to feel some pain on their way to experience a gain.

REFERENCE