Health-System Pharmacy Legislative Issues

**The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 314)**

Achieving provider status is about giving patients access to the valuable care that a pharmacist can provide. Becoming a “provider” in the Social Security Act means that pharmacists can participate in Part B of the Medicare program and bill Medicare for services that are within their state scope of practice to perform.

The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592 and S. 314) is bipartisan legislation that will amend section 1861 (s) (2) of the Social Security Act to include pharmacists on the list of recognized healthcare providers.

Medications have become the first line of therapy to treat patients with chronic diseases and acute complex diseases such as cancer and heart failure. Breakthroughs in new medications have led to more Americans living longer, healthier lives. Along with development and approval of new medications, however, new challenges have also emerged. Within the Medicare community alone, nearly 70 percent of Medicare beneficiaries have one or more chronic conditions, and many of these beneficiaries are taking multiple medications.

Lack of proper medication oversight and management can result in suboptimal therapeutic outcomes and in some cases, patient harm. For example, too many patients are unnecessarily readmitted to the hospital or have to visit the emergency department due to medication-related issues. These events also add to the costs absorbed by the Medicare Program.

As the medication use experts, pharmacists have the background and training necessary to ensure that patients make the best use of their medications, and are often the most accessible healthcare professional. Pharmacists in hospitals and ambulatory clinics work with physicians, nurses, and other providers on interprofessional teams to manage patients’ medications and ensure appropriate care transitions.

**REMS**

The pharmacy profession encourages the FDA to work toward a centralized electronic means for all REMS and the various registration, provider education, and patient documentation requirements. This effort could eliminate redundancies that exist and the need to maintain separate paper record keeping in thousands of patient care settings. This should include mechanisms to routinely and proactively inform practitioners on changes to REMS programs. Though the core components REMS are standard, the elements within each component should be analyzed in an effort to standardize.
**Pharmacy Technicians – Tiering**

The Pharmacy Practice Act Joint Task Force has been working with the MN Board of Pharmacy to begin discussing the idea of pharmacy technician tiers. This work is just beginning and we are looking for input and feedback from health-systems pharmacists and technicians.

Current ideas include creating a technician-in-training designation, as well as an advanced technician role that would require a higher level of training and have the ability so that they can be used more extensively to free pharmacists from drug distribution activities and allow pharmacists’ time to be redirected to additional clinical and cognitive functions, including drug therapy management activities. Some ideas for functions of the advanced technician role may include:

- Supporting facility wide medication reconciliation including obtaining and documenting patients’ medication information for pharmacists’ review
- Checking dispensing by other technicians (ie “tech-check-tech”)
- Supporting pharmacist clinical monitoring by assisting in gathering and maintaining specific patient data.
- Contributing to aspects of quality improvement programs regarding the advanced technician functions.

**340B Drug Pricing Program Omnibus Guidance (RIN) 0906-AB08**

The federal 340B Drug Pricing Program provides discounted drug prices on covered drugs to participating hospitals and other eligible entities. Many participating pharmacies use savings achieved through participation in the 340B program to fund clinical pharmacy services, anticoagulation clinics, charitable care, medication assistance programs, and other activities that improve patient care.

There are 3 main issues with changes that have been proposed to the program:

1. **Discharge prescriptions.** The proposed guidance, which includes a revised definition of a 340B-eligible patient, would require that each medication be prescribed or ordered in association with an outpatient care episode. This would seemingly prevent discharge prescriptions from being filled at the 340B price. This would likely result in a higher cost to patients, as well as Health-Systems, and make it more difficult to ensure seamless transitions for our patients.

2. **Infusion orders.** The proposed guidance states that having a provider–patient encounter is a necessary element of each episode of care between an eligible patient and a hospital or other 340B covered entity. But the proposed guidance also specifies that the administration of an infusion drug alone does not constitute such an encounter, and the recipient of the infusion would not qualify as a 340B patient. As a result, rural infusion centers may be forced to close or deny services because their patients do not meet the proposed 340B eligibility requirements.

3. **Employer relationship.** According to the proposed guidance, healthcare providers who have credentials at a 340B-participating hospital but are not direct employees or contract workers would not be considered 340B-eligible providers. Thus, these providers’ patients would not be eligible to receive drugs purchased through the 340B program. Most health-systems have a high percentage of providers that work under contract. This may mean, for example, that people seeking care in the emergency department would qualify as 340B patients one day but not another solely on the basis of who is on duty at the time of the visit.