COMMENTARY

New Directions for Health Care Law in the U.S.

Emphasis on Preventive, Holistic Therapies Offers Possibilities for Pharmacists

Stephen Barlas

The wide-ranging health care reform bill, passed by Congress in March and signed into law by President Obama, is a first step toward retooling and correcting the foundering American health care system. Beyond its core rationale—providing medical insurance coverage to 30-plus million uninsured Americans—the Patient Protection and Affordable Care Act (PPACA) makes an initial “down payment” on a series of health care delivery and payment reforms. Many of these changes are in the form of limited demonstration programs, aimed at steering our current health care model away from its unsustainable, expensive focus on multiple procedures and services for chronically ill and often repeatedly hospitalized patients. A new paradigm emphasizes preventive and wellness care that would be provided by holistic teams of health professionals in hospitals, at home, and in the community. Payment to providers would be based on outcomes to be measured by, for example, readmission statistics. Pharmacists are mentioned as potential participants in many of these coordinated care demonstrations, although the scope of their role is vague.

Currently, many of the PPACA’s hundreds of provisions are up for grabs. Although this new “ship of care” aims to be lighter and tighter than its predecessor, there is no assurance that it won’t leak. The U.S. Department of Health and Human Services (DHHS) is starting to turn out a flood of guidance documents for the myriad rule-makings that, ideally, will clarify the reams of ambiguous language in the PPACA over the coming years.

Lawsuits contesting DHHS’ interpretation of several of the PPACA’s sentences and phrases are expected to be filed. Two lawsuits are already bouncing around federal courts, filed by groups of state attorneys general claiming two separate alleged constitutional violations of the law in general. Some legal experts consider both suits to lack merit. For instance, Jack M. Balkin, JD, PhD, wrote in the New England Journal of Medicine1 that the “individual mandate” that some people object to is not actually a mandate but rather a tax, which people would not have to pay if they purchased health insurance.

Susan Relland, of counsel to the law firm of Miller Chevalier and a board member of the American Benefits Council, says: “So much of this law is not on the page. People are not appreciating how much of this law we won’t know for a long time.” “I don’t disagree that the fun is just beginning,” states Kristina Lunner, Vice President of Government Affairs at the American Pharmacists Association (APhA).

Not only do regulatory roadblocks threaten many provisions; a lack of forthcoming congressional appropriations could also sink some of them. That is true of one key provision for pharmacists: a new federal grant program to support the initiation of pharmacist-staffed medication therapy management (MTM) business units. This is just one of many provisions that could allow pharmacists to expand their scope of practice. Ms. Lunner says:

The bill recognizes that when pharmacists are provided an opportunity to team up with patients and prescribers, there is value in that, in terms of lower overall costs, and improved quality outcomes, whether in a new integrated care, or transition of care or these new home and community delivery grant programs.

Expanding payment for pharmacist-provided MTM services was pharmacy’s key objective, and three provisions address that issue directly. The MTM grant program, which may or may not be funded, was one.

Another provision puts the congressional imprimatur on a Medicare policy decision, made in October 2009, that would marginally expand Medicare’s Part D MTM program. Still another provision opens the door to bonuses to Medicare Advantage plans (the managed care alternative to Medicare’s fee-for-service model) when they include MTM “programs that are more extensive” than is required under Medicare Part D MTM.

The MTM grant program authorized by the bill will be run through a new Patient Safety Research Center, also created by the bill, plopped down into the Agency for Healthcare Research and Quality (AHRQ), which in turn is part of DHHS. The grants would go to licensed pharmacists employed by “entities”—an example of that foggy congressional language that will become better defined later—who are involved in collaborative, multidisciplinary care of chronically ill patients. APhA’s Ms. Lunner interprets this to mean that the grants would be for start-up costs for a physician practice, for example, that wants to hire pharmacists and set up a subsidiary business in order to qualify for grants. That is implied by the provisions requiring the entities submitting applications for grants to include a plan for achieving “long-term financial sustainability.”

Presumably, after getting the business up and running (if we substitute “hospital” for “physician practice” in this example), the MTM subsidiary would provide MTM services to perhaps a local public health agency or a health insurer or, in the case of a hospital, to patients going home after an acute-care episode. Ideally, those MTM services would be reimbursed, either as part of the grant or, even better, via payment to the pharmacists from the insurance company or agency. The entity could provide MTM services only to specific patient populations, such as:

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- individuals taking four or more prescribed drugs, including over-the-counter agents and dietary supplements.
- those taking any high-risk medications.
- those with two or more chronic diseases, as identified by the DHHS Secretary (more open-ended language).
- those who have undergone a transition of care.

It is particularly encouraging that the MTM grant provision enumerates 10 specified MTM services that can be provided. This list goes far beyond the MTM services that prescription drug plans (PDPs) are providing under Medicare's Part D program (when they are providing any services at all, which is rare).

Although the grant program sounds like a pharmacist's dream come true, nothing is said about funding. There is no annual authorization level that, when included as part of a provision in any bill, generally reflects Congress' expectation that there be some funding by the appropriators in an upcoming appropriations bill.

John M. Coster, PhD, Senior Vice President of Government Affairs of the National Community Pharmacists Association, has been discussing this matter with congressional staff. He considers it unlikely that there will be an appropriation for the new grant program in fiscal 2011, which begins on October 1, 2010. It is unknown whether the program will ever get off the ground, given the severe federal budget deficit.

Future congressional appropriations will not hinder the unrolling of MTM enhancements within Part D. Because Part D opened for business in 2006, Medicare has paid for only limited MTM services for eligible patients and pharmacist services. It has been up to the PDPs to decide whether they wanted to offer MTM services. Ms. Lunner notes that the PDPs have been hesitant to provide MTM services, beyond nurses making phone calls. PDPs are concerned that an aggressive MTM program, resulting in greater patient medication compliance, will cause patients to continue their medication regimens and that would cost the PDP money. The PDP doesn't consider that MTM programs save insurers money by reducing hospitalizations. In addition, Part D does not pay PDPs separately for pharmacist MTM services.

The PPACA doesn’t really alter this fundamental equation. Starting in March 2012, PDPs shall begin offering MTM services to those who qualify—again, this is referring to patients taking a certain number of drugs or those with a certain number of chronic conditions. These include, at a minimum, a person-to-person or telehealth-based annual medication review, something that Medicare has not paid for in the past. However, the 2010 Call Letter, which is published by the Center for Medicare and Medicaid Services (CMS) and announces administrative changes for each year, implied that annual pharmacist reviews would now be acceptable. The PPACA makes this a statutory requirement; however, Medicare beneficiaries must be allowed to opt out. That annual review may result in the creation of a medication action plan for which the DHHS Secretary would develop a standardized format. Therefore, the annual review may well give birth to follow-up services for covered patients.

Many pharmacist groups see the Part D MTM provision as a partial win, but the Academy of Managed Care Pharmacy (AMCP) views it as a loss. Lauren Fuller, AMCP's Director of Legislative Affairs, says that her organization opposed codifying the 2010 Call Letter because it "unnecessarily ties the Secretary's hands." She is suggesting that the Secretary of DHHS (and through her, the Medicare program) would have less flexibility to make MTM decisions because of the congressional fiat.

Besides the two MTM grant and Part D provisions, other provisions mention MTM programs both directly and indirectly as one of many services that are eligible—though not mandatory—to be included as part of new delivery models and demonstration programs, both on the hospital side and on the community/home side. In an effort to develop new residential care models, the Independence at Home Demonstration Program, a patient-centered medical home, a Medicaid health home, and a community-based transition program for Medicare patients are created. Pharmacists are cited as possible participants in all of these programs, as are services such as MTM, medication review, and others, with the aim of keeping patients out of hospitals.

For example, the patient-centered program is mentioned as a kind of aside in the section devoted to establishing a program for community health teams. These interdisciplinary teams might be free-standing (again, the language is ambiguous); they would support a primary care practice "within a hospital service area." These practices would be devoted to disease prevention, patient education, and case management. The program might include pharmacists and perhaps 15 other categories of health care professionals (e.g., alternative medicine practitioners, chiropractors) and may provide access to medication management services delivered by pharmacists, including medication reconciliation.

Almost all of these new home/community demonstration programs, like the MTM grant program, would require a congres- sional appropriation, which makes their flowering questionable. The only new program among them that appears to have money in the bank is the community transition program for high-risk, Medicare patients who are discharged from the hospital. For these individuals, funding of $500 million is specified for five years, starting in fiscal year 2011, to come from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. One of the services would be conducting comprehensive medication reviews, including counseling and self-management support if appropriate.

Joseph M. Hill, Director of Federal Legislative Affairs for the American Society of Health-System Pharmacists (ASHP), explained that all of these programs have potential for pharmacy, although some appear to overlap. That will get sorted out in the regulatory process, during which DHHS might consolidate some programs or pare them down.

In addition to the community/home programs, at least three significant new hospital programs would be designed to improve outcomes and reduce costs. Although these are not specific to any one hospital department, initiatives such as the endorsement of a hospital value-purchasing plan, for example, will undoubtedly affect in-patient pharmacies. A separate national pilot program on payment bundling is aimed at reducing avoidable hospital readmissions and hospital-acquired infections. A third plan authorizes hospitals to form new legal entities called Accountable Care Organizations, which would be paid a fee for each acute-incident or acute-hospitalization patient.
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The value-purchasing program gets under way in October 2012. In the first year, hospitals can earn 1% bonus payments if they meet specific quality and outcomes measures for certain medical conditions (e.g., acute myocardial infarction, heart failure, pneumonia); however, they could lose 1% if their performance is subpar. Those quality measures will affect inpatient pharmacies, says Blair Childs, Senior Vice President with Premier Inc., a performance-improvement alliance of 2,300 non-profit hospitals. The measures could include such possibilities as whether the hospital gives a heart patient an aspirin upon admittance and whether patients with certain conditions receive specific drugs and the like.

Pharmacies will also play a role in helping hospitals earn incentive payments in a second program in which they receive bundled fees. Starting in 2012, hospitals would receive 1% over their normal pay based on the hospital Diagnosis-Related Group (DRG) payment system for keeping readmissions and hospital infections below a preset percentage. Hospitals in the lowest quartile in performance would see their DRG payments cut by 1% in fiscal year 2013, by 1.25% in fiscal year 2014, by 1.5% in fiscal year 2015, by 1.75% in fiscal year 2016, and by 2% in fiscal year 2017 and each following fiscal year.

Blair Childs, who acknowledges that the rule-making process will help to clarify some of the language in the PPACA, stated: “This is not just talk; it will happen, and it changes the whole payment dynamic. There is a lot of ‘the Secretary shall’ language in that bill.”

One hospital pharmacy program relates to the Section 340B Discounted Drugs Program. Section 340B of the Public Health Service Act limits the cost of drugs to federal purchasers and to certain grantees of federal agencies. Public and private hospitals serving at least 12% of Medicaid recipients may buy discounted drugs for their entire patient population, Medicaid recipients, and everyone else. This discount has always been restricted to outpatient pharmacies. The hospitals can bill the insurance companies for non-Medicaid patients for the full price of a drug, thereby pocketing the difference between the discounted price they paid and the full price they received from the insurance company.

The PPACA expands the Section 340B program to several new venues such as rural referral centers; children’s hospitals that are excluded from the Medicare prospective payment system; free-standing cancer hospitals; critical access hospitals; and, perhaps more importantly, in-patient pharmacies. Retail pharmacy groups and drug manufacturers opposed the expansion of Section 340B to in-patient pharmacies because they believe that eligible hospitals are giving access to the discounted drugs to non-Medicaid patients and to hospital employees. Dr. Coster says:

The expansion of 340B concerns us. Some hospitals are using the program to raise revenue, paying the discounted rate for the drugs and then billing an insurance company for the full price, when those drugs are provided to non-Medicaid patients. Those actions cast the program in a bad light. The health care bill provision includes some oversight requirements for HRSA [Health Resources and Services Administration], and we will be aggressive with regard to making sure HRSA meets those requirements.

Rob Recklaus, Director of Government Relations for Safety Net Hospitals for Pharmaceutical Access (SNHPA), says that discounts have always been allowed as a way of helping charity hospitals fund their operations. SNHPA includes more than 400 hospitals that participate in the Section 340B Drug Discount Program. Section 340B also contains new requirements for program integrity for both participating hospitals and drug manufacturers. He says:

“We are actually pleased with the integrity provisions in the health care reform bill. We believe they will increase transparency and make for a more efficiently administered program.”

Greg Lopes, a spokesman for Pharmaceutical Research and Manufacturers of America (PhRMA), declined to provide details on his organization’s view of the 340B provisions.

Other provisions could affect pharmacies and pharmacists in hospitals, in long-term care institutions, and in drugstores. Retail pharmacies were the prime seekers of the pharmacy benefit manager (PBM) disclosure requirements. PBM transparency provisions apply to PDPs and the Medicare Advantage Prescription Drug (MA–FD) Plan as well as insurance plans offered in state networks.

PBMs, through insurance companies, must disclose information to the DHHS Secretary, including the percentage of all prescriptions that were provided through retail pharmacies, compared with mail-order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed by pharmacy type. The NCPA’s Dr. Coster says that the provision doesn’t go as far as his group would prefer. However, a more aggressive provision would have resulted in a cost being attached to it, which legislators opposed, given the already stratospheric $900 billion price tag of the entire bill.

“That PBM provision is a building block for future PBM reform; [it] gives us a foothold for going back to Congress and saying more needs to be done,” he adds.

Congress has also delved into formulary matters. Part D plans must cover all drugs that are distinct chemical entities. The six “protected” classes of drugs are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants to treat transplant rejection. They have been part of the Part D program since its inception; however, the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 made some changes and required the CMS to rule on setting up outside experts to help to determine whether Medicare should expand or contract the six existing categories. According to the provision, the DHHS Secretary may establish exceptions to allow some leeway for a Part D plan in terms of which drugs to offer in any of the categories or to otherwise “limit access to such a drug, including through prior authorization or utilization management.”

AMCP’s Ms. Fuller says that this section’s language cancels portions of MIPPA and strengthens the DHHS Secretary’s hand with regard to changes to the six categories. She implied that this would lead to a tightening—not an expansion—of the categories, which drug manufacturers and patient groups support. AMCP opposed creating the six categories to begin with.

“We are still vehemently opposed to government mandates on formulary development and think formularies should be left

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to P&T committees,” she commented.

Ms. Fuller is happy that P&T committees, whether they are attached to PDPs, MA–PD plans, or private insurance plans and PBMs, will get additional feedback on the relative merits of pharmaceuticals in specific categories from the Patient-Centered Outcomes Research Institute, which has been created by the bill. The Institute will have the authority to compare health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, or products, such as pharmaceuticals.

“The more information available to P&T committees, the better. But we would have preferred that the Institute looked at cost effectiveness of drugs, too,” Ms. Fuller explained.

That, apparently, will not be part of its mandate.

The Institute’s board of governors, which is scheduled to include a couple of industry representatives, will develop a research agenda and pay contractors to do original work, including randomized clinical trials and observational studies. The idea appears to be to move away from the present model, in which pharmaceutical manufacturers have conducted clinical trials and have occasionally published selective information, not the whole story about a drug’s potential benefits and risks. Maybe because of the possibility of these “competing” non-industry clinical trials, the provision, as it was making its way through Congress, struck terror in the hearts of the drug companies. Yet the final version contains language that limits the impact of the Institute’s research pronouncements. It says that any research the Institute publishes cannot “be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations.”

Many anticipate not only more access to information for P&T committees but also new categories of drugs for acceptance on formularies. A hotly contested provision opens the door to the FDA’s approval of generic biotech drugs, or biosimilars. Generic drug and patent-centric companies fought this issue tooth and nail as it was being debated in Congress. In the end, Jim Greenwood, President and Chief Executive Officer (CEO) of the Biotechnology Industry Organization (BIO), says that the biosimilar provisions should result in “improved treatments, cures, and cost savings for patients.”

However, Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association, calls the provision a sham.

“The bill provides a biogeneric pathway in name only, giving false hope to patients who desperately need access to lifesaving biogeneric medicines,” she says.

Beyond the regulatory challenges and funding uncertainties, the biggest cloud hanging over the PPACA is its effectiveness in the future. Many of the new programs devoted to the crowning of preventive primary care and quality measures and outcomes in hospitals are untested. There is no evidence that they will “right the ship of care” in the U.S. Many of the bill’s elements make good sense theoretically; whether they will work in practice is still unclear.

REFERENCE