



# Network News

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FEBRUARY 2017

## SPECIAL POINTS OF INTEREST:

- 2017 NPSC Expo & CE (back page)

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## How Did We Get Here?

By: David Benoit

When we talk among ourselves about our business, we use lots of abbreviations and acronyms. We take a lot of things for granted. To understand what I'm talking about all you need to do is try to explain how you get paid to somebody. AWP, WAC, discount, PBM, RA, EOB, DIR, copay, insured amount, rebate, clawback, etc. This is the barrier we face when talking to legislators. We are in a complicated business. They do not have the time to understand it. How did it get this way?

Wasn't it a lot simpler before computers and prescription benefit management companies? They started out as claims administrators, so much per claim; they were transparent. They made it efficient for insurers to collect and pay claims. Then, additional services were added. Somewhere along the way, they moved generics from the standard HCFA MAC to one of their own proprietary invention. As they developed formularies of covered and non-covered items, manufacturers of brands scrambled to ensure that their product was on formulary. Thus was born the manufacturer's rebate.

Along came Medicare D in 2006. PBMs scurried to put qualifying plans together because Med D represented an increase in utilization. There were going to be more prescriptions. About four years later, Humana agreed to have Walmart pharmacies be preferred pharmacies – for a price. It did not bother us that much to witness the birth of direct and indirect remuneration (DIR) at the time but in hindsight it should have. Then, in a plodding way preferred and exclusive networks worked their way

across the plans and grew insidiously. Independents were hypnotized into competing through their own preferred network called Smart D, an abysmal failure.

DIR fees morphed into fees that were based on generic dispensing rates and in other cases the 5-Star performance ratings at the individual pharmacy level. This occurred in the extreme to the point where DIR was morphed into performance payments. The words changed but the financial picture did not.

Many stores are just noticing DIR fees now. Fortunately for them, the Center for Medicare and Medicaid Services (CMS) has also noticed the rapid growth of these fees. In a January 19, 2017 report (<http://www.ncpa.co/pdf/advocacy/2017/cms-fact-sheet-part-d.pdf>) CMS noted that from 2010, DIR has been growing approximately 22% per year outstripping increases in drug costs. It appears that the use of DIR has helped maintain beneficiary premiums, but has also accelerated the patients' run up into the donut hole on the way to catastrophic coverage.

What does this mean? The plans and PBMs are maintaining flat premiums, which is a good thing you would think. You know that inflation applies each year, so where did the increases grow? CMS's share of the donut hole and catastrophic coverage has increased enormously. It looks like the PBMs and plans have found a way to maximize their discounts from providers and business partners through DIR, while simultaneously shifting increased cost to CMS. Sounds ingenious. Doesn't it? It was, right up to the point where it forced CMS to notice.



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It is complicated, but our protests and objections have helped CMS to see and feel our pain. This is just one dimension of our business. So, we need to move forward one step at a time.

This is the number one concern legislatively for NCPA for the coming session. Please let your voice be heard and your support felt. In Maine, we are hoping to initiate discussions that lead to a prohibition against DIR fees in commercial plans.

That is a short story about how we got here. But this brings us to the beginning of

the story about where we want to go. That's the theme of the upcoming NPSC EXPO. We have a robust program for the EXPO on April 25 and 26, 2017 at the Mystic Marriott Resort and Spa. It focuses on opportunities and in a departure from the past programs, there will also be an accent on execution. More about the details of the program will be provided over the next few weeks and in the next newsletter. Mark your calendars.



***Health Care Pharmacy, Hartford, CT***

***Langs Pharmacy of Wilton Center, Wilton, CT***

***Main Street Rx, Newtown, CT***

***Maple Pharmacy, Hartford, CT***

***North Amherst Pharmacy, Amherst, MA***

***Shoreline Integrative Pharmacy, Westport, CT***

***Southwick Pharmacy, Southwick, MA***

## **TUESDAYS AT 10**

Argosy Group is offering the NPSC network FREE monthly webinars with the best in DME information! This is a wonderful service that many of our network stores have come to look forward to. It will be the best 30 minutes you spend all day!



### **Next Webinar**

Date: March 14, 2017 Time: 11:00 EST

Topic: Business Topic: Working Denials

Register: [www.northeastpharmacy.com](http://www.northeastpharmacy.com)

Click on Tuesday at 10 Tab

## CT Legislative Update

*By Pat Monaco*

Mark Brennan and Kevin Hill (Powers, Brennan and Griffin) led the conference call on January 11<sup>th</sup> beginning with an overview of the financial situation. Connecticut starts this legislative session with the deficit of 1.3 billion dollars. There was some real cost cutting last session – and even with that, the problems and issues of the Connecticut state budget loom over the next legislative session. This session will be contentious at best as budget cuts will continue.

Many more Republicans occupy seats in the legislature as a result of the elections which may result in some change in the wind. Due to the increase in Republican seats, there are now 3 committee chairs for each committee. Those most relevant to us this session are: Public Health, Insurance and General Law.

Our legislative committee's initiatives begin with our **MAC bill**. Kevin Hill has requested a meeting to discuss the prospects of the bill with the Insurance Committee. Other bills that we have interest in is a **Drug Returns bill** that we tried a couple of years ago. Additionally, a **Pharmacist Provider Status bill** is of interest so pharmacists can bill for services.

We continue to have interest in having conversations with DSS with regard to audits involving tamper resistant paper which has caused a number of our network pharmacies problems during their audit

Kevin and Dave met with General Law committee chairs to discuss the attribute of the drug return bill on January 17<sup>th</sup> and will be meeting with DSS on January 31<sup>st</sup> to go over the reimbursement surveys that were done in New England which will be the basis for the changes to reimbursement for Medicaid which must go into effect by April, 2017. Kevin Hill (lobbyist) has also contacted Mr. McCormick at DSS to set up a time to discuss audits.

We are watching bills as they are submitted

and providing commentary back to our lobbyists as they are meeting with the chairs of the different committees.

We agreed on the call that **Provider Status** this session might be more difficult but one that we can begin to talk about now and weave into our discussions with the legislators.

The committee agreed to host an independent pharmacy event (which was talked about last session) at the capital and Kevin and Mark have suggested a breakfast. Both Mark and Kevin have experience in doing these events in one of the private dining areas of the LOB – inviting the legislators down for a meet and greet and then sending pharmacy owners with a targeted message out to meet with their legislators in their offices. Their experience is that these events are very effective. Kevin secured a date of Tuesday, March 14<sup>th</sup> for the breakfast. All of the workgroup participants on the call confirmed that they would attend. We will be sending out a separate announcement to the CT network and we are hoping that many attend. We expect it to be a half day commitment starting about 8:30-9:00 until about noon.

Ed Funaro reported on the strides that have been made on the billing of durable medical equipment through Surescripts that he worked on with the CT State DSS department. Karen reported on the progress being made with the state and the head of Drug Control in recognizing independent community pharmacies as being out in front with assistance for patients and their families dealing with an opioid abuse problem. While the opioid problem in CT was front and center last session, it will be continue this session as well. This promises to be an active legislative session and we will keep you informed on those issues of importance to you as the session continues.

## RI Legislative Update

*By Pat Monaco*

We will be actively watching the bills put before the R.I. legislature to either provide support for or supply testimony against anything relating to pharmacy that will affect our participating pharmacies.

## MA Legislative Update

*Ron Lanton, NPSC Lobbyist, True North Political Solutions*

The 2017-2018 legislative session is underway and the 10 day window for bill filing has concluded. Each piece of legislation has been given a temporary docket number. Several bills have been filed at the request of the associations (MIPA & MPhA) that are of importance to independent pharmacies. First, and most encouraging, House Majority Leader, Ronald Mariano has filed MAC transparency legislation. The Majority Leader visited Olden's Pharmacy this past summer and saw firsthand the problems caused by the lack of transparency of PBM MAC lists. He made a commitment to address this issue and has taken the first step by filing a bill to remedy the situation. On the Senate side, Senator Michael Rodrigues filed similar legislation. The support of these two influential legislators does not guarantee success but it an encouraging start to the session.

Senator James Eldridge re-filed a bill to stop the practice of getting around the state's any willing provider law by labeling a drug a "specialty drug" and limiting its distribution through the PBM's specialty pharmacy or closed specialty network.

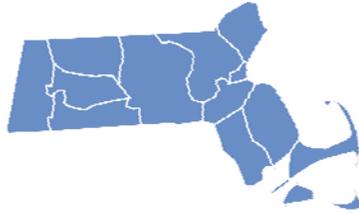
An Act Recognizing Pharmacists as Healthcare Providers was re-filed by Representative Angelo Puppolo, and this session; and Senator Michael Moore filed the same language on the senate side. Last session this bill was reported favorably from the Joint Committee on Public Health but made it no further in the process. Two developments provide us with optimism for this bill. First, the legislature requested a report on the bill from the Center for Health Information and Analysis (CHIA), which is tasked with assessing the costs of implementing a bill under consideration. That report came back very favorably. Recently CMS issued a letter endorsing pharmacists' involvement in public health efforts such as smoking cessation

and unwanted pregnancies contraceptives suggesting that these are services pharmacist can provide the community without a prescription. You can access this letter and the CHIA report by visiting [www.masspharmacists.org](http://www.masspharmacists.org) under the Advocacy tab for state legislative efforts.

Each of these bill sponsors has some connection to Association members and independent pharmacy owners or managers. To further support the involvement of independent pharmacies in the political process and help with the final passage of these important bills, the Associations have engaged Dennis Lyons, a pharmacist and lobbyist with many years of experience as an advocate for pharmacy issues at the state house. Mr. Lyons will help bolster our grassroots efforts and enhance our influence with lawmakers. If we all pull together, we can make this a productive and profitable legislative session.

A first step to support these pieces of legislation is for each of you to ask your state senator and representative to sign on as cosponsors. This can be done very easily by visiting MPhA's grassroots action center under the Advocacy tab at [www.masspharmacists.org](http://www.masspharmacists.org). A prewritten email will be sent automatically to your elected officials simply by entering your name and address. You do not need to be a member.

Finally, there are as many as 40 other bills that will touch pharmacy practice that are emerging this session. These include bills on med synchronization, step therapy, and PBM drug price transparency. In the weeks ahead these bills will be given their official bill numbers, sent to an appropriate committee, and the text of each bill will become available online. At that time we will be able to assess our position on each piece of legislation.



## ME Legislative Update

By Pat Monaco

The Maine pharmacy coalition has introduced one of the first state DIR bills nationally. LD 6 titled An Act to Prohibit Insurance Carriers from Retroactively Reducing Payment on Clean Claims Submitted by Pharmacies has been introduced by Senator Gratwick (D-Bangor) and has bipartisan support. The bill will be heard in the Insurance and Financial Services Committee in Augusta on January 24th.

Another goal this year for Maine will be to improve communications and relations with the Maine Bureau of Insurance. This is important

since the pharmacies have to interact with the current Bureau until the 2018 elections when a new Governor is elected.

Additionally, Ron Lanton will be increasing Maine pharmacy's federal presence this year with the new Administration. He has already opened communications with Senator Collins (R-ME) and has told her office about the need for the Senator's involvement in DIR and MAC issues. He also has a meeting scheduled with Congresswoman Pingree's (D-ME) Portland office on January 26th to discuss similar issues.

### DEA Report on Reducing Schedule II Medications

According to the Final Order of the Drug Enforcement Administration published on October 5, 2016, almost every Schedule II opiate and opioid medication manufactured in the United States in 2017 has been reduced by 25 percent or more. Sales data from the DEA and IMS Health has reported that sales are decreased as represented by prescriptions written. Reduction is also attributed to elimination of 25 percent buffer that was added to guard against shortages. It has also been reported by the National Survey on Drug Use and Health (NSDUH) that in 2015 6.5 million Americans over the age of 12 have used controlled prescriptions for non-medical reasons during the past month. The CDC issued guidelines in early October to practitioners to recommend they reduce prescribing opioid medications for chronic pain. Education continues regarding the dangers of misusing opioid prescriptions. For additional information, please read the full article at <https://www.dea.gov/divisions/hq/2016/hq100416.shtml>.

### IMMUNIZATION TRAINING FOR PHARMACISTS

Friday, March 3, 2017  
Northeastern University  
Boston, MA

<http://www.northeastern.edu/bouve/pharmacy/continuing-education/>

Thursday, April 6, 2017  
Aqua Turf  
Plantsville, CT  
7:00 – 5:00

<http://pharmacy.uconn.edu/academics/ce/immunization/>

**REMINDER:** There is a new version of the 855S CMS Medicare Be Enrollment Form effective 1/1/2017. Make sure you use the correct 05/16 version when applying for Medicare PTAN. Questions? Email: [HMEHELPDESK@argosygroup.or](mailto:HMEHELPDESK@argosygroup.or) or Call: 785-782-0779

# USP <800> How Your Pharmacy Can Prepare

Jennifer L. Bruckhart, CPhT, reprinted with permission, *America's Pharmacist*, December 2016

When it comes to compounding, federal regulation is increasing by the day. Whether it's the Drug Quality and Security Act potentially eliminating office use for 503A pharmacies, or the Food and Drug Administration issuing new draft guidance for industry relating to compounding for veterinary use, it's more important than ever for compounding pharmacies to stay ahead of the regulations and be prepared to make changes to their business. Perhaps the greatest challenge ahead lies in preparing for the implementation of United States Pharmacopeial Convention (USP) General Chapter <800>, a set of guidelines that sets new standards for the handling of hazardous drugs in health care settings, including pharmacies. The requirements are significant and impact nearly every pharmacy that performs compounding services. The current implementation date has been set for July 1, 2018, and barring a delay at the individual state level, pharmacies will need to take a serious look at what is needed to comply with the new regulations.

## HAZARDOUS DRUGS: A FOCUS ON SAFETY

USP <800> specifically looks at the handling of hazardous chemicals in the practice of compounding. It details a series of processes that will be required to minimize exposure to hazardous drugs (or potentially hazardous drugs) in health care settings. Its purpose is to protect the employees and patients who routinely come in contact with these drugs. The chapter was officially published on Feb. 1, 2016, after two years of comments from the industry. Its scope is not limited to pharmacies. The chapter also applies to hospitals, clinics, physician offices, and veterinary clinics—essentially any facility where hazardous drugs are stored, prepared, or administered. It's a common misconception that USP <800> only applies to sterile compounding. However, it's important to note that USP <800> applies to all forms of compounding, even non-sterile. Any pharmacy that performs any manipulation (such as crushing or mixing) to any drug identified as hazardous must follow the requirements of the new chapter.

## WHAT'S A HAZARDOUS DRUG?

As mentioned, USP <800> deals with a specific subset of drugs—those identified as hazardous or potentially hazardous by the National Insti-

tute for Occupational Safety and Health (NIOSH). NIOSH makes the determination based on a drug having at least one of the following six characteristics: carcinogenicity, teratogenicity, reproductive risk, organ toxicity, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity. NIOSH maintains and publishes the list of hazardous drugs. The most recent update came out in September 2016, and it added 34 new drugs to the list. The list contains the usual suspects—chemotherapy drugs and others that pose significant toxicity concerns. Visit <http://www.cdc.gov/niosh/topics/hazdrug/> for more information. However, it also contains some drugs that compounding pharmacies use on a daily basis, including hormones like testosterone, progesterone, and estrogen, along with drugs such as apomorphine, fluconazole, misoprostol, and tretinoin. As a result, nearly every compounding pharmacy will be affected by USP <800>.

## GETTING A HEAD START

As I'm writing this article, I'm preparing to head to PCCA's International meeting in Houston. I'm hoping to talk to other pharmacies that have read USP <800> and find out what they're doing to prepare. In the meantime, I thought I would share what our pharmacy is doing to get ready. Although the 2018 deadline seems like far away, as we've already discovered, there is plenty pharmacies can (and should) be doing now to prepare.

**Buy and Read USP <800>.** I recommend every compounding pharmacy owner read USP <800> to get the best understanding of the new guidelines. It's a relatively quick read at 18 pages, but it contains very explicit guidelines for everything from lab design to pharmacy operations. As you read, pay particular attention to the use of the words "must" versus "should." The chapter contains a lot of general recommendations and best practices noted with the use of the word "should." These are helpful, but it's imperative that pharmacies pay attention to the requirements that start with "must." A few of these are noted below. Pharmacies must:

- Maintain a list of hazardous drugs that includes the NIOSH list and review it annually.
- Implement facility and engineering controls. (*This one's a real doozy...more on this later.*)
- Ensure employees don appropriate person-

al protective equipment (PPE) during any potential exposure to hazardous drugs.

The only way to access the full text of USP <800> is to buy it directly from USP. Pharmacies can purchase the chapter through a 12-month subscription to the *USP Compounding Compendium* (\$150). The compendium also includes more than 40 general chapters relevant to compounding, including the full text of USP <795> and <797>. It is available to NCPA members at the online bookstore ([www.ncpanet.org/bookstore](http://www.ncpanet.org/bookstore)).

**Make Business Decisions.** With the new guidelines, it's almost impossible for a pharmacy to do "a little" compounding. Some pharmacies may look at the requirements for the lab design alone and make the decision to get out of compounding altogether. If you read the online message boards, that's certainly been the decision of some pharmacies. But for young compounding pharmacies like ours, we saw the new guidelines as a chance to improve our business and even expand our services. Either way, it comes down to a business decision that many pharmacies will need to make in the months ahead.

**Find USP <800> Experts.** Fortunately, a number of organizations are working diligently to develop resources to help compounding pharmacies prepare for USP <800>. In the past six months, industry groups such as NCPA, IACP, PCCA and others have hosted webinars and developed helpful FAQs to help pharmacies understand the new guidelines and make a plan. If you haven't done so already, visit these organizations' websites and access recordings of past webinars and other resources to help in your preparations. Additionally, given the chapter's new guidelines for lab design, PPE, and cleaning, find vendors who specialize in these areas and have experience helping compounding pharmacies and are familiar with USP <800>. The last thing you want to do is invest in an overhaul of your lab to find out it doesn't comply with the requirements.

#### **Review Your Policies and Procedures.**

For our pharmacy, this was easy; we didn't have any. As a relatively new pharmacy (less than two years old) with a small staff of 1-2 compounders, we had not yet developed any substantial standard operating procedures (SOPs). Once we saw the extent of USP <800> guidelines that detailed everything from cleaning procedures to processes for opening hazardous drug shipments to requirements for PPE, we got to work on our policies and procedures. We started by purchasing pre-written SOPs from PCCA (*Compounding Today* also can be a great resource for SOPs) and spent a full six months of 16-18 hours a week customizing the policies to fit our practice and our workflow. We also conducted a series of four one-hour trainings for all of our staff. In the end, we had a 200-plus page document, plus two dozen forms, checklists, and logs to standardize our pharmacy operations. It was not an easy task, but it was definitely worthwhile and helped elevate our business. Plus, it puts us in a better position to apply for

accreditation, something else we are considering.

**Budget for Facility and Engineering Control Upgrades.** As I mentioned, this one is the real sticking point. USP <800> lays out very specific requirements for facility and engineering controls to help limit employee and patient exposure to hazardous drugs. USP <800> mandates the use of a vented or double-HEPA-filtered powder containment hood, biological safety cabinet, or negative-pressure glove box for all particle-generating activities (such as crushing, stirring, and mixing). It further states that the hood must be located within a room that:

- Is separate from other compounding areas
- Is externally vented via HEPA filtration
- Maintains at least 12 air changes per hour (ACPH)
- Has a negative pressure between 0.01 and 0.03 inches of water column.

My guess is that most community pharmacies that provide non-sterile compounding do not have a room that meets

these stringent requirements. Ours didn't, so we began the daunting task of researching the costs to build such a room. We ended up looking at modular labs. We liked the flexibility that this type of construction offered, not to mention the fact that it could grow with us. It also offers some financial benefits, including depreciation considerations for tax purposes. After finding two vendors that came highly recommended and specialize in building pharmacy cleanrooms, we discovered the cost just to add the modular lab and the necessary HVAC upgrades would run in excess of \$50,000-\$75,000. Definitely not chump change. Additionally, as we discovered, many of the vendors are still learning the ins and outs and real-world applications of USP <800>. It's important to ask a lot of questions and look for partners who have actual experience and working knowledge of these new guidelines. Knowing USP <800> helps you spot the vendors who know their stuff. It's also very important to pay close attention to what your state determines to be the best course of action regarding uptake and enforcement of USP <800>. States are likely to have a variety of approaches, which may include incorporating only portions of the Chapter, delaying enforcement, or potentially not requiring compliance with the Chapter. (NCPA is tracking this closely. This is a huge, unnecessary, expensive burden for its members. NCPA is fighting and will continue to fight for fair guidelines and implementation.) Whatever your pharmacy decides in regard to USP <800>, it's important to do your homework. With a little planning and a lot of research, your pharmacy can be ready to meet the new requirements for USP <800> when it takes effect in 2018. ■

Bruckhart, Jennifer L., CPhT. "USP <800> How Your Pharmacy Can Prepare *America's Pharmacist*, December 2016. 1 Feb 2017.



2017 Expo & CE  
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Registration Available  
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*FREE to participating pharmacies.*

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Northeast Pharmacy Service Corporation  
 1661 Worcester Road, Suite 405  
 Framingham, MA 01701

Phone: 800-532-3742  
 Fax: 508-875-6108  
 www.northeastpharmacy.com



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