INTRODUCTION

As President Barack Obama and congressional leaders try to put Humpty Dumpty back together again, not all the pieces of the two health care reform bills now scattered on the Capitol Hill floor will find their way into a final compromise version—if, in fact, there is a final version. Any bill will have to contain pieces with a few Republican fingerprints on them. Given the chasm dividing the parties on health care reform, that will mean a smaller bill; therefore, some of the big pieces, which caused Humpty to fall from the wall to begin with, will not be included.

There is little chance, for example, that any final bill will bring 30 million new customers to the insurance industry; even Democrats are split on how to pay for this coverage and how to structure insurance for these newcomers. One doesn’t need to read the tea (Party) leaves to guess that widespread public concern over a new, expensive federal mandate makes the President’s chances of getting the uninsured covered dubious at best.

As for insurance, there might be a few provisions expanding options for individuals who already have their own health plans or who want to buy coverage with their own money. But the larger, political middle ground seems to cover both reducing health care costs for individuals and companies and improving the quality of that care. Both Republicans and Democrats have boarded the “preventive care” train and have been tooting their whistles on behalf of staunching the costly epidemic of hospital readmissions and its evil twin sister, adverse drug reactions.

Anne Burns, Vice President of Professional Affairs at the American Pharmaceutical Association (APhA), points out that the inappropriate use of medications costs individuals and payers at least $177 billion each year. Studies conducted by the Institute of Medicine, starting with its landmark 1999 report, To Err Is Human, have highlighted the number of preventable medication errors that occur in hospitals and pharmacies.

Ms. Burns states: “It is a silent epidemic, and pharmacists are highly trained and should be an integral part of the team to address those kinds of problems.”

That, in good part, explains why pharmacy groups have grabbed the poles of the banner of “collaborative care,” which has been paraded up and down Capitol Hill in the march to reduce medical costs and improve outcomes. Provisions that explicitly mention pharmacists or that imply their involvement can be found in sections of both the House and Senate bills authorizing the following:

- expansion of pharmacist-provided medication therapy management (MTM) services
- incentives for hospitals to reduce patient readmissions
- establishment of medical homes
- access to Section 340B drugs for nonprofit inpatient hospital pharmacies
- funding for education and training in allied health professions

It may well be that Congress might not be able to put any of Humpty’s pieces back together again. Even if this is the case, pharmacy groups agree on at least some key areas and have turned that consensus into legislative provisions that could come to political fruition via alternative paths, such as (1) health care reform “lite,” (2) amendments to other non–health care reform (HCR) bills, (3) free-standing legislation, or (4) separate Obama administration agency initiatives, which need no congressional consent.

In the last instance, that is already happening. In October 2009, the Centers for Medicare and Medicaid Services (CMS) issued a Call Letter for 2010 that expanded the number of Medicare Part D recipients eligible for MTM services. Call Letters are documents that make wide-ranging changes to Medicare.

Kristina Lunner, Vice President of Government Affairs at APhA, says:

When health care reform began, we convened a stakeholder group and looked at the landscape of our health care system. One thing that was clear is that the system is not optimizing pharmacists, who play an integral role in preventing and treating disease.

If nothing else, the intense debates over the House bill (H.R. 3962) and Senate bill (H.R. 3590) have accomplished two things: establishing a wish list of federal initiatives sought by the pharmacy industry (a road map leading toward that “optimization” Ms. Lunner alludes to) and exposing some rifts within the pharmacy community over how those initiatives should be structured. The top objective for nearly every pharmacy group in Washington was to secure new opportunities for the pharmacy industry (a road map leading toward that “optimization”) and exposing some rifts within the pharmacy community over how those initiatives should be structured.

Joseph Hill, Director of Federal Legislative Affairs at American Society of Health-System Pharmacists (ASHP), explains:

If Congress decides to move forward with a narrow health care reform bill focused on innovative delivery models, there would be a good chance that issues like MTM would be included, since some-
one saw fit to include new, broader MTM grants in both versions of the House and Senate bills. So they have pretty good momentum.

**MEDICARE PART D MEDICATION THERAPY MANAGEMENT SERVICES**

At present, there is no broad, federal grant program for MTM services, either in Medicaid or Medicare, and certainly not for employer plans and their pharmacy benefit managers (PBMs). Medicare and Medicaid do pay in a limited fashion for a small number of recipients. Medicare has been the high-profile MTM venue because of the Medicare Modernization Act (MMA) of 2003. The MMA established a specific MTM program for seniors who have more than one chronic disease, take multiple medications, and spend more than $4,000 per year on Part D drugs.

Since 2006, however, Medicare Part D plans have interpreted that broad language to suit themselves. Access to MTM services has been severely restricted. To take a extreme example, according to Katrina Burns, one Part D plan required a Medicare recipient to be taking 23 drugs before that patient could qualify for MTM services. To the extent that MTM programs are being provided to Medicare recipients, they are in the form of phone calls, generally from pharmacists.

The October CMS 2010 Medicare Call Letter revised the agency’s interpretation of the MMA requirements. The changes mandated that many more Medicare beneficiaries would be eligible to receive Part D MTM services because the requirements have been lowered for (1) patients with three or more chronic conditions, (2) patients taking eight or more Part D medications, or (3) patients spending more than $3,000 per year on Part D drugs.

This was a strong statement on behalf of MTM’s benefits and probably influenced Congress as it began to work on its health care reform bill. The Call Letter also required that prescription drug plans (PDPs) automatically enroll everyone meeting those criteria but that they give those individuals a chance to opt out of MTM. Fewer than 15% of PDPs had previously implemented that kind of MTM opt-in program.

The Senate bill (Section 10228) ratifies many, but not all, of the dictates on Medicare MTM services in the CMS 2010 Call Letter. That was done via one provision in a much broader Freshman Cost Containment Amendment, sponsored by Senator Mark Warner (D-Va). Most importantly, the Part D MTM reference in the Warner amendment seconded the provision in the 2010 Call Letter stating that all PDPs must provide an annual comprehensive medication review for beneficiaries. This includes a review of each recipient’s drugs and an interactive, person-to-person consultation. This would be a new requirement.

Although retail, hospital, long-term care, and managed care pharmacy groups found much common ground during the debate over health care reform, here is one instance in which the late comedian George Carlin could have done a modern-day version of his “Three Little Words” standup routine (not to be confused with his “Seven Dirty Words” act)—in this case, those three words would be “person-to-person.” Retail and hospital pharmacy groups have pushed hard to convince Congress and Medicare that MTM services are most effective when they are provided on a face-to-face basis.

The Academy of Managed Care Pharmacy (AMCP) disputes that. This disagreement flared while the Warner amendment was being considered on the Senate floor. That is probably why Senator Warner expanded the CMS reference to include “. . . or other telehealth technologies.”

William Hermelin, JD, the AMCP’s Director of Government Affairs and General Counsel, insists that because of cost, efficiency, and effectiveness, some MTM services are best provided via telephone or even mail. The CMS eventually assured the AMCP that telephone services are anticipated for the annual medication review. However, AMCP’s larger concern was that it was inappropriate for Congress to get involved with the intricacies of Medicare Call Letters.

**GRANTS FOR MEDICATION THERAPY MANAGEMENT SERVICES**

Bill Hermelin emphasized that the intra-pharmacy schism over MTM services is a relatively minor problem.

“The bigger issue is getting MTM services to a broader population,” he adds.

That was the objective of the provisions in the House and Senate bill sections establishing a new MTM grant program: the House (Section 2528), within the Agency for Health Care Research and Quality (AHRQ), and the Senate (Section 3503), through a new Patient Safety Research Center. The bills allow licensed pharmacists to provide the grants as part of a “collaborative, multidisciplinary, interprofessional approach” to the treatment of chronic diseases for patients to improve quality of care and to reduce overall costs in treating such diseases.

These grants are significant for two reasons. First, they provide support, at least conceptually, for expanding MTM services beyond Medicaid and Medicare into employer plans. MTM programs are rarely part of employer-provided insurance; they are typically provided through call centers. Second, the grants establish a list of 10 MTM services, based on APhA’s recommendations, which pharmacists can provide.

Joseph Hill explains:

The MTM provisions in the House and Senate bills would allow us to do some things we couldn’t do in the past. They provide a definition of MTM, which all pharmacy groups agreed to. [This] is significant because it is pharmacy-defined and driven, rather than someone at the CMS defining MTM services, which is the case now.

Eligibility requirements for MTM services performed by grantees are even lower than those in the Medicare 2010 Call Letter. For example, patients would qualify if they had two chronic diseases and took four drugs, including over-the-counter agents and dietary supplements.

**THE MEDICAL HOME**

The House bill specifies that MTM grants, when possible, should go to organizations that work closely with “medical homes.” The Senate doesn’t use this exact term but promotes the same concept, designating that the grants be used in conjunction with community health teams and primary care.
extension of the small practice with five or eight doctors and a staff pharmacist on the premises to a large academic medical center employing a team of practitioners, with some working remotely to coordinate care for vulnerable patients, often those with multiple chronic conditions.

A medical home typically includes a pharmacy adjunct of some kind. For example, the University of Nebraska Medical Center established a telepharmacy program that serves six rural hospitals that needed after-hours pharmacy coverage or that did not have a pharmacist on staff. The group reviews patient profiles, provides dose adjustments, makes rounds with physicians via telephone, and even takes part in one hospital’s monthly P&T committee meetings—all remotely.

Medical homes, another reflection of the drive toward collaborative care, quickly became an object of affection on Capitol Hill as the House (Section 1302) and Senate (Section 3021) began writing their provisions. The House and Senate provisions on medical homes differ, but both are restricted to Medicare or Medicaid recipients and clearly endorse the concept of multidisciplinary teams. Neither pharmacists nor any other allied health practitioners are designated as potential members of that team. Only primary care physicians and nurse practitioners receive this recognition.

The House bill endorses two types of medical homes: independent, patient-centered programs, which would most likely be run by physician groups and would be restricted to targeted high-need Medicare beneficiaries (within the upper 50th percentile), and (2) community-based programs, which would be run through community health centers or academic medical programs, perhaps in conjunction with hospitals. A wider variety of services, such as MTM services, would be included.

**REDUCING PATIENT READMISSIONS**

Although provisions relating to the medical home do not mention pharmacists specifically, they do highlight the goals of reducing the number of preventable hospitalizations and preventing hospital readmissions. That cause celebre also comes into play in another section of the bills expressly devoted to reducing hospital readmissions (Sections 1151 in the House bill, Section 3025 in the Senate bill).

As with medical homes, neither the House nor the Senate version specifically mentions pharmacists. However, the House bill does everything but spell out p-h-a-r-m-a-c-i-s-t. Section 1151 creates financial incentives for hospitals to prevent readmissions. Transitional services include an assessment of a patient’s drug regimen and adherence. Other transitional care activities include providing a summary of medication orders upon discharge from the facility.

The Senate bill endorses the creation of patient safety organizations to reduce hospital readmissions; it also endorses the existing Medicare policy of refusing reimbursement for readmitted patients with two conditions (see the next paragraph). The House bill would provide incentive payments to hospitals for keeping readmissions under control. The Senate bill also goes one step farther than the House bill by establishing a Community-Based Care Transitions Program for high-risk Medicare beneficiaries. Organizations that receive this funding would be expected to conduct comprehensive medication reviews and management, including counseling and support for self-evaluation when appropriate.

Here is another situation in which Congress appears to be applauding what the CMS has already started to do and may very well do more of, regardless of what happens on Capitol Hill. Medicare now refuses to pay a hospital when a patient is readmitted for reasons related to a hospital-acquired infection or within 30 days of discharge for surgery-related thrombosis, according to evidence-based guidelines.

Randi Vogenberg, RPh, PhD, Principal at the Institute for Integrated Healthcare, and Executive Director of the Biologic Finance and Access Council, explains that in order to avoid losing reimbursement for the care of those readmitted patients, some hospitals are giving drugs away to selected patients. The facility documents that it has written a prescription and has done everything it can—except put the drug into the patient’s mouth at home. He commented:

The readmission provisions in the health care reform bills, in effect, say that medical care is not just within the four walls of the hospital. They make hospitals responsible for care after patients leave the hospital, making hospitals, in essence, an old-style HMO economically responsible for fully integrated care.

**SECTION 340B DISCOUNTED DRUGS**

If hospitals can’t actually confirm that patients being discharged will take their medications at home, they can at least ensure that patients leaving the facility take an adequate supply of the requisite drugs with them or that they will be able to afford to buy the drugs on an outpatient basis. Both the House and Senate bills expand the number of nonprofit hospitals that qualify for the 340B program. With Section 340B, manufacturers may discount some of their drugs (although generally not the newest brand-name products) to outpatient facilities run by public hospitals or private, nonprofit facilities, plus federally qualified health centers, state AIDS drug-assistance programs, and clinics for family planning and sexually transmitted diseases.

As a result of the 340B discounts, participants have reported savings ranging between 25% and 50% of the average wholesale price for covered outpatient drugs. Both bills add outpatient pharmacies at children’s hospitals and cancer centers. The Senate bill adds outpatient clinics at facilities such as rural referral centers and sole community hospitals.

For the first time, however, the Senate bill opens Section 340B to inpatient pharmacies, thereby producing the second major intra-pharmacy dogfight during the health care reform debate. The expansion of 340B access to inpatient pharmacies, a key objective for Safety Net Hospitals for Pharmaceutical Access (SNHPA), was included in the version of health care reform that was passed by the House Committee on Energy and Commerce, but it mysteriously disappeared from the final bill passed by the full House.

Rob Recklaus, Director of Government Relations for SNHPA, says, “No one wants to fess up to being responsible for killing the inpatient provision in the House bill.” PhRMA, the drug manufacturers’ lobby, apparently opposed continued on page 157
the provision because its members don’t like to sell their products at a discount. A PhRMA spokesperson was unable to provide a comment for this article. Community pharmacies see the extension of Section 340B to inpatient pharmacies as a threat to their stores, especially in big cities with large Medicaid populations. John Coster, Senior Vice President of the National Community Pharmacists Association, admits that his group raised concerns about the provision.

Normally, this intra-pharmacy industry tiff might make the Section 340B inpatient pharmacy issue a political toss-up going forward. In this instance, however, the 340B provision would require hospitals with new access to 340B drugs for inpatient pharmacies to return a portion of their savings to state Medicaid programs to the tune of $1.2 billion over 10 years. That makes the Senate provision—in the context of a larger health care reform bill—a “pay for” (i.e., one of a number of valuable provisions that could counterbalance another requirement that costs the federal government).

One of those is the MTM grant program, which was apparently championed by Senator Barbara Mikulski (D-Md.), a member of the Senate Health, Education, Labor, and Pensions Committee. She inserted that provision into the health care reform bill; from there, it eventually migrated to the House version. Although the provision is in both bills and in similar language, neither bill includes a dollar authorization. Sometimes that is a sign that Congress is paying lip service to the demands of interest groups.

By contrast, the House attached dollar authorizations for its medical home demonstration provisions: $200 million per year for independent centers between 2010 and 2014 and $125 million per year for community centers between 2012 and 2016. However, even with a dollar authorization, a program doesn’t get off the ground until Congress actually appropriates money for it.

When asked about the absence of authorizations for the MTM grants, the APhA’s Ms. Lunner admits, “That is a fair question.”

Lack of dollar authorization also undercuts most health professional education and training programs, which are much more numerous in the Senate bill. Pharmacists are named as eligible for many of them. However, an effort by pharmacy groups to get pharmacists included in the National Health Service Corps (NHSC) list of health professionals failed, as did an effort to get pharmacists included in the NHSC Allied Health Loan Forgiveness Program. The NHSC underwrites the tuition of primary care physicians, dentists, and mental health practitioners who practice in underserved areas for a designated period of time after graduation.

A number of other pharmacy-related matters also came into play during the health care reform debate, such as comparative effectiveness research, long-term care, nursing-home dispensing of drugs, and adding the benefits of medications to the labels, just to name a few. For pharmacists and their advocacy organizations, then, there is plenty of unfinished business to pursue. Now all that’s needed is a legislative vehicle and a path forward through the political thickets.